# FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

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#### APPEARANCES

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EVA HURT Nestlé USA

ERIN HEALY USDA

### APPEARANCES

ERIC MOORE Testo

KATIA NOLL Subway

GLENN CAULKINS FreshDirect

JIM HARTTEN Wilson Sonsini

KRIS MARKULIN Lidl Grocery Stores

PATRICK BUCHAN Territory Foods

#### **AGENDA**

<u>Simultaneous Breakout Sessions Block #1</u>
Regency Room: Adapting to New Business Models and Retail Food Safety Modernization

Facilitators: LAURIE FARMER

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#### PROCEEDINGS

## SIMULTANEOUS BREAKOUT SESSIONS BLOCK #1

ADAPTING TO NEW BUSINESS MODELS AND RETAIL FOOD SAFETY MODERNIZATION

MS. DAS: Okay, we'll get started. We are hoping some more people will trickle in.

So good morning and welcome to the New Business Models and Retail Modernization breakout session. We're really happy that you picked this session this morning.

I'm Sharmi Das and I'm with the Center for Food Safety and Applied Nutrition and I have my cofacilitators, Laurie Farmer from ORA, Office of Regulatory Affairs and Glenda Lewis from the same center as me.

So we will not have time to do individual introductions because we have about an hour together today, but it would be really good to get an idea of who's in the room.

So if I may have a show of hands of folks from industry please? That's pretty good. Welcome

How about trade groups, trade associations? Anybody?

Consumer advocacy groups? Welcome, I'm glad you're here.

Other federal, local, state agencies? Wonderful.

International organizations? Wonderful. Welcome, welcome everybody.

Anybody from media? Okay.

So we will get started. Welcome again. We have a pretty diverse group which is wonderful because the whole -- the goal of this breakout session is to be able to get feedback from all of you which will help us put together a strong and robust blueprint as you heard this morning from Frank Yiannas, from Dr. Mayne. So please, please unleash your creativity and give us your ideas because that's why we are here.

We have a few ground rules. Just want to take a couple of seconds to go over them. As I said, your ideas are welcome. You received a packet this morning which includes the four questions, so I hope

you got a few minutes to take a look at that.

And then you also have another document called the "Food For Thought," which was put together by an internal brainstorming group within FDA, but we certainly don't want to limit ourselves to just those ideas and we want to get broad input from all of the expertise that we have in this room.

When you speak, if you can please introduce yourself with your name and your affiliation.

Because we want to hear as many of you as possible, we are requesting that you limit your comment to perhaps a minute at the most and, of course, communicating respectfully and in a constructive manner, if we can all do that.

And let's see if there is anything else. So this session is being transcribed for note taking purposes only. It's not getting webcast. The afternoon session will be webcast and we'll have roughly ten minutes per question, so we -- I will have a timer, and so when the timer goes off, that means it's time to move on to the next question.

With that, I am going to turn it over to Laurie Farmer.

MS. FARMER: Okay. Welcome. Thank you, guys, for being here. It's great to have you here and get your feedback today. What I'd like you to do is open up your folders so you can see what we're doing here. So open up your folders, and there are two things that I want you to look at. One is this document that has the public docket. If you turn that over, it will show you the questions that we're going to be going through today.

So we are really going to focus in on four areas today and we're talking about involving business models, present in the food safety challenges, as well as novel considerations around regulatory framework and oversight at the federal, state, and local levels.

So those four areas that we are talking about are going to be FDA actions, research, collaborations and of course actions of the food safety community and those challenges that we have, so -- and any change practices that we want to make.

So the second thing that I would like for you to look at in your folder to kind of help trigger conversation. As Sharmi spoke about, we had some internal brainstorming sessions and there is one sheet that says "New Business Models and Retail Modernization," and that is really just to get you going and thinking about, hey, you know, thinking about ideas. Definitely, as Sharmi said, we want to get as much feedback as we can from you.

So let's go ahead and get started. We have limited time, as she said, we're going to spend 10 minutes on each question. I ask that you limit your comments to one minute. And we have a timekeeper over here. MaryLee is going to -- she's going to be doing a lot today. She's going to be taking notes, she's going to be waving her pamphlet saying time's up, and we'll just keep an eye on MaryLee.

So I just want to talk to you about the first question then that we'll start with. What are the most significant actions FDA could undertake to help ensure the safety of foods delivered under a variety of new business models.

So Glenda's going to be our scribe on that question. And Sharmi's going to jog it out. So if you could just raise your hand.

What kinds of things do you see? What are the most significant actions FDA could undertake?

MR. ROGERS: Alright, I'll break the ice. My name is James Rogers. I'm the Director of Food Safety Research and Testing at Consumer Reports, and as you might imagine, we are very interested in this.

