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PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

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A P P E A R A N C E S

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AGENDA

Simultaneous Breakout Sessions Block #2
Roosevelt/Madison Room: Smarter Tools and
Approaches for Prevention

Facilitators:

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P R O C E E D I N G S
SIMULTANEOUS BREAKOUT SESSIONS BLOCK #2
SMARTER TOOLS AND APPROACHES FOR PREVENTION

MR. GORNY: -- is Jim Gorny. I'm Senior Science Advisor for Produce Safety, and I'll let my colleagues introduce themselves. We're up a bit of a --

UNIDENTIFIED FEMALE SPEAKER: (inaudible - off mic).

MR. GORNY: Yeah, it's on. I believe it's on.

So I'll let Sharon introduce herself. And I'm going to be the moderator for today. Sharon is going to be the notetaker. And Joann is going to run the mic around and --

MS. GIVENS: Get her steps in for the afternoon.

MR. GORNY: -- getting her steps in. So ...

MS. MAYL: We ran her rapid this morning.

MS. GIVENS: Work off my lunch.

MS. MAYL: So my name is Sharon Mayl. I'm Senior Advisor for Policy in the Office of Food Policy and Response.

MS. GIVENS: I'm Joann Givens. I am the Program Director for the Human and Animal Food Program in ORA.

MR. GORNY: Yeah. So just a couple of ground rules for today. Please introduce yourself and your affiliation. This is all being recorded so that we know who provided the comments. And we, of course, always encourage you to provide written comments, and there is a sheet in your packet to tell you how to do that to provide comments to the Federal Register.

It's -- all opinions are welcome. We're going to try and work through the five questions, give them about 10 minutes each. Sharon's going to capture some of the main points that you'll be making.

Great ideas. We're not trying to -- we're trying to create ideas, not come to consensus. So it's really important just to throw those ideas out there. There is no wrong idea.

Time is limited. Again, if you could,

please, you know, a couple of concise, two to three sentences or four sentences, that would be really helpful just to give others a little bit of time so that they can provide their input as well.

Specific rationale -- and we also have a parking lot in case -- oh, so as you can see, what we've done is we've written the questions across the board. They're also in your packet numbers 1 through 5 under the Preventive Measures. And what we've done is, in the former session, is we've captured them with bullet points just so we can summarize this at the end of the day.

So with that, Joann or Sharon, anything else? I think we're good to go. I think we'll start with the first question. And I like to say we'll give it about 10 minutes.

We're also going to stop about five minutes early because they really didn't build in time to transition from here back to plenary session. So we're going to stop at about 25 minutes after the hour as opposed to right at the bottom of the hour.

So the first question is, is: "What are the most significant actions FDA could undertake to promote and support the use of smarter tools for prevention?"

Please, just to be -- just raise your hand. Joann will run the mic out to you.

Wow. Okay. So if you could please identify --

MS. GIVENS: Once the first person leads off, it's like -- it's off -- it's -- we're on a pop-in after that.

MS. BRUNTJEN: My name is Jacqueline Bruntjen. I'm with the Dennis Group. We are an architecture engineering firm, and we are -- we build specifically for food manufacturers, so we have the pleasure of working with quite a few in a broad range of industries.

One of the things that I've seen through my research is that, once we get to the bottom line of when you're building a large facility or you're doing a large renovation, they only start with so much

capital expenses.

And I'm sure this is not the first time to say it. But towards the end of the project when you get down to the nuances of what are the large cost impacts and what can we cut down on because, quite frankly, we're out of money, traceability and these kind of finer, nuanced technologies happen to be VE'd, or value-engineered, out of the programs due to just, quite honestly, being out of capital expenses.

I would like to suggest that you model something after the Canadian Agricultural Partnership where they actually create programs, grants, federal funding, 0 percent interest loans to entice food manufacturers to be able to reach out for these programs and implement them.

MR. GORNY: Thanks for your comments.

MS. GIVENS: Great. Thank you.

MR. GORNY: Is there anybody else on the first question? What are the most significant actions FDA could take -- undertake?

MS. GIVENS: So if you don't start raising your hand, I'm going to call on names because I know so many people in this room.

(Laughter.)

MS. BOOREN: That's why I got the microphone now.

