FOOD AND DRUG ADMINISTRATION (FDA)
PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

Docket No. FDA-2019-N-4187

October 21, 2019
8:30 a.m.

Hilton Washington DC/Rockville Hotel
& Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852

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A P P E A R A N C E S

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AGENDA

Simultaneous Breakout Sessions Block #2

Regency Room: Tech-Enabled Traceability & Foodborne Outbreak Response

Facilitators:

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P R O C E E D I N G S

SIMULTANEOUS BREAKOUT SESSIONS BLOCK #2

TECH-ENABLED TRACEABILITY & FOODBORNE OUTBREAK RESPONSE

MS. HOWARD-KING: Alright, we probably should go ahead and get started because we have a shortened time period this afternoon. We've got 45 minutes to get through five great questions, and we are eager to get your comments on them.

So, good afternoon. My name is Vinetta Howard-King and I'm the Director of the Office of Human and Animal Food East in FDA's Office of Regulatory Affairs. And I am joined by several colleagues from Center for Food Safety this afternoon. I'll start with Kari.

MS. IRVIN: Hi, I'm Kari Irvin. I'm Deputy Director of FDA's Coordinated Outbreak Response and Evaluation Network, or CORE.

MS. VIERK: Hi. Good afternoon. I'm Katie Vierk. I'm the Director for the Division of Public Health Informatics and Analytics. And I'm leading the Traceability Rule Work Group for FDA.

MR. PASTEL: Hi, I'm Charlie Pastel. I'm a technical advisor to Frank Yiannas.

MS. HOWARD-KING: Alright, thank you all.

So before we get started, I wanted to go through the list of possible participants here so we can get an idea of who we have in the audience. So, are there other government agencies in the audience?

Alright. Well, do we have food producers or suppliers? Do we have people in parts of the supply chain, like transportation? Alright. Are there consumer representatives? Researchers? Are there any other regulators? How about media representation? Consulting firms? And what was a big surprise to me this morning, what about technology and software industry? And once again, you lead the group. Alright.

MS. IRVIN: I can't imagine why.

MS. HOWARD-KING: Alright. So the goal of this outbreak session, which is the Tech-Enabled Traceability and Outbreak -- Foodborne Outbreak Response session, so the goal of this outbreak session

is to provide an opportunity for stakeholders to discuss traceability -- can someone get the door? I'm sorry -- traceability, smarter tools and approaches that will greatly reduce the time it takes to trace the origin of 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 the ability to trace sources of contaminated food, to using new predictive analytics tools like artificial intelligence to assess risks, and to help prioritize the agency's work and resources.

So FDA is seeking your ideas and thoughts on how we can use new tools to improve traceability and how it will enhance foodborne outbreak response.

With that said, there are three goals for the Tech-Enabled Traceability and Foodborne Outbreak Response session, and they are to facilitate end-to-end traceability throughout the food safety system, to enhance foodborne outbreak response, and innovate communications approaches.

So I also want to reiterate, and I know it's in your packet, that if there -- that any reference to proposed changes to current food policy that's included in your meeting materials, it doesn't constitute an endorsement by the agency. These were just ideas proposed at various public forums and we just wanted to include them in the -- your packet to generate discussion.

So I don't want to go over ground rules because you all had sessions this morning so you kind of know, please, most of -- the main thing to do is make sure to identify your name and your affiliation when you respond to a question.

Alright. So regarding the Tech-Enabled Traceability and Foodborne Outbreak Response, new and evolving digital technologies will play a pivotal role in tracing the origin of a contaminated food to its source within minutes or seconds instead of days and weeks. With that said, the first question would be, what are the most significant actions FDA could

undertake to enable industry to enhance traceability across the entire global food supply chain?

And these questions are actually in your packet as well, so you can follow along. Any suggestions?

MS. IRVIN: Yeah, so I was going say some of the challenges, just to get you guys thinking in this realm, we heard a lot about the lack of standardized key data elements that are needed because standardized key data elements are needed for interoperability between systems. So we heard a lot of feedback about that. Anything else we want to highlight from this particular area? Obviously, costs.

