

U.S. Food and Drug Administration (FDA)

New Era of Smarter Food Safety Summit on E-Commerce:
Ensuring the Safety of Foods Ordered Online and
Delivered Directly to Consumers

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P R O C E E D I N G S

MICHAEL KAWCZYNSKI: Good morning and welcome to the New Era of Smarter Food Safety Summit on E-Commerce, Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers.

This is day two of our three-day virtual public meeting, so one, thank you for joining us, and I'm Mike Kawczynski and I will be one of your co-moderators today.

So, a couple little things. My job is to make sure that we are going to keep this thing rolling and everyone once in a while, you know, we do want you, though, to interact with us. So, I have my role. Here is your role.

We do really want you to submit written comments. There's a link up there on the screen right now, but for those of you that are watching us on

YouTube, right below in the description, if you expand the description, you will see this same link where you can also submit written comments to us, and we're very excited about those.

Additionally, we have a hashtag which is #smarterfoodsafety, so please if you're going to share this information on social media, please feel free to use that hashtag.

As far as the Q and A sessions today, we will have Q and A sessions. What we do ask, and we do have a mailbox especially set up for those, smarterfoodsafety@fda.hhs.gov; however, we want you to wait for those questions until we get to those sections. When we do get to those formal Q and A sessions, we will put this link back up there so you can submit those questions. We really do encourage those questions and we will be covering them throughout the meeting.

So, finally, I want to talk about you, the people that are participating. We had great attendance even yesterday. We're close to, you know, I think three or -- 3,000-plus that have registered to this event, and even yesterday we had more than 5,000

people participate, but for the industry, it's very exciting to see all the different industries that are participating today.

But even more importantly is how broad we are reaching the entire world. This event has already had 44 countries participate, and it's even growing beyond that with the replays as well. So, thank you, all of you who took the time to register and come to today's meeting. We can't thank you enough.

With that being said, let's get this show started, and I am going to hand it off to my colleague, Kari Barrett. Kari, are you there?

KARI BARRETT: I am here, Michael. Thank you. And what a pleasure to join you and all of our participants again today. As noted, my name is Kari Barrett and I am serving as the co-moderator along with Michael, and we have another great line-up of panelists and speakers for the day, and we really are pleased that all of you are back joining us for this important event and welcome any new folks as well.

So, as a reminder, the purpose of the summit is to help the FDA and interested stakeholders

improve our collective understanding of food safety consideration as we look at how foods are sold through business-to-consumer e-commerce models across the U.S. and globally.

And just a couple of quick reminders. As noted yesterday on our meeting website at FDA, there is the full meeting agenda. There are all the biographies for all the speakers. We also have a short background document that we think will be helpful for you as you hear the discussions during the summit, and as you reflect and consider post-summit as you draft your written comments that you'll be submitting to the docket.

Our meeting is being recorded. It's -- and it's also being transcribed. The recording and transcription will be posted to the website as well, and that does take a little bit of time so keep an eye out for it.

I also want to note on our website we have a one-pager reference on how to comment, and it just has the docket number and the date that the comments are due, so that may be useful to you as well.

But at this point in the program, I want to turn it over now to our host, Andreas Keller> he is the Director of Multi-Commodity Foods, Office of Food Safety, at our FDA Center for Food Safety and Applied Nutrition. So, welcome back Andreas.

ANDREAS KELLER: Thank you, Kari, and good morning, good afternoon, or good evening to our audience around the globe. Thank you very much for participating in this exciting day two yet to come with a loaded agency.

Yesterday, we heard important themes of how industry is advancing and implementing food safety programs, standards of care, and the challenges they face.

We also heard from consumer advocate groups and universities regarding their points of view and the areas they feel need to be addressed and improved upon, and we closed with a public comments session wherein a diverse group of organizations offered their views on how best to ensure the safety and proper labeling of foods sold in e-commerce as well as the importance of coordination or regulatory partners and

existing regulatory frameworks as we consider additional action in the e-commerce arena.

(Indiscernible) commended FDA's initiative and felt that the dialogue we are having at this summit is necessary and they offered to work and collaborate with us to build stronger and more effective food safety B to C e-commerce programs.

As noted previously, collaboration is a key theme of the summit, and today we will -- we will focus on how we work together in partnership and learn from each other as federal, state, and local government leaders to ensure the safety of food and e-commerce.