(Laughter.)

MS. BOOREN: Betsy Booren, Grocery Manufacturers Association.

This is more getting to the point when I think about it is if -- as my members come in or I think about industry is, when we're trying to find new approaches, many of those are probably outside the constraints of the current regulations.

So I think one of -- if I think about what's one of the most significant actions FDA could do in this area is try to figure out a framework where if industry is -- or other stakeholders are trying to solve some of these problems, is there a way to create a temporary regulatory framework for them to do that, to connect -- to collect data in meaningful ways?

I know many times we come in and talk to

regulators or other industries. And they said, well, you know, we just can't do this because of X, Y, and Z. I think there needs to be a level if we're trying to find approaches and think of the end goal, making sure we have a clear temporary framework to try some of these new approaches to collect some of the data in a real-time, meaningful way that cannot be penalized for them trying something new.

Hopefully that made sense.

MR. GORNY: Yep. Absolutely. That came up at the earlier session as well -- removing barriers to sharing data. Everybody's all for sharing --

MS. GIVENS: I saw you --

MR. GORNY: -- data --

MS. GIVENS: -- drop your head.

MR. GORNY: -- barriers.

MS. GIVENS: Do you have a question, a comment, contribution?

MR. GORNY: Any other questions?

MS. GIVENS: We want to be voluntary --

MR. GORNY: This is a free --

MS. GIVENS: -- not volun-told.

MR. GORNY: Yeah, this is big picture, this first one.

MS. GIVENS: Now, we know it's after lunch. And you know, you're starting to get all those things working.

But I know -- Leon, you have something to say; don't you? Come on.

LEON: Let me get worked up.

MS. GIVENS: Okay. He's going to get warmed up.

Who else might want to respond to this question?

MR. GORNY: All right. Well, we're not going to force it. I'm sure we'll get -- oh.

MS. GIVENS: Oh.

MR. GORNY: Natalie.

MS. GIVENS: Natalie.

MS. DYENSON: Hi. Natalie Dyenson. I'm with Dole Food Company.

I just want to kind of continue on with what

Betsy said because I think creating an environment that's conducive to sharing without fear of retribution is going to be huge for the industry. There's a lot of information that we could share, but the whole guilty until proven innocent doesn't work for allowing industry to openly share information.

MR. GORNY: Understood. Yeah. That was a major --

MS. GIVENS: So it was sharing outside of our regulatory framework or outside of an inspection, like when you -- there is something that perhaps you feel that we can collaborate on and it's not tied to a positive sample or an inspection report. Maybe that's some of the --

MR. GORNY: Yeah.

MS. GIVENS: -- ways to go around the regulatory framework that we have.

Other thoughts?

MR. GORNY: Other thoughts?

UNIDENTIFIED FEMALE SPEAKER: (inaudible - off mic).

MS. GIVENS: Sure.

MR. GORNY: Please.

MS. GIVENS: She came back. She's -- this is like she can --

MR. GORNY: This is her second session.

MS. GIVENS: This is her second session. She came back. She liked what she saw this morning.

MS. TIMITE: I did. I really did.

I just thought -- this is Sarah, Action for Sustainable Development.

I think that you working with the countries - - I'm more focused on the African countries where the FDA is just probably starting to get in, working with the government, actually, to kind of coordinate third parties for more training and education on the ground. So I thought that would be something that needs to be looked into.

MR. GORNY: All right. So it looks like Sharon's got that one.

MR. BROCK: Adam Brock, Dairy Farmers of Wisconsin.

I'm going to just say an example. Think about all the resources people have at their disposal, right?

MR. GORNY: Yeah.

MR. BROCK: How many websites? How many companies do you have to talk to? Is there a nice repository? And I point to on the dairy side. They've got one called the Safe Cheesemaking Hub. It's all dairy stuff. Can FDA do that with meat, with bakery, somehow so the small processors and the artisans can have some access to it? Because that's a gap. So just a -- here's the tools.

MR. GORNY: Yep.

MR. BROCK: Here's a resource link.

MR. GORNY: Yeah. We've all been told it's on the web. It's on --

MS. GIVENS: Yeah.