MS. HOWARD-KING: Creating data standards and communicating minimum data elements needed for traceability.

MS. VIERK: And I would just say any specific examples or ideas, especially around the technology challenges or incentives that could be offered. You know, we've heard that folks want incentives, but what kind of incentives? What would be enough of an incentive? And so thoughts around that or specific challenges or examples you might be facing around end-to-end traceability.

MS. HOWARD-KING: Any comments? Yes? Thank you.

MS. JONES: Katy Jones with FoodLogiQ. We're a food traceability software company. Definitely on the standards, drawing, you know a line, I think, when you have a multitude of different organizations across the entire supply chain that are trying to share that data, you'll all have to have that common language, which I'm sure you heard in the earlier session.

And then I think a roadmap or recommendation on kind of those, I wouldn't say a minimum, but where companies should actually start. So I think we've seen companies try to bite off the entire food chain all at once, and perhaps some guidance on how you may be able to roll that out or phase it in over time. So that's actually we're working with companies now to make a recommendation, and I think that's in line with some of the things that are already being done in

terms of the recommendations around high risk food and where to actually start. So those are the two things that we've found with companies that we're actually implementing traceability with now. Those common standards and then not trying to bite it off all at once.

MS. HOWARD-KING: Is the biggest challenge would be by -- that you've run into is just biting off more than they can chew, the scope of what they're trying to do?

MS. JONES: I mean, I think the biggest challenge has been it's not required. And so I think that, you know, they're asking their supply-chain partners to do things, you know. And predominantly we work with food service and retail side, so there -- that burden is being pushed down on the suppliers and what they have to do. We heard that in the session just now, the 30 portals that they have to submit this data to. So I think it's -- you know, I'm interested to hear from the supplier base in terms of those incentives and what would be beneficial to have and to really help ease that adoption, because that's where we see a lot of really great organizations working really hard to do it, but it is a burden on the suppliers.

MS. LANINI: Sharan Lanini from Pacific International Marketing, Dynasty Farms. This isn't really an FDA thing, but it's a CDC thing. The questionnaires you use when you talk to people are old. We'd like to see you talk to industry, because we have a lot of information and data about, you know, what are the common practices now? I mean, 10, 15 years ago, people weren't eating as much romaine as they eat now, but you're asking questions from 1960 on consumer consumption trends.

We would like to see more cooperation and collaboration between FDA, CDC, and industry because when the crisis comes, then you guys won't talk to us. And we've got a lot of information that could help you get there faster.

MS. HOWARD-KING: Thank you.

MS. KOWALCYK: Barb Kowalcyk from the Center

for Foodborne Illness Research and Prevention at the Ohio State University. I just wanted to follow-up on the last comment. I think that there's several things that FDA could be doing in terms of working with CDC on improving outbreak response and detection. One of the things, first of all, there hasn't been much research put into improving exposure assessment during outbreaks and illness. And I don't know exactly how to handle that, but certainly getting NIH to invest in some research in that area would be good.

But the other thing I wanted to bring up, and this may be a little tangential, is the increasing use of culture independent diagnostic tests and the impact that's having on our foodborne disease surveillance systems. And FDA is involved in that in the sense that they approved the test kits that are used in the clinical laboratories. So I just wanted to echo again more cooperation and collaboration between the agencies. And I know this is beyond CFSAN and the Office of Foods, this is actually over in the other part of FDA, but having them understand that when they approve these test kits and new clinical diagnostic methods, that it does have an impact on foodborne disease surveillance and the ability to detect outbreaks, which then impacts the other side of the FDA house.

MS. HOWARD-KING: Thank you.

MS. IRVIN: So, if I can -- just to dig into this one a little bit more, when, you know, we're hearing a lot of feedback about defining key data elements. Well, one day let's say those are defined, but there's still some challenges, I think, that we'd like to hear more about why it's so difficult to collect key data elements. Because defining them is one thing, but I think there are a lot of challenges. And for tracing systems that have been implemented, would have been -- how have challenges been overcome to track things through the supply chain that you have found important? Does anybody have any experience with that? All the way in back.