These leaders include the next two speakers who it is my pleasure to introduce to you. Our first speaker this morning is Dr. Susan Mayne. Dr. Mayne is the Director for the Center for Food Safety and Applied Nutrition, also known as CFSAN at the FDA. In this position, Dr. Mayne leads the center's development of implementation programs and policies related to the composition, quality, safety, and labeling of foods, food and color additives, and cosmetics.

CFSAN also receives diet and health

initiatives which include fostering development of healthier foods and ensuring that consumers have access to accurate and useful information to make healthy (indiscernible).

An internationally recognized public health leader and scientist, Dr. Mayne came to FDA from Yale University where she was the (indiscernible) Winslow Professor of Epidemiology and the Associate Director of the Yale Comprehensive Cancer Center.

Following Dr. Mayne, we will hear from Dr. Steven Solomon. Dr. Solomon is the Director of the FDA's Center for Veterinary Medicine, also known as CVM. He was appointed to this role in January 2017. He's a former private practice veterinarian and career public health regulatory official who has worked to protect human and animal health at the FDA for more than 30 years.

He begins a versatile background -- I'm sorry -- he brings a versatile background to this leadership role at CVM with experience in policy, public health, regulatory affairs, enforcement, and of course, veterinary medicine.

Dr. Solomon is a champion of the one health approach to addressing public health problems which recognizes the inter-connection between the health of people, animals, plants, and their shared environment.

I will now turn the program over to Dr. Mayne and Dr. Solomon. Thank you very much.

SUSAN MAYNE: Thank you, and thanks to all of you for joining us on the second day of our New Era Summit on E-Commerce.

As mentioned earlier, we have a very full day ahead of what promises to be robust discussion around regulatory frameworks and oversight of business-to-consumer e-commerce.

As we have seen and as highlighted in the discussions yesterday, industry has been developing new and innovative ways to produce and distribute food, development which has been accelerated to address the needs arising from the pandemic.

We, along with our partners, are all striving to prepare and respond to these new business models as well as innovations in novel ingredients, new

foods, and new food production systems.

We are here at this summit to share our current understanding and enhance our knowledge of possible food safety risks related to these new business models. We want to find answers to questions that can help to address potential food safety vulnerabilities.

What are the new approaches that FDA can take with respect to the business-to-consumer e-commerce models? How can we adapt our regulatory frameworks and oversight to help ensure the safety of foods produced, manufactured, sold, and delivered through these new innovative ways?

With these new models, the landscape is changing. New players are coming to the table. This includes traditional producers, manufacturers, and distributors now working directly with consumers, sellers of other goods now entering the food space, and grocery stores and third-party food delivery companies reaching consumers on their doorstep.

We need to inform and educate these groups on the importance of food safety issues including temperature control, cross-contamination, and other

safety issues. We also need to educate consumers directly about the safe handling of food delivered to their home.

Another consideration is labeling of these foods produced, manufactured, and sold through business consumer e-commerce business models. For example, are consumers presented with labeling for packaged foods purchased online that's different from labeling for these foods more generally? As always, FDA wants to ensure that packaged food labels can help consumers make informed food choices related to nutrition and food safety, including about important ingredients such as allergens and gluten.

We are building on the work we have already been doing to create a stronger, modernized food safety regulatory framework, one that uses new approaches in technologies to enhance our abilities to protect the food supply.

To address the growing complexity of our food system, our work needs to be based in the strongest scientific and regulatory expertise. This is at the root of our public health mission and the people of FDA

and our stakeholders are critical to future success.

We know we can't do this alone. We need collaboration among FDA food safety experts and a broad array of stakeholders including the food industry, trade associations, federal, state, local, and tribal regulatory partners, our regulatory counterparts in other nations, consumer and public health organizations, technology firms, academia, and of course consumers themselves.

This collaboration will enhance our knowledge and understanding of new business models and the opportunities as well as challenges and gaps that need to be addressed with regulatory approaches.

By bringing these diverse groups together, we can implement improved regulatory frameworks and oversight and find better solutions to protect public health. Together, we can advance food safety and improve the quality of life for consumers in this country and all over the world. We can work to create a future where consumers can have many options and great flexibility in how they obtain food, both for personal preferences and in response to unexpected

events such as the current pandemic.