One of the things that we've noticed is that there is a lack of standardization on a number of levels. For instance, if something goes wrong on the shipment, what do consumers do? Who do they call? How do they determine whether the shipment is bad? Temperatures, spoilage, that type of thing, so I would think the FDA, if they could set some standards for the industry to say here's some things that need to be in place to help consumers when something goes wrong, not on the, you know, regulatory side, but when something goes wrong, manufacturers have to include

these things. A 1-800 number, a website, someone they can talk to, to say, hey, it's seems like my chicken is warm that came in the shipment. Who do I call? What do I do about it? Are you going to replace it? What's the procedure? What's the process?

MS. FARMER: So what I heard James say is set industry standards and have resources (inaudible).

MR. MENDES: Alex Mendes with PepsiCo. Can we maybe apply the similar approach of following the hazards? So maybe a risk based instead of one size fits all? So I think we could be built from preventive controls, so that would be the suggestion just that we were thinking internally.

And then the second point is we always start with leveraging what we do in just putting to boxes and send to people's houses. That is then. Now, we're changing. We're actually developing the product for the e-commerce or different channels.

I think that is changing some nuances and adding some risks that we didn't have before because the first one was much more robust. Now we're taking other points in consideration. Not sure if others are doing the same.

MS. FARMER: So Alex who are you with?

MR. MENDES: I'm with PepsiCo. I -- yeah, I lead the global food safety.

MS. FARMER: So you talked about risk-based approaches and really thinking about (inaudible). And then now that history is changing so quickly (inaudible). At PepsiCo you're thinking about the last mile of your product. Is that what I heard you say?

MR. MENDES: Correct.

MS. FARMER: (Inaudible) the last mile?

MR. MENDES: We're developing (inaudible) for the last mile (inaudible) using standards (inaudible).

MS. FARMER: (Inaudible) what James said. Thank you.

MR. GUILHAUS: Hello. My name is David Guilhaus. I'm with the Publix Super Markets and I got two points.

One, when look at things like e-commerce and

we talk about product coming to people's homes, I really think we need to understand what are those traditional ideas we have about separation between raw and ready to eat foods as well as separation of proteins and that applies not only at home delivery, but also for home pickup.

So if we're making ready to eat meal kits or ready to make meal kits in our stores, how those things get stored, marketed, etcetera as far as what go over what and what are those expectations from an FDA perspective for the proper separation.

MS. FARMER: (Inaudible) talking about separation of products (inaudible). Alright. Thank you.

How are you doing up there, Glenda? MS. LEWIS: I'm good.

MS. FARMER: Are they going to fast? Okay. That's great.

MR. BROOKS: I'm Ozzie Brooks from RaceTrac. I'm going to add to the gentleman from Publix.

Also, proper separation and time and temperature indicators for preventive control around product that is being delivered to the consumer.

Just for example, here's a consumer and for food safety, there's times where the product will sit at my house and my sometimes my flight would get delayed. By the time I get there, I have no proper way of identifying if product is out of temp or within temp.

MS. FARMER: Ozzie, that's great. So time, temperature control, technology exists for that. And so considering ways to utilize that (inaudible). Very good.

MS. BOARD: Hi, I'm Elizabeth Board. I'm from GS1. I'm from the global office and we're a standards organization most well known, I think, for the barcode.

A couple of things -- I worked in Europe on 1169, which is a regulation some of you may know, to make sure that all of the ingredient labeling that is on a product is exactly the same online and we worked on the data models for that.

And I think that's important for consumer information especially with all of the concerns about allergens these days.

And I think that there's a lot that industry already does with product identification using GS1 standards and there's no reason that can't be leveraged for the last mile for fresh home food delivery and so forth.

So I think that the standards work that's already been done by industry is very important and it can be leveraged more.

MS. FARMER: Great. Elizabeth is talking about standards that already exist and applying those to the last mile. Alright. Great feedback.

MR. VON FRIEDEBERG: Hi, I'm Arnim von Friedeberg, CMA Global Partners German Foods. We're a small US based retailer and importer.

Everything I heard in the introductory meeting and now really involve costs. And these costs are prohibitive for anybody in the small business environment and are prohibitive to involve or to enable craftsman, who are not in the high-tech food, to deliver or produce food.

So what FDA really should set up from the beginning is that tools are made available to level the playing field as your British colleague very clearly said.

And that's incredibly important that businesses who will want to be profitable from the beginning and not just funded by massive guru money. I'm sorry to put a guru here, but that basically, you will venture capital money where they are unprofitable for many, many years. In other words, to enable profitable companies, more companies to deliver safe food, but in a way that it's still profitable.

Part of that is consumer communication that consumers are being motivated to also maybe pay a little bit more for craftsmanship food and be -- that tools are made available for everyone. Also for small business to actually download or use these tools to compete with the very large ones.

