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PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

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AGENDA

Simultaneous Breakout Sessions Block #1
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 #1

SMARTER TOOLS AND APPROACHES FOR PREVENTION

MS. MAYL: I have 10:35, and we have a lot to do today. So I am going to get started.

First, I'd like to introduce myself. I am Sharon Mayl. I'm Senior Advisor for Policy in the Office of Food Policy and Response. We're not going to spend a lot of time. If you want to learn about us, you can look in our -- at our bios.

Introduce yourselves. These are my colleagues.

MR. GORNY: Yep. I'm Jim Gorny. I'm Senior Science Advisor for Produce Safety.

MS. GIVENS: And good morning. I'm Joann Givens. I'm the Program Director for the Human and Animal Food Program in the Office of Regulatory Affairs West.

MS. MAYL: And together today we are Team Prevention.

So thank you for coming to our session. And we are going to try to get the logistics out of the way as quickly as possible because we really want to spend the bulk of this session hearing from you and your ideas.

I thought I was going to have a handheld. So I guess I'm stuck in my place.

So I wanted to -- obviously, we're here to talk about this discussion topic, which I have up there. I can let you read it, but, essentially, thinking about new ideas related to prevention. Hopefully, you've all read the Federal Register Notice and know a little bit about that.

I am going to facilitate today. Jim is going to be our flip chart person, and Joann is going to run around and try to capture all of your comments. So she's going to be our runner for this session. And we'll switch it up later this afternoon. But I'm sure you'll be at another session by then.

Anyway, so quickly to go over the ground rules, I'm going to pose a series of five questions, which should be familiar to you if you've read the

background materials. And we really want to spend this time hearing from you, soliciting ideas from you.

And so these are a few of the ground rules. Please introduce yourself if you have a comment, and please state your affiliation. Make sure your -- you have the mic on so that we can capture it during this session.

We are welcoming all ideas and opinions. You heard Frank say earlier they don't necessarily have to be based on reality. We'll put the reality check on it afterward. But right now, we want to hear creative thinking related to this topic area.

We are here to generate ideas. We are not here to build a consensus. So we want to hear from as many different stakeholders as possible from different segments, whether it's consumer, academia, business. We want to hear from as many as possible.

Unfortunately, we have a pretty short time here today, only about 15 minutes when I get done talking, to get answers to 10 different big questions. So please, if you're going to solicit a comment, try to be brief, maybe just a couple sentences stating your idea and your rationale about how this will advance our goal of prevention in food safety.

We do encourage you to submit -- and I'll probably say this and repeat this a lot -- more detail in follow-up comments or, if you don't get an opportunity to speak today, to submit comments to the docket, which will be open until November 20th. So please, please don't think this is your only chance to talk about these ideas. Please submit others in writing in comments.

So although I just said time is limited and keep it to a few sentences, also please be specific, if you can, in those few sentences. Think about what you're going to say so that we have something concrete that we can take under consideration and explore further. I think there will be other opportunities to talk about these ideas as well, in addition to today and the public comment period.

We are going to keep a parking lot for ideas, which may be a little bit tangential to this session

or might need additional follow-up. So we're going to keep a separate piece of paper over there with parking lot ideas.

And I also want to mention that this session is going to be recorded. So just keep in mind that we are recording for notetaking purposes.

So that's it for the ground rules. Are there any questions before we get going? Did I miss anything?

MR. GORNY: No.

MS. MAYL: Got it all?

So I think there's a series of questions that were posed, although I cannot remember exactly in what document they were posed.

MR. GORNY: In the FR.

MS. MAYL: In the -- okay, in the Federal Register Notice.

So we're going to go through them, and Jim is going to try to capture the big ideas on this piece of paper that we can take from there.

So let me start. I guess this is fairly broad. So the first question is: "What are the most significant actions FDA could undertake to promote and support the use of smarter tools for prevention?"

So I'm hoping that people have thought about this a little bit before they got to this session and are coming with new and bold ideas.

So Joann is waiting.

MS. GIVENS: I am willing to run to you.

(Laughter.)

MS. MAYL: Oh, we got a hand over here --

MS. GIVENS: So just raise your hand and -- thank you for getting us started.

MS. KOWALCYK: I'm always happy to go first. Barbara Kowalcyk with the Center for Foodborne Illness Research & Prevention at the Ohio State University.

So I think, obviously, one of the quick answers is to better leverage data that's already existing in the food system and making that data more accessible and developing partnerships with industry and academia that have the expertise in data science.

MS. GIVENS: Thank you, Barbara.

Running over to Sandy. It's wonderful to know so many faces in the room here, too.

MS. ESKIN: Good morning. I'm Sandra Eskin. I am the Project Director for Safe Food at The Pew Charitable Trusts.

I'll use three words and then, kind of a parallel, two words -- root cause analysis, environmental assessment. The Agency does them, not as often as I'm sure they would like to because they're resource-intensive. But that's the only -- that is one of the most effective ways to get to the how something got contaminated as opposed to what it was. You need that "what it was" first, get the food off the shelves, out of people's kitchens.