Thank you for your time today. I will now turn it over to Dr. Steve Solomon, Director of FDA Center for Veterinary Medicine, to provide some additional remarks.

STEVE SOLOMON: Good morning, everyone. I'm Steve Solomon, Director of FDA Center for Veterinary Medicine. I'm pleased to have the opportunity to speak at the summit today as we discuss and collect more information on how FDA can enhance our knowledge and understanding of the e-commerce landscape and how we can continue to modernize our human and animal food safety system to better protect consumers, including our pets.

I know many of you attending today will not be as familiar with the Center for Veterinary Medicine as you are with our human food side of health. To give you a very brief background, CVM protects and promotes the health of humans and animals by ensuring the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness of animal drugs.

We recognize that business-to-consumer e-

commerce is growing in the animal food market where pet companies and online private brands are selling their pet food products directly to the end consumer throughout online platforms.

The pandemic is certainly responsible for growth in online demand for pet foods, but in what I consider a substantial silver lining, the pandemic has also brought about more pet adoptions and increasing pet ownership this past year and a half.

According to market research from Package Facts, online pet product sales now make up 30 percent of the total pet market. Notably, this number has grown from just an 8 percent online market share in 2015.

Another market research firm projects pet products and other pet products will account for 15.5 billion worth of e-commerce sales in the United States in 2025.

Given this rapid evolution of animal food e-business models and activities, we're interested in working with our human food regulatory and public health colleagues, state partners, and other stakeholders to build a dialogue on how we as food safety regulators can

identify food safety issues unique to e-commerce models and develop tools to address them.

FDA regulates animal food including pet food and treats under the Food, Drug, and Cosmetic Act in a manner similar to how we regulate human food. The law requires that all food which includes both human and animal food be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled.

From retail food establishments like grocery stores, they sell both human food and pet food online and they may use third-party delivery services to deliver that food to consumers.

For example, this year Door Dash began working with pet retailers like PetSmart. You can now Door Dash food for yourself and Door Dash food for your pet.

(Indiscernible) native brands of pet food are on the rise and operate primarily online. Some specialize in niche pet foods, pet treats, and made-to-order diets.

Bark Box is an example of a monthly

subscription service that delivers a box of pet treats, chews, and toys to your home. Similar to human food, not all pet products are shelf stable and some customers are opting for fresh or frozen pet foods. This adds more complexity to the transportation and delivery of these products.

With the variety and growth of retail e-commerce models, we're interested in hearing from online retailers and other stakeholders to better understand third-party seller models. In the event of a recall, this information can help us develop new methods to ensure recalled products information gets to customers and distributors to get these products removed promptly from the market to keep our pets safer.

The FDA Food Safety Modernization Act, or FSMA, and its implementing regulations, ensure safety of both the human food and the animal food supply.

However, there are some key differences in the regulation of the supply chains when we talk about the retail area between the human and animal supply chains.

The FDA Food Code, which guides human food safety at the retail level, doesn't apply to animal

food. There isn't a corresponding animal food code, so states and local jurisdictions have to -- can't use that to regulate retail animal food establishments.

Almost every state has a program responsible for regulating animal food under the laws and rules of their specific jurisdictions. These are usually associated with the state's Department of Agriculture.

What does this mean in practice? It means that animal food retail businesses, including those that use business-to-consumer e-commerce business models, may not be subject to the same FDA or state requirement as a human food facility with a similar business model.

The regulatory framework differences between human and animal foods will require further review by FDA and our stakeholders together as the retail and business-to-consumer e-commerce market continues to expand to attract a wider customer base with a greater variety of products.

We look forward to listening to the speakers during the summit and receiving input from our

stakeholders in the public that will improve our understanding of human and animal food sold through business-to-consumer e-commerce models.

We plan to use this knowledge to modernize and advance our approaches to ensuring a safe pet food supply. Thank you for your attention and let me turn it back to our summit moderator, Kari Barrett.

KARI BARRETT: What a pleasure to hear from Doctors Mayne and Solomon as leaders of our FDA CFSAN and CVM centers respectively. Now, at this time we're going to turn to our first state and local government representative panel with Laurie Farmer as our moderator. So, take it away, Laurie.

LAURIE FARMER: Good morning. Thank you, Kari. My name is Laurie Farmer and I'll be moderating today's panel titled State and Local Perspectives on E-Commerce and Food Safety, Regulatory Framework and Oversight.

