CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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"The Future of Pharming: Can it Be Done Safely"

A CSPI Conference on Emerging Technologies

1:00 to 3:00 p.m.
Tuesday, December 17, 2002

National Press Club: Holeman Lounge
Washington, D.C.

[TRANSCRIPT PREPARED FROM AN AUDIOTAPE RECORDING.]

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P A R T I C I P A N T S

Michael F. Jacobson, Executive Director, CSPI

Dan Charles, National Public Radio

PANELISTS:

Dr. Rhona Applebaum, Executive Vice President, National Food Processors Association

Gregory Jaffe, Biotechnology Project Director, CSPI

Julia Moore, Woodrow Wilson International Center

Dr. Michael J. Phillips, Executive Director, Biotechnology Industry Organization

Dr. Allison A. Snow, Professor of Biology, Ohio State University

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P R O C E E D I N G S

MR. JACOBSON: [In progress] -- executive director of the Center for Science in the Public Interest. CSPI is a non-profit consumer advocacy organization that focuses on health and environmental issues, especially nutrition, food safety, and alcohol problems. You can learn more about our activities on our website, www.cspinet.org.

For the past 2 years, CSPI's project on agricultural biotechnology has sought to provide a moderate voice in what is often a shrill debate. This forum is part of CSPI's effort to inform the public and improve the appropriate regulation of their technology.

I would like to welcome attendees here at the National Press Club in Washington, D.C., and C-SPAN viewers to CSPI's forum on so-called pharma, p-h-a-r-m-a, pharma crops, one of the most controversial applications of agricultural biotechnology. We will be debating the use of food and other crops to produce drugs and other industrial chemicals.

That topic is particularly timely considering that only 10 days ago, the U.S. Department of Agriculture fined the ProdiGene Company $3 million for failing to fully

contain two corn crops that it had engineered to produce an animal vaccine.

Pharma crops have the potential to provide tremendous consumer benefits, but if misused also have the potential to doom the technology here and abroad. The issue is how to move forward in a manner that safeguards human health and the environment, if that is possible.

Government regulators seem to need some help, and maybe this panel discussion can begin a dialogue that leads to better regulation of this technology. Knowing the participants both on the panel and in the audience, I am sure we are going to have a lively discussion. Then, after the panelists have their turn, I hope the audience will ask plenty of questions and provide their comments.

Viewers on C-SPAN can send in questions by e-mail to bio@cspinet.org.

Our panelists today will be introduced by Dan Charles, who will moderate the forum. Dan Charles is author of "Lords of the Harvest," a highly praised and highly readable book about agricultural biotechnology. He is also a contributor to National Public Radio and the Journal of Science.

Dan?

MR. CHARLES: Thank you, Michael.

It is very good to be here. I am glad to see all of you out. I am glad to see such an illustrious panel.

When corn isn't corn anymore, it turns a lot of people's worlds upside-down. I think this is one of the reasons why this has gotten so much attention. The grain handlers and food processors of this country found that out, to their shock and their horror, a couple of years ago with the so-called Starlink Episode, when that gene in corn showed up in grain elevators in the Midwest and wasn't supposed to.

In recent weeks, as Michael mentioned, there has been this case involving a company called ProdiGene with corn plants that were drug factories, weren't supposed to be in food. Some of those kernels fell on the ground, sprouted the next year. Chopped-up bits of those corn plans ended up in an elevator full of soybeans and had to be, in effect, quarantined. This is not something that any farmer or grain processor could have imagined a few years ago: corn and soybeans getting quarantined.

Ever since Starlink, ever since a couple of years

ago, I personally have been wondering and waiting and writing when is the food industry going to put its foot down and put an end to this, very quietly, very effectively, how are they, if they will, going to pull the emergency brake on the train of agricultural biotechnology. And in recent days, I have started wondering if, in fact, that is now happening.

It certainly seems that way when you read a position paper from the National Food Processors Association, and I quote from it, "There is an unacceptable risk to the integrity of the food supply associated with the use of food and feed crops as factories for the production of pharmaceuticals or industrial chemicals," quite a surprising statement, to me at least. Maybe other people saw it coming.

Today, in this room, we are going to figure out exactly what is happening on this technological frontier, pharmaceutical production in plants, and we will hear what should be happening.

We have all the right people right here in this room, but before I introduce them, I will explain the format for our discussion. For the next close to an hour, 45

minutes to an hour, I will lead a discussion with our panelists. I will ask them questions. They can also ask questions of each other. Then we will open it up for questions from the floor and also from our television audience.

Viewers on C-SPAN have an e-mail address that they can use to send in questions, which will then be shuttled up to the front of the room. The e-mail address is bio@cspinet.org. You can send e-mail questions and they will get here.

You can write your questions down on little sheets, little cards that Asher Wolf, who is standing in the back of the room there, will have available to pass out to people, or when the question time comes, you can go to the microphone. I guess there is just this microphone over here. So, anyway, that will all come later in the question time.

I should say also we have had two cancellations from the panel that we sent out that we announced in the invitation. Anthony Laos from ProdiGene for personal reasons had to cancel over the weekend. So I am sorry to report that he is not here today. Also, Jim Brandel from

AgCanada throughout his back, and he can't get in a car or an airplane to get down here to Washington.

We do, however, have the panel, and I will introduce them quickly and briefly. Rhona Applebaum comes to us from the National Food Processors Association, the organization that I mentioned earlier. She is executive vice president of the National Food Processors Association for Scientific and Regulatory Affairs. That means she handles all things having to do with regulation of food, food safety, and such things. She is also a scientist with a Ph.D. in microbiology, food microbiology, from the University of Wisconsin.

Next to her, we have Allison Snow, who is one of the country's leading experts on what has come to be called "gene flow" from transgenic crops, from genetically engineered crops. She teaches at Ohio State University. She is professor of Biology there, was trained as a plant ecologist, and her current research focuses on molecular and ecological approaches. That has to do with the question of how crop genes move into other plant populations, how they cross-pollinate, how the genes move naturally in the field. Some of her recent research that was published had to do

with sunflowers, transgenic sunflowers and their wild relatives, of which there are many.

Next to Allison, there is Greg Jaffe from the organization that has organized this event, the Center for Science in the Public Interest. He is director of the project on biotechnology at CSPI. He has had a long and distinguished career in the Government before he came to CSPI as a trial attorney at the U.S. Department of Justice and also as a senior counsel with the Air Enforcement Division of the EPA.

Julia Moore is an independent scholar now at the Wilson International Center for Scholars. She in the past has been director of Legislative and Public Affairs at the National Science Foundation and has also worked for the State Department, has focused on questions of public acceptance of new technology and public reactions to it.

Finally, Michael Phillips is -- your exact title is executive director for Food and Agriculture at the Biotechnology Industry Organization, or BIO. It is the largest trade organization that represents the life sciences industry, biotech companies both for pharmaceutical and agricultural uses. Before joining BIO, he was executive

director of the Board on Agriculture and Natural Resources for the National Academy of Sciences.

So we are happy to have this panel here. I am going to start the questioning with you, Rhona Applebaum, because I mentioned this statement in my introduction and it struck me. Your organization has in the past been supportive of biotechnology and its application in agriculture. You have defended its record of safety.

Here, we have this example. It is a tiny amount of acreage. It is a tiny amount of product. It has been, apparently, safely contained in an elevator, but you have raised the alarm. You have talked about risks, unacceptable risks, and I am curious why now.

DR. APPLEBAUM: Thank you, Dan.

Very quickly, regardless of how small an amount there is out there -- and again, we must realize that it is not being commercialized at this point in time, it is still under test development -- the food industry, the processed food industry and the food industry as a whole, we live under zero tolerance. So any chemical, any compound that is unapproved for human consumption, any level, deems that product unadulterated.

So, with that, above our support for agricultural biotechnology -- and we are supporters of agricultural biotechnology, absolutely -- this is just a sharp left turn off of what we consider the agricultural biotechnology highway, and that is why we are focused on this because we are dealing with substances that are not approved for either human or animal consumption, and with that said, any level that might escape, any level that can't be contained or confined with 100-percent certainty would deem the food supply unadulterated, and we cannot live with that unless there are in place the necessary preventive measures and the necessary regulatory oversight to ensure 100-percent prevention.

MR. CHARLES: I need to turn to Michael Phillips, then, at this point. Rhona ended with if there are no measures to ensure 100-percent prevention. Are there measures that will assure 100-percent prevention of escape of these, what have to be called, contaminants into the food supply? Can you ensure that the activities currently underway can be carried out safely?

DR. PHILLIPS: Thank you, and I appreciate the opportunity to be here today.

First of all, I would just say that I couldn't agree more with what Rhona has just said. Not only does the food industry live in a zero tolerance, but that is the law. Any product that is not approved for food or feed use, if it is found in the food supply, the food supply is considered to be adulterated, and so what is needed here and what we have, to a great extent, already are mandatory regulations. This is a very regulated industry.

The recent incident with regards to the ProdiGene example is a perfect example of how this regulatory regime does work because it does work. What we are dealing here with is a company that has a compliance issue. They did not follow the rules of the game that are laid out, and when you don't follow the rules of the game, you pay a huge penalty. I think paying 3 million-plus in terms of reimbursement to the Government and to -- in terms of fines is a really heavy price to pay, and I think that has sent a signal to any company or university that is in the business of conducting field trials that you do have to follow the permit conditions upon which you are by law to follow.

Having said that, we at BIO also have a very rich stewardship policy that runs parallel to that of the

Government regulations, and we are going to continue to work on that policy. We are going to continue to support the regulators in terms of the types of regulations that are needed in this area, so that when you are living in a zero-tolerance world, you can ensure the public that, indeed, there is a zero policy, containment policy that is being met.

So I will say at the end of my brief comments here what I said at the beginning. We could not agree with the food industry more. We support exactly what Rhona has said, and realizing the environment that we all are working in, we need to have regulations, mandatory regulations, which we do have today from both USDA and FDA in this arena and upon which we are all working in terms of providing comments on even further enhanced regulations that FDA and USDA have put out for comment, and we will continue to work with both the food industry, the grain industry, and the Government regulators to ensure that, indeed, we are meeting a zero tolerance.