MR. GORNY: -- the internet. Yeah, the entire knowledge of humanity is on the web. But you know, finding it in a concrete place -- that's a good idea. That's a great idea.

MS. KROUT-GREENBERG: Thank you, Joann.

Natalie Krout-Greenberg, California
Department of Food and Agriculture.

So I look at this from a little bit of a different perspective in that we are the regulatory body, and we're out there performing in the inspections. And so one of the things that we've talked about internally and I know that we've shared before is a place to house as a repository for our inspection work that we're doing for food safety on farms. But that doesn't just stop in California when we have partners or growers who are also in other adjacent states.

And so you can start to house your information and start to see trends early on and then going to the points already made that there's an opportunity for proactive approaches and conversations before it leads to an outbreak or an event.

MR. GORNY: Thanks, Natalie.

MS. MAYL: Does that capture it right with regulatory --

MR. GORNY: Yep. Yep. Repository of inspectional information with regulators. And then you can data mine through that and things like that. Understood.

Anything else on this point?

Just carefully watching the time. Let's move on to Question number 2, if you don't mind. And we can always come back.

"What predictive analytical tools and data streams are best suited to helping identify potential contamination events?"

So again, this kind of brings it down to the detailed level of, you know, what predictive analytical tools and data streams. You know, what's the important data? What's the important stuff?

We just talked this -- in this last session about what the right data is. You've got to collect the right data.

Oh, Natalie again.

MS. GIVENS: Natalie.

MS. KROUT-GREENBERG: I won't be bashful.

MS. GIVENS: Don't want a contest. I can't give the mic too much to Natalie. So I won't --

MS. KROUT-GREENBERG: Yeah, I don't want to go.

MS. GIVENS: (inaudible - off mic) you here.

MS. KROUT-GREENBERG: So I think there's the obvious information around testing. There's a lot of testing that's done by the industry, and I think that information aggregated together. And it's been mentioned a couple times in a central database. I think the meat industry has done this very successfully. It would be very helpful to the regulatory agencies as well as the -- kind of the metadata around that from a general standpoint.

MR. GORNY: So what I heard this morning, also, as well is we need to segregate and differentiate between aggregate data and company-specific data. Those are two very different things and have different meanings and liabilities associated with them in jeopardy.

MS. BOOREN: Betsy Booren, GMA.

But this comment will be really reflected to my past lives, and I'll follow up a little bit on the meat industry. I spent a lot of time working in the meat industry and working with that industry on this question. And so I think it gets to you have regulatory data, and then you have company-specific data. And I think using --

MR. GORNY: Yeah.

MS. BOOREN: -- data to drive and taking a holistic approach to find those answers becomes really important and not being penalized for, again, taking that data in facilities.

So how do you do that in a way to find what the problem is? Can you use new testing methods? And this evolves constantly, but always collecting the data at a very high level and not being penalized for it.

The idea -- and I'll use LM (ph) as an example -- the idea of when they made the shift in the early 2000s of we need to test more to find it versus not wanting to test to find it was a significant culture shift for the processed meat industry. And that changed the risk profile for the last two decades of that.

For us to use tools for predictive models, industry, government, other stakeholders need to think about that data and what does it mean and what's the end goal because whole genome sequencing might not be the exact test that could be done. We could gather a lot of information and make a lot of predictive analysis on different types of testing. So having that flexibility in those systems becomes really important to get to that end goal.

MR. GORNY: Yeah. This morning there was a lot of discussion about metagenomics and using that and not just necessarily human pathogen testing and using that. So that was one of the takeaways from this morning.

Anyone else? Predictive analytics. Oh, a very quiet bunch.

MS. GIVENS: Oh, it's -- lunch was too good.

MR. GORNY: I think lunch --

MS. MAYL: Right. That's --

MR. GORNY: -- was too good, yeah.

MS. MAYL: -- what I was going to say --

MR. GORNY: It was --

MS. MAYL: -- what data as well as how to analyze it.

MR. GORNY: Yeah. And how to analyze it, yeah, exactly -- what data and how to analyze it. So I think you went back to the aggregate versus individual firms, the potential of regulatory jeopardy is what I'm hearing and potential liability issues and being sensitive to that.

Anything else?

I guess we'll move on to the third question, and we can always come back.

