

FOOD AND DRUG ADMINISTRATION (FDA)
PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

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AGENDA

Simultaneous Breakout Sessions Block #2

Plaza Ballroom: Adapting to New Business Models and
Retail Food Safety Modernization

Facilitators:

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P R O C E E D I N G S
SIMULTANEOUS BREAKOUT SESSIONS BLOCK #2
ADAPTING TO NEW BUSINESS MODELS AND RETAIL FOOD SAFETY
MODERNIZATION

MS. DAS: Can I please request people to move to the center of the room, please. Good. Thank you. Okay. Welcome everybody. We will get started. So good afternoon and welcome to the New Business Model and Retail Modernization breakout session. We're really happy that you picked this session this afternoon. So I want to welcome all of you and also this session is getting webcast. So welcome to all of those who are joining via webcast. I am Sharmi Das, and I'm with the Center for Food Safety and Applied Nutrition. And I have my co-facilitators here; Glenda Lewis from the same Center and Laurie Farmer from Office of Regulatory Affairs and Mary Lee Hannah (ph), she's hiding there, Office of Food Policy and Response, taking detailed notes so that we don't miss anything here.

It'll -- we don't have time for individual introductions, and we have only about 45 minutes, but it'll be really nice if we can get an idea of who is here in the room. So if I can have a show of hands of folks from industry, please. It's wonderful, great. Welcome. Consumer advocacy groups. Welcome. How about Trade Associations? Great. International, Federal State, Local agencies. Welcome. Welcome. Okay. Anybody from Media? Okay.

So as you heard this morning, these breakout sessions are critical for us. We are trying to get all your input. And the goal today is for us to be able to have an open conversation on how we can advance safety, both for new business models like e-commerce and home delivery of foods, as well as some of the traditional models like retail food establishments. Quick, let's see where we can find here, the ground rules, if I can get your attention here just for a few seconds. So as I mentioned, we are looking for your ideas. So unleash your creativity and give us all your ideas. When you speak, if you can please introduce yourself, your name and your affiliation, please. And also because we want

to be able to hear from as many of you as possible, we are requesting if you can limit your comments to one minute max. And last but not least communicating respectfully and professionally.

So with that, I'm going to turn it over to Laurie Farmer. Quickly, we have about eight minutes per question. So we will have a timer. So when you hear the buzzer, it means that it's time to move on to the next question. Thanks, Laurie.

MS. FARMER: Thank you, Sharmi. And welcome, welcome, welcome. Alright. So if you guys would look at your folders, just -- I think you probably did this in your last session, but just to remind you, open up, we're at adapting to New Business Models and retail Food Safety Modernization. And those are the four questions that we're going to be talking about. So you're ready and already looking at those. Food for thought, there's a whole another section of ideas there, they're brainstorming ideas that we came up together with and FDA. And they're just to get you started and thinking, if you wanted to have something to trigger your thinking process. But here today, we're talking about evolving business models in the present food safety challenges as well as novel considerations around regulatory framework and oversight at the federal, state, territory and local level.

So we're going to be talking about four specific areas. We're going to talk about actions FDA can take. We're going to talk about research, collaborations and also actions that the food safety community, each one of you, all of us together could be taking. So what we're looking for is active engagement from you during this session. So as you're thinking about what -- how you want to answer question number one and engage, raise your hand, so Sharmi can see you or I can see you on this end, and Glenda is going to be taking notes for us. So let's start with the first question. What are the most significant actions FDA could undertake to help ensure the safety of foods delivered under a variety of new business models such as e-commerce?

MS. DUCKETT: So hi, I'm Jeanne Duckett from Avery Dennison Corporation. I also sit on the board of AIM Global Standards Organization. So actions that the FDA could take earlier this year as up in Ontario and I don't know if this is the FDA or the USDA, but Ontario is funding new technology for farms because of a the ongoing expectation of population going up and, you know, the ability to meet it. And one of the things they are funding is traceability technology.

MS. FARMER: So there's incentives there that the government is providing in Canada for traceability and other technology. Okay. Thank you. Thank you.