Both of the first speakers have talked about zero tolerance and how that is important and that is necessary. I want to turn to you, Allison Snow.

The specific case of the ProdiGene example has been using corn as a pharmaceutical factory. Zero escape in corn, is that actually possible?

DR. SNOW: Yes, thank you.

I think on a field-testing scale, that is possible, but on a commercial scale, it is very impractical because corn is an out-processing species. It is a food commodity that is trade all over the world. The seeds are alive when they are shipped to other countries, and they are taken by farmers and grown illegally in other countries.

So, while we might be able to regulate field tests within the U.S. and maybe even commercial scale within the U.S., from the committees I have been serving on and the meetings I have had with scientists around the world, I think we need to take sort of a global perspective and not use a crop like corn because we know already that these transgenes are able to move across international boundaries.

They are probably in Mexico, and I would be happy to talk about that further if anyone is interested.

So we really can't contain transgenes that are in a food that is traded so widely and a crop that out-crosses too freely. So I would recommend what Rhona was saying is

that we separate the food crops from the pharmaceutical crops and not use the same species for those purposes.

MR. CHARLES: I think I want to follow up, actually, a little bit with that.

You say you can't do it, but what if, as requirements has been suggested, the crops that are pharmaceutical production crops are in fields separated somehow or far away from other corn crops? Why do you say it can't be done?

DR. SNOW: Well, even within the U.S., I think it would be difficult because the distance that genes move -- I guess that is what you are getting at is how do genes move around and could you isolate them physically --

MR. CHARLES: Yes.

DR. SNOW: -- we know that most pollen from a corn crop lands near that crop, but a small amount goes a very long distance and it is hard to tell how far. It might be as far as a mile, but that is really a small problem compared to where the seeds go, and the seeds can be in the farm machinery. They can fall to the side of the road. They can be shipped around the world inadvertently perhaps, after the pollen has taken the transgene with the

pharmaceutical trait into someone's crop. There are a lot of ways that these genes are getting around. So I just don't think it is feasible on a commercial scale, even with all the best intentions, to get zero -- well, complete containment, 100-percent containment.

MR. CHARLES: Okay. Greg Jaffe, turning to you. The current regulatory system, you have written has weaknesses. What is possible to do with the regulatory system? Because you have also said you want the technology to continue being developed. You see value in it. You see potential benefits. So what kind of regulatory system in your mind would actually allow that to be realized?

MR. JAFFE: Thank you, Dan.

It was interesting to hear from both Rhona and Mike that they want a mandatory system, and I think that is what we want, a mandatory system that checks to ensure that these products before they are commercializes are safe for human consumption and for the environment, and I think that the system that we have today doesn't do that.

How could the system be improved to do that? I think there are several things. First, I think you would want a mandatory permitting, an oversight system, that

before you have even a field test, before any of these are grown at all in the open, they require a mandatory pre-market review, in the first case for environmental -- an environmental assessment and then a permit issued by USDA.

Currently, USDA does not require permits for food crops that contain non-food substances. A lot of them do get permits, but it is not required by the law. There are industrial compounds that have been out there that have been grown in food crops without getting a permit under what is called a notice-and-go where there is no environmental assessment done for that crop. So I think that is the first thing that would need to be done is a mandatory permitting system that does a thorough environmental assessment before these crops are released.

The second thing would be a pre-market mandatory approval process at FDA to ensure that when and if these crops -- or these products get into the food supply that they are safe to eat. I hear people talking about zero tolerance and I also hear Allison saying that, sooner or later, these are going to get into the food supply if you use something like corn, and I think the appropriate thing to do is to do a food safety assessment of these before they

are commercialized so that, if and when they get in the food supply, we know that they aren't a harm to humans, and that if they are there in small quantities, we don't have to have billion-dollar recalls, like we had in the Starlink case.

Now, to do that would require legislation, and somebody like Senator Durbin who introduced his Genetically Engineered Foods Act back in October, his bill would do something like that. It would require anything grown in a food crop, whether or not it is intended for the food system or whether the engineering there is used to produce a pharmaceutical or industrial compound, that it would require a food safety assessment before that product could be marketed. So I think those are two things that need to be done in addition to, as Rhona and Mike and BIO and the food industry have said, strict containment and strict oversight of that containment.

MR. CHARLES: Now, up until now, we have been talking about science. We have been talking about risk, and, Greg, you just said if we can do a food safety assessment and ensure ourselves that trace quantities are safe, we wouldn't have to abide by this zero tolerance, this impractical, apparently, zero-tolerance level, impractical

at least if we believe Allison Snow.

But there is another thing, and I wanted to ask you, Julia Moore, how far do we get addressing things like scientifically evaluated risk of these things or is there a whole realm of public reaction that we are missing here that has to do with perceptions that aren't necessarily correlated with what some laboratory might come up with in terms of risk to a human population, when we are talking about things showing up in food crops that weren't originally intended to be there.

MS. MOORE: Well, I think you are seeing a zero-tolerance policy on the part of the National Food Processors Association because, in a global marketplace, consumers have zero tolerance for what they perceive as unsafe food products -- again, what they perceive as unsafe food products.

Consumers attitudes aren't formed, really, by scientific measurements. They are formed on the basis of whether they see mandatory rather than voluntary policies. They are formed on the basis of whether they see consumer groups supporting or not supporting existing regulations. They are based on how industry comports itself in a global

marketplace, and I think that if you look at the genetically modified food debate in Europe, what is more commonly known as the Franken Food Debate ,you can see what happens in a world when that confidence in the regulatory system and in industry's ability to introduce a new technology is dashed.

These pharmaceuticals grown in plants, I think, have a lot of potential, and we haven't mentioned them here. We are looking at edible vaccines. We are looking at antibodies to fight against measles or the bacteria that causes tooth decay. This has enormous potential for good, but for that potential to be realized, I think we are going to have to see an industry that accepts some of the regulatory strictures that have been talked about by Greg and others.

MR. CHARLES: We can have our discussion, get a little more free form here at this point. Feel free to interrupt and contradict each other, but I do want to come back to you, Michael Phillips, on sort of a detailed question, really, this question of how to contain genes from pharmaceutical production in corn.

I wanted to clarify your policy on, for instance, growing corn plants with pharmaceutical-producing genes in

them in corn-producing regions. Would any of your members apply for a permit, for instance, to do that kind of production on an open field in the Corn Belt anymore?

DR. PHILLIPS: Well, with regards to geographic areas in which these crops would be growing, corn -- we are talking about foreign here, but before I answer that question completely, we have many other plants that are being used besides corn, and I think everyone just could put all of this into perspective in terms of this being used in crops such as rice, crops such as safflower, alfalfa, a whole host of different types of plants and crops.

Corn is one of those. Corn is one that many universities and companies do focus on because, as it is sort of the miracle crop for food, it turns out from a scientific perspective to be the miracle crop for pharmaceutical production, as well as in many industrials. It is a very, very unique plant that we certainly are very blessed to have in terms of being able to do this type of research.

However, when we are talking about the many uses that a plant like corn can be used for, we have to be very careful about how we do put production systems together.

There is no comparison at all between the way in which we go out and farmers go out and raise a commodity corn product that is used for food or feed and the way in which companies and universities go through the process -- right now where we are in field testing -- in terms of the types of systems that are used. We use a very closed system within -- when we are using that crop for a pharmaceutical product, and by that, we mean it is a closed system in terms of the way the stewardship is handled as well as the way in which the Government handles it because, as we have said before, this is a regulated industry. You have to meet the conditions of the permit for you to be able to continue in this business, and if you don't, there are severe penalties that are placed.

With regards to where crops like corn are grown, we are looking at all types of alternative ways in which you can ensure the safety of whether if this protein would ever potentially escape to be found in the food or feed supply, and there are many avenues upon which companies and universities are exploring, not the least of which is from a technology standpoint, how you basically raise a pollen-free crop.

We are not there in terms of the technology, but that is what companies and university research is working on. So it makes many of these types of issues very moot when you basically have the situation where no pollen is traveling at all, but until we get there, we have to look at alternative ways of which to ensure that we are meeting this zero tolerance.

One of those is that of spacial isolation, to get into your question, in terms that you have to put the distance between where these crops are grown for commodity purposes versus where they are grown for a pharmaceutical or industrial purpose, and that is a commitment that our companies have made is that that is a very serious alternative that they look at to ensure that they are meeting the conditions of their permit.

And by the way, that has worked out in conjunction with the Government. Companies or universities aren't free to decide where they are going to grow these crops and the Government just hands over a permit. That isn't the way it works at all. You have to convince the Government regulators that from a scientific point of view, you have met all the conditions that will ensure that you will have a

zero tolerance. So that means that for companies and universities, they have to think long and hard about where they will be growing these crops so that they can convince the regulators that there is enough spacial isolation that you can meet a zero tolerance.

MR. CHARLES: I do have one specific follow-up, though. BIO at one point, as I understood it, said our members won't grow, as the practical example here, corn in the Corn Belt. Is that true? Your members won't grow pharmaceutical-producing corn in the Corn Belt?

DR. PHILLIPS: Our members will not grow corn that is in proximity to where a commodity corn is being grown. You have picked out something like the geographic area of the Midwest. That is one where it becomes much more difficult for a company to get the isolation that is needed to basically ensure that there would be a zero tolerance.

If in the Midwest you can find that configuration of spacial isolation where you can meet, then, the conditions of what the permit will allow, then you can certainly be there, but if you cannot, then you have to be looking elsewhere.

MR. CHARLES: I would actually like to go back to

you, Rhona Applebaum.

The requirements of the permitting process, if satisfied, does that satisfy you?

DR. APPLEBAUM: Me personally?

MR. CHARLES: Your organization.

DR. APPLEBAUM: The organization. Well, one of the things, we still have doubts associated with not only the current requirements, but what is going to be necessary when this technology is commercialized.