So the third question is: "What further steps can be taken to advance the safety of domestic and foreign commodities that have been subject to frequent contamination incidents?"

MS. MCENTIRE: Jennifer McEntire with United Fresh.

I would submit that it's not the commodities, per se, that are of higher risk. There are probably specific practices that result in contamination. And we may see that certain commodities implement unique practices that need to be addressed or that, within certain commodities, the communities producing those commodities need increased education or training.

But I would be very reluctant to say that there are specific commodities that the commodity, the category, as a whole has issues that need to be addressed because we know that there are always people who do great and people who don't. And so I wouldn't want to vilify or generalize around an entire commodity, but look at those specific practices and make sure that you're educating and training and providing resources to the communities who are maybe not properly implementing those practices or don't fully understand those practices that result in repeat contamination.

MR. GORNY: So diving a little deeper than just it's a commodity or --

MS. MCENTIRE: It's not a commodity.

MR. GORNY: -- it's not a commodity. It's what are the procedures, policies, and practices that they're utilizing.

MS. MAYL: It's the 3 Ps.

MS. GIVENS: The Ps.

MR. GORNY: Any others?

MS. GIVENS: Anyone else want to contribute to the -- that particular question?

Yes.

MS. BRUNTJEN: (inaudible - off mic).

MS. GIVENS: I like this.

MS. BRUNTJEN: Jacqueline with the Dennis Group again.

Again, advocating for spreading of knowledge and information is an approach that I think that, if you're going to start holding exporters or importers overseas to these standards, holding potentially, like, a conference or something, a gathering information sharing thing on their side so they can come and learn instead of having to go find the information and then being fearful that they aren't in compliance, don't really know the rules, get a lot of questions, so holding informational, just gathering overseas so they can come and find you instead of -- and make it more of an open dialogue.

MR. GORNY: Great. Any other comments on ...

MS. GIVENS: I think you had mentioned about some of the foreign African countries. Your thoughts on this particular question since there is a foreign element to it as well?

MS. TIMITE: I just want to push a little bit further what I mentioned in terms of education and training. What we take for granted here, it does not exist there -- I mean basic training.

And to touch on what she said -- I forgot her name --

MS. BRUNTJEN: Jacqueline.

MS. TIMITE: -- Jacqueline -- you have to make a dialogue, open a dialogue, first and make the awareness a little more broader and maybe localized, too, because you have to go into the fields and work

with the people on the ground.

That being said, there is a part, also, that needs to be looked into, is penalties. I know FDA has some penalties in place in terms of pushing people to comply. But are there fear -- are they being enforced?

So I think to look into that and really work on penalize because that works -- you know, if you flag -- red flag sources that are contributing to contamination, that may trigger a more responsible attitude.

MS. GIVENS: Great.

MR. FROST: Thanks. Jason Frost from the New Zealand Ministry for Primary Industries.

I think Question 3 might say foreign -- sorry -- import -- domestic and foreign foods apply. So obviously, New Zealand is a mess of producer and exporter of food globally and to the U.S.

So just quickly, I'm going to -- there are some tools that are already in place that are very effective that we have found with working with the FDA on ensuring the food -- you know, the supply of safe food from New Zealand. And I'd just like to point out that the food safety systems recognition agreement has proved to be very useful. And there's some tools in there, I think, that still need to be considered useful moving forward.

MS. GIVENS: So our system recognition --

MR. FROST: Yes.

MS. GIVENS: -- agreement that --

MR. FROST: Yes, yeah, yeah.

MS. GIVENS: -- New Zealand.

MR. FROST: I won't go into too many details. I've only got a short period of time.

MS. GIVENS: Yeah.

MR. FROST: With not just New Zealand --

MS. GIVENS: With others.

MR. GORNY: Other countries as well, I'm sure.

There is one more.

MS. MINER: Hi. Jennifer Miner, the Embassy of Canada. But I represent the Canadian Food

Inspection Agency.

So we -- like Jason was saying, we're another one of the countries that have systems recognition. And I think there are definitely tools that we can share about the safety of our own products. But it's also looking at the safety of products from third countries.

So we have very similar supply chains of products moving in from third countries. So we do share a lot of information about products coming from our own country, but it's really trying to enhance that. And how can we share information that's coming from other countries so that we can have those -- that data and that information to make some of these predictions and sort of track trends?