MS. WOOD: Hi, Sharon Wood with HEB, we're a Texas and Mexico retailer. You know, the train has left the station. There are so many out there, you know, doing e-commerce and all of the mid mile, last mile. So I would recommend and I know that many way you could work through our industry representations, but really educating yourselves with those that are doing it, have been doing it and these are -- these -- most of us that are doing it are good stewards of food safety. But again, we're trying to apply what we know from the food code and what we know to be the right thing and I think many of us are learning. There are some different legal obstacles, 1099 employees, for example, of what you can and can't do and tell them what they can and can't do. And so I think just this collaboration with those that have been doing it even much longer than HEB, but what is -- what are we learning and collaborating together to educate on exactly what this entails because it's more than what's just described in the graphics. Thank you.

MS. FARMER: Right. Thank you, Sharon.

MS. WOOD: You're welcome.

MS. FARMER: Yeah. So educating ourselves on -- from this industry experts that have already learned so much, what can we learn from each other. Very good. Did we have a question right here.

MR. ALKHALDI: This is Suf AlKhalidi from ORA. One of the things I think the FDA would really help and I said that in the previous sessions where I communicated and allow the industry to have something

called like smart food tracking is like we are doing something like organic food, the FDA control the labeling. If we allow the industry to do that, that will allow them to increase their market and selling it and at the same time tracking it. And it works through so many business models. I think that's one thing.

And the second thing is, I mean, the information and I, you know, share the sentiment of the people here about the frustration about knowing, like the FDA or anybody knows. I think the knowledge nowadays is available for everybody. But what's really is not, it's very hard and I say that from my position, navigating through the knowledge. There's so much noise, so much noise, it takes a lot of work to go through the noise to get the signal. And this is where we are. I think all of you are like that nowadays. We have so much information, the information is available. Click in YouTube, you get it, and you don't make that YouTube.

MS. FARMER: Yes, challenge is on navigating the knowledge. Absolutely. Others.

MR. DURM: Don Durm with PLM. We're a fleet management company, but we also do a lot of technologies that help solve problems for our customers. One of the things you already have is you already have this very robust program through FSMA that you could transfer down to the last mile. We always joke and say, you know, hey, FDA didn't encounter the new last mile just when they were passing these rules, you know, it was now really from the grocery store or even the restaurant back to your home now. And that's where the new last mile is at.

So just one quick example would be within the sanitary transportation and food act, you require training for drivers in order to do food safety handling and everything. And -- but you have no requirement for the guy that's taking it from your restaurant or from your grocery store to the facility on what they should be doing. So you already have a lot of robust knowledge already or industry agreement to do certain things. So maybe you could extend that out to that part.

MS. FARMER: So Don, you're suggesting training for that last mile, be assistance.

MR. DURM: Yeah. Absolutely. Absolutely.

MS. FARMER: Uh-huh.

UNIDENTIFIED SPEAKER: And let me ask you, I put here transport FSMA to the last mile.

MR. DURM: Yes. You're making the whole industry do this and all of a sudden that's where you break this down.

MS. FARMER: Right. Good feedback.

MS. PHILPOTT: My name is Amy Philpott with Watson Green, a public relations firm. I say this with the caveat that it may already exist. So if it does, maybe it needs to be promoted. But the idea of also educating the consumer retailers are driven by what their shoppers, their consumers want. So a CDC and FDA and many of the government agencies are excellent at providing tips to consumers. But a tip sheet on what to look for when you're ordering from an online grocer or an online home meal kit. I myself have ordered those kits and called ahead of time. Most of the time, the consumer or the customer relations desk has no idea what temperature the food is shipped at or what they do. And educating the consumer would help drive or push some of that awareness to the retailers, I think.

MS. FARMER: Great. Great. So educating the consumer that is purchasing in this arena. Speaking of consumers.

MR. HANSON: This is Jaydee Hanson from the Center for Food Safety. Many local governments do a pretty good job of inspecting restaurants and posting on their website the results of who they shutdown and why and when they're allowed to be opened. This is something that the local operations here in Rockville and in Baltimore and in D.C. could do fairly easily. And it seems that's more their purview really than it is the FDA. I mean, we've sued the FDA and Food Safety Modernization Act. But, you know, I think for the most part, being short of resources, you know, FDA maybe needs to focus, you know, where most of the pathogens originate and let the local, state and city inspectors do that last mile.