With that said, one of the things that we have done is we put together a task force to get the stakeholders around the table to identify and discuss what are the necessary procedures, what are the preventative practices that are needed in order to meet our hurdle -- we have raised the standard, the standard is 100-percent prevention -- and to determine what is going to be necessary, all the way from propagation to disposal and everything in between because, at any point in time when we are looking at this, there is the potential for contamination, and we need to make sure that there are the necessary interventions, the necessary preventive procedures in place to ensure that these compounds that are unapproved for either human or

animal use -- when I say animal use, we are talking about the feed animals' consumption -- from getting out. That is our number-one concern, and we have to see whether or not that mousetrap, as we are calling it, exists.

If it is thrown on the table and we are going to all be asked to look at it and to try punch holes in it -- because when we are looking at a confinement or a containment system, that system is only as strong as its weakest link.

A few links have been identified recently as being weak. They have obviously been strengthened and secured, but we want to make sure that there is no weak link in any chain associated with this particular system, and that is what we are looking at.

MR. CHARLES: I guess just to follow up --

DR. APPLEBAUM: No, please.

MR. CHARLES: Michael Phillips' answer implied that the mousetrap exists already. The current permitting process ensures control at 100-percent level. Do you believe that that exists already, or are you looking for further assurance?

DR. APPLEBAUM: We are looking -- the food

industry is a very trusting sector of the economy, but, in this case, we are going to trust, but verify. We want it verified that there is something in place right now or there will be things in place when this technology is commercialized to ensure with 100-percent certainty that there will be no cross-contamination of these compounds, again, that are unapproved for human consumption from getting into the food supply.

MR. CHARLES: Greg Jaffe?

MR. JAFFE: I think that in some ways, when I hear the two different speakers and the distinction is sort of a difference between theory and practice -- and Mike is right that a lot of these do have permits and a lot of them have different standard operating procedures in place, physical containment, biological containment, segregation procedures, and the question really is are those in practice carried out and how well are they carried out, humans are fallible and mistakes eventually will happen, and are there safeguards in place and is there oversight to ensure that if those mistakes happen they are caught quickly and corrected before there is a problem.

I know that USDA and the biotechnology industry

has sort of touted the ProdiGene situation as example of the system working, and I am not sure the system really worked. I think the system got very lucky. If the system had worked, they would have caught the problem with the soybeans on the farm and had to throw out 500 bushels of soybeans. Instead, they got to the grain elevator, which is sort of the last possible stage before it starts getting into the food supply and, in fact, had to destroy 500,000 bushels of soybeans instead. So I don't look at that as a success story. I look at that as luck that we caught it in time.

And I guess what I think really needs to be done here is if you do have permits -- and I think we have good scientists and good technical people who can put in place lots of containment, be it physical containment or biological containment, what I think is missing is this sort of oversight and inspection and education and certification and the procedures that need to be done to ensure that those steps are met along the way.

The USDA can't be out there inspecting on a daily basis these -- each one of these field tests. There are hundreds of them that have occurred so far, and I think we have to look harder at ways to ensure -- through auditing,

independent auditing, documentation and other things to ensure that not only the permits themselves as written will ensure containment, but that in practice they also ensure containment.

MR. CHARLES: Is anybody advocating no use of food crops, period, for -- as drug factories basically, or are we talking about mousetraps and containment?

Allison Snow.

DR. SNOW: I am just surprised to hear Mike say that corn is a miracle crop for pharmaceuticals because I think any food crop has problems that we have already identified here just now and that it is very impractical to be able to get this 100-percent containment. So we ought to steer away from food crops and look at these other ones that you mentioned, like tobacco or safflower or -- I don't know -- other --

MR. CHARLES: Safflower is a food. It is a food product. Once you move away from tobacco, Allison, what crop do you go to that is not a food crop?

DR. SNOW: Petunias, kanaffe [ph]. I don't know. I am not in that field.

But I am just saying that if there is one fatal

flaw, it doesn't make it an ideal species anymore to be working with, and I think the flaw with corn is that it is a widely disbursed food and a commodity and it out-crosses. It has multiple flaws. It is probably, from a gene-flow perspective only -- it is probably the worst species that could be used, and yet, companies like ProdiGene are investing -- they are only testing corn. I don't understand the lack of interest in other species when there are these serious flaws.

MR. PHILLIPS: There are good scientific reasons why corn is used, and we could have a whole forum just on that, but to say that because there are some risks, we should just move away from it entirely, you know, our industry could not disagree more.

There are ways, and we have got it in the existing system that we have today. We are going to enhance this system. We are going to support many of the things that Greg just talked about. Absolutely, we are going to be supporting things such as self-audits, such as mandatory inspections by third parties, such as training, such as -- of all the workers that are going to be in this field, confinement systems which we have already published a paper

on, mitigation plans, transportation plans, the whole host here that Rhona has been alluding to. We are in complete support of all that.

You can put systems together, and besides that, there is evolving technology out there that it needs time yet, but it is clearly going to pave the way for many of the things that we consider to be risks today. It is going to eliminate, if not -- mitigate, if not eliminate many of those risks.

MR. CHARLES: Actually, at the risk of getting slightly biological and technical here, I am curious about -- again, to Allison Snow -- some companies are using wheat, for instance, or self-pollinated crops where essentially the flower is self-contained, the pollination happens within the plant, very little out-crossing, as you say. Does that solve the problem, or are there still problems?

DR. SNOW: I think it is preferable, but it doesn't solve the problem because the seeds are moving around, even if the pollen isn't moving around. People are trading seeds, and they are being exported and they are alive. So the genes are moving in the seeds.

So I think it is still a problem with any type of

food crop that your industry is going to be very concerned about.

MR. CHARLES: Okay. Further follow-up questions here. What about the issues of environmental risks that have been much in the air with genetically engineered crops generally, out-crossing to weeds in this case as opposed to crossing within the crop itself? Is there anything peculiar about pharmaceutical production in crops that raises particular environmental concerns?

DR. SNOW: Are you looking at me?

MR. CHARLES: Yes, I am looking at you again.

DR. SNOW: Okay. This is a bit outside my area.

MR. CHARLES: Oh, sorry.

DR. SNOW: But it would depend on the pharmaceuticals, if there was any effect on livestock or wildlife. You are thinking of other than the health concerns that we have mentioned.

MR. CHARLES: Other than health concerns, yes.

DR. SNOW: So it depends on the scale that they are grown at. They probably wouldn't be grown in a large scale.

MR. CHARLES: Let's say an anti-diarrhea compound

gets into wild relatives of sunflower. Does anyone have any idea?

DR. SNOW: I don't know whether other people want to talk about that, but I really think there could be some environmental effects, but it is so speculative right now and you need to know what is the crop, what is the trait, what scale will the exposure levels be before we start thinking about -- I mean, it is good to consider that.

MR. CHARLES: Yes.

MR. JAFFE: If I could answer your question, Dan. I can't answer the question about the anti-diarrhea crop in particular, but I think the NAS had a panel that came out with a report on transgenic plants back in February of 2002, and they specifically raised that issue that there are environmental risks associated with these pharma applications such as genetic engineering and that they aren't really being looked at, that there really needs to be thorough environmental assessments.

And I think one of the things that hasn't been looked at very closely on these -- and maybe it is because they are small field trials, but there still are non-target effects. Birds still do eat corn, and you have deer getting

into fields and other kinds of animals. And I think there haven't been looked at -- the USDA doesn't do environmental assessments on a regular basis when they issue these permits.

So I think that you do need a more rigorous system in place. I think until you have that in place, I think you should consider not using food crops because I think you will have problems until you can have food safety assessments and environment assessments of these. I think we should be using things like tobacco instead. I think we should put in place in the system incentives so that non-food crops are chosen to be used by these companies.

MR. CHARLES: And, Julia Moore, you had something else you wanted to say, but I wanted to ask you how has this episode, this recent episode, been covered abroad because this is something apparently you have looked at.

MS. MOORE: The ProdiGene incident has been more covered in Europe than it has been in the United States.

In Europe, consumer groups and environmental groups have said, "See? This is not a perfectly regulatory system because, guess what, people are imperfect," as Greg said, and you are always going to have these problems unless

you have a more restrictive system that is the mousetrap that you can punch these holes in and not penetrate.

I think we have talked a lot about science, and I think in terms of biotechnology, this has been an unusual discussion because we have tried to focus in on the realities of the existing regulatory structure and the science, but there is a lot of politics in this.

One of the reasons that corn, which has pros and cons for use in pharmaceutical plants, is being discussed is because there is this expectation in the Middle West which is where I come from that this is the gold mine.

Iowa is the next Silicon Valley, and they are going to be rolling in green, green money, which is plants that produce these wonderful miracle drugs.

I contend that the jury is still out on whether corn is the ideal crop, but, certainly, if it is and if you are going to address the concerns of the food industry, you are not going to be able to grow this corn in America's bread basket.

MR. CHARLES: Yes, Michael.

DR. PHILLIPS: If I could. I think we are getting a couple of things here mixed up, and I think we need to

keep them separate.

We are dealing with the ProdiGene case as not an issue with regards to what the regulatory structure is. What we are dealing with there is a company that did not follow the rules.

Now, you can have the most stringent regulatory system that man has ever invented. If a company does not follow the rules, you are still going to be in the same problem, and that is why -- and we applaud the USDA and the way in which they have handled this situation where you send a loud signal, i.e., through penalties and through fines, that this will not be tolerated, and if it means a company goes out of business, then so be it. That is the way that this is going to have to work.

So I think we need to separate the two because, if you are going to have institutions that are not going to comply with the rules, i.e., they are breaking the law -- and when you break the law, you pay a huge penalty. So I think we need to focus on -- when we are focusing on this to keep these issues separate.

We are as an industry extremely supportive of the Federal agencies in putting out the most stringent

regulations that we can, so that this area can move ahead. There are too many benefits, as Julia has I think very well laid out, for us not to move ahead because we have huge issues in the medical arena that this alternative source of developing the proteins for therapeutic compounds that can save lives and that people need, that the -- it is just so commanding that you must find a way to make something like this work.