And it also sort of goes one step back in terms of having those discussions and the tools that are in place that talk the same language. So we were talking a lot this morning about common language for traceability and these things. It's having the systems that talk between countries as well so that when we get into this information sharing, we are able to do so more easily because we've already got the common language in place.

MR. GORNY: Yeah. The key words I heard in this last session are interoperability, a thing that -

MS. GIVENS: Yeah.

MR. GORNY: -- gets right to the core of it. You can't have 23 different systems as -- you can, but it's not efficient.

MS. LARSON: Kirsten Larson with the Association of Public Health Laboratories.

And I'm guessing this was said earlier this morning, but I think it's really important that FDA continues to support those laboratories, especially the MFRPS laboratories, designated laboratories, to either achieve, maintain, or expand their scope of ISO accreditation, and that they also continue to work closely with Public Health Laboratories on data acceptance so that import alerts and other types of recalls, or whatever, can be issued quickly and

effectively.

MR. GORNY: It's like an interoperability to some degree in that it's an acceptable standard coming in, but also that the information is accurate and precise.

MS. LARSON: And ensuring that the states have the resources they need, too.

MR. GORNY: And that making sure the states have the resources to do that. Got it.

Steve in the back.

MR. MANDERNACH: Steve Mandernach with AFDO.

I would -- I think it's even broader than that. It's also seeing that CDC, FDA, and USDA all work together on the foodborne illness prevention front and are moving in the common direction.

Right now, we see cases where we're funding one thing in CDC, but reducing funding over here in FDA and maybe doing something different at USDA. That is not going to do well in prevention in the long term if we don't figure out a way to coordinate the three programs and really focus where we're going together. It's not going to be successful as it could be.

MR. GORNY: So coordinating and integrated food --

MS. GIVENS: Funding, funding, funding.

MR. GORNY: -- and --

MR. MANDERNACH: Using the funding well.

MS. GIVENS: Yeah.

MR. GORNY: And using the funding well. That's what Steve said.

MR. BROCK: More of a model on the animal health side is looking at OIE and their setup for animal disease traceability --

MR. GORNY: Okay.

MR. BROCK: -- and the interoperability between countries, states -- so more just a comment.

MR. GORNY: Yeah, yeah. Exactly. We seem to have hit on a theme there, which I picked up earlier in the day.

Let's move on to the fourth question, if we don't mind, just to keep on track here.

The fourth one is, is: "In what ways can FDA

support the use of environmental assessments and root cause analysis in industry prevention efforts?" So how can FDA support the use of EAs and RCAs in industry prevention efforts?

Yeah.

MS. KROUT-GREENBERG: Hi again. Natalie Krout-Greenberg, California Department of Food and Agriculture.

So one of the things that -- since we're a state that's obviously involved with FDA performing inspections on the produce rule as well as animal feed rule, there's been considerable effort up front to educate before and while we regulate. And so that's been the mindset, obviously, going into FSMA.

Now that we're actually doing inspections, we're starting to see an opportunity where, when we are in a situation either with a grower or an entity, that there is some proactive work that can be done on the back end for root cause as well as prevention.

And so I take that mindset of educate before and while you regulate to also take a deeper dive and look into root cause and then another opportunity to educate because we obviously learn something when situations arise. And whether that rises to a level of an outbreak or whether that just rises to a level of a need for reinspection, there's tremendous opportunity to be able to create a framework where we can learn and piggyback on those lessons.

MR. GORNY: Got it. Well said.

MS. MCENTIRE: Jennifer McEntire, United Fresh Produce Association.

I think there -- it would be helpful to have some guidelines or clarity around, first of all, what constitutes -- if an industry member were to do a root cause analysis, what does that look like? And what is their responsibility in terms of reporting findings to FDA? What needs to be disclosed? Dipositive findings need to be disclosed if there are, say, environmental findings, but not a product that's gone into commerce.

And then also, I think the recognition that, by undertaking such an endeavor, especially if you do uncover an issue, you -- once you know something, you

can't unknow it. So what are the expectations in terms of resolving the issue? Again, what is the support that's provided?