MS. FARMER: Okay. So focus more on the regulatory authority to deal with the last mile as opposed to the feds doing that. Is that what I heard?

MR. HANSON: You know, there are lots of strapped communities too. So, you know, FDA could extend its resources by helping some of those poor communities do a better job of doing their inspections.

MS. FARMER: Okay. Very good. So capacity building by the feds or states, locals. Okay. We're going to have to wrap that question up and move to the next question. So maybe those that had their hands up, this could be relevant to the second question. Let's talk about research and what research is currently being conducted to understand the potential health risks posed by foods provided by new business models such as e-commerce. So we could talk about available research and then gaps in research, what is needed. Who wants to talk about research?

MS. JENNINGS: Hi, my name is Allison Jennings. I'm with Amazon. I would say in terms of one of the challenges with research in this space would be the assumption that all business models within delivery or home delivery are the same. And lack of standardization, I think, would present a challenge when you're looking at research within the space. The one thing I wanted to say with respect to the last question was that there are, I'm sure this was brought up in your last session this morning too, is that there are industry regulatory technical working committees both within the conference of food protection and within GFSI that are focused on this initiative, looking at developing best practices within industry to suit all of these various business models. So I think making sure that FDA continues to partner with those committees, looking at guidance that are coming as Sharon said from companies that have been in this industry for a quite some time also, you know, in collaboration with researchers and in collaboration with regulators is something to continue to investigate.

MS. FARMER: Alright. So leverage whatever -- what else is already out there. That was a lot. It

was research, its third parties that already exists. It's the conference for food protection. A direct to consumer work group was one of the things you mentioned, GFSI, very good. Lack of standardization. There's multiple models is what I heard you're saying. Yes.

MR. DURM: Right. So yeah, so when you talk about new last mile and -- oh, sure. My name is Don Durm from PLM, a fleet management company, we also do technologies for the last mile also. The last mile, the new last mile is really kind of like the Wild West now at this point. If you've got a driver's license and a car, you can potentially -- I'm not talking about companies that train and do all these things, but it's the Wild West right now.

There is a study done in, by Coleman (ph) that really talked about green leafy vegetables going into restaurants. And they found that 50 percent of them that they tested were above the safe zone, essentially above 42 degrees which -- so you know that research that they could cause pathogens to grow. And I think about 10 percent of it was above 65 degrees. So, you know, you've got reports being done by Oceana, who talk about food authenticity, a third of our seafood is mislabeled and not what it's supposed to be. So there's lots of individual studies have been out there, that when you put it under e-commerce or last mile, it can actually accentuate what's happening out there.

MS. FARMER: So a conversation around food fraud and then also the research that exists out there that's already talked about, what temperatures -- the studies that have been done around temperatures and packaging and all of that. Thank you.

MR. CHEN: Hi, my name is Liwen Chen. I'm coming from Unisys. I'm leading the emerging technologies and certainly, sorry, I'm not aware, you know, I'm really not in this industry; safety food or something, but from my personal experience I notice a lot of incidence was not reported because of lack of aware, to a poor knowledge and some, you know, immigrants, they have no idea how to report. So you know, ideally if we can easily, you know, something,

probably blockchain or something certainly I'm also, you know, aware and also leading that practice, but with the low hanging fruit easily we can put a post on the restaurant and the food stores or whatever and then once they use their cell phone and scan it, they can have their own language. And then easily can report those kinds of incidents. And with those kind of, you know, big data coming and then with this AI, you know, machine learning and the FDA probably easier to, you know, to learn those kind of things in the -- not, you know, put very good use of predictions, those kind of incidents, but that's just my thought.

MS. FARMER: So would you say that's a lack of standardized process for consumer concerns?

MR. CHEN: Nowadays all the data varies and that every, from teenagers to, you know, senior guys, we cannot standardize it.

MS. FARMER: Right.

MR. CHEN: And that's the trend. Okay. So we have to adapt to, you know, more smart systems and get, you know, get it more predictable and make the system more flexible and easy to be to be used.