MR. GILLAM: Tim Gillam with Subway. One of the challenges we have is warehouse. Transportation.

I see none of them are here today, but they are the biggest challenge that we have because we'll have two, three, four cases going out to a store. So when traceability happens, we cannot trace -- we are able to get from the supplier to the warehouse, but then from the warehouse to the store, we lose traceability completely.

And forcing the warehouses to implement programs is very difficult. We have 60 warehouses currently; we have 7 who have that capability. And pushing them to do it -- if FDA could push for us, it would help us out considerably.

MS. IRVIN: Thanks for that.

UNIDENTIFIED SPEAKER: (Inaudible) how it's being done on the warehouse end, the retail end, with scanning. You have any insight?

MR. GILLAM: The 7 that do it actually have the capability to scan, so they scan at the store, they scan at the warehouse. They know what truck it went on to and which store it went to. Getting that into the other warehouses has been very difficult because there's a cost associated with it. And it's always cost driven.

MS. HOWARD-KING: Okay, thank you. It was very good information.

I'm going move on to question two. How could FDA make it more likely that companies utilize new technologies to enhance the traceability of their products? So for example, our earlier today, we got -- we had an example of it needs to be affordable, and it needs to be harmonized. So the fact that you have to input data into several different systems, that is not harmonized. And especially for mid-sized and small firms, it has to be -- this new technology has to be affordable all the way down to the farm level. So that was some of the comments we got back this morning. Anyone want to add to that? Is the bottom line affordability?

MS. CARLUCCI: Casey Carlucci, LGS Specialty Sales. My company is a broker/importer, and similar to Dole, we have to upload a lot of audits on to different websites, such as Azul. I think not only

the cost, but the organization of it all. It's hard to keep track of what every retailer wants you to put your audits -- what system they want it on. So it'd be nice if maybe FDA, similar to GFSI that has one benchmark standard, and then you pick whether you want to go SQF, BRC. It'd be nice if there was one standard that you could upload your audits into and streamline it more to be more organized and cost-effective.

MS. HOWARD-KING: Okay. Thank you.

Kari, you have a --

MS. IRVIN: Oh, great.

MR. DETWILER: Hi, Darin Detwiler, Northeastern University. Attending a number of food traceability, food safety technology events, it's clear that there's a differentiation between who the consumer or the customer is.

When we talk about farm-to-table, we assume the customer is the person who is buying food at a grocery store or restaurant retail. When we're talking about technology, often the customer is the retail location which provides a significant differentiation in terms of how the information is being used.

Last year, at the Conference For Food Protection, the CDC requested a look at the idea of being able to access loyalty card information in the middle of an investigation to find out if there are other people who were impacted by an ongoing incident. Resoundingly that council said no, that the retail establishments are the consumer of that information. They do not want to allow that information to be released to the federal government. That the CDC would be allowed to request each individual person to sign a legal document to release that information, as opposed to getting that from the retail.

It makes no sense to me in terms of having all this information, having the one point of transaction where you have codes, information, everything you need about food, and then it's sold to the shopper/consumer, whatever you want to call the people, and after that point, there's almost zero

chance of being able to track that. Packaging is removed. You don't know who -- you got lettuce, but you don't even know where you got it from.

So if we were to look back at better defining the customer/consumer in terms of the data information, and even looking at who and when is appropriate access to that information as opposed to just what some lawyer said retail would define it, that could be a better way of addressing this issue.

MS. HOWARD-KING: Thank you. Any additional comments?

MS. IRVIN: Just one other. So, for anyone out there that's implemented some type of traceability system, what types of incentives propelled you to do that type of work? I think we heard that several warehouses have opted to do traceability to restaurants, so what was the incentive to do that? I'm not asking you specifically, I'm just using you as an example, I'm sorry. Anybody?

MS. CARLUCCI: For the programs that we've implemented, it's the contractor with the retailer or the food service operator. So they're writing it into their contract, so it's become a requirement and a cost of doing business. I do think that -- and I think this is more Frank encouraged us to kind of just think boldly and think big, but I envision a day where there is a fully enabled, you know, digital solution where, you know, payment is contingent on that data. And compliance of that is just that, that the, you know, the lots are labeled, it's based on a GS-1 standard, like all of that data is being pulled, and that payment is actually being released when that shipment comes in and it's fully traceable.

