FOOD AND DRUG ADMINISTRATION (FDA)
PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

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AGENDA

Simultaneous Breakout Sessions Block #1

Plaza Ballroom: Tech-Enabled Traceability & Foodborne Outbreak Response

Facilitators:

VINETTA HOWARD-KING
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P R O C E E D I N G S

SIMULTANEOUS BREAKOUT SESSIONS BLOCK #1

TECH-ENABLED TRACEABILITY & FOODBORNE OUTBREAK RESPONSE

MS. HOWARD-KING: Alright. Why don't we go ahead and get started. I was asked for folks that are way over to the left and way over to the right, I don't -- there aren't people way over to the right. Way over to the left, if you could move in because this session is going to be webcast and we want to make sure that you can see and we get the folks in the audience in the webcast. So, if you want to be a star today, can you kind of move over towards the middle? You won't be able to see us but you're adults and I'll leave that to you.

Alright. Good morning. My name is Vinetta Howard-King and I want to welcome you to the new era of smarter food safety, tech-enabled traceability and food borne outbreak response session. And so, a lot to say here. Again, my name is Vinetta Howard-King and I am the director of the Office of Human and Animal Food Operations East in FDA's Office of Regulatory Affairs. I'm joined today by several of my colleagues from FDA and I'm going to let them introduce themselves, starting with Ms. Kari.

MS. IRVIN: Hi, I'm just saying --

MS. HOWARD-KING: On now.

MS. IRVIN: Okay, great. Hi, my name is Kari Irvin, I'm deputy director of FDA's Coordinated Outbreak Response and Evaluation Network aka, the people that sit and dig through the bins of records during outbreak investigations that Dr. Mayne so affectionately mentioned today.

MS. VIERK: Hi, I'm Katie Vierk. I'm the director for the Division of Public Health Informatics and Analytics at the Center for Food Safety and Applied Nutrition at FDA. And I am leading the FDA traceback rule writing workgroup.

MR. PASTEL: Hello, I'm Charlie Pastel. I'm an assistant at the Office of Food Policy and Response, working to provide technical assistance with the visibility workroom and any other issues that Frank brings forward.

MS. HOWARD-KING: Alright, thank you. So, before we get started, I want to go through the audience and kind of know who's got -- who showed up here today. So are there any other government agencies in the room, if you could just raise your hand? Okay. Thank you. Are there food producers or suppliers in the room? Okay. Are there consumer representatives here? Thank you. Any researchers? Are there any regulators besides FDA in the room? Okay. Do we have any media representation here? Alright, thank you. And are there others that I did not mention? Well, I hope you introduce yourself when you answer some questions, but thank you.

So, the goal of this outbreak session is to provide an opportunity for stakeholders to discuss traceability, smarter tools, and approaches that will greatly reduce the time it takes to trace the origin of a contaminated food. The input FDA receives today will be used to shape an agency blueprint for a new era of smarter food safety.

The blueprint will outline how this modern approach will address public health challenges, ranging from being able to trace sources to contaminated food, to using new predictive analytics tools, like artificial intelligence to assess risks and to help prioritize the agency's work and resources.

FDA is seeking your ideas and thoughts on how we can use new tools to improve traceability and how we will enhance food borne outbreak response. With that said, we have three goals of the tech-enabled traceability and food borne outbreak response session. And they are - we want to facilitate end-to-end traceability throughout the food safety system. We want to enhance food borne outbreak response and we want to innovate communications approaches.

So also, I would like to reiterate that any reference to the proposed changes to current food policy that's included in your meeting materials that doesn't constitute an endorsement by FDA. These were ideas proposed during various public forums, and FDA included that information in your package just to help generate discussion.

So, I want to go over some ground rules right before we get started. When speaking, please introduce yourself and your affiliation. Any idea or opinion is great and welcome. We're not looking for an active group consensus. We are asking you to be specific as possible with your comment, explaining its rationale or evidence, and how it advances our food safety goals.

Please be mindful of time limits and Charles is trying to keep us on schedule. For parking lot issues, we will definitely jot those down and we'll try to identify those for further discussion and considerations depending on time.

And just a reminder that this session is being recorded to help facilitate note taking. So, regarding tech-enabled traceability and food borne outbreak response, new and evolving digital technologies will play a pivotal role to enhance tracing contaminated food to its source within minutes or seconds, rather than days and weeks.

So with that said, I want to start with the first question for you all. What are the most significant actions FDA could undertake to enable industry to enhance traceability across the entire global food chains -- food supply chain? And these questions are actually in your packet as well.

MS. IRVIN: Anybody want to get us kicked off? Simple question, right? Please come on over here. And just make sure you state your name and who you're with.