And again, in terms of promoting and incentivizing, there's got to be a way to help companies, particularly small ones, do these type of root cause analyses because, again, they are absolutely fundamental to a truly preventive system.

MS. GIVENS: I'm trying to get to everyone.

MS. MAYL: Joann's getting her exercise today.

(Laughter.)

MS. STOMBLER: That worked.

Hello. I'm Robin Stombler with the Food Laboratory Alliance.

Two issues: First is, and very importantly, to move forward, we need to remember where we've been, which is FSMA Section 202. We need to promulgate the regulation that addresses laboratory accreditation and model laboratory standards. That's critical to move forward.

Secondly, we need to know how to fill in the gaps. So as we're looking at new technology, particularly in the testing area -- metagenomics, whole genome sequencing -- we need to know what the gaps are when it comes to reference materials and proficiency testing. And so to have a better dialogue to understand what those gaps are so they can be filled is important.

MS. MAYL: Thank you.

MS. GIVENS: Thank you.

Do I see a hand over here?

MS. WETHERINGTON: Hello. Diane Wetherington, iFood Decision Sciences.

Two ideas: One is we need a technology roadmap for what technologies are possible today versus 5, 10 years from now.

The second thing is a suggestion you work with the National Research Council that -- as part of the National Academy of Engineering to convene a group that would consist of public-private government, maybe even military groups who have done this before, can look at everything from user interfaces, cost, that type of thing.

MR. THATTE: Hello. My name is Dileep Thatte. I am with the manufacturing extension partnership of NIST, National Institute of Standards and Technology, which is a part of Department of Commerce.

Our focus is on small- and medium-size food manufacturers. And as more and more digitization is happening, cyber security is becoming extremely important. And cyber security can lead to prevention as well as optimization of the processes.

NIST is extremely -- they are working on cyber security. And one of the things you can do is collaborate. We do have an MOU with the FDA for the small- and medium-size manufacturers. And I think that would be a good way to protect and prevent any safety issues within smarter tools.

MS. MAYL: Thank you.

DR. BRACKETT: I'm Bob Brackett. I'm with the Institute for Food Safety and Health at Illinois Institute of Technology.

I wanted to follow up with what Barb Kowalcyk said to -- about the access to data on the private sector. But in this particular case, I'm not sure what FDA can do, but they may be able to work with federal partners to make it less risky for the private sector to share their data because, right now, they just won't. And that includes genomics data, but it also includes lots of other things as well that could be useful.

MS. GIVENS: I think Barbara has a follow-up.

MS. KOWALCYK: So just to follow up, two things: One, I agree with Bob. And there is some -- it would be useful to get involved in developing data governance models that would outline what the roles and responsibilities are of various stakeholders and who owns the data, and that may be a good starting point.

The second piece I mentioned -- I forgot to mention is I know that there's a lot of interest in going with new technologies. But quite frankly, based on my experience, some of the FDA existing IT infrastructure is quite lacking. Can I say --

MS. MAYL: It's --

MS. KOWALCYK: -- antiquated? And just to give an example, I'm on the FDA science board. I was the chair of a subcommittee looking at FERN. And we interviewed one of the public health labs involved in FERN. And there is -- impossible for them to email lab results relevant to FERN to FDA. So the paperwork -- and this was just a few years ago. The paperwork was being faxed over to FDA and reentered by hand.

Now, we can talk about all these great new technologies that we're having. But until we address the IT infrastructure issues within FDA, it's going to be really hard for you to undertake to promote and support the use of smarter tools for prevention. So I think that has to be top of your list. It is addressing that infrastructure.

MS. MAYL: Thank you.

MS. GIVENS: We got a little better.

MS. MAYL: Yeah. I see one --

MS. GIVENS: It got a little better.

MS. MAYL: Oh, I see more hands in the back. I'm a little worried about going over time on this question. But let's quickly get to both of you.

MS. GE: My name is Melody Ge. I come from Corvium. And we're a company doing environmental monitoring data analytics.

So I echo Bob. It's totally true that we want to emphasize on how data is sharing from the industry.

But another comment I have is the awareness in the industry as well besides the private -- besides the facility, also the inspectors, like the FDA inspectors, how they react on -- to the technology that the facility is using, how they can tell. It's going to be different when they audit the traditional records versus the technology records. So that's some -- that's one comment besides the data sharing.

MS. MAYL: Thank you.

MS. GIVENS: Last call?

MS. MAYL: No, I think over -- there was a hand over there.

MS. GIVENS: Where?

MS. SPOTZ: I was pointing.

Kristen Spotz from GMA. And I think the -- it came up before, but I'll just echo it.

I think, in terms of a tool, smarter tools for prevention, I think if we look at, like, the medical and pharma industry and what they've done in terms of root cause analysis and CAPA systems and things like that, I think FDA could do more capacity building for smaller and midsize companies and, really, root cause analysis. And until you get to that root cause and fix the problem, it's just going to keep happening over and over again.