So I think that's where it's all going. I think we've got many, many, many steps to get to before we can get there.

MS. HOWARD-KING: Okay, question 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? So what are the challenges of having a more digital, traceable food supply?

UNIDENTIFIED SPEAKER: Well, from a grower-producer of fresh produce, when we're forced to do blockchain by certain entities, they don't even understand what the -- what and how the industry works. They make high level assumptions that every grower has a global location number for each ranch they're producing on. They make assumptions that those ranches are used over and over in the desert, they're on like a three-year rotation so they're on Ranch X one year, they're on Ranch Y the next year. There's a lot of logistical difficulties that nobody asked us about but they just said, you got to do this.

So I would encourage anybody that's into this to talk to us and work through some of these things instead of just demanding these things, because it isn't that simple.

MS. HOWARD-KING: But it's not an impossibility?

UNIDENTIFIED SPEAKER: It's not impossible, but we're a long ways from really doing blockchain, quite frankly.

MS. HOWARD-KING: Okay. Thank you. Any additional comments? What are some of the challenges?

MS. IRVIN: Frank's in the room now, you guys have to speak up.

MR. HARRIS: Yeah, Phil Harris from RPO. We would never demand or force you to do anything. We'd come have a nice conversation with you around your farm table.

Look, we have been at this for three years, and we've seen a real mixed bag of those reactions. That was full of anger and frustration, and I felt that, right? But it's going to happen. It's inevitable, okay? The food industry has to digitize, and it has to do it fast and it has to get going now.

When you bring in people from other industries, myself, and my colleagues, we come from financial services, and so we changed from trading, you know, hogs or corn or currencies or bonds from paper to electronic means. The industry has just excelled in many, many, many dimensions. So it's just data to us, data and analytics and software to provide

a service.

So I think you need to be more forward looking and provide this wisdom and counsel through the channels that the FDA are opening up.

UNIDENTIFIED SPEAKER: We can trace it now (inaudible).

MR. HARRIS: Right.

UNIDENTIFIED SPEAKER: In less than --

MR. HARRIS: Right. But it's a bilateral conversation right now between you and a spreadsheet, or you and someone else with a spreadsheet. If you think about how Twitter has evolved. I can have a conversation with 74,000 people in a second, right? That's the scale of what this technology will do, you go one to many. And these are the advances.

So I agree, we have lots of clients that never got called by the FDA that had every bit of information that they ever could need, but no one asked. So it's about kind of the connectivity of the sharing of this information which is paramount.

UNIDENTIFIED SPEAKER: Well and it's also the end of that chain. They admit it, it's the last mile. We've been doing PTI for years.

MR. HARRIS: So I'm just saying that this is an amazing forum to have this kind of conversation. I'd like to see more growers, more producers in the room sharing their frustrations, their concerns. Well, yeah, but you're one person. I've been here all day, you're the only person that actually put something forward that I find very valuable as a provider.

MS. HOWARD-KING: And thank you.

MR. HARRIS: Yeah.

MS. HOWARD-KING: And that's what we need to hear. Thank you. And thank you.

MR. SUAREZ: I'm German Suarez with The Fresh Fruit Group. I just wanted to add to that point over there. I think that, you know, we're users of fresh fruit and vegetables locally and imported products. Some of the challenges that we've run into is standardization. I think the agency's going to have to be a lot more prescriptive in terms of what's

standard or how the information moves. I think everybody's doing their own thing out there, and it creates a lot of inefficiencies in the process.

So going forward, I think it'll be good to standardize and come up with two, three different systems that the industry can use out there in order to be efficient. I think it's important to understand, unlike the USDA side of the business, that where most -- that there's a lot of vertical integration in poultry and, to a certain degree, pork, and beef, in the fruit and vegetable world out there. It's very segmented. And as much as I would like to tell you that the farm to fork is a straight line, it's not. There are so many handles. There are so many hands in the middle that creates quite a challenge. So if we have to have standards in every one of those hands change over there, it becomes very difficult, very costly, and in the end, we have to find somebody that's going to pay for it.