And I think that we are definitely working with the Federal agencies, exactly on the right path here. We are going to continue to work with the agencies in terms of supporting them and making the regulations as tight as possible so that we can ensure that we do have zero containment.

MR. CHARLES: Greg Jaffe, in the ProdiGene case, was the fine huge? Was that an adequate deterrent, do you think?

MR. JAFFE: I mean, I think that from USDA's perspective and given the kinds of fines they give, it was a very large fine, $250,000, and the payment to recoup for the destruction of the soybeans, I think is a significant deterrent. How that will affect ProdiGene's bottom line, I

am not sure.

I don't know exactly what were their compliance problems, how they got to the stage they were, and so it is hard to comment about whether this is just a company-specific thing or whether it is endemic of the industry, although we did have a Starlink issue before we had Pioneer and Dow violations in Hawaii. We have had a number of other incidents with the industry not complying with permit or registration conditions that at least begins to make somebody think that if the agencies looked harder -- and again, it is unclear how hard USDA or EPA has really looked -- if they looked harder at all the permits that are out there, then we might find significantly more violations.

So I think there really needs to be a lot more oversight and inspections to ensure that they are. In the ProdiGene case, they put in, in that settlement, a fair amount of injunctive relief in terms of education certification, documentation, auditing, all kinds of things in place specific to Prodigene, mandatory permits.

It is unclear for me whether those are just going to become standard practice, but I think at a minimum, they need to become standard practice for every pharmaceutical

and industrial application that is submitted, and right now, USDA has not come out and said that.

MR. CHARLES: One thing, before we go to questions from the audience -- and we are getting there soon -- I wanted to get your response, Mike Phillips, to one proposal that was made from the panelists that any time you actually were doing a pharmaceutical production in a food crop, that you at least get approval for that as safe, at least in trace amounts in food. In other words, you would have to go through a food safety process before you even did this in a food crop, even if it wasn't intended for consumption. Is that something you would agree with?

DR. PHILLIPS: Where that is possible, absolutely.

MR. CHARLES: Where it is possible.

DR. PHILLIPS: Where it is possible, but, I mean, you will be dealing with some proteins upon which they make excellent therapeutic proteins, but you could not possibly get a food or feed approval. So you end up constraining yourself unnecessarily at times.

But where it is possible, by all means. I think we do have to look at that very seriously.

This is an issue that I think FDA is going to have

to give a lot of serious thought to because if, as you read the law, this is -- they give approvals based upon intent, and lawyers know this much better than I do, but you have to be very careful about the way in which you are asking because, if it is not intended for the food supply, then it puts FDA in a bit of a box, how then you can approve it to be. So it ends up being a circular argument, to some degree, but I think those are things that we can all work on.

I think those are things that -- we do know that there are some compounds out there, like trips in that does have GRAS status when it is intended for the food supply.

MR. CHARLES: GRAS for those in the audience who don't know it?

DR. PHILLIPS: GRAS is generally recognized as safe by FDA, and the question there is can that transfer over to when it is used in a non-food way, that it could still have that type of status, and I think that is an open question that has to be addressed by the agencies and the industry.

MR. CHARLES: We can have one more question to the panel before we go to questions from the audience, and this

is to you, Rhona Applebaum.

This morning, I went and looked through this document that was put together. It is a document from the USDA and FDA on exactly the topic that we are talking about today, and particularly in the section that dealt with containment in the field of genes and gene products, there was a lot of language like "companies should consider the use of crops that are not food crops" or they should think of this. It seemed very vague and mushy to me. Is that how you see it? Is that enough, or do they need to be much more specific?

DR. APPLEBAUM: Your first question, yes, it is mushy, and that is one of our major concerns as it relates to the guidance. It is "you should consider," "look at this." There is a big difference between "looking at this" and "you shall do," and that is one of our concerns, but I think listening to my colleagues on the panel -- I think we are all in agreement that once the system is identified that truly has been proven to contain and confine with 100-percent certainty, there must be regulatory oversight and regulatory requirements put into place to make sure that that is the system that is being used to achieve that

particular standard that we are looking at. So I think there is an agreement amongst the panelists as it relates to that particular issue.

MR. CHARLES: Okay. So I would now like to open it up to questions from the floor, and let me explain a little bit how we will run this.

Let me also remind viewers on C-SPAN of the e-mail address to which you can send your questions, and that is bio@cspinet.org. That is the e-mail address to which you can send questions.

If you have a question, feel free to wander over to this microphone. Raise your hands first. I will recognize you, and then you can go ask your question at the microphone. I also will mix in some questions from these cards.

Please do identify yourself and your organization if you are from an organization so that both we and the audience on C-SPAN knows who you are.

So are there any questions immediately?

MR. CLAP: Yes. I am Steve Clap [ph] with Food Chemical News.

Greg mentioned the Durbin bill which would require

these food safety assessments and environmental assessments. This is an area of legislation that the food industry has been opposed to in the past saying basically it is unnecessary.

Rhona, does the ProdiGene affair cause you to change your mind at all about that?

DR. APPLEBAUM: No. The issue is we need to make sure that the necessary regulations, regardless of what laws there are on the books, if you don't have the appropriate implementing regulations in place, there is nothing for the companies to abide by.

We feel very strongly that this particular issue with the stakeholders in agreement as we are can be done at the USDA level, the FDA level, as well as the EPA level as it relates to this particular issue of PMPs.

MR. CHARLES: Adequately answered?

What was that last thing?

DR. APPLEBAUM: Oh, I'm sorry. The plant-made pharmaceuticals. I'm sorry. The issue we are discussing at this point in time.

MR. CHARLES: Okay.

MR. : It is great to have a response to

that.

[Laughter.]

MR. CHARLES: The question from Food Chemical News is does Greg have a response.

MR. JAFFE: I mean, I think that the problem -- and I am surprised that the food industry had that position, especially it sounds like Mike in his answer before to your questions says the bio industry is at least willing to look at a food safety assessment for these crops. Is that the -- FDA system now is really voluntary, whether it is for -- intended for food or not intended for food. It is voluntary, and clearly, as Mike said -- and he was correct, even though he wasn't a lawyer -- that the FDA's mandate only is for things that are intended for food. So, if you grow it in a food crop and it is not intended for food, it doesn't fall under FDA's authority until it gets in the food, until it gets into one of Rhona's client's food, and then it becomes adulterated. So there is a gap there where FDA doesn't have oversight until it is too late, until it is already adulterated, until we have got to recall it, until we have to worry that humans have eaten it and it may be dangerous.

I think what the Durbin bill does -- and I think it does it in a realistic sort of rational way -- is say FDA takes a look at these crops for things that are intended for food. It will do a close look because, in that case, humans will be exposed to it in fairly high doses potentially, and for things that aren't intended for food, it can look at it in a much more cursory way, but it can ensure that if it does get into food, it is not an allergen or a toxin or doesn't -- won't cause any problem, again, that doesn't -- does not still -- does not mean that we still shouldn't try to contain it and prevent it from getting in the food, but when it does get in, you know, the consumer doesn't have to worry that he has eaten something that is dangerous for him.

DR. APPLEBAUM: I would just like to respond to that point because we have a concern with that, and the concern is regardless of whether this compound that is unintended for human or animals gets into the food supply, regardless of the fact that it might have gone through a food safety approval process -- and I question that very -- you know, to a great deal -- we have a concern because it has gotten out. That is our concern, and we want to make sure that if the use of food and feed crops, as Dan put it,

as factories for the production of pharmaceuticals and industrial chemicals, if the system in place cannot confine those crops to the point where it doesn't get into the human or animal feed supply, then you should not be using food and feed crops for this purpose.

I don't care whether there is a safety issue involved or a non-safety issue involved, Greg, because the way you are doing it, you are developing a bifurcated system. If it is a safety approval process, yeah, you can use corn. If it is not approved from a safety perspective for corn, then you put it into tobacco. That is not acceptable to the food industry, unacceptable.

Perception is reality on the part of the consumer, and to have these compounds getting into the food supply that are not intended for them to be consumed, we have a problem with, and that is where we are beginning to differ in regards to the use of food and feed crops. The bottom line is yes, use of food and feed crops for this technology is appropriate if the necessary preventive procedures are in place.

In the absence of those preventive procedures as well as the regulatory requirements to support them and, if

need be, in terms of other factors involved, you don't use them. You find something else. You find another vehicle. You find another factory, but you don't use food and feed crops.

MR. CHARLES: Greg is asking for the last word here.

MR. JAFFE: Just one little follow-up on that. I guess that is what it sounds like is then you don't use it in food or feed crops because I think that humans are fallible and that you are going to have -- I mean, you can set up the best containment system. You can set up the best inspection system. You can set up the best oversight system. But how do you prevent the fact that, you know, some farmer or the person who is growing this has a son or daughter who is 8 years old that goes and mixes the bag of seeds by accident or something? I mean, accidents --

DR. APPLEBAUM: Because --

MR. JAFFE: -- do happen.

DR. APPLEBAUM: Absolutely, and we also have to be aware of the environmentalists who hate this technology, who could use intentional sabotage to bring agricultural biotechnology to the ground, and that is one of our major

concerns, but we have to make sure that, you know, we work to identify the best system, if the system exists. If it doesn't exist, again, guess what, you don't use food and feed crops, but if it exists, you have to make sure all the mandatory requirements, the stringent requirements are in place, including, but not limited to licensing farmers and everyone from propagation to disposal to make sure they know what they are doing.

MR. CHARLES: Does anyone want to feel themselves called upon as an environmentalist to Julia?

MS. MOORE: Environmentalists do not hate this technology. In fact, one of the pieces on my biography that Dan didn't talk about was my stint as executive director for Physicians for Social Responsibility.

I first became interested in this issue because I wanted to reduce the levels of pesticides in the diets of infants and children, and at that time, I saw biotechnology and the industry saw biotechnology as a means of reducing exposures to pesticide.

Like any technology, this technology can be used for good purposes, a healthy environment, to improve human health, that are good for medicines, or they can be used for

bad purposes, and I think what the environmental community and basically what all consumers are saying is let's make sure we get this one right.