MS. MAYL: Okay. I think I'm going to move on to the next question. And again, if -- oh, Julie, would you like to …

MS. PIERCE: (inaudible - off mic).

MS. MAYL: Oh, no, no, because we can't record it --

MS. GIVENS: Because we can't --

MS. MAYL: -- unless it's --

MS. GIVENS: We can't record it.

MS. PIERCE: Thank you very much. Yes. Julie from the FSA.

I would just like to echo some of the comments about FDA technology. And I have no personal experience. So -- but I have a huge amount of sympathy and empathy, having to provide the technology for the FSA.

A couple of things I would say is, one, we do

have to get our own house in order, and we have to clear out, modernize, get our own tech right. Otherwise, how dare we preach to everybody else about being smarter and more modern? So we have to do that.

And also, I think about industry sharing data. We also ourselves have to live by that rule. We have to be open and transparent. We publish the vast majority of our data we generate. Some of it doesn't have anything particularly to do with the food system, but we do believe that we have to do that. Otherwise, why would industry take our lead? So please.

MS. MAYL: Thank you.

MS. PIERCE: All regulators, please live by those rules.

MS. MAYL: Thank you.

All right. I'm going to move on to --

UNIDENTIFIED MALE SPEAKER: Just one more.

MS. MAYL: Oh.

UNIDENTIFIED FEMALE SPEAKER: Super quick.

MS. MAYL: Okay.

UNIDENTIFIED FEMALE SPEAKER: So I was thinking back about the whole generations thing -- my 25-year-old daughters, in my mind, going is there an app for that?

There's the CFR app, but that's all that I know of. Is there any way that we can do more that way? I mean, maybe that's just --

MS. MAYL: Thank you.

UNIDENTIFIED FEMALE SPEAKER: -- too simple. But --

MS. MAYL: No. That's a great idea.

MR. GORNY: Thank you.

MS. MAYL: All ideas welcome.

MS. GIVENS: Absolutely.

MS. MAYL: All ideas welcome.

Okay. I'm going to move on to the next question. "What predictive analytical tools and data streams are best suited to helping identify a potential contamination event?"

Dr. Brackett?

MS. GIVENS: You guys tag-teaming here today.

DR. BRACKETT: I think that the whole area of genomics has been used very well for epidemiology and to track down problems that have occurred. But I think the whole area of metagenomics and understanding the microbiome of the food plant itself could lead to some predictive or -- I'm trying to think of what I'm saying here -- predictive analytics that could be applied to figuring out where pathogens might emerge in the plant.

MS. MAYL: Okay. Thank you.

MS. KOWALCYK: Barb Kowalcyk, CFI at OSU.

So I think that there's lots of predictive analytic tools. They've been out there for decades. I'm a statistician by training. So I've heard about these. I think what's different is we now have the capacity to do that.

And again, I'm going to come back to leveraging data across the system. Basically, right now, we conduct a huge observational study in food safety every single day. And all the data that's collected by the industry and by the government agencies isn't being leverage to understand and try and predict where we could focus our efforts.

I think the speaker this morning on the panel -- Julie, I believe it is, from the UK -- gave a great example. And those data streams are readily available. You have weather data, GIS data that are all available.

What tends to be the problem is getting access to either government streams of data, being from academia and consumer perspective, and the -- and industry data, which is being -- hardly being used for these purposes. From my conversations with industry, a lot of this data is being used for a go, no-go decision and then is put in a drawer somewhere. And we should be trying to leverage that historical data.

MS. MAYL: Great. You -- I'm just going to put something out there. We're going to go -- we are going to go to you. But one of the things I haven't heard yet is about the third-party audit data that's out there. And I'm wondering if you want -- you guys want to contemplate that while other people are

talking.

Yes.

MS. STOMBLER: Hi. Robin Stombler again with Food Laboratory Alliance.

And again, this is a good example of where accreditation and model laboratory standards are important to have in place for the accuracy of the data. I specifically want to mention proficiency testing again and reference materials.

MS. MAYL: Okay. Again, we're talking about analytical tools and data streams.

MS. PIERCE: Hi. It's Julie again.

Yes, we are looking all of those different data streams. We are pushing back on industry to say this data is pretty competitive, and there's no reason why you shouldn't share it.

But at the same time, we are also exploring data trusts so we can see whether there are ways that the right people who need to access the data can do so through data trusts.

So I think there are ways around all of this stuff. But again, it's a matter of going for it and working out what -- in an ideal world you'd like and then working out how it can happen.

MS. MAYL: So one of the things that we think about at FDA is whether data can be sort of generalized at sort of a higher level or specific to facilities and farms. I'm just putting that out there again to spur some creativity.

MS. KOWALCYK: So Barb Kowalcyk again. Sorry. I will take a back seat if there are no other questions.

But I think, one, third-party audit data I view as part of industry data. It's just a different part of industry. So when I say that, I mean all data related to the food industry.

I do think that there are ways to get around the proprietary information and concerns around that. There's methods called statistical disclosure limitation methods that have been used by the Census Bureau and other areas to deal with this, but maintain the interpretability and generalizability of results.