MS. ANGARITA: Hello, my name is Lucelena Angarita. And I'm with IPC the supply chain arm of Subway. I think one of the main things is that we focus on the foundational elements. So, it's one of the first things stated in our material. What kind of key data elements do we need, regardless of the technology to communicate, to be interoperable? So how are we going to identify products, locations? And then how are we going to use that information to integrate it into our systems and make it available; so, all of us are sharing one common language.

MS. HOWARD-KING: Thank you.

MS. DUCKETT: Hi, I actually have two roles. My name is Jeanne Duckett *8and I'm with Avery Dennison

Corporation. I also sit on the Board of Directors of standards organization that's here today and AIM Global.

MS. HOWARD-KING: Welcome.

MS. DUCKETT: So that's another one of your group, that's here. So anyway, in answer to your question, I think, to build off what Luce from IPC said was, I think an interoperability suite. So when you build those foundational elements of identifying places and things, the next thing you need to do is decide what points you're going to capture things. And I think defining a minimum viable product, like these are the minimum things that everyone's going to capture, whether they're capturing a fish, whether they're growing corn, or lettuce or meat, so that you can test the interoperability of different platforms. That's how you get that seamless experience.

And then the other thing, one of the things that AIM Global has done is they have testified on different upcoming regulations such as at UDI and Drug Supply Chain Security Act of 2013. So it would be good if in the code of Federal Regulations, we had a requirement for traceability. I think that would encourage all aspects of the supply chain to adopt.

MS. HOWARD-KING: Okay. Thank you.

MR. DUFFIELD: Okay, good morning. Ian Duffield, Procurant. We are software company in California. And 13 years ago now in 2006, of course, Frank mentioned the spinach crisis. Following the spinach crisis, there was a significant industry wide effort to improve traceability. One of the major activities was the PTI initiative, Produce Traceability Initiative. And across the industry that was reasonably successful. We're now 13 years later on we just last year had two major outbreaks with romaine. The Romaine Task Force, which just released its report last week, recommended very heavily in that report more traceability.

We've been talking about traceability for many, many years now. And we've also heard about technology that's going to miraculously solve all of our problems. It's going to make our coffee and look

after the kids when we're at work.

The technology that was available in 2006 could have solved traceability. In fact, I worked for a software company that introduced PTI and item level traceability back then, nobody cared. The growers and shippers built some traceability into their processes. But it wasn't followed through all the way through. The -- for example, and there were many breakdowns in that flow of data. But the data wasn't tracked all the way through to the -- excuse me -- to the end point. And so even though some of the growers shippers put PTI labels on their cartons, when it got to the stores the cartons weren't scanned.

So part of that challenge that the FDA has is the implementation and maintenance of such a system all the way through from the beginning to the end. And I realized we have a government that's not very enthusiastic about more regulations. But I believe that unless there are more regulations about managing the implementation of traceability, then it's -- we're going to be talking about this in another 13 years. The technology was available before it's available today. We don't seem to want to do it. So we're going to have to be told to do it. Thank you.

MS. HOWARD-KING: Okay. May I ask a follow on question for you, sir? Given the protocols that were put in place after the spinach outbreak, and now the recent romaine lettuce outbreak, where do you see the gaps there?

MR. DUFFIELD: Thank you. That it's not implemented across the entire supply chain.

MS. HOWARD-KING: Okay.

MR. DUFFIELD: The hardest part of the implementation of a traceability system is the beginning and the end, picking the real, the live data in the fields, for example, for produce, and tracing it all the way through to the store, and potentially to the consumer at the end. There's been a lot of -- and my apology to Frank in advance. But there's been a lot of press recently about tracing mangoes in 2.2 seconds. I watched the video many times. And there are -- and there are companies signing up with the companies who

are launching those programs. Frankly, my interaction with those has not been terrific. There's a lot of knowledge about getting information in the middle. If we can just upload a advance ship notice, the whole problem will be solved. But it's not. You have to collect the data in the field and track it through the cooler through to the distribution all the way through the process to the store. If that doesn't happen all the way through the process, having the data in the middle doesn't help you.

MS. HOWARD-KING: Thank you. We'll get back to the next.

MS. McGILL: Hi there. My name is Julie McGill, and I am with FoodLogiQ. We're a SaaS based software company that provides traceability with supplier management tools.

MS. HOWARD-KING: Welcome.