MS. FARMER: (Inaudible) make tools available

to lower (inaudible). We were talking about that when you came in (inaudible).

Hi, Eva.

MS. HURT: Hi, I'm Eva Hurt. I'm the Vice President for Regulatory for Nestle here in the US. I wanted to follow-up on a couple of points.

Yes, we're also very much producing meals specifically for e-commerce in terms of our SKUs rather than just boxing up what is already existing and that influences the shape, the format, the size, etcetera.

What I wanted to talk about a little bit was mentioned by one of the panelists this morning is about Kodak's and standardization. Because when we, Nestle or I guess I speak on behalf of PepsiCo and others, we work with Walmart, we work with Amazon, etcetera. It's a relatively controlled process and we sell our products through a very transparent supply chain.

However, we're also battling the ongoing issue of parallel imports. There are distributors involved, et cetera. And information such as allergen labeling could be very unreliable in that scenario, so really this is going to increase.

I mean, we're talking about e-commerce as if this is the latest invention. It's really like the most basic of the new business models, so I think we have to be prepared to be much more flexible and much more agile.

And for me, from a regulatory perspective, I think greater harmonization internationally could really make a huge difference for the consumer.

MS. FARMER: So that was your connection, greater harmonization to the global community (inaudible).

MS. HURT: (Inaudible).

MS. FARMER: What do you have, Glenda?

MS. LEWIS: (Inaudible) be flexible, agile, harmonization in the global community.

Ms. HURT: Regulatory harmonization to make sure that wholesale safety and labeling (inaudible).

MS. FARMER: And you talked about allergens

as an example, I know you said Kodak. Yep. Great.

MS. FARMER: Great.

UNIDENTIFIED SPEAKER: So we'll move on to the second question. Yeah.

MS. FARMER: Okay. Great. (inaudible) we're going to talk about research now. What research is available or should be conducted to understand the potential health risks (inaudible) provided by (inaudible).

Now, as some of you work for organizations that are already doing that research, I'm aware of research that has been shared. But then just -- I'm thinking about the (inaudible) connection and the direct consumer (inaudible).

So when you think about what research isn't available or what should be conducted, first of all, what do you know that's out there, the research that's happening? Anybody? James.

MR. ROGERS: I know there is some research on the ability of home delivered meals to be delivered on time and the proper temperature and testing some of these companies to see under various conditions, from the heat of the summer in Arizona to the cold in the winter in Minnesota, do the meals actually get delivered at the proper temperature, how many ice packs are in there or not, the construction of the delivery vehicle itself. So there is some information out there on that, probably need more, but --

MS. FARMER: So research on the equipment, the delivery methods, what's effective, what's not effective.

UNIDENTIFIED SPEAKER: Also, there's some research out there to clean and sanitization of vehicles for like Uber Eats, Grubhub. We have, at RaceTrac, we use Uber Eats and that's one of the things that we focus on is food tampering, making sure the bag is fully closed, sealed to give the consumer some kind of indication that the package has not been tampered, that shows some kind of where the bag is supposed be closed. And then we also inspect the vehicle that carry our food from our destination to the consumer.

MS. FARMER: Sure. Sure. So I know that's a topic being discussed right now a lot (inaudible).

MS. LEWIS: So it's the vehicle and the packaging (inaudible)?

UNIDENTIFIED SPEAKER: Yes.

MS. HEALY: I know that the focus is food safety and not -- oh sorry. Erin Healy from USDA.

I know the focus is food safety and not environmental sustainability, however, considering that that is a big trend and a focus for consumers and when I look at a lot of these meal delivery kits, that's the first thing I'm startled by is the amount of waste.

So I'm wondering if there could be some research to connect -- is it possible to use reusable containers especially for members who are using this weekly, but still ensure that there's food safety, still ensure that it's sanitized and it's clean and the temperature is consistent. I'm thinking of Amazon Prime where they have a lot of the cooler packs and they just throw them away instead of reusing them, so that would be something that I think would be just cross cutting and interesting.

MS. FARMER: Yeah, so a potential gap there, Erin is talking about, is research around consumers' interest in reusable containers. Maybe there is research out there. And concerns about the environment, (inaudible) are really looking at that.

UNIDENTIFIED SPEAKER: For me, maybe is a more broader question is, maybe the agency could help with where is all the research. Right? We're trying to identify, you know, different companies, different areas.

And the second point is, we're trying to understand data as well from people that are taking that in and then now you have different players. Right? It's not no longer a 1-800 of your company. They may call Amazon. They may call somebody else.

So data consolidation is a little bit of a challenge as we speak, so I'm not sure if it would be different or how to increase the transparency.