And I think that there are lots of ways that we could deal with that.

Now, I think to your last suggestion was whether or not generalized results at a high level or more detailed, obviously, more detailed results are always better. Having as close to the raw data as you can is better when you're trying to develop models like what you're talking about.

MS. MAYL: Right. And it -- you know, it may be that each type of data has different uses. Generalized data can help us predict trends. Specific data is something, obviously, we might be able to use when -- in our oversight in -- when we're looking at risk-based oversight. So there are different uses, and I think they're -- they both have a place.

MS. GIVENS: So I'll pose a question. So how do you get around potential lawsuits? I think that that's the fear of why we don't -- we're not advancing and sharing data now. So I mean, that's our reality. I mean, I don't -- I'm not creating a barrier, but it's a reality.

So any thoughts about that?

MS. SOUTHEE: Jacqueline Southee, FSSC 22000.

So I represent a third-party certification program, and there is a fear of industry that, you know, if they do have an issue, that -- because of social media, because of regulations, that that's going to tarnish their brand because that's what's the most valuable to them.

But having said that, they are all, you know, conducting management systems. They all have their food safety preventative plans. They all have their preventative controls in place.

And we collect that data through audits. And the audits are used for business-to-business benefits. But we also collect the nonconformity data. And so on a higher level, we are going to be in a situation again through our own, you know, data streams of being able to collect where areas of nonconformity arise, and that can be general.

So we are going to be in a situation where we're not going to be disclosing sort of individual

companies, but certain trends, time of years, you know, where contamination arrives, where there are problems in certain controls. And it could all again relate to, you know, the bigger picture that Julie talked to. You know, it's a communication thing.

So again, FDA and industry and the existing standards all have an opportunity to communicate, to share.

MS. MAYL: Okay. I think we'll take one more on this question, and then I think we are going to move on to the next.

MR. CROWNOVER: David Crownover. I'm a Food Safety and Strategy Consultant. But I'm soon to be with AIB International.

I'm going to kind of also go back to somebody who mentioned data governance earlier in reference to your topic about lawsuits. I think there's a lot of concern as it relates to next-gen sequencing about how long is this data going to be available, how long is it going to be for maybe the DOJ to come in and use it as a means of, you know, prosecution. I think that's the concern.

So if, you know, we go back again to the data governance, if there is a way of saying, okay, this is, you know, statute of limitations, or something along those lines, that needs to address both when these are being made available because a lot of that data has been around, from an auditing perspective, for decades. How far back does it go back?

And if these companies are continuing to, you know, progress and improve, is it really right to go back 10 years, 15 years, 20 years when the people who were there aren't there anymore, the systems aren't even in place anymore and have possibly improved, and those products aren't even around anymore? So that's just something to keep in mind to kind of link all of that together.

MS. MAYL: Great. Thank you.

MS. GIVENS: Thank you.

MS. MAYL: And that actually --

MS. GIVENS: Great point.

MS. MAYL: -- leads us a little bit to the

next question. "What further steps can be taken to advance the safety of domestic and foreign commodities that had been the subject of frequent contamination events?" In other words, looking back in the history. So thanks for that lead-in.

Cindy.

MS. KRUGER: Hi. Cindy Kruger from PepsiCo.

So I think this question is interesting and a point where we're still looking to try to implement FSMA because I think that implementing FSMA is probably going to take you huge steps into the future on this. And you don't need a particular data tool to do that. You have to do that. You have to -- you can have a wide range of data tools to be able to do that.

So I don't think you need to jump to the next -- I don't know what -- when you've got a really good tool before …

MS. MAYL: I'm wondering if there are ways to work with industry to identify best practices learned from contamination events. So again, thoughts related to that.

MS. WETHERINGTON: So Diane Wetherington, iFood.

I just want to echo the last comment. So I know I'm hearing from companies in foreign countries, in particular, that they're just waiting to implement the Foreign Supplier Verification Program. They haven't really seen the FDA other than, I think, some brief conversations early on. They're not really seeing from the FDA a lot of follow-through in terms of being there visibly working with them.

MS. MAYL: Okay. Thank you.

MS. TIMITE: Hi. I was just going to second what she said. My name is Sarah Timite from Action for Sustainable Development.

I believe that the third-party centers are something that needs to be more looked into in terms of data collection. Essentially, like she said, there's some of these organization, public and private, are ready to release this FDA. CDC is on the ground in Africa, essentially. And maybe looking at their model could be something to look at.

MS. MAYL: Thank you.

MS. GIVENS: I saw a new hand. Did you have your hand up?

UNIDENTIFIED MALE SPEAKER: No. I was going to pass it to her.

MS. GIVENS: Oh, you were going to pass it to her. Okay. You're assisting.

MS. SOUTHEE: I just wanted to follow up on that point. So we have a database of 20,000 facilities which are outside of the U.S. that we certify. And I think every day I have a call from somebody that says I'm FSSC-certified; does that mean I'm FSMA-compliant?