So going forward, I think we have to find a path, a more efficient path to get to what we need to. And then under the same time, we have to interpret the data in the same way, so that's another standardization I think it needs to be in place.

Just alone today, I think the industry can do a fairly good job tracing to a packing house. But the amount of blending and exchanging and shifting of product that goes on in a packing house today, it's just incredible. You lose it all. So something small becomes very big very quickly, and it's time-consuming in assessing what the real issue is. So that's my thought from an end user living it every day.

MS. HOWARD-KING: So thank you. And in talking about packing houses, and we talked a lot about blockchain, tell me how -- we know there's a lot of commingling that goes on in packing houses, tell me, do you see a way that blockchain can help with that?

MR. SUAREZ: Well you know, I'm going to give you a real --

MS. HOWARD-KING: I'm not all --

MR. SUAREZ: I'll give you a real-life

scenario because I was just having this conversation at the PMA meeting in California yesterday or the day before with somebody who could actually help. And say we buy an awful lot of watermelons, so I was looking at a system over that, let's say we have watermelon come from different ranches, could somebody put a bar code to every single one of the melons out in the field and that way we would know exactly. We will assign a bar code to that ranch, that location, and it will trace it all the way through.

It was all great until I asked the question, what do you do with pineapples? So that bar code was thrown out completely, and so the digital side would be lost. So we will have to solve some of those issues. Now could that be done to the point that if they commingle at a packing house, if it would automatically barcode and reads where you're going through, it would be very simple. But we've got to solve some of the most basic issues out there, and that is how do we ID the product from the field to the packing house out there.

And you know, like I say, USDA has figured that out because it's a lot easier. You know they got different systems in place. But we have to come up with technologies that we don't have today. But I think it's just a matter of creating -- the agency, industry, academia coming together and discussing what are the -- why things are not being done. Money will always be an issue, but the cost of not doing it is what we need to be talking about. Okay. When something small becomes very big, that's when the companies really say, why didn't we spend the money to be proactive about it? It's a react.

So there are limitations in technology today that we've got to overcome in order to facilitate this. Standardization will have data flow to the blockchain will be a pretty good thing for the agencies to get involved with.

MS. HOWARD-KING: Okay, thank you very much. I appreciate that.

MR. SUAREZ: That's from an end user.

MS. HOWARD-KING: Alright, so I'm going to

move on to question four. Let's see. Are the mechanisms FDA could -- what are the -- are there mechanisms FDA could employ to incentivize adoption of real time end-to-end food traceability throughout the food sector? So could you give us some specific examples maybe?

So this morning we heard, yes, the agency, if there were some incentives, we could probably get more smaller and mid-size firms to adopt more technologies, but we didn't hear about any examples of some incentives. Any ideas? With the industry you're that you're speaking -- you're talking with, what could incentivize them to develop more technical processes? Okay.

UNIDENTIFIED SPEAKER: Tax credits.

MS. HOWARD-KING: Okay. Thank you. Anything else?

MR. HARRIS: Hi, Phil Harris, RPO again. You can track a physical thing, but you can also track the elements of its growing conditions, its water consumption, its chemical usage or non-usage, IPM. So what I'm saying is that you can actually track the sustainability of how this thing is actually being grown and moved through the supply chain. And in some sectors of the food industry, that data has more value in the hands of the brands that represent that to the consumer than the actual storytelling or narrative for the origin of the item itself.

So as an example, you know, we could say that, you know, these animals were treated in a fair way. They were fed these certain things, you know. They were healthy, their medical records, all of this information which is then given to the brand, and the brand holds that knowing that the buyers of this brand demand that level of care of the animals back to the consumer. Imbedded in that is a natural premium for the product itself. That's the incentive for then growers or ranchers to sell into the brand at a premium that then gets carried through to the consumer.