MS. DAS: If I can please remind people to

state their names and affiliation. It's for transcription purposes.

MS. FARMER: That's helpful. We'll consider all those points you made.

MS. BRUNTJEN: I'm Jacqueline Bruntjen with the Dennis Group. We actually are a design, build, architecture and engineering firm who focus solely on food manufacturing and beverage manufacturers.

And one of the big problems that we see is that the hold times associated with -- for example, you've got cases and cases and cases going through the line, the time of the sample analysis at those critical control points, the analytical data can take a long time to be able to be analyzed, interpreted, so that product has to be held and stored and not gone out to market for a very long time.

So seeing any sort of development within that area to reduce the hold time, increase the speed of turnaround of those analytical results to increase the availability to shorten that return time would significantly reduce the cost and problems with tracing, you know, failures within the system earlier, so that was --

MS. FARMER: Jacqueline, we were really talking about laboratory -- the laboratory component (inaudible). And so what are some research -- are there quicker methods that we can consider for products to move more quickly through to how to marketplace. Is that what I heard you saying?

MS. BRUNTJEN: Yes. Yes ma'am. Yes ma'am.

MS. FARMER: Great. Thank you.

MS. DAS: We have four minutes left.

MS. FARMER: And what are the gaps in research? I appreciate the fact that you want to know what the landscape is in research, I heard that loud and clear. Right? FDA, help us figure that out.

MR. MENDES: This is a different -- Alex Mendes of PepsiCo.

Shelf life impact on the new delivery systems is an area that we don't know of the research and maybe that's product specific as well.

MS. FARMER: Okay. Very good. Shelf life.

MR. VON FRIEDEBURG: Arnim von Friedeburg, CMA Global Partners. I want to add to the shelf life of shelf stabled product. It's extremely important that FDA starts to educate consumers that not all products are unsafe if they are beyond the shelf life, so that makes a big different in e-commerce.

And the other -- the opposite part is on meat products or on perishable products that, again, not everything that has been warmed up is necessarily building bacteria.

So there's a -- let's say, there's a variance in the cooling period of certain products, so the differentiation byproduct and what really becomes dangerous if it's arrived at home either at a warmer temperature or cooler temperature, that would be helpful for, you know, companies like ours.

MS. FARMER: More consumer education?

MR. VON FRIEDEBURG: Consumer education and differentiation.

MR. MOORE: Hi, Eric Moore with Testo. I would actually say to combine a couple of these thoughts is maybe establishing or doing some research around ways that small to medium businesses could follow defined processes for validation techniques around products that they would like to see enter the e-commerce market. Right?

So and maybe even applying like process HACCP to specific product categories or delivery types, if that's possible, because then you're bridging a gap where these independent operators and very small businesses could have a tool to help them compete on a larger scale.

MS. FARMER: Yeah, so almost like existing models for different commodities.

MR. MOORE: Yeah, yep.

MS. FARMER: Is that what you're saying,

Eric?

MR. MOORE: Yeah.

MS. FARMER: Okay. Thank you.

MS. DAS: I'm going to get my 10,000 steps in early today.

MS. NOLL: Hi, Katia Noll from Subway. So I

just wanted to build off what the gentleman from RaceTrac said earlier.

So we're very heavily invested right now in third party delivery, so Uber Eats, Grubhub, DoorDash, things of that nature. So our window of time between when the food is leaving the restaurants versus getting to the consumer is much shorter than other ecommerce things like meal delivery. But we are certainly concerned about the integrity of the products. So it would be very interesting to understand in building off the bar-coding, but I'm worried more about actually tampering.

So I know there's been sort of anecdotal research or things that we've heard in the news about the percentage of drivers that will open product and taste it and touch it and things of that nature, so, yeah. It would be good to understand sort of how other companies or other competitors are approaching it from a process standpoint. So what is the packaging that they're using? Do they have tamper-resistant bar-coding or seals or things like that?

But also from an allergen standpoint, how are we ensuring that what the consumers are receiving is accurate compared to what they're ordering because there's an assumption that it is made properly and that it's what they have specified and that's not always the case.

We know that there is a large number of deliveries that are not their sandwich or not their food and that can be a big risk.

MS. FARMER: Very good. Very good. So what I've heard is defining best practices in the last mile and ensuring -- so the concerns around tampering and then (inaudible) concerns around allergens and prevention measures around allergens. Thank you for that.

MS. DAS: So it's time to move on to the third --

MS. FARMER: Alright. Question number three?

MS. DAS: Yes.

MS. FARMER: Alright. Sharmi, how you

feeling?

MS. DAS: Good

MS. FARMER: Okay. The next one is about collaboration. I know you guys are here, this is -- food safety is a noncompetitive environment (inaudible) said that you're all here and sharing. And are there specific collaborations between FDA and industry that would help to ensure the safety (inaudible)?