MS. FARMER: Great. How are you doing over there, Glenda? You good. Okay. Thank you. How much more time do we have on research? Okay. Thanks. Anybody else? Gaps in research. What do you want to know about that you don't? What -- we're in academia. Do we want to do some more studies? I think we have one. Yes, ma'am. I think we have one. Yeah. She's thinking, I can see, I'm turning.

MS. DUCKETT: So Jeanne Duckett from Avery Dennison. I'd like to see, you know, kind of like we talked about earlier for Codex for the food safety standards. I do like to see if there's a harmonization of last mile delivery across the globe. You know, what's Europe doing? What's Australia doing? You know, what's Asia doing?

MS. FARMER: Nice thinking bigger. You know, what is going on globally that people have already learned that we don't need to learn -- have those same learnings. Very good feedback. I appreciate that. Very good. Let's go to the fourth question. What are

-- oh, do we have -- I'm sorry. Yeah.

MS. BOSCO: Hi. Mary Lou Bosco with AIM. I'm were a trade association for anything that tracks assets, you know, using the barcode and RFID. And we've been involved with a lot of your counterparts within the FDA, and learning from their trials and tribulations as well, with the UDI regulation, with medical devices, with Department of Defense, with their IUID. A lot of what you all are doing don't start from scratch. Learn from your peers.

MS. FARMER: So are you suggesting learning from other commodity groups? Like within FDA, like the medical device groups. Right. Okay. Very good. Yeah, so those are all last mile models that we could use. Very good. Very helpful. Thank you. Thank you. Alright, last question. What are the most significant actions that office, us as a food safety community, FDA, states, territories and locals, did we -- did I miss? I did. So let's go to third question. Collaborations. So this meeting is all about collaboration. What other collaborations need to happen between FDA and industry that would help to ensure the safety of foods, these foods?

MR. DURM: Sure. Don Durm with PLM again. Actually I'm going to present a question to you and I've asked these questions before the FDA was, are there any correlations between companies that go through audits and pass those audits like SQF or BRC, and then passing your audits that you do? It'll be interesting to find out what that statistically. Whenever I asked somebody from the agency, I was said, that's a really good question. I'll get back with you.

MS. FARMER: I think that's something we could look at. I can't personally say that I've experienced doing that analysis, but it's certainly something to look at to consider leveraging that data.

MR. DURM: So maybe internally I can flip this around and say is that, you know, the correlation between the audits that are being conducted from private organizations and to see if there's any correlation on what that is.

MS. FARMER: Very good.

MR. DURM: For consumers and for companies.

MS. FARMER: Yes, helpful. Thank you.
Collaborations.

UNIDENTIFIED SPEAKER: So I actually didn't know these existed until I started looking at food traceability. But like the CDC, the USDA, there's different, like there's an app for food keeper. There's the ask Karin food safety questions. There's these different resources. There's the e-mails, which I have never met anybody other than me or any -- probably anyone else probably in this room that actually gets recall or e-mails. So there's this variety of things available that I think the general public in general knows very little about. And down at IFT this summer, they were teaching microbiologists the fact that pathogens can still continue to grow in freezers and refrigerator is kind of an education process and that was even something they didn't know. So there just seems to be, you know, as we've gotten more away from nuclear families, there seems to be a lack of knowledge about how to treat food.

MS. FARMER: Right. So more along the lines of consumer education and consolidating, a place for resources. Yes, very good.

MS. SOUTHEE: Jaqueline Southee, FSSC 22000. I just want to follow on a couple of things. You were talking about data collected by BRC and SQF and FRC. FSSC is also in the business of third-party certification and we are looking at this. FSSC is actually based on ISO standards. So everything that we do has to, you know, be done on an already existing standard. And just for your information that ISO is currently working on a standard on temperature control, packaging. So it is, you know, talking about collaboration, we all need to keep in touch because we're all looking at this worldwide. You know, we're monitoring the, you know, the transporter packaging in the U.S. overseas and everywhere and ISO is looking at this too, so.

MS. FARMER: Very good. So the ISO standard is looking at time, temperature control. So looking at the universe globally. Yeah. Very good.