We met briefly yesterday at the end of the day. I am the FDA Director of the Office of State Cooperative Programs where I'm responsible for FDA's national field operations for retail food protection,

Grade A milk and shellfish sanitation.

The FDA field specialists are the face of the agency to support these regulatory jurisdictions. Since this is the first panel on day two of the summit, a reminder. The purpose of the summit is to engage with stakeholders and invite input on issues. We really want to hear from you. We're talking about the new era for smarter food safety blueprint element 3.1, new business models in retail modernization.

I encourage all of you viewing to actively think about comments you want to submit to the docket as well as questions to the panelists during this meeting. We intend to use information resulting from the public meeting to determine what action, if any, should be taken to help ensure the safe production and delivery of food sold through new e-commerce business models.

The retail stakeholder community is immense, and for FDA to be effective, we will need to encourage stakeholders now and in the future to engage in this topic.

Today, we are fortunate enough to have

three very accomplished panel members from state and local regulatory agencies. I appreciate the time our panel members took to prepare and their willingness to share their knowledge with us today.

Our panelists for this session are Galen Baxter, Director, Environmental Health at Fulton County, Georgia Board of Health; Heather Buonomo, Director of Environmental Health, Department of Environmental Health and Quality, County of San Diego, and she is also representing the California Conference of Directors of Environmental Health; and Cathy Feeney, Chief of the Center for Food Protection, Rhode Island Department of Health.

Welcome panelists. As background, core element 3 of the blueprint looks to address how to protect foods from contamination as new business models emerge, a change to meet the needs of the modern consumer. This panel is about where the rubber meets the road.

We will discuss together the current regulatory structures that apply to business-to-consumer e-commerce, the regulatory gaps and challenges

identified by panelists, approaches to overcome the gaps and barriers, and defining a path forward to continue to advance the public health in the e-commerce area.

We're going to start with a registrant's question, because it sets the stage for the rest of the panel. For the first question, I will ask that each of you individually describe your existing state and local regulatory food safety structure, including how you regulate business-to-consumer e-commerce.

So, let's start with Cathy.

CATHY FEENEY: Thank you very much, Laurie. It's a pleasure to be here. So, in Rhode Island, we have a centralized public health structure. We don't have any locals. We have Rhode Island Department of Health, and within the Rhode Island Department of Health we have the Center for Food Protection, and we're responsible for all food sold or served to the public in Rhode Island, so we do retail foods and manufactured foods.

For retail, we've adopted the 2017 FDA Food Code and the 2019 supplement for manufactured. We have regulations equivalent to the Code of Federal

Regulations.

Thank you.

LAURIE FARMER: So, this model is one state agency covering all food safety, all categories of retail and manufactured food. Thanks, Cathy.

Galen, how does this work in Georgia?

GALEN BAXTER: In Georgia, we actually have two agencies that are responsible for the oversight of food safety, the Georgia Department of Public Health through the local health departments regulate the food service establishments, so your restaurants, your mobile food service operations, your catering, et cetera.

And then our sister agency is the Georgia Department of Agriculture, and they handle the food sales side, so your grocery stores, convenience stores, and they also handle the manufacturing side of food safety.

In Georgia, we currently are operating under a version of the 2013 FDA food code, and at this time, we don't have any specific regulations that are specific to third-party delivery companies.

LAURIE FARMER: Thanks, Galen. So,

Georgia is both health and ag at the state level and restaurant inspections are conducted by local health departments, environmental health specialists.

So, let's move on to Heather. How does this work in California?

HEATHER BUONOMO: Hi. Good morning, everyone. Well, good morning from California that is, anyway.

In California, it's a little bit of a mix of what both Cathy and Galen said. We have for retail food service such as restaurants and mobile food, that is handled by our local public health jurisdictions, and then the California Department of Public Health, the state, handles wholesale processing and manufacturing for -- so, that would include more of the e-commerce at the higher level.

And then I did want to mention also just as it relates to e-commerce in 2021 it -- I should back up -- in California, we're on the California Retail Food Code. We're not on the model food code, and in 2021 we did have a bill that became effective, AB-3336, that introduced some regulations into our retail food code

for third-party food delivery service, so just starting to touch on some e-commerce there in our local food code.