I know you have thoughts about that. Eric does.

MR. MOORE: Eric Moore with Testo. This is an opportunity I would say is for FDA to be involved with an existing study that NC State is conducting, that is comparing technology-based safety -- food safety management systems to traditional paper-based management systems in food service operations. It doesn't necessarily apply directly currently to e-commerce, but it does directly apply to the retail industry of itself.

MS. FARMER: So is it paper-based (inaudible)?

MR. MOORE: It's a comparative study between a digital food safety management system compared to a paper-based food safety management system.

MS. FARMER: And are you talking about RTI thing that Ben Chapman is doing?

MR. MOORE: RTI isn't involved yet.

MS. FARMER: Okay. Okay.

MR. MOORE: But Ben is. Ben is.

MS. FARMER: Ben is? So this is where utilizing academia to find better systems where (inaudible) more efficient, more validating?

MR. MOORE: Validating the effectiveness of the systems over traditional approaches.

MS. FARMER: Yep. What other collaborations? Glenn has some.

MR. CAULKINS: Yeah. I was just wondering if -- my name is Glenn and I'm with FreshDirect out of New York. We're an e-commerce company entirely.

I'm just wondering if there is opportunity for FDA to go through these type of companies and find out best practices from each because there's things

that we're doing, I think, are best practices and there might be other best practices out there.

You can come up with some sort of a guideline for how you navigate food safety particularly cold chain compliance to the customer. That would be my recommendation.

MS. FARMER: Guidance. You're looking for more guidance. Guidance documents, Glenn? What else do I hear you saying?

UNIDENTIFIED SPEAKER: Glenn, I want to offer a point.

So I'm on the board of the GFSI and maybe there are some third-party associations that can bring up some of the standards and adopt them as best practice, so that's yet another vehicle.

MS. FARMER: So Alex, (inaudible) leverage what already exists?

UNIDENTIFIED SPEAKER: Yes.

MS. FARMER: Don't duplicate. Take the best practices --

UNIDENTIFIED SPEAKER: Yeah, I think it might be a burden to the FDA because we're meeting as industry companies, so unfortunately, it's dominated by large food companies. So maybe there's a different venue for companies that are not, you know, with the same size of revenues.

MS. FARMER: Very good. Collaborations. What do you want to say, what conversations, groups do you want to see, talk to?

MR. HARTTEN: Hi, Jim Hartten with Wilson Sonsini. I'm with the food and drug practice.

One thing in collaboration, you know, I think about existing FDA guidance that could be improved, expanded and other guidance developed that would expand this. You know, one guidance area -- expand it to taking new approaches.

But what I'm thinking about is, you know, FDA has their defect action levels guidance, basic guidance for foods and contamination levels. That may be an area where FDA could -- because that's an older guidance, update guidance like that, work with industry to get sort of their points of view and

perspectives on some of those defect action levels because I think if that's up to date and expanded, that's a good tool for industry to have.

MS. FARMER: Okay. (Inaudible). Is there anything else that you were thinking or other guidance areas, anything specific to defect action levels (inaudible)?

MR. HARTTEN: Yeah, I mentioned that just because there was an older guidance that has been useful to us over the years and perhaps to a lot of other people.

And, you know, that's -- there may be other guidances, food safety guidances of that type. I'm not familiar with all of them off the top of my head, but other guidances that could be updated with participation from industry and new guidances developed to, you know, facilitate the growing food technology that people are starting to implement.

MS. FARMER: Very good. So collaboration is more of an industry, in looking at the guidance that we have that might be something or developing new guidance.

MS. MARKULIN: Hi, Kris Markulin with Lidl Grocery Stores. I also think there needs to be some kind of training consideration. Typically we require, according to CFB, food manager training in a retail setting, and then those that work under them are supervised. But at least for deliveries, these people are working independently and do they have any training or are we requiring training of them?

So I think there should be some mandatory training.

MS. FARMER: Specifically on the delivery?
MS. MARKULIN: Food handling, delivery in general.

MS. FARMER: Yeah. Training for that specific segment.

UNIDENTIFIED SPEAKER: Just to provide some perspective on that.

The Conference for Food Protection will be having a meeting in 2020 where there will be a report out of a four-year working group and a large portion

of the work that has been done is focused specifically in that area on what kind of training should these people have and what kind of training do they not need.

And it's sort of specific as to what their role and coming into direct contact with food is, so.

MS. FARMER: So Eric, are you on that work

group?

UNIDENTIFIED SPEAKER: I am.

MS. FARMER: The direct to consumer work

group?

UNIDENTIFIED SPEAKER: Yes.

MS. FARMER: So where would somebody find that information? That's interesting.