MR. CHARLES: We had one question from the Internet specifically -- well, to you, but you have answered it, but also to Mike, whether you agree with this Durbin bill requirement, I guess specifically on FDA approval of the engineered -- this question may assume some facts that are not quite right, but FDA approval of the pharmaceutical production in a food crop.

DR. PHILLIPS: I think it is as Rhona said. The statutory legislation laws that we have today is very adequate to address this whole area, and we see no reason why we need any kind of new legislation whatsoever.

There is ample room within the statutory authority for FDA, USDA in this area to promulgate all the regulations that they need to assure the safety of the food and feed supply.

MR. CHARLES: Question from the floor. Please identify yourself.

MR. METTS: Matthew Metts [ph], fellow from the American Association for the Advancement of Science.

Sorry. This isn't a question, but I wanted to inject something that seemed to be missing from the discussion up until this point, and it comes down to intellectual property and infrastructure as being some primary reasons why you see food crops such as corn being used currently.

The industries that use these technologies have a great deal of licensing issues and a great deal of expertise and personnel invested in using particular crops, corn being one of them, and until there is a realization that the expense in terms of liability and public relations is so great that they need to invest in using other crops and will, unfortunately, see things like corn continue to be used.

MR. CHARLES: Any response from the panel?

MR.PHILLIPS: Well, I would just say that there is more than corn that is being used here. I think we are focusing a lot on corn, and for the reasons that the moderator has listed, but we have companies as well as universities that are working in all different kinds of plants. So I would hope that everyone would just take away from here that this is not just corn. There are many other

crops that are being used that I indicated earlier from alfalfa to rice to tobacco to safflower, a whole host of different plants that are being used. So the focus is not just on corn that companies are concentrated on.

MR. CHARLES: Question?

MS. THROW: I should thank the previous questioner because it ties in exactly with what I wanted to mention, and it is also related to what Michael Phillips just discussed for us.

One of the themes in our discussion here today is what public goods are we looking at.

MR. CHARLES: Could you identify yourself?

MS. THROW: Oh, I'm sorry. Anne Marie Throw [ph] from USDA, CSREES, Cooperative State Research Extension and Education Service.

We are looking at public goods. We know that investment opportunities are a public good. Any of us that have retirement funds know that. New sources of pharmaceuticals, as Julia Moore mentioned, new drugs of public good, public safety, consumer confidence is an important public good.

A fourth one, when you are looking from a national

perspective, you are looking at the entire map of the U.S. and your job is to try to think of what are some sustainable income streams for other rural areas. Here is an opportunity to perhaps put some of these new marketable products in crops that do grow well in some of these other areas, like you are on the Eastern Seaboard. Tobacco would be an example, sugar beets, maybe even [inaudible], something like that.

So my question particularly for BIO, but for anyone, would be: To what extent would that have to be a public sector investment? To what extent and under what conditions would joint ventures with the private sector be feasible, be practical, so that we don't miss that opportunity from this technology to develop income streams for other parts of the rural United States?

[Side B of audiotape begins.]

MR. PHILLIPS: The answer is yes in terms of any kind of public/private partnership. In fact, a number of our companies already are in those types of partnerships of various forms, not only here in the U.S., but in Canada as well, and what we are certainly encouraging is more of that.

I think both the private as well as the public

sector could do an even better job than we have to date of looking where those opportunities are and where there are avenues upon which we can collaborate and work together on.

MR. CHARLES: Any other response to that?

[No response.]

MR. CHARLES: Let me shuffle in a question on a card here. It says the message so far today is confused. Do we have and will we have a zero tolerance and, therefore, safe food? Let's get a clear message to the public based on science.

The question, I guess, assumes that zero tolerance equals safe food, and is that your position?

MS. APPLEBAUM: The issue is not one of safety at this point in time.

What we are looking at and what we live under in terms of the current laws that the food -- the processed food industry, the food industry in general lives under is zero tolerance. No level, regardless how small, can be in food if it is an unapproved substance. That is what we are living under.

So it is not an issue of safety. Even if you have a safe compound that isn't approved for human food, the

product is adulterated. That is why our number-one concern continues to be and will remain safe, wholesome, and unadulterated food, and that is where the concern is.

So the issue is not necessarily, Dan, one of safety because we have situations where there are unapproved substances found in food that are safe, but we still have an adulterated product and it has to be removed from the food chain and the food supply. The risk is too high because the food industry is left holding the bag, the risk bag, and we are the final step to the consumer.

And we do appreciate -- absolutely, we appreciate the benefits that this technology can bring, whether it is for -- you know, in the therapeutic area, whether it is for the farm sector, whether it is for new jobs. Absolutely, we appreciate that. We also appreciate the challenges that are not only presenting themselves to the particular areas of the country who want to have this type of technology, but we also can't forget in terms of what we have to deal with as it relates to ensuring that our products and the products that we sell our consumers are, again, safe, wholesome, and, in this case, unadulterated.

MR. CHARLES: We are getting quite a line over

here. Let's move on.

MR. : [Inaudible.]

MR. CHARLES: Oh, we do. Well, that will confuse things. Are there people waiting over there, too?

MR. : Just one.

MR. CHARLES: Well, you have been waiting. So why don't you go ahead.

MR. WHITE: Hi. My name is Jim White. I am at USDA APHIS Biotechnology Regulatory Services, and I have four comments to make.

First of all, about field testing, the ProdiGene incidents were discovered by APHIS and State inspectors who were inspecting these facilities. I want to remind everybody that is listening that before any field test occurs or any importation to a contained facility like a research lab or a university, the State has to concur with that.

The inspectors -- the State inspector and I will also -- was there when the ProdiGene incident in Iowa was detected. We talked a lot about other crops, and you can read a letter from me dated May 20th of 2002 on our website where APHIS has some concerns about other crops.

I would say that a crop like sunflowers would never receive approval. One big issue is the plant cannot out-cross to pre-living sexually compatible species. So that eliminates many plants like sunflower and alfalfa.

We are also concerned about seed dormancy. That is where seeds would lie on the ground and won't germinate. For brassica species, this can be for 7 or 8 years. We can see you could have to monitor forever for that kind of thing. Those are two things that corn doesn't have a concern about.

One thing that we thought about, about this technology, is that we really need -- and I think Rhona has a very good point. We have to have a system in the United States. We are very concerned about it going to China or someplace overseas that might not have the infrastructure of regulations that we do in the United States, and they could still end up in our food supply. So that is something that I think we have to balance, too, because if the benefits of some of these technologies do get through the FDA regulatory process and be approved as new therapeutics, where are they going to be produced, and where would they be safer produced to protect us since we do import a lot food for foreign

countries.

We have thought about moving to other crops, but I don't think that addresses very many concerns. I have mentioned pasture [?] beans, for example, because I don't have any one better, but if you grow large acres of pasture beans anywhere in the United States -- and we looked hard -- there is always other productions. If you are concerned about seeds going from one place to another place, crop debris, those issues don't go away. So, personally, I don't see the corn seed mixture issues about people planting things or something like that being any different than planting any other plant product. So, I mean, that is all open to debate.

We have thought about those things. There is no perfect system. There is no perfect plant, and humans are fallible.

MR. CHARLES: Any responses from the panel directly? We have lots more questions.

Go ahead.

MR. MENDELSON: Thank you. My name is Joseph Mendelson [ph]. I am with the non-profit group, the Center for Food Safety.

It is part response and part question. With all due respect to Ms. Moore, I don't think the environmental community -- it is not a question of love or hate. I think it is a question of reasonable skepticism that the actual environmental review has taken place for this technology. I think this is a very good case in point that we are talking about. We are talking about issues after the fact here, issues about containment, about spread of the seeds, about what might the impact be on wildlife.

The USDA, with due respect to Jim, has never done a full environmental impact statement on this particular sector of genetically engineered crops. It would seem that the system should take -- that that review should take place before any planting were taking place, before we are dealing with these issues as a way to find out how we can contain this, whether we can contain it, whether we can geographically contain it, whether it is food crops or not, and I guess the question part is yesterday our organization and a coalition of environmental groups filed a legal petition asking the USDA to institute a couple of things, a moratorium on any outdoor planting or the use of food crop planting for these types of genetically engineered crops,

that that moratorium be in place indefinitely until a strict regulatory system is actually in place.

With all due respect to Mr. Phillips, we are talking guidance here. We are not talking regulation. I think Ms. Applebaum pointed out a lot of the mushiness in that system.

And I think the other issue is conducting a programmatic environmental impact statement for these crops, to look at all these issues, and finally put some public -- robust public discussion fostered by our Government to discuss this matter.

The last issue is to revamp confidential business information in FOIA requests. When it comes to the ProdiGene example, we are still not quite sure what type of material even got into the food supply. There had been varying press accounts, and we would like to see that reform.

My question, then, is directed to Ms. Applebaum. If these type of things would be supported by the National Food Processors Association and some of its members, I would be interested in your response to that.

DR. APPLEBAUM: Your point regarding the

moratorium on outdoor planting of these food crops until the regulatory systems are in place, we have concerns even during the testing phase, not so much with the regulatory system in and of itself, but the fact -- the regulatory system can only regulate the mousetrap. And our concern at this point in time is we haven't seen the mousetrap.

Stakeholders have said it is there. The farming community, various farmers within the farming community, have said they had it. Mike has said his folks have had it. His folks have come to his companies in terms of we have a system.

What we want to do is we want to take place -- because it is not just a system, you know, in isolation. It has to be a continuum. It has to be, again, from propagation to disposal. We want to make sure that there is, indeed, a system in place, and, of course, that system must be regulated.

MR. CHARLES: The question was they are calling for, if I understand it, a moratorium on all open field planing.

MR. MENDELSON: All open field planting and on the use of food crops in general. So, in other words --

MR. CHARLES: Starting now.

MR. MENDELSON: -- you couldn't do indoor crop food -- indoor plant food crops.

MR. CHARLES: Right. So is that a reasonable [inaudible]?