LAURIE FARMER: So, Heather, why is it that California has so many innovative things? Can you share with us more about this bill that you just talked about?

HEATHER BUONOMO: Yeah, so AB-3336 really was the first attempt to bring some e-commerce and specifically third-party food delivery platforms under regulation. They're not under other regulations here in the state of California, and there is a lot of concerns expressed from the public, from our restaurants just with the food safety concerns once that food leaves the food facility, the permitted food facility, whether it's manufacturer or the restaurant.

And so, the goal was to just introduce some standard food safety elements, and what the bill ended up as is having requirements for no tampering with the food and it's nothing earth-shattering. It's really in the form of a sticker that seals the food package before it goes out the door that makes sure that nobody

is opening it up before it gets to the consumer.

The bill also included some requirements for the transporter, the third-party food delivery transporter, to have a clean and sanitary area for that food to be transferred in and to hold that food under property temperatures during that transfer.

LAURIE FARMER: So, what a great start. And how do you manage compliance and enforcement of that bill?

HEATHER BUONOMO: That's a challenge. Yeah, so often times our inspectors are not there at the restaurant when the food is being picked up and we don't have visibility or access to those third-party food delivery platform drivers, and so, our enforcement and compliance is really working with the restaurants to have them be set up for success, you know, educating them, making sure that that food is in different containers that's going to hold it properly as it goes out the door, making sure that they are using those tamper-resistant stickers so that the food can't be touched, and just as much as we can educating at any opportunity on the food safety items.

LAURIE FARMER: Thank you for that. So, now that we've really set the ground work, let's having more of a conversation among the panelists. Does the existing regulatory structure suffice to regulate foods produced or sold through e-commerce? What are your thoughts?

CATHY FEENEY: So, if you want to start with Rhode Island, I see that there's a big gap with e-commerce and that the regulations don't cover the delivery of the food, so we don't really address the third-party vendors that are actually delivering the food to the consumer and we don't really have a way to regulate food that's being sold online or even interstate.

So, there might be some lack of food safety oversight during those deliveries, and I think what happens is maybe the food businesses, hand off the food assuming that it's the driver's responsibility, you know, to make sure the food is kept safe when they might not have that expertise.

LAURIE FARMER: I agree --

CATHY FEENEY: And you know, after

listening to yesterday, I see that there is no one model for direct-to-consumer delivery, there's all sorts of different models, but I see that as kind of a common gap in the system.

HEATHER BUONOMO: And I would totally agree with Cathy. I think you're definitely right here. In my opinion, it doesn't quite go far enough. In California, as you mentioned, Laurie, AB-3336 was a great start, but it's really just a start and an introduction to more work that needs to be done.

I would love to see required food handler training for the third-party food delivery platforms, I would love to see more clear temperature control added in for that food delivery, and I'd also like to see delivery zones being set, you know, how far can that food travel and still be safe? How far is it traveling and being held at safe temperatures?

And then even just from a food quality perspective, how long can that travel -- that food travel before it's losing some of those quality standards that our partners in the restaurant industry want to maintain?

GALEN BAXTER: And you know, this is something that might be helpful where we could get, I don't know, some kind of cooperation with some of the social media platforms that advertise where people are selling food online, where maybe if they could flag the facilities that are actually permitted and maybe have some kind of link or way that consumers can go and check the food safety scores, that way they know when they're making these orders that this is a valid, permitted establishment that they're ordering from.

LAURIE FARMER: And what about licensing and permitting? You're talking about that. In this space, how does that work?

CATHY FEENEY: So, for Rhode Island, I see our biggest challenge is the unlicensed food businesses. Many are not using the commercial setting. They might be operating out of their homes. They might not have adequate equipment and space to do it safely, and they do not get licensed with us, and we probably won't find out about them until we get a complaint.

And you know, they might be selling online. Normally our inspectors will see a brick-and-

mortar establishment and they'll know if it's licensed or not, but they're not seeing that if it's out of a non-commercial setting.

So, sometimes it's catch as you can, and usually it's based on a complaint. But we see that as a major challenge, and that we see as also a direct result of the pandemic where more and more people were getting creative and starting to operate out of their homes.

GALEN BAXTER: And some of the challenges that we've had with the virtual online ordering platforms or just that model in general referred to commonly as a ghost kitchen or a virtual kitchen or a dark kitchen, they all have all these different names, but you know, here in Georgia at least, we're kind of unique in that all 159 counties operate under the same version of the food rules, and those rules don't allow people to share equipment or space.