MS. MCGILL: Thank you. So, to build off of his last comments, one of the things, you know, when Frank talked earlier about building that food safety culture, we have companies that are doing what we're talking about here that are sending data across the entire supply chain. But without the culture, companies don't, people who are part of the process don't understand what their role is. They -- their companies might not make this a priority. So where we're seeing breakdowns is, I might have perfect data for three months. And then all of a sudden, somebody in the middle of the supply chain stops sending it and then it's -- you're chasing down that data. And so data quality isn't just about the data that's being sent, it's about sending it every time. And so, part of the education that has to come for the industry is that, you know, the technology, yes, we need the technology. We need you to understand your role in the supply chain, and you know, participate. But then once these are in place, it's now part of your business. It is no longer -- it's not a project, it is not a onetime thing. And so it has to be built into your standard operating procedures for your business. And if -- you know roles change, people move on that that these things continue because it's part of how you do

business.

MS. HOWARD-KING: So FDA should focus some on better educating industry to what their role in the process is?

MS. MCGILL: Yes.

MS. HOWARD-KING: Okay. Thank you. I want to -- well, I know I saw, Betsy's hand for -- and then we got someone up here.

MS. BOOREN: Good morning, Betsy Booren, Grocery Manufacturers Association. When our members looked at your Federal Register notice, and our members are not only food and beverage, but personal care and household we actually had a significant part of our membership interested in this because traceability affects the entirety of the consumer packaged goods industry, not just food and beverage. And when I think about some of the most significant actions, FDA could take is to consider what are the other -- if we look at the entirety of a chain, and of a company that's a multinational chain that's across personal care food and beverage to use new technologies takes significant capital investment. So aligning around what is needed to enhance that both from a regulatory compliance standpoint is really needed.

So one action from -- would be to see where are the other industries regulated by FDA and how they're looking at traceability to make sure we have the most consistent, harmonized regulatory framework being proposed. That would be the most easily implemented by industry as a whole.

MS. HOWARD-KING: Okay. Thank you. I know we had a question here. Well, I'm sorry response here and then we want -- go back.

MR. NUNES: Leandro Nunes, MasterCard Labs. And I think I just got a little bit of what you're saying there. There is a need more than the technology discussion, a need on the governance and the incentive model that we can create to the industry in general, and that it goes from sourcing, right, that we're addressing here to big brands. I don't believe asking big brands to lead this discussion would solve the problem of asking them to go to the suppliers. That

shouldn't be enough. So I guess in a governance and an incentive model -- I'm not talking about money in an incentive model, I'm talking about, you know, how we can incentivize this, all the actors in the supply chain, the value chain to be part of it, and really bring it down to -- bring them on board regardless of the technology.

MS. HOWARD-KING: Thank you. And we can take one more in the back here. Okay. We'll take two more afterwards. Then we're going to have to move forward.

MS. PALOMBINI: Hi, there. I'm Maria Palombini with IEEE Standards Association. And we are actually doing a blockchain for farmer's incubation pilot. And one of the interesting -- I know, it's like really far ahead when you think of the farmers. One of the core things in this matter along with what everybody was saying is when we talk to the farmers about this they're -- the real key problem is not a regulatory problem, it's not a technology problem; it's really a problem, where they're like how hard is this going to be for us, if we're going to track stuff from the source, right? If we think about farmers or growers, they're in the field. They're working 24 hours a day, 7 days a week and they're like, what's the incentive, like the gentleman said upfront, for us to want to do this, and how easy is it going to be, right? We're talking blockchain, which is like foreign to them, but at the end of the day they want to be a part of things, but they don't want it to cost more money and they don't want to make it harder. And, if we're talking from source to table, that's really fundamental otherwise we're going be talking middle to table. So, I just thought that was really interesting feedback at this workshop, we hosted last week, with farmers. And I think it's really important, and they actually said, you know, do people really understand what it means for us when you start saying, we're going to put an RFID chip on an ear tag like, they're like this, what does that mean? How much is that going to cost us? Like, how long is it going to take for us?

So these are really core questions we have to think from a tech side, when we're developing apps user

interfaces for -- at that level. And also from a policy perspective how -- what's going to be the direct impact at the grower and the farmer.

MS. HOWARD-KING: Thank you. And we have two gentlemen upfront and then we'll move forward.

MR. HANSON: I'm Jaydee Hanson with the Center for Food Safety, the nonprofit one, not the one that's part of FDA. One of the challenges that we at the Center for Food Safety think that the FDA has is a difficulty in actually enacting and implementing regulations. We had to sue the foods -- we had to sue for the Food Safety Modernization Act and we are -- we understand that one of the issues really was funding, because the Food Safety Modernization Act didn't give the FDA enough funding. So as we try to move forward, you know, there are these other areas that were unfortunately still in discussion with you in courts now. But, you know that the challenge is how does an agency that is consistently underfunded by Congress and in the administrations appropriations implement things that are -- that really will cost you more money to do right?

MS. HOWARD-KING: Thank you. And we have right here in this -- thank you.