UNIDENTIFIED SPEAKER: It's not available for public consumption yet. I believe there is a draft from the first two years work available on the Conference for Food Protection website.

During the next Conference for Food Protection, if the guidelines are accepted, they would then be subsequently published sometime later in 2020.

MS. FARMER: Very good. Do you want to add anything about that with CFB? Direct to consumer.

UNIDENTIFIED SPEAKER: And the website is FoodProtect.org.

MR. VON FRIEDEBURG: Arnim von Friedeburg, German Foods. It would be helpful, not just from a collaboration, but also from a study point of view is to identify weather patterns and weather inferences, particularly in the United States what that might do to food safety.

Because we're having increasing outrageous weather patterns in the summer and the long-term trends that will impact the food delivery, could be really helpful if FDA could identify that, put studies out there so that anybody, you know -- and I'm speaking for smaller company, can actually look for what to do when temperatures go beyond or going through storms and so forth, what happens if.

So all these adverse weather events have a huge impact on e-commerce now and it's probably going to increase.

MS. FARMER: Weather events (inaudible) saw something today about predictive analytics, too, that we could be using that.

MS. DAS: We have about a minute left, so we can get another question in.

MS. FARMER: Collaboration.

MR. BUCHAN: Good morning everybody, Patrick from Territory Foods. I'd love to see if there could be a study done with the FDA in finding -- for example, we work with a lot of local chefs in food production. Some of them work in small collaborative kitchens and shared spaces. I'd love to see the impact on the share of spaces because we can drive food safety initiatives all day for some of our chefs, but if the site itself doesn't have a good idea as to what a good practice should look like, how are they controlling the potential impact of bad players in that kitchen and how that could impact the food of the people doing the right thing in the operation.

MS. FARMER: So shared kitchens. Yes. I know (inaudible) state regulators.

UNIDENTIFIED SPEAKER: So is that research on shared kitchens?

MR. BUCHAN: Yes. Yes. More of a research into the impact of how they affect just the space as a whole.

MS. FARMER: Alright. Very good. Alright. Let's move to the fourth question.

What are the most significant actions that, and I'm going to call this the food safety community, the FDA, states, territories, local industry, local agencies, and industry could take to change practices in the retail food industry that present risk to public health? So what can we do, it's all about behavior change or (inaudible) behavior, or educating around behavior on the risks? What do you feel that would be significant actions that any of us in the food safety community could do to impact?

MR. CAULKINS: Glenn Caulkins again from FreshDirect. I would think the first thing that would have to -- would need to be done is to make sure that when you have different inspectors come through the

course of a year that the message is consistent and you start with that. I found that that's not the case.

There's different levels of knowledge and interpretation of what they're looking at, so to me that's a major roadblock if you're talking about moving the bar. You have to make sure that the auditors actually are consistent.

MS. FARMER: So what I think I heard is calibration of inspectors, the uniformity of how they're approaching risk and so providing education around that. Very good, Glenn.

UNIDENTIFIED SPEAKER: Actually, I'm going to provide the other side of the coin that manufacturers stop challenging as much the finding from inspectors, so that is also component of it.

MS. FARMER: Did you say manufacturers stop (inaudible)?

UNIDENTIFIED SPEAKER: Or be more selective when they challenge the findings from the inspectors.

MS. FARMER: Oh, okay.

UNIDENTIFIED SPEAKER: If I can say it in a better way.

MS. FARMER: So really decide --

UNIDENTIFIED SPEAKER: Yeah, I mean basically that ties in with the food safety culture, so we drive that. We, meaning we professionals, but the real game changer is when your CEO embraces --

MS. FARMER: Right. So really looking at the risk and what to do, focus on when it comes to risk.

MR. BROOKS: Ozzie again from RaceTrac. I think what I see a lot is being very subjective and not more of a teachable approach.

If you don't know it, right, and the regulatory comes into your store or come into your manufacturing plant, don't just point them to the reference, but kind of like teach them. Because when you leave, they'll still going to do it bad and that food can still cause a foodborne illness.

So it's more of a partnership I would like to see and a teachable, a coaching moment, than more of hey, this is wrong, go research it yourself and when

we come back, if it's not fixed, then we'll take action.

MS. FARMER: So great, Ozzie. I hear you saying you want the inspector to move out of an inspector and more a facilitator of the food safety culture, a coach. That's what you want to see.

MR. BROOKS: Yes. Can it be both? You know, (inaudible) both.

MS. FARMER: It can be both.

MR. BROOKS: Because if we don't have these (inaudible) doesn't get it done.

What do you got, Glenda?

MS. LEWIS: (Inaudible). Consistency of the inspector or the auditor. Have knowledge (inaudible). Industry decrease the challenges to regulatory (inaudible). And educate, partner and coach when (inaudible).