So, sometimes when companies come in from other states where this is allowed we have to work with them and explain that this is something that you would have to have individual spaces for these different permit-holders.

So, that's kind of been a challenge for us is just trying to work with them in that aspect.

HEATHER BUONOMO: California is probably one of those states where people come over and give you some problems.

GALEN BAXTER: Yes.

HEATHER BUONOMO: In California we do allow shared kitchen spaces. We have a variety of models, whether it's a multiple-kitchen complex or just multiple people going into kitchens at different hours to use that same equipment and same space, and we really view this as a way to help some of those folks that might be operating in an illegal or unpermitted fashion at home, you know, be able to get into a restaurant or a commercial space that's safer in a more affordable manner.

And so, we're actually trying to promote more of kitchen sharing and some unique and different ways to reimagine how people are getting permitted while using commercial kitchen space to help combat some of the challenges with the unpermitted home cooks.

CATHY FEENEY: So, Heather, I'm glad you

brought that up, because we also allow shared kitchens, commissary-type kitchens. So, one of the things we do with the home kitchen people when we find out about them is try to get them set up in the commissary or use some sort of commercial kitchen, because we do not allow residential kitchens.

GALEN BAXTER: We do have some shared kitchen space for people who are trying to do, like -- a catering business, where it can be controlled with space and time. But you know, for a full-service restaurant, that's where the issue comes in for us.

LAURIE FARMER: In food safety, we're really focused on risk prevention and response, and you guys are starting to talk about the current challenges you're seeking in these models in your jurisdictions, and you know, I wanted us to talk about as regulators what really -- when you think about this, what is really keeping you up at night?

CATHY FEENEY: So, for me, one of the things that keeps me up at night is the unlicensed, unregulated food businesses that might be operating out of their homes that are doing high-risk products and

they might not even realize it.

So, one of the issues we had recently was raw juice. They were making low acid, raw vegetable juices and they were selling them to the public.

And one of the problems was, they were leaving them on doorsteps unrefrigerated because there was no one there to accept the order and it was just being delivered and dropped off. And you know, those are the kinds of things that really make me the most nervous.

LAURIE FARMER: Other things -- big safety risks like that?

HEATHER BUONOMO: I can jump in. I think probably some similar things to Cathy. I've probably been saying this mantra since I was first in the field doing inspections, I won't say how many years ago, but an uneducated food handler is really what keeps me up at night, and that kind of ties back to the unlicensed vendors or operators, because we don't have the opportunity to interface with them and educate them and provide them food safety, knowledge, and information.

In California, there was a bill passed a

couple years ago called Micro-Enterprise Home Kitchen Operations, and it allows for an at-home mini restaurant that can serve up to 60 meals in a week, and this is taking place at home.

But you know, one of the great things about it is for the counties that have adopted it, they now have the ability to interface with those home cooks, make sure there's education. There's required training, you know, food safety manager courses, and the ability to check in, inspect them, and see how they're doing, so I am a big proponent of more education for all of our food handlers.

GALEN BAXTER: And just to kind of add a little bit too that as well, and I agree both with Cathy and Heather on what they brought up as far as serious concerns, but one of the other things that kind of came to our attention regarding these virtual platforms is do the menus all have consumer advisories. if they need that, is the regulator able to follow up and check on those things. Do they have the actual address of where the food is prepared so that in the event that we do have, God forbid an outbreak of some sort, we'll be able

to trace it back to that facility because, a lot of times these virtual brands, there may be multiple brands that are working, that come out of the same kitchen.

The consumer thinks they may be different restaurants, but they're all actually being prepared in the same place. So, just having that ability to do that trace-back, you know, for those type of things and for consumers to be able to find the inspection reports, because we post those scores online and you know, a lot of people like to check those before they make the order.

So, just kind of making sure we can stay up-to-date with that and communicate that to the restaurant owners.

CATHY FEENEY: I also worry about allergen control. With these models, you don't have that direct hand-off from the food preparer to the consumer because, there's an intermediate, somebody delivering the food, so I always get concerned that the consumer doesn't have the opportunity to ask whoever prepared the food if it has certain allergens.