MR. MANDERS: Hi, my name is Alex-Paul Manders with the Information Services Group where I'm a Director. I would say that, you know, one of the more obvious collaborations that the FDA or any legal entity should stand up as a collaboration with technology firms or technology advisory committee. For example, there's a number of technology solutions and providers in the room. Everyone has a different agenda or perspective on what their solutions can offer. And I think that the federal government among other entities or industry players needs to have an objective, an independent voice to make sure that the things that they're subscribing to or potentially purchasing are truly objective, operational and to the benefit of the consumers in the United States.

MS. FARMER: Very good. And we all need that assistance and technology advisors. So thank you.

MS. HOLLINGSWORTH: I'm Jill Hollingsworth with Chemstar Ecolab. One of the things that especially as we now go more and more into e-commerce and food is the issue of privacy. And there has been a real struggle of even with FDA and CDC and USDA trying to get, for example, loyalty card information, which on the one hand can be great information for doing an investigation. Even helping somebody who doesn't -- may not realize they have a contaminated food, but on the other hand we're often challenged with privacy issues. And so I think one of the things when we talk about collaboration, it's how do you share information that really belongs to an individual. It's their private information, yet, knowing that it could help with the investigation or even help that own individual with their food safety, but respecting their privacy. And I think that issue has not really been discussed nearly enough.

MS. FARMER: Right, so we're looking at Jill is suggesting we look at and consider privacy issues when it comes to notification and traceability of product, is that where you're going Jill?

MS. HOLLINGSWORTH: Yeah, especially now with e-commerce.

MS. FARMER: Yes, very good. Alright. So

let's move to question number three, Sharmi, what do you think?

MS. DAS: Fourth one.

MS. FARMER: Four, numbers backwards, don't -- Glenda anything? Okay. Okay. Alright. So let's talk about the most significant actions that we can take, any of us in this food safety community, to change practices in the retail food industry that present risk to public health. So this area is all about behavior change. What can we do here, suggestions? What are our most significant actions? I see lots of hands popping up. Just for those in the webcast, if you are wondering, these people are so active.

MS. DUCKETT: This is Jeanne Duckett from Avery Dennison. So I think that the FDA approach of educating by regulating is a really good approach. And, you know, we talked about hand washing and there's positive ways that you can tie, if you can tie hand washing into your business; that would be good. And there're different tools now on the market that look and check for clean hands. So if you can tie that into your business process; that would be a positive way of trying to train it. And we have some experience with that and usually it only takes a month.

MS. FARMER: Nice.

MS. DUCKETT: And then it goes up.

MS. FARMER: Yeah, how long does it take to make behavior change, about a month?

MS. DUCKETT: About a month.

MS. FARMER: Okay. Very good. Ms. Sharon.

MS. WOOD: So is it a general comment or...

MS. FARMER: Yes, just a comment.

MS. DUCKETT: Hand washing. So, yeah, hand washing monitors. Look at new tools that you can integrate into your business processes that kind of encourage, you know, educate and, you know, aren't really penalty. You're not -- you don't fine the person, but really enforces compliance or encourages compliance.

MS. FARMER: Nice.

MS. WOOD: Sharon Wood, HEB, Texas and Mexico based retailer. So on looking at this question, it

says the most significant actions, you know, there's a lot of actions that could come out of this meeting. But it's not just by FDA. It's by state, territory and local agencies.

MS. FARMER: Uh-huh.

MS. WOOD: So I'm going to take two things, two recommendations. One, again I'll go back to understanding what retailers are already doing. Some are leading edge with food safety practices. Are we perfect? No. But there's a lot. And so I also think that leads me and segue into the second point, more of this. This is amazing. I've been doing this for almost 30 years.

And this is frank feedback, brainstorming, but actually taking action. And so what's next? You know, hopefully there's segues into more conversation. But I think retailers in general, there's so much pressure there. We want to lead out. And a lot of times, it's I've gotten into situations where regulators don't always understand the retail process. I mean, they can inspect, but understanding that retail process.

So again, education, and then this open communication, I think, on all levels those could be the most significant actions for true change.

MS. FARMER: Education and collaboration and you really like this forum, Sharon, where you're able to provide feedback. So actions FDA, state, territory, locals and industry could take to change behaviors.