MS. APPLEBAUM: Our -- and you have a copy of our position statement. Our position statement says avoid the use. It doesn't say whether it is in testing situation. It doesn't say whether it is during commercialization. Avoid the use of food and feed crops unless -- without -- you know, if there is -- you know, minus the established preventive procedures. So that is what our position is, and the fact that even in the testing phase, there is the potential for contamination, we have a concern with, and, again, we talked about what recently happened in Nebraska. All we can say is thank goodness, it was contained. Thank goodness, we had alert regulatory professionals out there to find it and contain it.

But what would have happened if they didn't? Again, we are talking about 500,000 bushels of soy. We are talking about very, very small levels of this plant being in there, very, very small levels, extremely small levels, but

extremely small levels are still greater than zero and that is what we live under.

MR. CHARLES: Any other response?

[No response.]

MR. CHARLES: Okay. Let's continue.

MR. : Hi. I am Michael [inaudible] of the National Academy of Sciences.

I was wondering, the panelists are discussing biological containment, and they are referring to biological confinement, but none of you has yet distinguished the conceptual difference between the two because I think there is an important underlying conceptual difference. So, for the sake of the audience and the general listeners, I was wondering if you could just engage me a little further and distinguish between containment versus confinement.

MR. CHARLES: Go ahead.

MS. SNOW: That is a really good point, and a lot of people think those are the same terms, but when you start looking at these issues, we talk about containment meaning total containment and confinement just meaning reducing as much as possible the amount of gene flow or contamination that might occur.

So confinement is actually the only thing that is practical in field tests. You can find the genes. You don't really know how far they are going or how many are escaping, what tiny, tiny fraction is getting out. So, usually, "confinement" should be the proper term because containment is so difficult to achieve, even though we are assuming that it is possible. That is my point of view.

MS. MELLON: Well, I guess my question --

MR. CHARLES: Identify yourself first.

MS. MELLON: Oh, my name is Margaret Mellon [ph]. I am with the Union of CONcerned Scientists.

And my question, at least the first one, concerns the mousetrap and who is going to build it. In fact, we are relying on the USDA primarily to build the mousetrap that we are talking about, and I think it is important to realize how weakly that agency has performed as a regulator up until now. It has been under heavy criticism, certainly from the environmental community, for the last 15 years for the weakness, the structural and weakness in practice of its regulatory system.

It was the target of a report issued last year by the National Research Council pointing out the deficiencies

of the Department's regulatory process, specifically its lack of scientific rigor, its lack of participation. It does -- almost everything it does in secret doesn't seek out the participation of either the scientific community or citizens, the lack of transparency. I mean, you really don't even know now what they have done and the reasons for which they have done it.

So, with that as a background, I would like to, I guess -- I would like to ask whether the USDA has even embraced the standard that Ms. Applebaum has articulated of zero contamination of the food supply as the standard against which it is going to measure its own regulatory system.

I mean, I have not heard them say yet that is where we are going, we are going to make sure that we will not contaminate our food supply. So that would be -- you know, that would be one of my questions.

My other one, which is perhaps more rhetorical, is that -- I mean, I am pleased that they got ProdiGene. How do we know that other companies have not escaped their net? I mean I, for one seeing that net as full of holes, really doubt that they are the only ones that slipped up to the

extent that they did. These kinds of crops have been grown for almost 10 years now. So that is my question.

Congratulations for ProdiGene, but who else is out there?

Then I guess I will ask one more, one more specific question, to Ms. Applebaum, and that is whether your policy -- I think the answer is yes, but I just want to be clear. Your policy of zero contamination embraces not only the crops that have been grown with an intention to produce a pharmaceutical, but also those crops that have been grown to produce other chemicals for industrial uses, for example, plastics.

DR. APPLEBAUM: Yes, but can I ask --

MR. CHARLES: We had multiple questions there. Did you just want to --

DR. APPLEBAUM: Your last question is yes.

Now I am going to jump to you first question. We don't expect USDA to develop the mousetrap. With all due respect -- and I love the folks in the regulatory agencies, FDA and USDA, but if we waited for our regulatory brethren to develop the best tools by which we operate, we would be -- I doesn't want to say where we would be. Their job is to

regulate, their job is to enforce, and their job is to protect the public's health. You can't expect them to come up with everything in terms of meeting the needs of the industry. It is going to be everyone engaged.

For example, the farmers have to identify how they are going to be able to contain -- thank you very much -- these compounds that are unapproved for human and animal use or animal consumption in their part, in their sector, and we also allow and we also expect the tech providers to also be engaged in that because who knows better how to do that than the industry that is engaged, whether it is the farming community, whether it is the tech providers. We are going to be at the table, not that we are going to tell them how to do it, but we are telling them what they need to achieve, but, absolutely, the Government agencies need to be involved because they are part of the stakeholder community.

MS. : Well, I mean, I just couldn't agree more that those are exactly the stakeholders who should have been invited not next week, but, in fact, 4 years ago to the table to help fashion the USDA system which we saw right now.

I mean, I don't think that the environmentalists

are the only folks who were left out of that process. In fact, I think there were numerous other stakeholders, including the food industry, who weren't there, who should have been there, and who did not really have much of a say about the current system that we are now relying on.

MR. CHARLES: I would be curious -- yes. Well, first of all, we could do something interesting here and have a back-and-forth between two microphones. Does anyone from the USDA wish to reply to the charge that you have been weak, lacks, ineffective, and possibly missing lots of other violations apart from ProdiGene? I mean, it is your opportunity. You shouldn't feel required to, but I wanted to give you that opportunity, if you like.

MR. WHITE: As Marty well knows, I called Jane Wristler [ph] at Union of Concerned Scientists, invited her to the public meeting in Iowa and pay their way, and Jane declined. That was the public meeting cosponsored by FDA and USDA in draft of the public guidance document that is now currently available for public comment.

You can read about the inspections and read the totals and our analysis in the OSTP case study that was published right at the end of the Clinton administration.

You can reach that from the APHIS biotech website, and that will summarize the number of compliance infractions to that date. That is the best public data that I have right now, that I can remember right offhand, and that was 60-some from '95 to 2002, give or take a year or two. I don't remember, but that is where you can read the numbers.

MS. : Well, those are at least -- I mean, that is at least 2 years old, and it is only one. So those are moving in the right directly, and as I said, the USDA has been moving in the right direction over a number of years. I think they still have a long, long way to go.

MR. CHARLES: I think I am going to have to move things along here a bit.

A couple of responses from the panel. Greg, and then Julia.

MR. JAFFE: Yes. Based on the last comments both by Rhona and Marty and Joe, it seems to me that maybe there is a consensus-building around here that USDA should be having a mandatory permitting system for these crops before they are grown and that that process should be public, bringing in all the stakeholders as Rhona is saying to look at the draft permit, to look at the conditions that are

going to be put in place. That doesn't happen now. Most of the permitting that does occur, the companies submit their proposed conditions. USDA may add some conditions or not add some conditions. It is all done primarily in secret, and then the permit is allowed.

I am wondering, asking Rhona, Mike, and others, whether there would be consensus around, at a minimum, having -- agreeing that for food crops that are used to grow pharmaceuticals or industrial compounds that there be a mandatory permitting process that they all be required to have permits and that that process be an open process within an environmental assessment beforehand and a public dialogue beforehand.

MR. CHARLES: Are you all ready to sign onto the Greg Plan?

Just quickly, I am curious. He has asked for a direct response from Michael and Rhona here.

DR. PHILLIPS: Well, there is a lot of things I can agree with, with what Greg is saying.

Clearly, you knew -- first of all, we do have a mandatory permit system. Let's not forget that. The point has been made that if for certain classes of proteins that

are used for industrials that you can do that under notification, and I think the APHIS folks that are here will concur that that is true. That is an area in which we as an industry when we provide our comments on the FDA/USDA joint document, we will be saying that there should be no protein which is not intended for the food or feed supply that should be done under notification. All of this should be done under mandatory permitting.

That being said, I think there is going to be ample opportunity for all of us as stakeholders to be able to comment to the agencies about the system that needs to be put in place and the way that that should be run and that should be handled, and that is a good thing.

We cannot, however, get it to the point where we are holding up permits for companies or universities until we get the input from all stakeholders. Stakeholder input is good in terms of helping lay out the rules of the game and how things should be done, the certain types of assessments that should be mandated under certain conditions, but at that point, you have got to back off, turn it over to the regulators. They make the final decisions with regards to what they will or will not accept

from all of us as stakeholders, and then they by law are the ones that are responsible for then laying out what the conditions of the permit will be for either that company or that university or whatever the entity is. And that is the only way you can have an operational system.

MR. CHARLES: Do you have a quick response, Rhona, to the Greg proposal, mandatory --

DR. APPLEBAUM: I agree with what Michael just said in terms that it is mandatory, the permit process. So I think, does it have to be continually refined? Absolutely. Absolutely. But I question, if you will, making sure that everyone, you know, all stakeholders -- once the system is in place and it is mandatory in terms of going beyond the permitting process as it relates to everything that is necessary for these plant-made pharmaceuticals and the industrial chemicals, then, again, our regulatory agencies are responsible for not only regulating, but enforcing and ensuring the public's health.

MR. CHARLES: Okay.

DR. APPLEBAUM: They are there to do the job.

MR. CHARLES: Julia?

MS. MOORE: I think there are more than 75 people

in this room and I think there are probably 75 different opinions on USDA.

I think USDA, given the resources that it has got, does a reasonably good job, and, in fact, we shouldn't lose sight of the fact that America has a pretty good safe food supply compared to the rest of the world.

I think there are some focused individual questions about the regulatory system, but I think there are some larger questions that we shouldn't forget. One is that I think USDA is terribly under-resourced in this area, and I think if you want a better USDA regulatory system -- and everybody at this table wants that and everybody that is watching this program on C-SPAN wants that -- you have got to give USDA more resources.

I think the second point is we are dealing -- and we deal every day in Washington -- with an alphabet soup of USDA, FDA, EPA. We have a system, a regulatory system that is politely called Patchwork Here for Food and Drugs Now that I would contend is inappropriate to 21st-century science. We are looking at pharmaceuticals and plants coming together in a way that we have never seen before.