So we are -- you know, we are reaching foreign facilities. They do know what FSMA is. But that's my job. I tell a lot of people what FSMA is and how we can help them meet it. So I do believe that the third party plans are going to help do that.

MR. THATTE: I'm Dileep Thatte from NIST.

I understand that most of the -- a lot of foreign suppliers are supplying spices and ingredients and things like that. And there is some reference material being generated at NIST, but its scope is relatively limited. So perhaps expansion of the reference materials from NIST so that the industry can compare and make sure that, you know, the important ingredients meet certain standards.

MS. MAYL: So reference materials -- can you just elaborate?

MR. THATTE: For the standard -- standard reference materials.

MS. MAYL: For the safety standard --

MR. THATTE: As far as safety standards. That's just a thought.

MS. MAYL: Okay. Great. Thank you.

MS. HOLLINGSWORTH: Jill Hollingsworth with Chemstar.

I think one of the things, too, that -- and I mainly focus on retail -- one of the things that I think a lot of the retailers have been trying to do is to learn best practices and root cause analysis and prevention methods from the manufacturing side. And

all the way back to produce best practices, manufacturing best practices, and then take those and adapt them to a much smaller, very different environment. In a restaurant or a grocery store, you can't wrap yourself in a little protective bubble, but you can take some of those learnings and try to adapt them.

And if there is one thing when -- in looking at how can FDA help facilitate that, I think it would be for FDA to start looking at how do we get restaurants and retailers to take those very big controllable prevention practices and scope them down to a retail environment. It will be a different environment, and we'll have to make adjustments. But I think retail can and wants to learn from what the industry is learning. You don't necessarily have the kind of ability to do root cause analysis as detailed in a restaurant or a grocery store as you can in manufacturing. But you can certainly learn from what they have learned.

And I think getting support and encouragement to the retail industry to do that would be very helpful.

MS. MAYL: Great. Thank you, Jill.

MS. KOWALCYK: Barb Kowalcyk again.

So I think I want to -- going back to leveraging the data across the industry, when you leverage that data, you can go ahead and identify best practices when you've aggregated the data. So figuring that out will help you get towards identifying best practices in certain situations because you can use data mining techniques to do that.

MS. MAYL: Great. And again, a lot of these ideas obviously need a lot more detail and further discussion. So we're really interested in having people follow up with written comments.

And Cindy, we're going to move on, so just real briefly.

MS. KRUGER: So the last thing I want to say is back to basics is training. I think that -- so someone in the opening talked about you have to be able to execute. And I think the Agency can probably

help by, you know, really helping training irregulars, training availability for industry. It's basic, but that's where the real food safety is happening. So …

MS. MAYL: Great. Thank you.

All right. So we're going to move on to -- let's see. I think we're on 4, right? Okay.

"In what ways can FDA support the use of environmental assessments and root cause analyses in industry prevention efforts?" I know we touched on this a little bit more, so this is an opportunity to dig a little bit deeper into these subjects.

MR. QUERRY: Good morning. I'd like to talk specific to the root cause analysis. I'm Randy Querry. I'm with the American Association for Laboratory Accreditation.

The root cause analysis -- if the FDA were to implement Section 202, I'd encourage the use of third-party accreditation bodies. We rely and use ISO standards for all of our accreditation programs as a baseline. All of the ISO standards include root cause analysis as a core principle and build upon that.

So with ISO 17025, that's specific to laboratory testing. Also, there's a standard for reference material producers and proficiency testing providers that also rely on root cause analysis and has principles in place for that.

And what we see is that it creates a culture, which we brought up in the earlier sessions today, a culture of quality and continuous improvement, and that when we go in to conduct follow-up renewal assessments, we are seeing fewer and fewer findings. The organizations that do effective root cause analysis and internal audits are coming out with cleaner assessments than those who don't have the -- as well as a root cause analysis system.

Thank you.

MS. MAYL: Great. Thank you.

MR. HEINZELMANN: Good morning. Joe Heinzelmann with Neogen.

I think something that Melody talked about applies here, and it's really important. And that's taking the inspectors and making sure that their

assessment and understanding of digital records accelerates as a technology does in the food safety space. So as different technologies are adapted and inspectors come in, making sure that they, one, understand it, two, accept it because, if those two things don't happen, that will really slow the adoption of these types of technologies for prevention.

MS. KRUGER: So I really didn't intent to say anything the whole session, but I can't help myself.

(Laughter.)

MS. KRUGER: So first of all, I think you could finalize listeria guidance.

And second of all -- this is not going to be popular in the room, necessarily -- but I think that you need to be very careful about, in those inspections, that you do not collect records and that you are very respectful and careful with company data because, you know, we're generating that data and we're -- it's driving continuous improvement. And I think it's very important that the agency really respect that. I don't want you going in my third-party audit reports.

I don't want -- but I think that, you know, it depends on what's incentivized. Sometimes I'm incentivized not to create data. To Joann's point, there's a lot of legal liability that I face.