MR. DURM: Good morning. My name is Don Durm, I am with PLM. Pushing food down the food supply chain is a 2 percent business at best. Okay. There's not a lot of money in that, to do that. And so we -- you know, and technology in itself is a disruptor in it, just in itself. So you have to really work with businesses first to say, what's the ROI that I can get from this in order to reduce my cost in this? And so, technology can help you do a couple things. It can help you to reduce transaction costs between trading partners. And so that's where you can get this money that can help businesses to be able to do this. To go out and just mandate certain technologies is going to be really hard for business to -- in order to absorb that into their cost and then to put that on to people. And, you know, when we're talking about -- and they're all coming from a good place, I believe. They all want to provide safe food to the industry, because they all

understand that, you know, when you have an outbreak or something 55 percent of the people are not going to buy your food right now, okay. 15 percent will never come back again to buy your product and stuff. So the impact of them is huge. And so, if we can find ways in which we can work with industry to get ROIs before we actually implement a technology it does make a lot of sense.

I know in Europe they do ear tags for cattle and they do mandate a certain ear tag. In the U.S. we say, you can have RFID, you can have metal tag. So, different technologies are all spliced together through here. So, we got to figure out how we can bring all this together to make it seamless, because it's not working right now. Thanks.

MS. HOWARD-KING: Well, I think that's an excellent segue to the next question. How could FDA make it more likely that companies utilize new technologies to enhance the traceability of their products? So how can we convince industry to use technology just so that we can trace back your product?

MR. BRAUNER: My name is Matt Brauner. I'm with the National Customs Brokers Association.

MS. HOWARD-KING: Welcome.

MR. BRAUNER: And I think one of the things that FDA could do is to work with some of the existing systems that are out there and simply enhance them. Also for example, with imported food safety, Customs and Border Protection gathers a lot of information on the supply chain from a security standpoint. If there was a food safety component to that program that importers have already invested in and developed, it would go a long way. And then to see one government at the border to utilize some of the other information that's given to all the other government agencies, I think, would go a long way to making it cost effective and palatable to enhance the food safety.

MS. HOWARD-KING: Right. Thank you. Kari we have a gentleman here?

MR. ALKHALDI: This is Suf Alkhaldi. I work for the FDA. So, I mean, I think to make it very good for that businesses to keep or adopt the technology of

trace back like blockchain, I think, and that's mean allow the industry to put labeling on the food that extract and that will open a lot of businesses or at least market for the people, which they could not sell before, that's number one. Number two is going to increase their trust. I mean, the big industry of Walmart and Sam's Club and Costco, they have money and they have a very good name that's why people go there. But the small people basically, they don't have a name, so the only thing to do, allow them to put the labeling that is tracked and that will open business for them and sell their product outside the normal market they used to, so it increased their income.

MS. HOWARD-KING: Can I ask you? Do you think that's doable at the grower level?

MR. ALKHALDI: I think it's doable. It's like a pilot, you start doing it as a pilot, because there is so many factors are involved in it, you have to establish what's the standard of tracking? I mean, we in the FDA work so hard, not the FDA only, USDA as well work for -- so hard to establish what's organic food, you know, so people can put in their food, it's organic. So, I don't think it's hard for us to put these rules or what is track -- what does smart tracking means, or what blockchain means. We talk to the industry. We sit together and we agreed on it and we'll decide that's the label. So, and we're the people who basically give labeling. We control the labeling at the FDA.

MS. HOWARD-KING: Okay. Thank you. Kari?

MS. IRVIN: I'm going to start here since it's closer.

MS. HOWARD-KING: Okay.

MR. MANDERS: Hi, my name is Alex-Paul Manders. I'm a consultant with ISG Information Services Group --

MS. HOWARD-KING: Welcome.

MR. MANDERS: -- and I run our global blockchain services and solutions line. I think the most beneficial thing throughout, at least my past several years of journey through blockchain and working with clients of all shapes and sizes is that there

needs to be some sort of research mechanism or vehicle that is made publicly available to all participants in the supply chain so that they're getting the same information in terms of who technology providers are, vendors, solutions, application development, change management. Because right now, you know, your large organizations and enterprises have access to expensive research and otherwise access to information that your harvester or your grower doesn't. And so, to kind of take the mystery out what blockchain is or IoT, I think it would be beneficial to give the people some access to proven and validated research from the FDA to help them make sound decisions that are educational and fact based.

MS. HOWARD-KING: Thank you.

MS. IRVIN: And we have a young lady here. I think they will come back to you.

MS. HOWARD-KING: Okay. It's a long walk, sorry.

MS. WOOD: Hi, I'm Sharon Wood. I'm with H.E.B. Grocery Company.

MS. HOWARD-KING: Welcome.