The panelists all had lunch together to sort of

sharpen our knives and get to know each other, and we talked about nanotechnology which is going to be another piece of new science that will be a part of this whole equation. We are not ready for that.

I think there is a final point, and that is that in our regulatory system, particularly FDA, there is a dual mandate, a mandate to both promote American food products and also to protect public health.

I believe that in the future, it is going to be very hard to convince consumers that any regulatory structure can do both, and I think in Europe, they are taking a very hard look at regulatory agencies that have both mandates and they have decided to separate them out.

MR. CHARLES: Question?

MR. FREEZE: Yes. I am Bill Freeze [ph] with Friends of the Earth.

We prepared a comprehensive report on biofarming this summer and talked a lot about ProdiGene because they are one of the leaders in the field and actually warned about the risk of contamination then.

I think what most convinced me that open-air biofarming is not feasible without contamination is when I

read the leading -- the editorial in the leading biotech journal, Nature Biotechnology, and the authors just flat out said current gene containment strategies cannot work reliably in the field.

I think what several panelists have said is correct that you can have perhaps 100-percent containment on paper, but things are very different once you get in the field where you have human error, where you have the vagaries of nature. Nature is simply not a pharmaceutical factory.

To add to this, of course, is the problem with USDA regulation, and I believe Greg mentioned the NAS report which came out recently. Some of the specific criticisms that they had were that the USDA had too few personnel, that they inspected some field trials just once at the start of the trial, and, in fact, with industrial chemicals, many of those field trial plots are not inspected at all by the USDA, and that many of the inspectors are often not trained.

So I think it is fair to say that, in essence, the USDA lets companies regulate themselves in this area. I hope that will change with the recent ProdiGene contamination incidence.

Just one other comment and then a question. The NAS report also questioned the extreme degree of secrecy surrounding this enterprise, specifically confidential business information by which the companies hide the identity of the great majority of the substances that they engineer into these crops and also never reveal the location of the field trials so that neighboring farmers could protect themselves or, for instance, consumers would at least know this is going on.

What I found most startling was that a lot of these crops are planted in unmarked plots, as anonymous planting of biofarm crops is supposedly the best way to hide them according to a ProdiGene official and also USDA officials.

Then just one more point of information. There has been a lot of talk about other plants, and yet 70 percent of the biofarm field trials conducted to date have been in corn. So it is by far the most popular plant.

I guess my question is for Ms. Applebaum. I was wondering what you think about the general issue of confidential business information, secrecy in planting locations, and especially the idea of anonymous planting in

unmarked plots.

DR. APPLEBAUM: The issue as it relates to what may or may not be genetically engineered in terms of if it can be presented in such a way that it is not going to divulge, if you will, proprietary information from a business perspective -- you know, if you could say it is a protein to do X, Y, and Z, I think that type of information is important.

The divulging of where this stuff is being planted at the time raises concern, and the reason is not everyone is as reasonable nor as law-abiding as everyone in this room. And what you do when you provide that type of information in terms of the exact directions on how to get to a particular field raises concerns to me as it relates to the potential for sabotage and the potential for the mischief-makers to make an issue. I have a problem with that as I have a problem with anything that has the potential to impact security across the board.

So I do have a problem with that. Again, it is only because if we were all of like mind, all reasonable, all moral, ethical citizens, we wouldn't have anything to worry about, but there are the mischief-makers out there,

and that concerns me.

MR. : I would actually like to expand on that question to you, Allison Snow, as to whether in your research on gene flow, issues of intellectual property and confidential business information, have ever [inaudible].

DR. SNOW: I would say yes because it is difficult -- in my research, it is difficult to actually collaborate with companies and get hold of transgenes that you want to study, and as I was preparing to come today, it was hard to find out what pharmaceuticals are as we have talked about.

So I think from the point of view of knowledgeable discussion and doing research, it is a very serious problem. I don't know how to overcome it because we want to have access to this information that is very important to the companies to keep secret. It is a very difficult situation.

MR. CHARLES: I would actually like to run through a couple of questions from the Internet. So here is a three-parter for you, Michael.

Part one, if the USDA policy works (Phillips' statement), why did BIO feel it necessary to issue its own policy with respect to planting areas, I think they are referring to?

Part two, what was the rationale for changing BIO's policy in Iowa? And you will have to elaborate on whether there was a change or not.

Part three -- or no, question two. BIO issued its biofarm policy just before the USDA's announcement. This is, I guess, the USDA's announcement with respect to Prodigene. Apparently, USDA knew about the contamination weeks earlier. Did BIO also know?

And I am going to actually throw in one more question for you here. This is State restrictions on where biofarm crops are grown. Senator Grassley also got assurances from a USDA official that Iowa was okay for biofarm corn. Is our regulatory system affected by politics?

[Laughter.]

MR. CHARLES: So there is a collection of questions for you to address.

DR. PHILLIPS: Well, in terms of -- I take the first one in terms of why does BIO have position statements or policy. This is something we do all the time.

This is a part of what we consider to be good stewards of the technology, and we develop policy, position

statements on how we are going to maintain the stewardship of the technology, whether we are talking about BT corn or we are talking about roundup-ready soybeans or anything of that nature, as well as the pharma and industrial products. This is something our BIO member companies felt very strongly about in terms of having the spacial isolation that is necessary to assure our colleagues in the food industry and the grain industry that we take these things very seriously and that we are not going to do anything intentionally that is going to harm the food or the feed supply.

So that is the long and short of why we have policy and position statements, the type of thing that we do on a fairly routine basis.

There has been no change in terms of what our policy is. We have a policy that you can see it up on our website, that basically says that we are looking at all alternative ways in which we can assure the fact that we can meet zero containment.

Spacial isolation is one of those areas upon which you can achieve that about as well as any other techniques out there currently today. When we get to the point where

we can develop a technology that can assure that for open-pollinated crops, they are no longer going to be open-pollinated and assure then that you can meet zero containment that way, that is a good example of why then you don't need to be focused so much on spacial isolation. But short of that, you have to come up with ways in which you can meet zero containment or you will be in violation of the conditions of your permit. Companies will be in the same position that ProdiGene is today, and companies clearly do not want to be there. So that is the reason for why we have talked about that as a position statement and it is something that we have every intention on following through on.

Each of our BIO member companies that are in the business of having field trials today is very committed to that statement.

I forget. In terms of --

MR. CHARLES: Did you/BIO know about the ProdiGene violations before the announcement?

DR. PHILLIPS: There were rumors around that there was possibly something in the works, but that did not -- this is a policy statement that we have been spending -- we

spent roughly 13 months developing, and we were doing that in the course of educating all of our members as to what the risks were and looking at different alternatives, and it took us basically that long in terms of discussions, over a 13-month period, before we could come to a unanimous resolution within our companies that are in this business that we could then feel comfortable in issuing a position statement. So that is the genesis of that.

Your last one was on States?

MR. CHARLES: Well, it was a reference to, if I understand it correctly, the idea as stated at one point at least on the BIO website that there wouldn't be planting of open -- of out-crossing crops in areas of major growing of those crops, commercial growing of crops.

Then there was a statement by Senator Grassley, I believe, saying that is a terrible idea.

And then it seemed, at least to me, that the statement on the BIO website softened that a good bit. It said there might be other ways of assuring containment wherever it is grown.

DR. PHILLIPS: Sure. And what that is, is a clarification of our original statement where we did not

specify as much in terms of looking at alternative ways.

If there is an alternative way, we certainly will follow it if it gets us to the same point, but short of that, our member companies are committed to spacial isolation to ensure that we can get the proper separation so that there is no contamination of the food or feed supply because of finding a substance that is not approved for food or feed.

If that can be done in the Midwest, companies will certainly try to find a way to do that, but I think it is pretty obvious to most folks that it is easier to find that spacial isolation in areas of which there is not major productions of that crop that is used as a commodity. So it just makes it easier for companies to try and do it in other parts of the U.S. or offshore, but there is always the possibility that if we can find ways to work that in areas where we can assure that there is adequate spacial isolation, out companies will do their best to try and follow that.

MR. CHARLES: I don't know who was first, but I will go back to a question on that side.

MR. RAND: A quick question. Matt RAND [ph] with

the National Environmental Trust, actually three quick questions here.

We have been talking all afternoon about the weak regulatory system, the weak mousetrap. Ms. Applebaum stated that it appeared that USDA was lucky in this case in the ProdiGene incident. Is it possible that there has already been a biocontamination that has already entered into the food supply that the USDA did not catch? That is one question specifically.

Two, FDA has stated that this contaminant was a human drug. ProdiGene states that it was an animal drug. What was the contaminant?

Then, lastly, according to the last question, also according to the news, that USDA knew about the contamination for weeks before it was actually reported. What was the rationale for USDA not alerting the public to this incident?

MR. CHARLES: Who would like to take those questions on?

DR. APPLEBAUM: I will just go with your first one, and the answer is I don't know.

One of the things I want to make sure that is

understood is that the National Food Processors Association has not said the mousetrap is weak. We have identified a weak link in the system that is currently being used, but that was one system that was being used out there. We have heard from other folks that they do have systems in place that are secure, that will contain to meet our standard. So we can't say that they are all weak. We just haven't seen them yet.

MR. CHARLES: On the issue of exactly what the contaminant was, does no one know exactly what it was?

MR. JAFFE: I was going to answer both, the first and the second question, with I don't know either.

I think that one of the problems, which has been brought up here before, is the lack of information that comes out of APHIS and USDA. I can't answer because I don't know. I don't think they have specifically stated what proteins were in the ProdiGene instances both in Nebraska and Iowa with certainty, at least I haven't seen documents regarding that.

Similarly, I think as to whether we have had containment up until now or whether there has been a breach and things have gotten into the food supply, I don't think

we know. I mean, I know that APHIS has said in their OSTP statements that they have had inspections and they have found some violations and they have dealt with them, but I think that generally we don't have a good idea of what their inspection system is, what their oversight system is, and we haven't seen inspection reports or other kinds of things to give some confidence that the proper precautions have been taken to make sure that they haven't overlooked a mistake that happened.