What is the communication with customers, may they be perceived to be a company? Rather than being seen in a good light of doing the right thing, seen as somebody who had a problem that now customers want to avoid.

And you know, we've had many conversations on root cause analysis, and there are many disincentives to doing a root cause analysis. On the government side, when FDA -- the states are going to come in after an issue is -- has been usually well-publicized and do an environmental assessment, I would encourage FDA to seriously consider their role as a regulator and an enforcer versus as a public health agency because those two hats are maybe in conflict, especially in trying to cooperate with the entity that's the subject of an investigation.

And if the perception is that someone is here as an enforcer, it's probably not going to be as useful or productive or collaborative of an exercise as if FDA is there as a public health agency.

MR. GORNY: Got it. Well said.

MR. MANDERNACH: So Steve Mandernach of AFDO again.

This is an area I've been spending a lot of time thinking about and working on. And I think one of the things is exactly -- you hit on it right. We can't be both the regulator and the public health agency at the same time.

And I'll be honest with you. I normally looked at an outbreak situation, or one of these situations where we're getting into a root cause analysis, as I'm a public health official first. If the industry is responding, I don't have to become a regulator most days. If we can get what we need done without that hat, I don't get to that point.

And I think that's the -- maybe something to be thinking about. Are we always building a case, or are we really looking to have the right public health outcome? And I think sometimes we can do better about

working on the right public health outcome if we're getting the right types of responses versus trying to build a case.

MR. GORNY: Thanks, Steve.

MS. GIVENS: Jennifer, any rebuttal? You're never short on words now.

MS. MCENTIRE: I concur. I think that if a regulator went in without that, you know, I need to collect evidence -- either -- so is it -- doing an environmental assessment, is it trying to understand a problem to protect public health moving forward, or is it collecting evidence? I think that's the fundamental difference.

MS. GIVENS: Duly noted.

MR. GORNY: Duly noted, yes.

MS. GIVENS: Any other thoughts on that? Oh, this is getting good.

I think we got -- they're fired up now, Jim.

MR. GORNY: They're getting fired up.

MS. BRUNTJEN: This is a bit of a change in direction. Jacqueline with Dennis Group.

Creating an understanding around the environment itself, quite a bit of these people within the food industry are, again, based in science fact. You know, they're very focused on the actual process and production. But the housing in which those production elements are based can absolutely cause a lot of the environmental issues.

So creating an understanding of what is a maintenance plan, how recent should you reduce your cost (ph)? Do you have -- still, are you maintaining proper airflow throughout your hygienic zonings? Have you maintained your HVAC (ph) system? So kind of creating a little bit more understanding that it reaches outside of just the sciences of the food, but it does relate to the building itself.

MR. GORNY: Thank you for that.

MS. BOOREN: Betsy Booren, GMA.

When I was looking at this question, I automatically go we don't -- we're not talking about the next two steps of that process, which is corrective actions and then verification that

everything is working the way it's intended. I think if FDA wants to support the use of environmental assessment and root cause analysis, it's also being aware that you know what you know when you know it. And if you're using data, you may know more the next day.

And so this is a dynamic system and still evolving. And so it's easy to come in on one day and review and say, well, you didn't take the actions at that time.

So again, supporting industry's efforts is really looking at the entirety of the system and better understanding what caused the issue at that day versus what may have caused a new issue or the same issue, but now we have more data. And having a systems approach on this I think would better help that tension between public health officials and regulators and industry and other stakeholders.

MR. GORNY: Got it.

MS. GIVENS: Okay. We're looking for that guidance document from Pew, huh?

MR. GORNY: Yeah. We --

MS. GIVENS: We can all use it.

MR. GORNY: -- very carefully.

MS. GIVENS: Yeah.

MR. GORNY: We can get to Steve.

MR. MANDERNACH: So I think one other thing that can be helpful is if we do the same type of training as both industry and regulators. For example, I know industry ASQ's training is very common. Those type of trainings, if we can do them together, it even makes it better. I think we've seen that with the alliances. Doing the training together helps.

So that's another example. Let's both go to the same training and learn the same skills and work as a team when we hit these situations.

MR. GORNY: And that was a strong theme from this morning --

MS. GIVENS: Yeah.