MS. WOOD: From a retailer perspective, we have tens of thousands of suppliers. And we know that our suppliers believe in this, but I want to reiterate a couple of things. One affordability, so, there's the concern of costs. We know it's the right thing to do. But also another word that I think is very important is this harmonization.

So suppliers have choices, but then sometimes they feel like, if they are supplying to 50 different retailers, different retailers may have different systems and those systems aren't talking to one another. So now that supplier has the onus to try and get that information into, I don't know, 15 different options. So this to me is a challenge, because we all believe that we need the technology, but it needs to be affordable. It needs to be harmonized somehow so that my suppliers don't feel the pressure, because they have 15 other people that they're trying to please. And there has to be a cost effective way to maintain and sustain. And I'm not so sure that FDA is going to be

able to regulate that. But certainly with this new imagine, imagine the influence and also with the technology providers here, how do we stay competitive, but yet work together. This is going to be a big challenge. Thank you.

MS. HOWARD-KING: Thank you. And Kari, we have young lady upfront and then Betsy in the back.

MS. DUCKETT: Those were some excellent comments. I just want to -- a couple of people made this comment here in the room, this gentleman here and this one over here.

MS. HOWARD-KING: And I'm going to ask you to tell me your name and for the --

MS. DUCKETT: Again?

MS. HOWARD-KING: Yes, please.

MS. DUCKETT: Alright. So I'm Jeanne Duckett. I'm with Avery Dennison Corporation. I stay on the board of directors of AIM Global.

MS. HOWARD-KING: Okay.

MS. DUCKETT: Okay. I think the concept of building up an ROI model to show what the different supply chain participants are going to see what the return on investment is. Because a lot of people, and I hear the comments all the time that this costs money. And technology does cost money, your iPhone costs money. But the question is whether it costs money. It's whether it costs more money than what you get back in return. And if it does, even in the short term, maybe there needs to be government grants, but I think there is ROIs for those farmers. I mean, we heard from the gentleman this morning that most farmers are willing to pay or most consumers are willing to pay more money, 42 percent of consumers are willing to pay more money, if they can trust the data.

MS. HOWARD-KING: Thank you. And Betsy Booren. Betsy?

MS. BOOREN: Betsy Booren, GMA. I want to follow up and do a plus one on Sharon Wood's comment. My biggest recommendation would be allowing the flexibility to have the complexity of the supply chain; the complexity of corporate versus individual facilities managing and thinking through this.

Customer expectations, having a harmonized system, having the flexibility of evolving technologies that will occur, whether it's a small producer or a very large will be needed in this space to be effective. I'm not sure what the right way of doing that, but again, allowing that flexibility to find the solutions that are workable within each supply chain is going to be needed here to be successful.

MS. HOWARD-KING: Alright. Thank you. I can get one more question upfront -- well, I'm sorry, one more response upfront. And then we'll move on to the next question.

MR. PRABHALA: This is Pradeep from McKinsey.

MS. HOWARD-KING: Yes.

MR. PRABHALA: I have a comment on the incentives that need to be created. I think one of the issues that we're deeply looking is, today there is a lot of money that gets invested in the farm sector either through subsidies or there are ways in which I think you can channel consumer premiums. I think the real question is often I think food is a 1 percent, 2 percent business so how do you actually drive behavior change especially at the last mile. And I think there is a need to relook at how we deploy some of the incentives that we already have control over. For instance, is there an opportunity for FDA to collaborate with USDA to make some of the access to subsidies contingent on behavior changes at the farm level and what would it mean? Right, similarly for instance, you could think about ways in which an access to a particular label that certifies that your food is safe, would only be available, if you inform certain changes and that label could actually carry a premium in the marketplace. So, there is a real need to rethink about ways in which we could channel incentives, which could be from existing investments that governments are making, or new ways to, sort of, channels revenues from other sources that could drive behavior change because expecting the corporations to just do it by themselves is going to be really challenging given the cost barriers.

MS. HOWARD-KING: Okay. Thank you. Okay.

Question number three. What are the challenges to creating a more digital traceable global food supply? And how might FDA approach this in a manner that creates shared value for all participants? Steve? Good, Katie?

MR. MANDERNACH: Sure. Steve Mandernach the Association of Food and Drug Officials. I think the one thing I would say is, if we can get some unity across the government agencies, let's start here at home with USDA and FSIS and look for the same things, it's a lot easier that we do that internationally too. If we can do that it makes it simpler for industry to move toward these platforms and go forward. The other piece of that is, in an outbreak is no time to be figuring out what the difference is between the agencies. In those emergency situations, it should be standardized and we should be doing the same thing, so what's easy, quick and we don't have to think about the differences.

MS. HOWARD-KING: Thank you. Kari, you should have worn tennis shoes.