MR. CHARLES: And actually, I think your third question was asked earlier about whether the contamination was known earlier, and the answer earlier was there were rumors and so forth.

Question over here?

MR. SAFFORD: David Safford [ph], Bureau for National Affairs.

I would like to take two points and integrate them a little bit. One point is that the food industry is currently operating under a zero-tolerance requirement for unapproved substances in food. We have also had Dr. Snow's interpretation of events coming up soon that essentially it is going to be exceedingly difficult to contain a lot of

these genes which to me implies that a certain amount will get out.

I would like the panel to predict the future for the policy of zero tolerance. Will it actually be a realistic policy for the future?

MS. APPLEBAUM: I will go first with the plant-made pharmaceuticals and the industrial chemicals, we don't know. We don't know.

Zero tolerance absolutely is a high hurdle, and it is a very high hurdle when we are dealing with naturally occurring contaminants. Here, we have an intentionally introduced unapproved compound, but with that said, as a scientist, I am not going to predict with lack of evidence, with lack of data what the future is going to hold. Again, we are leaving the opportunity to the stakeholders to come to the food industry and say they do have that better mousetrap. So I am not going to prejudge or put words in, in terms of what my thoughts are, what my views are. As a scientist, I can't do that without the data. That would be irresponsible for me to do.

MS. SNOW: I think you bring up a really important point which is to reiterate that. I don't think zero

tolerance is practical. I don't think we know enough about how far pollen goes, where seeds are disbursing, human errors, seeds that come up the next year in someone's soybean field. This is really the first discussion I have been at where people have required zero tolerance. We are always saying maybe we could settle with like .1 percent or .05-percent contamination, and that is achievable, but I have never been in a discussion where scientists were saying that zero tolerance was possible, including the USDA when they set up the isolation differences for field trials. They know that they are aiming for confinement and not containment.

So it is one of these abstract concepts that I don't think is achievable, and so there is a definite problem here.

MR. CHARLES: Identify the problem here. Yes, Greg.

MR. JAFFE: I mean, I might also add that if you look at USDA's documents, if you look at the OSTP proposal that occurred in August, the USDA/FDA guidance, they never talk about zero tolerance. They talk about confinement or containment. They never say what they are trying to

achieve, and that is one of the problems is they don't say what their goal is.

I also might just comment that although you are talking about the zero-tolerance world, just because something gets in the food -- one of these things gets in the food supply doesn't automatically make that illegal. The statute that FDA works under says that they have to prove that it is adulterated, that the burden is on FDA to come in and show that a product has been adulterated before they can get that product off the market.

So I just wanted to clarify that from some of our earlier comments before that the system as it is set in place now really -- if these things get into food, it is really the burden of FDA to come in and get it off the market.

MS. MOORE: I love speculating about the future.

I think that zero tolerance is an admirable goal, but I also see problems as to how in a fallible human world we achieve that.

If I had to predict the future, I think that we will probably not have zero tolerance as it has been thrown around as a sound bite today, but we will have a safe food

system.

I think in deference to Rhona, we will also have a much more transparent system. You are going to have to identify where these products are grown. You are going to have to deal with those security systems in a way that still allows the public some knowledge, and the interested public, the farmers or communities around these fields to know what is going on.

In Europe, they have tried a system in the area of genetically modified food even for their farm-scale field trials, not reveal to the public the locations of these field trials, and I think they have, in fact, encouraged the kind of vandalism and security problems that all of us worry about.

I believe we will have a stronger regulatory system. I think the responsibilities will be more clearly delineated. I believe there will be more resources available for USDA and FDA and EPA not only to do the kind of policing that Greg has talked about, but also to set up independent laboratories to do much of their own testing and to rely less on industry information.

My hope -- and this is not a production -- and

that is that there will also be more public monies, re taxpayer monies, being put into developing these biopharmaceutical products, not just the businesses of this world, but public sector dollars devoted to public good. That is my hope.

I think that the error where you can have voluntary industry standards in almost any regulatory context is dying out. I really think that we are going to see that end because public opinion will not tolerate voluntary.

I finally believe that one of the good -- whether it was intended to not -- consequences of the information age is that you are going to have a much more sophisticated, educated consumer, whether it is in the United States or Bangladesh, and they are going to require this kind of a future that I have just tried to broadly outline.

MR. PHILLIPS: Just one quick point.

MR. CHARLES: You will have to be brief. We are running out of time.

MR. PHILLIPS: Okay. But just to your point, I think one thing that we haven't mentioned -- there are a lot of things that I agree with that my colleagues on the panel

have said in response to your question, but one thing we have not really pointed out here is that a reminder to all of us that this area is regulated by what we call the coordinated framework, and this is working -- the agencies working together in terms of coming up with the regulations that is going to meet all of the statutory requirements for the agency.

So the fact that FDA is working in conjunction with USDA in these matters, that is going to continue. That is what APHIS takes as its guidance in terms of knowing that for FDA we have got to meet a very, very tight standard here in terms of zero tolerance. So that clearly weighs heavily on the thinking within APHIS of what are going to be the permit conditions that allow that to happen.

MR. CHARLES: Just so we get all of the questions in before we have to shut down at 3:00, I would actually like to get both of your questions in, in a row, if that would be all right, so both of you from this side.

There are no others waiting on that side? I don't think so.

MR. KONKOO: I am Greg Conko [ph] with the Competitive Enterprises and I actually have a follow-up.

David trumped half of my question.

I guess my question is to Rhona, probably to Mike, and I would be curious if the other panelists had thoughts on this.

The food industry, the technology industry for a long time have worked very closely with the regulatory agencies in developing policies and in some cases even led the regulatory agencies in asking for heightened scrutiny of certain things related to transgenetics and bioengineering.

So I guess my question is: Is there any effort underway or a plan to go to the regulatory agencies now and ask them for the development of procedures that would allow -- establish, say, a tolerance or a permissible exposure level of proteins or other gene products in much the same way that there are permissible exposure levels to things like rocks, sticks, rodent feces, alflatoxinal [ph], a whole range of other impurities that are not considered adulterants under the act?

MR. CHARLES: I would like to take a note of that question. Don't forget it. If we can get the next one as well.

MS. Kochenderfer: I have a statement as well as a

question. I am Carol Kochenderfer [ph] with the Grocery Manufacturers of America, and we have been heavily invested in the biotech issue for nearly 5 years. In fact, we have had a panel of food industry executives looking at this issue for nearly a year.

I think it goes without saying that -- I think to Julia's point, biotechnology continues to create very exciting opportunities, but it also continues to challenge conventional agriculture in many new and unforseen ways, and it is those challenges that we need to continue to live with.

I think GMA members have some very grave concerns about the ability of the regulatory system to isolate and contain these products, but I think it is more than just the regulations alone. It is a mind-set. To address issues of human error and 100-percent isolation and confinement, it is not the regulations alone. It is the mind-set with how these products are handled and managed.

That said, I want to kind of ask Mike a question. I think there is an impression a little bit earlier that this is an economic opportunity for every Midwestern farmer, and it is my understanding that that is not the case, that

this is just as communities are isolated and selected for pharmaceutical manufacturing plants, that is the rare and unique farmer that would be selected to growing these crops.

MR. CHARLES: Got the questions. Why no tolerances, Rhona Applebaum?

DR. APPLEBAUM: Oh, I thought Mike was going to go so I could try to remember question number one.

But I was wish you right until the time you started talking about the tolerance, and I have a -- we have a problem with tolerances. I have a problem with tolerances.

When you are dealing with -- and again, it is not the defect action levels that we deal with on a day-to-day basis when you are talking about the naturally occurring contaminants that are out there. If you grow crops in a field, you are going to get rocks. Unless you can isolate and contain or confine the rodents, you are going to have hairs and droppings. This is different. This is different.

You are introducing something into the corn plant, into the environment, into the food system that isn't there, that is going to be used in a pharmaceutical production facility to produce wonderful therapies for mankind.

So my point to you is no, we are not accepting of the tolerance.

MR. CONKO: Irrespective of whether or not a particular substance could be determined as safe?

MR. CHARLES: We are going to be shut down here in about 2 minutes.

DR. APPLEBAUM: The answer is we are not for tolerances in terms of this particular situation.

The issue as it relates to perception is reality for the consumer. Oh, we only have a little bit of this protein that is, if you will, the antidiarrheal or something. It is a tough one. We want the public to stay with us on ag biotechnology. It is of great benefit. Whether you are talking about the environment, whether you are talking about the foods you eat, whether it is talking about human health in terms of what you can glean from naturally occurring substances in foods, but when you go outside that realm, whether it is an industrial chemical or whether it is a pharmaceutical, there is a problem there, and we must maintain the confidence of the American consumer. We don't want to go the route that the Europeans did, and to do that, we have to -- that consumer trust is so

valuable to us and so dear and so tenuous, we are not going to risk it.

MR. CHARLES: Michael, in 30 seconds or less, have you been over-promising the American farmer?

DR. PHILLIPS: Well, I think there has been a lot of misinformation about with regards to what the economic bonanza is going to be out in the Midwest and other places around the country for this technology. The long and short of this is it is going to mean for a few farmers on a few acres that they are going to -- if they are selected by companies to grow and they will be licensed to grow these crops, they will receive an economic benefit, but we are not talking about thousands of farmers. We are not talking about tens and hundreds of thousands of acres. This is going to be very small scale because the amount of protein that can be produced for what is needed by the pharmaceutical industry is so small, and that is one of the great benefits is that on a very small acreage, you can basically grow what would be the demand for a year for a pharmaceutical company.

MR. JACOBSON: The plug is going to be pulled, I am afraid.

I am Michael Jacobson. I just wanted to thank our panelists for traveling long and short distances, the audience for making this a very stimulating event, C-SPAN participants out there. This is, obviously, a very controversial issue. The discussion will certainly continue.

Thank you very much.

[Applause.]

MR. JACOBSON: One last word. The transcript of this forum will be available at cspinet.org in about 4 or 5 days.

[End of audiotape recording.]

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