MS. NOLL: Katia from Subway again. So there's one bullet point on the handouts that I thought was really key which was expanding the food code to require retail establishments to have food safety management systems. I think that's something that we struggle with. There's no consistency between states and different municipalities and local health departments.

And we try to have a single unified approach and we have restaurants in every single state and territory, but it would be fantastically helpful if we could have sort of a single government regulation, just like we had for FSMA from a manufacturing background, for retail establishments. Because right now, there is, I think, a mentality that it's not an obligation, but more of a recommendation and that mindset needs to shift because that's where we're losing control over food safety is at the operator level.

MS. FARMER: Yeah. So requiring that a food safety management system (inaudible) uniformity across the board state-to-state is what you're saying (inaudible) and you're dealing with different (inaudible) and different requirements.

MS. BRUNTJEN: Jacqueline with the Dennis

Group again. What we see a lot is whenever these large companies are coming through the line, either they're doing a greenfield and it's a huge capital investment. When they come to the value engineering phase, technology, and anything extra, we're already doing paper copies, why would we do it in duplicate? So we see that get value engineered out quite a bit.

So I mean it goes without saying, but, you know, the Canadian government has done a really good job with offering incentives, rebates, financing programs especially with zero percent interests for food safety technology, so that would be a very helpful avenue to implement to ensure that people could at least apply for them or make it a little more approachable.

MS. FARMER: Interesting. So fiscal incentives. That's great.

MS. BRUNTJEN: Traceability technology, it gets value engineered out rather quickly.

MS. MARKULIN: Kris Markulin with Lidl Grocery Stores again. I just wanted to second what you said about the vast differences between jurisdictional requirements.

A lot of my time is spent catering to individual jurisdictions with their different nuances of their codes and it would be extremely helpful for large chains who operate nationwide to have -- to just fall under one code. And right now, I mean we've got some states that don't even inspect us and some that will come in multiple --

MS. FARMER: (Inaudible) with that? How (inaudible)? How do you think -- what do you think will be helpful (inaudible) playing field (inaudible)?

MS. MARKULIN: It is state by state and I'm not sure that industry can fix that. That would have to be in and of something that would come from the government, but I don't know, I don't have the answer.

I just know it's a lot of -- there are a lot of hours spent on what I view as unnecessary nuances in just different codes as opposed to having one national retail standard.

We have a national standard for processors,

but in retail, it's, you know, we're hiring people just to keep up with the differences in the different local jurisdictions.

UNIDENTIFIED SPEAKER: So just to your question, I think that clearly there's at least a couple people that think there's a need and you would probably have a lot of willingness from people within the retail industry if you wanted to have a working group or some kind of focus group to help give you feedback on where we see those gaps and where we see the challenges occurring, which states are better than others, which codes are laxer than others.

I mean there's such wide variety in terms of even which year of the food code states have adopted. You have some that are over a decade behind the version. So I think there's a lot of people that would be willing to give you specifics that might help set what that retail standard could be.

MS. FARMER: So establish a work group to talk about differentiation across (inaudible).

MR. BUCHAN: Once more, Patrick with Territory Foods. I would love to see some implementation, I know we've talked about this, but on the requirement of education for those that are that final last mile transportation of direct to consumer food from a restaurant to the consumer. A lot of the individuals that work for your Uber Eats or even some of our delivery drivers, don't have that even fundamental food safety knowledge. So that when you go in and you are the regulator or you are the educator, sometimes they're just looking at you like what do you mean? This isn't even within my wheelhouse, when in actuality, it most certainly is, and that education would be very important for them.

MS. FARMER: Yes. Thank you. We've talked about that, education for last mile. And then coming up with a standard for that, what would that be, what would that look like?

MR. VON FRIEDEBURG: Arnim von Friedeburg, CMA. What I already told you in person is, my hope is to keep international standards harmonized to -- that FDA communicates with primarily Europe and from my

point of interest, but with the rest of world, to take best practices from other countries and not create trade barriers with new technologies or new ways to implement that.

MS. FARMER: That's very helpful. Don't create trade barriers. Is there one last burning thing?

MS. BOARD: Elizabeth Board from GS1 again. I just want to add on the point of state harmonization. It's really hard to work at the state level and I've done that on legislation before. You have states that are not very regulated and to get them to change when you have a lot of small operators who don't want to do it. So it would be really helpful if the FDA came out with a scorecard and with, you know, the minimum requirements that every state should have at least and really put the pressure on the state legislators because it's really hard for industry to do that because the small players in the market are not going to ever want more legislation. That's the way it works in the US today.

MS. FARMER: Yeah. Thank you, Elizabeth.

MS. DAS: Thank you.