MR. GORNY: -- the training and --

MS. GIVENS: Absolutely.

MR. GORNY: -- making sure the inspectors or auditors know what they're looking at --

MS. GIVENS: Great idea.

MR. GORNY: -- critical --

MS. GIVENS: Thank you.

MR. GORNY: -- that this morning as well.

So the next logical step here is Question 5, which are: "What are the changes that FDA can and should make in the way in which it conducts EAs, environmental assessments, and root cause analysis and reports its findings to industry to better facilitate the use in industry preventive measures?" So how can FDA communicate more effectively about EA and the root cause analysis that they're involved in?

MS. GIVENS: Oh, Jennifer, this is near and dear to your heart; isn't it?

MS. MCENTIRE: Jennifer McEntire, United Fresh.

I want to commend FDA and thank FDA for getting the environmental assessment of the Thanksgiving-related romaine outbreak out so quickly. I think that the -- that that issue occurred or, you know, was public the end of November, and the report came out from FDA. I think it was February 13th, which also spanned when FDA was shut down.

So it's a pretty remarkable turnaround, I think unprecedented in terms of the Agency getting something out. I think it's absolutely a step in the right direction and concluding an investigation and reporting out on it quickly enough that industry as a whole can learn from those findings and take quick action. So we would certainly encourage that sense of urgency on the Agency's part in getting those reports out.

I think, in reading the reports and reading the information there, it's always of interest to me to have an opportunity to ask questions because reading a report is a unidirectional feed of information. So I think having some opportunity to discuss the findings of an investigation, of an environmental assessment, would also be helpful, recognizing -- and maybe this is the topic for the

other session -- that FDA is limited in what FDA can share and that, usually, what's in the report is pretty much all that FDA is going to say, which is, again, a different issue that I do think needs to be addressed.

MR. GORNY: I think, Betsy, you had another comment and then Steve.

MS. BOOREN: Betsy Booren, GMA.

I would probably say ditto. Very simply, I think that, from an articulation standpoint, it gets to the point. We need to know sooner, better, faster. And I think there's ways of -- and understanding the constraints in which public health and regulators may be is perhaps finding a mechanism where more sensitive information can be shared real time -- so when we learn more information and perhaps the pivot has occurred, getting that context around and making sure stakeholders know so we're not wasting resources down one lane when we know it shifted.

I would also reiterate doing a retroactive lessons learned broadly becomes really important. There's a lot of recalls that I read or outbreaks where I would like to ask one or two questions.

And to Jennifer's point of it's going one way, can we create the right environment where we can have those discussions? Because then we can share them with our stakeholders as well.

MR. GORNY: Thanks, Betsy.

MS. GIVENS: I think this is what you were speaking from the pulpit earlier about timeliness. So they're spot on.

MR. MANDERNACH: They are, yeah. The -- so I think another thing we can learn from -- and this isn't something FSIS has started doing -- is as those outbreak investigations and incidents finish, they're doing a lot of after-action reviews that then become public. And I think there is something to be said for making the public commitment on here are some ways we can improve what we did from a regulatory investigative standpoint. And there's been some really positive outcomes because of that, and the Agency's made some pretty big commitments because of

that.

So I think there is some merit to thinking about should those -- you know, we're making the environmental assessment public, but we aren't making the outbreak after-action review necessarily public. And maybe we should do that, also.

MR. GORNY: Got it.

MS. GIVENS: Any other thoughts?
Natalie? Oh.

MS. TANNER: I know a few of my colleagues and I have discussed this widely. But we've had a wide variety of -- oh, I'm Marie Tanner, and I actually am with Dairy Farmers of America.

And I tell you, throughout my career, I've seen a wide variety of FDA people come into my plant. I've had nurses and people in medical devices that might not be familiar with the particular technology that we have.

I think that you could really benefit the industry if you had subject matter experts that would go into the different plants. And it would be more value to not only the plant, but to the public as a whole.

MR. GORNY: Thank you for sharing --

MS. GIVENS: So I'm going to do a little PSA here, public service announcement. Was talking about program alignment that took place in 2017. We are all programmatically aligned. So you should not have a medical device or anybody other than a food person coming into your facility.

MS. TANNER: (inaudible - off mic).