And then compound that with if it's

somebody operating out of a home kitchen, they might not have the space to keep foods with allergens separate from each other so there could be some cross-contact there, and those are the kinds of things that worry me both about residential kitchens and also because there is that indirect transfer of food from the producer to the consumer.

LAURIE FARMER: Cathy, I heard that allergen issue loud and clear yesterday, too, so as a regulator, I think it's really important that you are validating that.

Galen, you're one of our folks that is very involved with the ghost kitchen concept. Can you talk a little more bit about that. As regulators, we like to do our regulator speak, we like to put things in a box and know the risk level and oversight.

So, can you talk a little bit about ghost kitchens and models and why it's important to understand the different models to ensure regulation? What does that look like?

GALEN BAXTER: Sure. Well, like I said again, looking at it from the aspect of being in Georgia

and what our rules are with not sharing equipment and space, we've seen about four different model types so far.

One you could kind of equivocate to like a food court in a mall where it's all in the same building and everybody sort of has their own individual stall, but then we also move into these other concepts where they may be operating out of the same kitchen and a regular, health inspector may not notice what's going on unless they ask some good questions.

And a prime example would be one where you may have an established restaurant that people come in, sit down and eat, just traditionally like you would think of as a restaurant, but then there may be someone who wants to come in and use the equipment and prepare nothing but just for a virtual brand, and the customers out in the dining area would not even know that there's a virtual operation going on essentially where the only place people can order the food is online.

And so, with those two different owners trying to operate in that same kitchen space. That's a model that we wouldn't allow here. Food safety issues,

oversight, sharing of equipment, trace back, that kind of thing.

But then another model that we've seen is one where it seems to be gaining some traction and it -- realistically if it's done correctly, it's no issue here for us, but you may have one building, one kitchen, and several different virtual brands that are owned by different people, and so, they essentially contract with the kitchen workers there to prepare these food items off of their menu based on specific recipe, et cetera, but it's their brand being prepared by someone else.

So, as long as that kitchen has control over the food that's coming in, they place the orders, they can track everything from start to finish, you know, that to us would fit in within our rules and regulations.

But it would be a little concerning if we had different people placing orders to have it delivered to that establishment so you couldn't have that trace-back.

But it has been very interesting and challenging because it seems like in the last few months

we are exposed to these new, different models that are popping up all over the place, so it's always a challenge to try to stay up-to-date on what's going on with that and then find ways to help them operate within our rules and regulations that we have.

HEATHER BUONOMO: I think that's one of the reasons we all love this field-- Constant change and constantly having to think outside of the box and work with industry to find a way to, you know, make their innovation work within our regulations, or when necessary change the regulations if the practice is safe.

GALEN BAXTER: Right. Right.

LAURIE FARMER: I appreciate that comment, Heather, about really trying to support innovation, because we all know the government is going to always be a little bit behind innovation, right?

And so, we're always trying to catch up and see how we can ensure safety from our end. One of the things, Galen, I heard you talking about was, you know, who's responsible for the resources, the staffing, the equipment, the food storage in the facility, so

trying to understand that.

I heard hints of that yesterday. So, you know, the focus is around safety and allowing for innovation but within the rules that we have. So, you know, trying to see different models is what this thing is about. Who is doing what out there and how can we continue to support that.

Are there any food safety issues specific to food delivery models which are utilized in your jurisdiction, you know, really specific to business-to-consumer e-commerce?

CATHY FEENEY: For delivering within Rhode Island, unlike California we don't have drones yet, but we do have things like a boat that actually delivers to boats in a marina and also to boats at moorings, and as long as they can operate it safely, we're okay with it, as long as the food is protected.

This particular boat actually has a commissary associated with it on the island, so they're able to do it safely, and that's really the bottom line for us.

We know people are creative. They're

coming up with all different ideas, whether it be a bicycle, somebody mentioned roller skates, you know, however they want to do it as long as they can do it safely and they can protect the food, and if it needs to be kept under temperature control that they do so.

We're okay with different, you know, modes of transportation basically.

LAURIE FARMER: So, Cathy, what does your boat -- what does your boat guy say when he's out driving around -- It means life with love, and he's Italian, and he pretty much wakes everybody up in the morning. So, all these people are in their boats on vacation and they hear that first thing in the morning, and he goes to boat to boat with coffee, and then around, you know, the afternoon, dinnertime, he brings, like, appetizers and desserts, but he does it safely and he operates out of a commissary, and he's been doing it for many, many years, and he's pretty, like, famous.