MS. IRVIN: I'm going to get Angela to help me next time.

MR. FISK: Also, I wasn't trying to make you run. Good morning. Mark Fisk from IBM.

MS. HOWARD-KING: Welcome.

MR. FISK: I wanted to add on to that last comment and then the comment earlier that Mr. Brauner mentioned. I thought you're going to get to the question on communications, but because I was with the order --

MS. HOWARD-KING: We'll get there.

MR. FISK: -- but we'll get there. But I think it's applicable. We talked a lot about blockchain and the capabilities of blockchain and, you know, how leveraging some of the capabilities that are out there today are really important. But having been in the public sector for 25 years, I wanted to kind of switch gears and say, there is still going to be inherently challenging insights that government is going to get from this information. And the need to be able to leverage and connect into the kind of the

commercial networks, but also, to be able to take that back and say, how do I take that insight that I've gotten from agency "A" and share that with the agency "B". Not just the data, but the actual insight, the results, the models, the actions, right? And that's going to feed into a lot of this.

So I think, when we look at blockchain capabilities there is a lot to leverage from what is going on in the commercial world around standards, around traceability, around -- there is already participation going on, but I think we can also take that in and bring that back to some of the inherently government capabilities. And the biggest thing there is security, right? At the end of the day it's still going to have to be something that's protected. It's still going to have to be something that is, you know, meets the other spelling of FSMA right, FedRAMP and some of those other government capabilities.

MS. HOWARD-KING: Okay. Thank you. Any additional responses? Okay.

MS. McGILL: Julie McGill, FoodLogiQ. As I said SaaS based traceability software. So when you ask the question and you said, challenges for more global and traceable, certainly having a common language, right? We -- if it's going to be global then we all have to be able to speak in a language whether that be deciding on, as Jeannie said earlier from Avery Dennison, common attributes, a common format, a common standard. So that whatever system you're on, whatever tools that you're using, when you produce it and you share it outside of your four walls that we're sharing -- were speaking that same language.

MS. HOWARD-KING: Okay. Thank you.

MS. ANGARITA: I am Lucelena Angarita from IPC. And just to top up what Julie mentioned. I think it's very important to stay focused on that end goal, because scope creep in this digital era can be very challenging. We want more data. We can get it faster, IoT, all that stuff. What do we want to get end-to-end traceability and just stay focused on that? I think that will help, what Julie just said.

MS. HOWARD-KING: Thank you.

MS. FERNANDEZ: So I'm Angela Fernandez with GS1, a global standards organization. And I just want to build off of these comments, because I think, you know, this goes back to the analogy, I think, Mike or Frank was making earlier. We -- the way we listen to music has changed, but music has not changed, right? And so, when you look at identification, I think, getting to that minimum set of data, irrespective of technology, is what we need to be focused on.

This helps with the harmonization piece. It helps with companies being able to grow and then start utilizing additional things. But I think it also allows the interagency sharing comment that was also brought up, right? This isn't -- there is a lot of similarities and I think Jeannie, you brought it up with the global unique device identifier database. It's identification. Global identification, so that we can all talk and share what's needed to do. So I would just encourage the agency to look at that minimum set and really focus on identification so that we can leverage it however we need to depending on our size, organization, as well as the channel in which our product is following through.

MS. HOWARD-KING: Okay. Thank you.

SPEAKER: Save you some steps.

MS. LLOYD: Save you some steps. Thank you. My name is Brenda Lloyd. I am currently BLloyd Consulting; 20, heading toward 30 years now in the restaurant industry. 23 years with another major brand. But the point being that there were several of us in the room, we were laughing earlier, who were here in Washington celebrating the day we passed FSMA and we said, great, we can now get it done. Here we are today talking about many of the things we struggled with then.

The point I want to make is that in working with all of the people I've worked with since we passed FSMA and even before talking about traceability, we need to keep it simple. If people can't get started they don't get started and that is the excuse they've used. We keep looking for the perfect and we're ignoring the possible. There are technologies today,

base technologies, they're not sexy, but you can do traceability from the fields. I've spent time in the fields helping people figure out labeling through distributors. I've spent a lot of time with distributors figuring out how to -- what is the minimum scanning that we can do that I can give you the data big brand so that you can then link that together and get it to your restaurants.

And what's a simple solution in a restaurant or a retail environment that I can have, things I can afford, but I can capture that data. I don't have to link it, there are -- yes, there are amazing things you can do with data, but there are simplistic ways today we can see how food moved. I use a very simple slide and it's an odd-looking thing on a -- it bounces along and I have people describe it. They describe it differently that's what we're doing today we talk different languages. We need to talk a single language and we just need to capture that product as it changes hands, as it skips through the supply chain. There is very simple ways to do that.