MS. GIVENS: Yeah. No question about it. What I would also ask of you -- if you have some tutorials or videos, or whatever you might want to share with us, we could certainly make them available to our staff as well. I --

(Crosstalk.)

MR. GORNY: -- that training aspect so that, you know, anything you can provide --

MS. GIVENS: It's a multipurpose, you know, (inaudible - off mic).

MS. KROUT-GREENBERG: Natalie Krout-

Greenberg, California Department of Food and Ag.

So just looking at this, I know we're talking about, you know, reporting out the findings. But I think, going back to the comments made earlier about a systematic approach to things, looking at the cooperative agreement as it stands right now and just how the funding mechanism rolls, one of the things California actually had to go out and do when we need to separate our regulatory hat from the education outreach hat was go after general fund and the state to hire a technical assistance person. And you know, that will happen in the next couple weeks here that that person will be onboarded.

But my point with all of this is that, when we're looking at root cause analysis and we're doing good up unto the point of educate before and while you regulate the inspections, but then there's that component, that third really important component of closing the systems approach, that looking at the next cooperative agreement, earmarking funds specifically to that effort so that we can create a clear divide between what's regulatory in nature and what is education and outreach in nature.

And I know FDA has done this with its drug residue program because we also hold that contract. And looking at California and just the work that we've done over the years and reducing that from a preventions-based approach and now we're in an educational mode, that's been really effective.

MR. GORNY: Thanks, Natalie.

We've got about four or five minutes left. I'll just throw it open to anything that isn't necessarily on these -- within the scope of these questions. Or we can keep going on any --

MS. GIVENS: We've got the parking lot here.
So ...

MR. GORNY: -- revisit --
(Crosstalk.)

MS. GIVENS: Shoot. Just ...

MS. MAYL: Lots of spaces, you know.

MR. GORNY: Yeah. Lots of spaces in the parking lot, which is pretty rare in Washington.

MS. MAYL: Someone mentioned earlier penalties for actors that are bad. What about incentives? What kind of incentives can FDA --

MR. GORNY: Good question.

MS. MAYL: -- offer for the good actors, the ones who are compliant?

MS. GIVENS: And not having an inspection is off the table. Only kidding.

MS. BOOREN: Betsy, GMA.

Sharon, I'm going to turn that question just slightly around. I think if the Agency wants to incentivize the industry for using this, this gets to my first comment about being innovative and thinking about approaches that might be outside the box. And we may not have an equal framework.

I think the Agency willing to come up with that gray area framework to be innovative and do that, industry will rise to the challenge. And that will encourage them to engage in other ways.

And so finding that right nexus of where the agencies feel comfortable with what the industry is doing while protecting public health, but perhaps not having the exact regulatory framework, will move the needle forward.

MS. MAYL: We'd love for you to submit some comments about your ideas on that.

MS. MCENTIRE: Well, and the obvious in-the-box incentive is decreased inspection frequency, decreased likelihood of having a sample taken, being the subject of a sampling assignment. So there are tools that FDA uses today that I think can be adapted and are already being adapted to recognize people who have that good track record.

It is a real -- I think there's a disincentive, at least in the produce industry has experienced a disincentive of making the investment into these preventive tools when there is a broad don't eat advisory that it doesn't matter if you're the best in class or the culprit. You're equally affected. And so making that investment becomes a real competitive disadvantage if it means that your product is going to be more expensive compared to your

competitors and everybody is treated equally.

MR. GORNY: Understood.

Any other last comments? We've got about a minute or so left.

MS. GIVENS: Anyone who's -- hasn't had an opportunity to speak that would like to speak?

MR. GORNY: Yeah. So just a reminder on the comments, there is a sheet in your packet that explains how to submit comments. They're due November 20th, on or before. So submit often; submit early. There's no limit on the amount of comments you can put in.

We do take those very seriously. We -- they -- we will -- you know, we look at all of them and, you know, categorize them. And then that will help us develop that blueprint.

So with that, I think we'll wrap it up. And I'd like to say thank you to everybody. Give yourself a hand --

MS. GIVENS: Thank you.

MR. GORNY: -- for staying awake.

(Applause.)

MR. GORNY: We're going to move back to the plenary session.

(Whereupon, the breakout session concluded.)