MS. HUSSEIN: Good afternoon, Sima Hussein with Ecolab. So a couple things. One is an idea that came out earlier and it's a really basic idea, is positive recognition. So often we hear about food safety in a negative light. But when individuals are doing the right thing, we don't hear a lot about that. So what can regulators do and shedding a light on the positive recognition and positive behaviors that they see. Another part of it was how can we get the regulatory community also involved in food safety culture at the, you know, store level, the restaurant level where could that even be a part of the questions that they are reviewing as part of the inspection where they ask about a particular food safety culture as it

relates to what is the importance of the role that a particular individual or a food handler is doing as it relates to food safety, how they view it, so.

MS. FARMER: Very nice. So incorporating food safety culture questions and two, an inspector's role, you know, beyond health, wellness, all of that. Yeah, very helpful. And we'll take two more questions. Okay. Sounds good.

MR. DURM: Don Durm with PLM again. Again I just say, you have to apply the rules equally back all the way down over the entire. So as a food distributor that you're moving into a restaurant, you have to do all these certain things. You have to have the training. You have to have a temperature-controlled vehicle. You have to, if the customer asked you for temperatures, you've got to do proof of delivery as far as the temperature goes.

But if I own my own restaurant, I can, you know, wander on down to the local Big Box store, load my car up at 98, I live in Florida, so it gets pretty hot there. So the temperatures could reach 140 degrees inside that vehicle. And I go in and make another stop at the GoPro Shop. And there's no regulations on that, they just say, that's the local food code or something and that they were entrusting those people to do that. And so these rules have to really be applied all the way down the supply chain for food for that e-commerce in that last mile.

MS. FARMER: So a level playing field through the food safety continuum.

MR. DURM: Right, because people are saying the supply vehicle.

MS. FARMER: Right. Helpful.

UNIDENTIFIED SPEAKER: The FDA has some new tools in the Food Safety Modernization Act that it's not using particularly aggressively. And one of them is a mandatory recall. And, you know, why, you know, why you didn't use that with when the mango distributor was refusing to do their own recall? Maybe it's too cumbersome. If the process is too cumbersome, then there's a way to change that. But you have to find a way to stop the bad actors faster.

MS. FARMER: Uh-huh.

MR. DURM: Can I make one more comment.

Again, Don Durm with PLM. I am Ex-Law Enforcement Officer. I spent 12 years in law enforcement, okay. And at some point you have to actually act. And just lumping on what you're saying is that when I go in and I do a lot of speaking and I talked to food distributors and supply chain actors and stuff said, Don, we don't see anything, nothing has changed. You keep telling us to have the training, they're coming, you know. But, you know, until the agency actually, I hate to say this, until you like make an example or something out there. You know, you do talk about educate, educate. I think we've been educated. And I think we've one more comment.

MS. FARMER: Thank you. Last question.

UNIDENTIFIED SPEAKER: Piling up on what Durm and they said over there. I think maybe a more positive way you could do that is like a survey, show compliance rates. So here's what we think compliance rates for last mile. The FDA is considering start doing auditing of these. That in itself is going to impact change.

MS. FARMER: Yeah, so more positive feedback, what we heard over here as well to change behavior because people are more willing to change when they're getting accolades. But also I heard using the authorities that have been given to the agency when they're needed. So I just want to thank you guys for your engagement today. Really appreciate it. Good work.

Really our highlighted points as you guys have already talked about their significant actions that FDA could be taking. There's research that we could be doing a lot of collaborations. But what I heard mostly was don't reinvent the wheel and think globally. So what exists out there, let's utilize that. Let's find those best practices. And let's learn about those as a collective food safety community together as we move towards this blueprint forward.

So thank you so much again for all your feedback. What we're going to be doing is including

all this information as the blueprint, gets considered or gets developed. Also we're looking for you to put in your comments formally into the docket. So please do that. And I want to thank you for, you know, just taking the time to be here, be present. I know that you guys are very busy. And it's really important to FDA to get your feedback.

So at this point we're going to go ahead and break. And I think the next session starts in just 5 minutes in this room, if I have the agenda, correct. So if you just want to take a quick stand up break and I want to give you guys a round of applause for your active participation. Thank you.

(Whereupon, the breakout session concluded.)