So when you think about traceability and tracking, I wouldn't isolate it just to the physical

attribute of the thing, animal, you know, plant or fruit and vegetable. You could also expand that to actually how was this thing made and in what context.

MS. HOWARD-KING: Okay. Thank you.

MR. SUAREZ: I guess I think of insurance, insurance policy or insurance break. That could be another incentive (inaudible) business insurance, if you're able to. That could provide an incentive as well. I mean, your business insures that every company has it out there. If you were to have the traceability programs in place, that can provide a break to motivate.

MS. HOWARD-KING: Okay, anything else? I've heard some great examples.

MR. DETWILER: Darin Detwiler, Northeastern University. This might sound extreme, but perhaps in order for a company to be allowed to distribute their product across state lines they have to meet some threshold of traceability technology provisions, very much like what you see up in Canada where there are some limitations across Provincial lines for some sectors of industry, or some companies I mean, that aren't able to meet certain standards. They can stay in the market but only within their specific, more hyperlocal area. Perhaps we could think of something like that as well, the idea that they can still stay in the market, but there's limitations.

MS. HOWARD-KING: Okay. That's a different one. I've never heard that one, thank you.

MR. NUNES: Leandro Nunes, MasterCard. We've been doing something related to incentives which is to give some digitized payments and solutions to the communities. Like to the farm to use a lot of cash or, have no idea when and how they're going to receive their monies from the buyers and others. And it's for working as a very high incentive for them.

MS. HOWARD-KING: Thank you.

UNIDENTIFIED SPEAKER: (Inaudible) their cash flow (inaudible)?

MR. NUNES: The cashflow, yeah. We all know how important is it for the next harvest, right? You know, (inaudible) the banks and even though the loans

are sometimes a nightmare to this type of communities, so that helps.

MS. HOWARD-KING: Okay, thank you. Anyone else? Okay, we'll go on to the last question. What can FDA do to facilitate and expedite outbreak-related communications between government agencies, industry, and consumers? And so this morning, we heard someone mention that to have more transparency in communicating sample results, and being able to get that information to the firm quicker so they can make business decisions rather than waiting for the complete results to be in, the final results. And we know when you're doing whole genome sequencing, that could be up to a couple of weeks between the time the sample's collected until the time you get the results, the final WGSN. Any other improvements in communications?

MS. KOWALCYK: Barbara Kowalcyk, CFI at OSU. I think one of the things, and it was touched on earlier today, is that we need to do more to educate consumers about the risks that are present in food. We don't do a good job of that. We like to tell them about safe food handling practices, but in terms of informing them that risks may be present, we don't do that very well. WHO has five keys to safer food, the first one of which is use safe food and water, which the US has not adopted. And that sends the implicit message that our food supply is already safe. People tend to not hear relative terms, so we tell people, you know, we have the safest food supply in the world, but they hear we have a safe food supply. And then we're always kind of surprised why are they not using meat thermometers.

And I've been saying this for quite some time, but I think in terms of facilitating and expediting outbreak-related communications, it's really hard for consumers when they're getting mixed messages all the time about the safety of our food supply, whether it's intentional or not. And then the way we communicate about those outbreaks and recalls is really difficult, you know, because we don't say it at a regional or a store level oftentimes.

So I live in Ohio, and if there's a recall, and I mean, we've been having this discussion for 15 years, but if there's a recall in the news that it was distributed in Ohio, well Ohio is a fairly big state with lots of grocery stores. How do I know that it was my grocery store? Now some retailers are doing a great job. I had King Arthur flour in my cupboard, and I got a text message from Kroger, as well as an -- it printed out on my sales receipt. And I did check my cupboard, and I did have it and it was part of the recalled flour. So we are making strides, but, you know, that's because I signed up for a shopper card. And there are major retailers that don't have shopper cards.

So I think there's a lot more that we can do around consumer education. And the thing I would start with is trying to get people to take this more seriously is letting them know that there's risk in our food supply. And I know that's something that makes a lot of people uncomfortable.

MS. HOWARD-KING: Thank you.