On that possible, we as an industry can begin to look for the perfect. We can't get to perfect by the end of the year. We can get to possible by the end of next year. And I think that's what we need to focus on.

The biggest thing I find when I'm talking to two different people -- and it's not just small, it's large companies as well, what are the first three steps I need to take? Don't talk to me about this massive beautiful thing I'm going to have. Tell me what I need to do in the next 90 days. So that basic gets started, steps, checklists, simple things that can let people actually take action instead of excuses that we've used for close to 10 years now and just get started. And I think Julie touched on it as well this morning, just find what you can and get going.

MS. HOWARD-KING: And thank you. Great comments.

MR. ACCOLLA: So Riccardo Accolla with Ripe Technology. We have a blockchain powered platform for food quality and traceability. So I think -- agree

with all the comments, make it simple, define the ID's that can track from farm all the way to consumer. And then one of the biggest challenge was mentioned by a lady down there, was getting the onboarding of the farmers. So, we are trying to focus as much as possible our energy on this first step of the supply chain, which is the one that is currently more difficult to track. And so, make the onboarding for medium and small sized farmer as easy as possible. And if possible, completely free of charge. So that's one of advice I would give.

MS. HOWARD-KING: Thank you. I will make this the last one, so we can move on to the next one. Okay.

MR. ACKER: Hi, excuse me, Jeff Acker, vice president of food safety for Dairy Farmers of America. We move 64 billion pounds of milk and it's complicated. So the milk side of the business isn't complicated. From the farm to our factories, we've got 42 producing factories and we can tell you what the cows ate in the morning. We can tell you how many times they milked. What kind of antibiotics they might be on, we can tell you all that.

What gets complicated is the product itself once it gets produced it can be made into many different components, it gets fractionated, it gets commingled, it gets really complicated. So when I'm listening to, you know, keep it simple, in theory I would love that. We have traceability, but a lot of it is grump labor, paper. We always wrap our arms around much more than we need, because you can't pinpoint the bookends on a lot of this stuff.

So, from a solution factor I am looking for something that can help me not only with my own company, but I heard some other people talk about the retail side. So we have a lot of retail customers and they all want something different. It's not feasible, it's not practical and I'm always getting into discussions with our CFO about the difference between ROI and prevention. They don't have a measurement for prevention. They can only tell you how much it cost after a situation, because there is no ROI. So when you look at big companies that were -- are willing to

spend money on that, it's hard to justify that until you have a really big recall, then they're all like, money falls from the sky.

So one of the things I'm trying to get out of this is, I'm familiar with blockchain, but it will only help me to a certain point. What's in between a blockchain that maybe, you have blockchain up until the factory, then you have something else and then maybe blockchain takes a handshake and goes further. So I don't know, if there is people in here that can help me with that solution, but that's what I'm looking for.

MS. HOWARD-KING: Okay. Thank you. Okay. Let's move on to the fourth question. Are there mechanisms FDA could employ to incentivize adoption of real time end-to-end food traceability throughout the food sector? So I know I heard a few comments about, on incentives. What do you think about those?

MS. SCHROEDER: Good morning. My name is Lindsay Schroeder. I'm with the Dennis Group. So, we're actually a design, build firm strictly for food and beverage. But where we are seeing the biggest problem is, any greenfield facilities, they're going to put everything in the building first. That gets funded first instead of these sensors versus innovation in the industry. If they're just going to replace a line in their building, that's when they would go and they would try these new smart sensors. And they would've then changed the rest of their plan.

But until these companies have an incentive or even just information from the FDA saying there is, this ability to trace out there that you should be looking into, they're not going to fund it. So we've been talking with them and they say, if they do see incentives for the money to either match them or throughout the years it helps with their ROI with it, they would look into those smarter sensors and traceability technology. So it's something we've been hearing a lot about in design build for all manufacturing.

MS. HOWARD-KING: Thank you. Any additional responses? Okay.

MR. NAJERA: Hello, I'm Miguel Najera from

Schneider Electric. We don't only do the energy part. And now that you're talking about the incentives, normally, you have incentives from the government coming from California for energy or this kind of things. So I think that if the FDA has the ability to incentivize all the companies that are moving to these traceability, end-to-end traceability that will support a lot of you guys on this. On all the ROI, like a bonus, or if your products are really on the trace and they -- you have all these implemented. As simple as it is that could help a lot of these to be followed, you know.

MS. HOWARD-KING: Okay. Thank you. Alright. I'm going to move on to the last question. What can FDA do to facilitate and expedite outbreak related communications between government agencies, industry and consumers? So how can we get the message out? How can we better communicate?