So I think it's important that we do these assessments. And I think that, to help broader industry, you could -- again, training -- help people understand what they're supposed to look for. Even in a very large company like ours, it is -- you know, we are working on training globally, making sure everybody understands what they're looking for and why and why it's okay to find a hit.

DR. BRACKETT: Bob Brackett, Institute for Food Safety and Health.

This goes back to data sharing. But in this particular case, I think that if FDA were to share the results of the root cause analysis -- they did this a number of years ago with halogen recalls where it listed all the different causes. But I think having

the public know what the real problems are and where in GMPs they might be occurring may be helpful not only to training, but also to enforcement.

MS. MAYL: Okay. So better transparency on FDA's part.

Are there ways to develop new models for environmental assessments and root cause analyses? If people have thoughts on that -- pilots?

MR. GUMMALLA: Sanjay Gummalla with the American Frozen Food Institute.

And I really want to commend everyone for speaking up. It's great to hear everyone being open and candid.

Four years ago, almost five year ago now, I came to the Frozen Food Institute, and listeria became a major issues, as Jim can attest to for us, specifically. And one of the questions I was asked by a member was: What advice do you have for us? What -- how do we monitor? How do we assess what the risks are?

And I was -- frankly, there was a blank -- I had a blank face. I didn't have any data. And so we embarked as an institute to collect data -- environmental monitoring data from various facilities representing all sorts of frozen foods and categories. And it took us two and a half years to come up with a multi-blinded protocol with conversations with legal counsels at various companies, my own -- our association's legal counsel.

And we did come up with a paper-based-blinded study, which I think if I look back and look at the digital transformations that are occurring in our field and how that can be used, I think we could have possibly used a more digital sort of -- and I know I'm going on. But I -- the point I want to make is, at some point, there has to be an intersection of what the industry and the Agency needs in terms of data to make -- I don't know -- science-based policies and drive their guidance.

Obviously, the *Lm (i.e. Listeria monocytohgenes)*alum (ph) guidance has -- is now in abeyance for, again, a couple of years since it's been

redrafted. And we have data. Now we can -- we're going to publish this data, and we would earnestly hope that you avail of this data.

The second point I want to make is around what is the impact of zero tolerance to all of this conversation the risks it places to generating this data. I mean, there are companies -- or I shouldn't say companies -- there are facilities out there that still can't embark on Zone 1 testing, which we know is critical to understanding and implementing a food safety program that addresses the risks of listeria -- mono.

And if the free pass, or however we want to call that, was groundbreaking for the FDA and was, you know, given to us two years ago, well, I'm not convinced that that has, in fact, allowed the industry.

And so we need to look back. We need to introspect. And when I say we, I earnestly say industry and the Agency together.

So I just want to --

MS. MAYL: Thank you.

MR. GUMMALLA: I want to put that on the -- because that is the elephant in the room in terms of generating data.

MS. MAYL: Yeah. I'm also hearing from several of you a role for either certification programs or trade associations as both being sort of a conduit for some of this data, the ability to collect it and filter it in some way that could be useful for the Agency. So I think I'm hearing a little bit of that from various stakeholders.

Yes, Jill.

MS. HOLLINGSWORTH: Jill Hollingsworth.

And in addition to Chemstar, Chemstar now also has merged with Ecolab. So this is on the Ecolab side of it.

One of the things that Ecolab has done is put together a management system where they actually collect all of the inspections that are done by -- on the regulatory side -- health departments, both state and local. And much of that data is freely

accessible, anyway. Some of it takes a little more digging. But we collect all of that data, and we can slice and dice it by regions or type of facility or any way we want. But then we also do independent third-party inspections of retail facilities and look at that data side-by-side.

And you're right, though. I think one of the beauties of private companies doing that is we can blind the data. We can aggregate it so we take away the fears of legal liability, yet we're still able to tell an individual company here's how you're performing compared to the norm or the best.

And it also, I think, is very useful. And one of the things I'm encouraging here is that we try to stack that data up with FDA's risk factors and look at it all together in aggregate and see there's got to be some places where we know we can do better and how and why aren't they as good as they could be.

And one last thing, too. I've -- I have seen on a lot of these audits is a real push to get away from the concept of failure and critical and, instead, identify things as opportunities or areas for improvement. And I think it makes people think of a more preventive long-term control as opposed to this is critical. Just do something right this minute and fix it, but don't really look at what you can do to control it.

UNIDENTIFIED FEMALE SPEAKER: Right.

MS. MAYL: So terminology matters.

MS. GIVENS: Do I see any other (inaudible - off mic)?

MS. MAYL: No. I think there's …

MS. GIVENS: David, did you want to -- did you have your hand up before? No? You're still passing the mic?

(Laughter.)

MS. KOWALCYK: Barb Kowalcyk.

I think academia also plays an important role in potentially aggregating and blinding data and, also, for a couple reasons. One, we're on the cutting edge of the developing new statistical methods and applying it.

But also, as we talk about this new era of smarter food safety and the increased use of data analytics, there is a significant workforce development issue that we have here. And training the next generation of food safety experts that understand data analytics is going to be really important. And so engaging academics in this process is really important.