MR. DETWILER: Darin Detwiler, Northeastern University. I'd like to expand this just a slight bit. To quote Dr. Phillip Tarr, a pediatrician who specializes in foodborne pathogens, or HUS, etc., "It's either in the gut or it's not, it doesn't matter where it came from."

We've been talking about foodborne illness and we've been talking about foods, but we also talk about things like HACCP, critical control point. One thing the FDA could do differently is look at critical control points, such as petting zoos, state farms, where we have incidents of people becoming ill from foodborne pathogens, not through consuming, but through animal contact. We have to remember there's other ways of people becoming sick. We can look at the fact that it should not be new news every single time when someone becomes sick and dies, a young child, because of animal contact at one of these things.

Perhaps we look at some of these behaviors in terms of critical control point situations where we

can now increase the consumer education by categorizing certain events and how the FDA can better work with other agencies and with state and county resources to better facilitate not only proactive communication and education, but even that awareness that could increase more timely follow-up and awareness should a problem arise.

MS. HOWARD-KING: Thank you, great comments. Anyone else?

MS. HANSEN: Kuki Hansen, Association of Public Health Laboratories. Most of the discussion regarding expediting outbreak-related communication has been between once you've already detected the outbreak, however I just want to kind of emphasize, I think CDC mentioned earlier, improving the data flow from laboratories in states up to FDA. Also, you know, maybe improving the data infrastructure there so things can be transmitted better between CDC and FDA, but also just from the states and locals up to FDA.

MS. IRVIN: Just to kind of piggyback off that, I know NCBI, the whole genome sequencing database, there's a publicly available database with the clinical sequences that are uploaded in real time for all to see. Interested to know if you guys have any experience in -- or if anybody's been approached that, hey, you know we're kind of looking into this database. We're identifying our own sub-clusters of illnesses. Just interested to hear if anybody's encountered that.

If you had -- I'm not asking you about that.

MS. HANSEN: Okay. So I didn't want to answer that specifically. I will though. I'm not aware of anyone that's doing that, and I'm in academia. I think one of the challenges, because that's a very -- you do -- in academia, you don't find a whole lot of people that are working on food safety out of public health departments, and from the clinical side, and that's because NIH largely doesn't fund applied food safety or foodborne disease epidemiology research, and that's something that I've argued for.

But I wanted to come back to the IT piece

because I've raised it in another session about, you know, one of the challenges we need to do is update the IT infrastructure within FDA because a lot of it is antiquated. But that's not just at FDA, it's across the Federal and state and local government systems. So if you want to improve the outbreak-related communications between government agencies, there's got to be a wholistic approach to updating IT infrastructure. And I know that's broader than what FDA can do, but you can certainly push for it.

And just to come back to Darin's comment, I think one of the issues again, and this is not really within FDA's purview but it is a challenge, that there is no government agency that has oversight on the farm from a food safety perspective. And I'm talking oversight not presence. And so, you know, that's a challenge in our food safety system. But again, I don't think that those are things that FDA can do, but you can encourage your government partners to pursue those things as well.

MS. HOWARD-KING: Okay. Anyone else? Oh, cool. Thank you.

MS. STOMBLER: Hi, I'm Robin Stombler with the Food Laboratory Alliance. Picking up a little bit from Ms. Hanson's comments, and a little bit, I'm a little off topic but close enough. One thing that we are hearing about is the need for standards within the laboratory. So when you're mentioning online sequencing available, for example, we need to make sure that reference materials are available, proficiency testing is available, and that's a gap we have right now. So it's one thing to put the technology out there, it's another thing to make sure that that technology is going to be accurate and the information that the laboratory produces is accurate and available and useful.

MS. HOWARD-KING: Okay, thank you. So we have about three minutes before our next part of the activities, so what I want to do is close this session and remind everyone that we do have a -- FDA does have a public comment session that's open until November 20th. You can submit comments via electronically or

in the mail, and the instructions are actually inside of your packet. So please, please, please, we'd love to hear from you. I know we didn't have a lot of time today, but there's plenty of time to get comments into the agency. And I want to thank you all, and we'll see you back in the main room. Thanks.

(Whereupon, the breakout session concluded.)