MR. FISK: I'll just come back to this one. Mark Fisk from IBM. So I think, you know, we talked about blockchain in a couple different places. If you do have a blockchain in place, one of the biggest challenges I see in the communication space is, who are you communicating with? Who is being shared this information? So this concept that's kind of built into blockchain called permissioning really helps with that, right? You have the ability to easily take some of that insight and source of truth, share it across entities that need to know and then, if you need to grow that to additional entities whether it's within government or outside of government, a blockchain is a really good way to be able to do that. So I love the idea there was mentioning an app to be able to do that, but what is the source of truth for that?

The other thing is, I think there is a lot of sensitivity around this information, sensitivity around some of this communication and recalls. So to be able to say: I will share this information in the event there is a recall and it's used, but it's going to be, you know, shared in a permissioned way, so I know who it's maybe going to be shared with, right? So kind of that quid pro quo, I will share it. If I need to put

break the glass in case of fire and there is a challenge, right I will do that, but I'll do that in a certain way. And you can use blockchain to kind of enforce some of those rules in the network. Okay.

MS. HOWARD-KING: Okay. Got to be careful with those terms. Okay.

MR. GARRISON: I'm Oscar Garrison. I'm the senior vice president of food safety and regulatory affairs for United Egg Producers.

MS. HOWARD-KING: Welcome.

MR. GARRISON: We're a farmer cooperative, been in business since 1968. We -- our farmer members own about 290 million birds in various types of production systems that represents about 89 percent of the eggs we eat every day in this country. What we have seen that we think is going to be crucial in moving forward is during the outbreak investigation there is a proper communication with the farmers. And during whole genome sequencing, is they just come on board, there is a real lack of understanding with that technology and the farmers out there in exactly what's going on. When you go back to some of the recent outbreaks that we've had, you know, whenever -- the old days of an epi curve are kind of gone out with the baby in the bath water. You know we're seeing very sporadic illnesses out there coming off some of these farms where you've got a farm that's producing 200 -- or 2 million eggs a day and 30 illnesses over 6 months. And that's just kind of hard for the farmer to swallow with that point that he has put out that much product, but only seeing that much illness out there.

The timeliness of the communications is really going to make these farmers make the right decision in a much more rapid time period and going to limit the amount of food borne illness out there that occurs after the outbreak has initially been detected and while it is being investigated.

In some cases we've seen instances of over 2 weeks to get those results from when the samples are polled actual positives back to the farmer, if they've been found in the environment there. You know we're talking about large number of samples there, you know,

180 in a processing room and a couple of 100 in -- inside the hen housing, you know. And that's a farm with 1.5 million birds that's involved with it. So, we just really urge the agency to have a lot of transparency (ph), have a lot of communication and education through that process, because it is a -- it's a very complicated situation that we're moving through. And in order for them to make that right decision very early on, which is what all of us in this room want, we've got to have that communication, going forward.

MS. BOOREN: Betsy Booren, GMA. I don't -- I believe there is an easy and immediate way that FDA can immediately start improving on this communication process. And one way is to hold more frequent stakeholder sessions updating when there are outbreaks as well as watches. Other agencies are briefing stakeholders on a monthly basis and getting a debrief of the watches and investigations that are ongoing. I understand the complexity of what that would be to FDA, but having just those insights of understanding of watches across multiple states potentially vectors is useful. Leadership within companies are going back, they ask the questions of their stakeholders. It's a very quick and easy way. Would -- happy to work with FDA in finding ways of making this as easy as possible for the agency. But those type of regular frequent stakeholder sessions outlining when there is outbreaks and watches would be critical to speed up this process.

MS. HOWARD-KING: Okay. Thank you. And we can take one more upfront. I don't want to cut into your lunch.

SPEAKER: There are products that are part of which are regulated by the USDA and part of it regulated by the FDA. Just looking at what might happen with different kinds of salmonella, you know. We know now that certain kinds of salmonella are found more in large production facilities handling pork that is minced. We call that sausage. When those sausages just go on pizzas, you regulate them.

The Center for Science in the Public Interest, many years ago asked the USDA to declare some of the most dangerous kinds of salmonella to be adulterants.

One of the things I would hope that FDA would continue to do is to push the USDA to clean up its act so your act can stay clean.

MS. HOWARD-KING: Okay. Alright. I want to thank you all. In closing, this concludes our breakout session. However, there is plenty of time for you to send your comments to FDA via electronically or via mail. So you received a document in your packet entitled, "Instructions on how to comment on a new era of smarter food safety." So public comments are due by November 20 of 2019. So we hope to hear from you. If we didn't get to you today please, please, please send us your comments. And I want to wish you a great lunch and we'll be back here at 12:30. Thank you.

(Whereupon, the breakout session concluded.)