MS. MAYL: Great point.

I think -- oh, one more.

MS. GIVENS: Time, time.

MS. MAYL: I know. Well, this last one on this question. I think we have -- still have 10 minutes for the last question unless my watch is off.

MS. PIERCE: Thanks very much.

And I think I may be building on the training skills point made there. And listening to the conversation, I think everything that's being said is really valid, and they're great, great ideas.

I also think it's beholding on us to have a bit of a mindset shift that this isn't going to be done. We're not going to have sort of like a two-year program and build a thing, and then we'll have a new testing approaching and we'll be done. This requires us to have a completely different mindset and to be much more open-minded and to try to make progress, but do it in a way where that world is changing continuously. So we need to build that capability and skill ourselves.

MS. MAYL: Okay. Thank you.

All right. I'm going to move to the final question. And if we have a little time, people can throw some additional thoughts in at the end.

Okay. "Are there changes that FDA can and should make in the way in which it conducts environmental assessments and root cause analyses and reports its finding to industry to better facilitate their use in industry prevention efforts?" And I think we've already touched upon this. We've already heard a little bit on this. But I'm happy to hear more.

MR. GUMMALLA: Thank you, Joann. Thank you

again. Sanjay Gummalla with the American Frozen Food Institute.

We are coming up on the -- probably the anniversary of the Frozen Berry Sampling Program, which started in November of 2018. And it has over the last 9 months -- or 9, 10 months has really given us a lot of opportunities, I think, to potentially look at surveillance programs, the way they're structured, and the way they're rolled out in a completely different way.

We've made a lot of -- we've offered a lot of alternatives and changes and modifications, and FDA has helped us maneuver some of those in the right way based on science and so forth.

But I would like to add two important pieces that are critical, I think, to surveillance programs. One is that all of their protocols should be published from start to end, from the standpoint of how you're going to sample to the point of a confirmatory testing. And in doing that, I think FDA will have a better picture, and so will the industry in terms of what is the relevance of these testing systems as well as the protocols that they're using. It's just a good way to double-check ourselves. So that's one.

The second is I would go to the next step and say that any of these protocols should be published in peer review journals. I think these tests should be published. It can't be within the domain of -- and that -- what that does -- I think it helps us, also, so we're aligned on the testing protocols. And it just makes for a better surveillance program, and the data is more reliable that way.

MS. MAYL: Thank you. Thank you, Sanjay.

So again, I'm hearing themes of better -- more transparency --

MS. GIVENS: Transparency.

MS. MAYL: -- on the part of the Agency. And again, please, please don't hold back. We have thick skin here at the Agency. So if you think there are ways that we can do things better, we want to hear them.

MS. GE: Thank you. Melody from Corvium

again.

So first of all, if FDA ever thinks a pilot program with the industry, I volunteer to join because we're doing environmental monitoring data. And I -- really, I'm happy to share and help, like, in any ways. One thing --

MS. MAYL: Thank you.

MS. GE: -- I'm curious about this question is more on the reports perspective. Like, we all know inspection is a snapshot. Like, with nowadays, technology -- actually, in the facility, there are 24-7 technology monitoring in the environment and then have the testing results.

So I'm curious to see, like, the results from inspectors versus the routine results the industry -- the facility actually have. Is there a significant surprise, or is it the same? What was the reason causing the surprise? What was the reason it's the same? Like, what was the percent -- what's the percentage of the significant difference?

Like, data like that from FDA will be really helpful to the industry. And it -- well, again, this is based off the current situation that data can be shared to the public. Inspection data is inspection data.

Of course, if we can go back to the data sharing, then that will be another story. But right now, I'm curious about those percentage from the FDA inspection.

MS. MAYL: Thank you. I heard a little bit in there just to, again, prompt some thoughts on real-time monitoring on the part of industry and how we can use that. So I don't know that all industry does that all the time or farms do that with respect to water quality. So those are things we're very interested in, in how we can work with industry on that.

Again, things that we at the Agency could be doing better in these areas. Again, all thoughts welcome.

MS. GIVENS: Let me see who I know in this room that I might want to --

MS. MAYL: Oh, Joann's going to --

MS. GIVENS: -- ask a question.

MS. MAYL: Joann's going to target you. Always a scary thought.

MS. GIVENS: Always voluntary.

MS. MAYL: Well, I'm -- we have a little bit of time. So if people want to go back to other questions, we're more than happy to get thoughts on some of the previous questions. I think a lot of these questions are overlapping. So feel free.

MS. ALUMBARTINI: Elizabeth Alumbartini (ph), RTI International --

MS. MAYL: I'm sorry. Say that again.

MS. ALUMBARTINI: Elizabeth Alumbartini. I am a nonprofit research institution that works on food safety and risk analytics.

Three quick points: One, in terms of root cause analysis and leveraging data, the -- one of the known knowns is environmental contamination and, basically, human and animal manure management. So that -- the suggestion is to not forget the work that's been done in the environmental realm -- water, soil, and others to be included, especially looking at the food shed and watershed level.