MS. FARMER: (Inaudible) scorecard be?

MS. BROAD: It would be ranking states, for instance, (inaudible) education, it would be an FDA scorecard (inaudible) state level.

MR. MOORE: So, just -- this is Eric with Testo again. Sorry to -- taking over here, but the food code is a minimum, right?

So if you establish the most stringent expectations at a state, local or territorial level within your operating environment, you are going to exceed all other regulatory expectations. I've done that for four different companies. It will make your life a lot easier.

It might aggravate some individuals that have lesser restrictions, but it will at least enable you to measure apples to apples against Ohio, North Carolina, Florida, Georgia as opposed to trying to create solutions or resources for all of those. Because it is impossible. There is over 3,000

different codes that you would need to try and understand. It's impossible.

MS. FARMER: Glenda knows our food code, so she's going to share.

MS. LEWIS: Just a point in the code. Thank you for your comment. We appreciate that.

Actually, we put a lot of rigor into the code and so we kind of think of it as not so much as the minimum, but more the higher standard. And you're correct, if you meet that standard, you will meet others, absolutely.

But, you can more stringent than the code and so that creates some difficulties as well. Yeah, so good, we're on the same page.

MS. FARMER: Right. So you have the option of (inaudible) more stringent.

So I want to thank you guys all for the feedback that you provided. Some of the things -- you had a question?

UNIDENTIFIED SPEAKER: Set standards for industry for consistency and I thought we should have an example. That was your comment.

UNIDENTIFIED SPEAKER: All I was trying to say is that in cases where something goes wrong or there is an issue, that there should be certain standards like there's always a 1-800 number involved, 24/7, there's always someone who's going to pick up (inaudible), there's very clear messaging on the websites or whatever if you find this. Or, this is the expectation when it arrives it shouldn't be leaking, it shouldn't -- you know, that type of thing.

And because what we're seeing is consumers can go to different food delivery companies and see differences on the websites or the messaging (inaudible) inside the boxes of what they should do (inaudible). Is if there's a way to set a standard for all to have the same expectations.

MS. FARMER: Standards around consumer complaints or how to deal with product received out of temperature, or any concerns with the product.

UNIDENTIFIED SPEAKER: Yeah. And also who has jurisdiction.

MS. FARMER: There you go. There's a big one.

UNIDENTIFIED SPEAKER: (Inaudible) call the

FDA.

MS. FARMER: Okay. Let's put that in caps. Who has jurisdiction?

Very good. Yes, so, you know, we talked about four areas, significant actions that FDA can take, research that can be done, the significant actions.

I think we all recognize that there are standards out there that we should -- why -- let's not reinvent. So let's look at best practices. Let's figure out what already exists and how do we do that. We're going to that by leveraging all folks in the food safety community. That's going to industry, states, locals, tribes, and territories.

Research, we already know that there is some research that exists. We talked about the CFP direct to consumer work group that Eric is on and some of the research that's done there. But there are some additional areas and what I heard was around, let's find ways where can be more transparent with the data and more consistent

So we talked about reusable containers as an option for research.

Laboratories, let's look at methods, maybe test kits or other methods that could be used more quickly, give us results more quickly.

Tamper resistant concerns, I heard that. Let's find some best practices around that as well.

Collaborations with universities, large organizations such as GSFI. I could hear repeatedly find best practices, don't reinvent, partner with academia.

And I don't think that -- did we have anybody from academia in this group today? So that was a missing group.

And then significant actions that can be made towards uniformity around inspectors and training. They are educating as we regulate. And looking at the regulation and trying to find ways to get a more

standardized regulation across the country is what I heard.

So I want to thank you for the time that you spent sharing these. We've documented all that.

MaryLee is going to help us with all that.

I also want to say please put your written comments into the docket because we are going to be looking at those.

So as a result of this meeting, we're going to do this session again, so you don't need to come back to this session if you don't want to because it's going to be same drill, so you might want to pick another one. But we're going to take the feedback that you guys gave us. Then, we're going to go get the information from the public docket that you guys are going to provide. So real excited to see that. Then, we'll come back as an FDA group and talk about what the findings were. You know, put them in buckets. What are we seeing and that will help define what this blueprint is.

So, as was told earlier, Frank Yiannas said that his expectation is that our blueprint will be issued around -- did he say January?

UNIDENTIFIED SPEAKER: Early in 2020.

MS. FARMER: Early 2020. Early, I like that because that gives a lot of flexibility.

So we're going to go to lunch now and we'll come back at 12:30. We'll start promptly at 12:30 and we'll meet in that main ballroom that we started out in and then so be thinking about at lunch, what is the second breakout session that I want to go to.

So thank you for your time. I really appreciate it.

(Whereupon, the breakout session concluded.)