Second, as a modeler, I have to support model open lists (ph) as well as data open lists and suggest more harmonization of risks and other modeling methods and the assumptions that go with it. And often, each -- there is a one-off modeling effort that happens that may or may not jive with other efforts. So working on the model open lists and sharing as well.

And lastly, in terms of data content, I think something that was mentioned before on more attention to microbial communities versus pointing at (inaudible) pathogen, I think with issues of changing environment, managing issues like virulents and antimicrobial resistance, we need more attention to understanding the whole community.

MS. MAYL: Thank you.

Other thoughts?

You're getting your steps in, Joann.

MS. GIVENS: I sure am.

MR. WILSON: Hi. I'm Gabe Wilson from Hormel

Foods Corporation. I also wasn't going to say anything today, but here I am.

One thing I think from a prevention standpoint that we'd like to see is thinking more from, like, an epidemiological perspective. If we're starting to see things that may point something back from that perspective to a product that's mine or produced to my company or my plant, I want to know about it, even if it's not completely conclusive so we can take action, do our investigation, do our root cause analysis, and we can work with the Agency to help identify or solve that problem and help eliminate some of that public health risk that could potentially be there.

MS. MAYL: Any other thoughts before we close?

MS. KRUGER: Why not? So I also think if the Agency could recognize not-ready-to-eat food that that would help people understand where and when to apply pathogen environmental monitoring, since you said I can be controversial and hard on you.

MS. MAYL: It's okay.

MS. KRUGER: And you know, I -- as not a technical person -- I'm a lawyer; a lot of people know that -- but I want to make sure that we can rely on the technology that's being applied so that the whole genome sequencing is accurate and applied accurately. And I think the Agency can help a lot with that. Government can a lot of times set governmental standards for that sort of thing.

And I think we have to be risk-based in how we approach these programs. And maybe some day there will be a real list of high-risk foods. But you know -- and it would be nice if we could -- if there's certain concerns with, say, certain categories of produce, it's not great that the CDC is saying, okay, I think there is, like, an illness somewhere.

And I mean, there was even an alert that said there are illnesses. And we don't know what it could be, but we just want to tell you all that there are illnesses. And that was sort of ridiculous to me. Like, I don't understand how that was helpful at all.

Like, we know there are illnesses.

And so they connected it all to, you know, a specific -- I -- so I think we know there are specific pathogens that are causing illnesses as well. And I think we have to get a little bit more serious about, you know, how we can best protect the public health.

And where I know the Agency's under a lot of pressure for recalls to get the right recalls and the right timing, and you're always making decisions in recall situations where you don't have all the information. And I think that's one of your challenges, is to try to work on that in light of all technology.

And there are other people in the room here who maybe aren't speaking, but have a lot more knowledge about it. And they will speak up, I'm sure. But I -- you know, I think that's part of this conversation. So …

MS. MAYL: Great. And that is a great lead-in to closing.

MS. GIVENS: You want to close it? I have one more.

MS. MAYL: Oh, one more? Okay. Well, remember that thought because I'm going to pick up.

(Laughter.)

MR. GUMMALLA: I would just, in closing, really ask for reliance on the three-legged stool as we talk through outbreaks. I've heard several folks at FDA now sort of walk away from that on a case-by-case basis. And by three-legged stool, I mean the epidemiology, the traceback, and the food.

And I don't know if this is the domain of CDC or not and if they are considering a revision of how consumption surveys occur.

I think that would be critical particularly to your point, Cindy. Those are antiquated. Those forms are still decades, if not more, old -- years, if not decades, old. So I -- there's a huge opportunity in the way -- and maybe there's a digital-something, new technology, that I think there's a way for us to get -- garner that information from sick individuals and then be able to connect that with the

contamination events.

MS. MAYL: Great. Thank you, Sanjay.

MR. GUMMALLA: Thank you.

MS. MAYL: So just in picking up where I left off -- first of all, I want to thank everyone who provided comments in this room, particularly those that didn't think they were going to speak and then ended up speaking. So I hope that we made everyone feel comfortable enough to put forth these ideas.

For those of you that maybe are still thinking about it or would rather do it not in a public setting, again, I encourage all of you to submit comments to the docket, which will be open until November 20th. And I think in your packet there was a sheet about how to submit comments-- if you didn't -- I mean, you can look in Federal Register, but a sheet on how to submit comments.

Later this afternoon, we're going to have a session where everything is summarized. Jim is going to take our -- the comments that you made and, plus, from our session this afternoon into a fabulous --

MR. GORNY: Three minutes.

MS. MAYL: -- summary -- three-minute summary of two hours of comments. But he's up for the --

MR. GORNY: I talk fast --

MS. MAYL: He talks fast, and I think he's up for the task.

So again, thank you for participating. We hope that you have a good afternoon and participate in another session and enjoy your lunch. There's lots of restaurants around here.

(Applause.)

(Whereupon, the breakout session concluded.)