HEATHER BUONOMO: That sounds fantastic to me.

CATHY FEENEY: Yeah, well, you know, the boats are on moorings and so they can't really get to

the island without getting in their dinghy and driving there, so it really does serve a purpose. They get hot coffee and all kinds of stuff.

HEATHER BUONOMO: And that's what it's about, right? How can we allow people to be innovative while making sure it's safe. Cathy, you talked about, you know, roller skates, we have those. Bikes, we have those. Drones, we have those. There were pilot cities done in San Diego testing out drone delivery of third-party platform delivery food items checking to see how that food safety works.

And you know, also to kind of go back to your question, so we have a lot of methods. We're also similar to Cathy open to any method of delivery. As long as you can show us how is that going to be safe, how are you mitigating the food safety risk factors for that method of operation. And if we could do it safely, why not do it?

Some of the things that I see our restaurants doing to enhance food safety as they've all changed their models to do so much more food delivery and third-party platform delivery services is

reorganizing kitchens to have an actual staging area for food delivery pick-up that has a hot and cold holding right there, that has all the right types of stickers that they need to send it out the door so it's not going to be tampered with, and I've also seen a lot of folks really redesign and reimagine how and what food they're serving.

So, for example, you know, people may be changing from a quality perspective from fries to chips because those really travel a lot better from a quality perspective but also looking at the safety perspective and switching up the types of containers that they're using that better, you know, hold temperature for foods that they're sending or maybe even modifying their menu to limit it down to just a small, select group of foods that they know are traveling well from a quality and safety perspective.

So, again, really allowing for that innovation but you know, checking the food safety boxes and being open to all of the different modes.

GALEN BAXTER: So, we don't have anything that I'm aware of of any sort of unique delivery aspect,

but one thing that we did see, since we don't have any current regulations for third-party delivery companies, we did see our industry restaurant-side start moving to, you know, look at the contracts that they would make with the third-party deliveries and wording them in such a way where it almost, you know, makes those drivers employees of that establishment, so that gives them a little bit more control over the delivery of their food.

LAURIE FARMER: We all know that the pandemic has created staffing shortages, and we talked about that earlier in one of our prep sessions. What are you seeing as any impact on the industry and food safety as it relates to staffing shortages?

CATHY FEENEY: So, I can start with my -- one of my concerns with the third-party deliveries is inexperienced drivers, because drivers are so hard to come by, and so they might not get the same kind of quality because they're more desperate for help and they need to get somebody to deliver the food, so that's one concern.

And I also see the restaurant industry really, really, trying very, very hard to make it work

with a lot less staff, and I think it's really difficult for them.

That's one of the reasons why we want to really be open to the conversations and innovations. It's because we want to see them succeed, and if it takes doing a different thing like, you know, there was way more take-out during the pandemic, that's when they had to really shift gears, we had restaurants selling groceries and things like that, just so they could survive, and I think that's why, when Heather mentioned a couple of times we want to be open to innovation, we want to help them succeed.

I see like the challenges are unbelievable with the labor shortages and in the restaurant itself trying to prepare food and also, you know, to get people to deliver the food to the consumers.

HEATHER BUONOMO: Yeah, and the same here. Just everybody -- all of our industry reimagining what they're doing, modifying their operations to do as much as they can with less people, and just -- I've seen actually some increased food safety information and

requests for information from our department, requests for us to go speak at different industry groups and associations, because people have a lot of questions.

And when you have that full team, and you know, you maybe have multiple food safety managers that could help and jump in, it's one thing, but when that gets scaled down, I've really seen industry reaching out asking for help, asking for information, how could we do this, what are your thoughts.

I talk a lot about the lemonade out of the COVID lemons that we've brought, and we've just had such tremendous partnership with local industry and our restaurant association to partner and help in situations like this. It's just been fantastic.

GALEN BAXTER: It's been pretty much the same here as well. Just some of the concerns or challenges, like Cathy was mentioning with the labor shortage in the restaurants, and you know, Heather spoke to the same thing.

I've seen restaurants that have had to completely change their hours of operations because they just don't have the staff to manage or they've dropped

down so severely that there may only be one or two people in there.

And again, looking at experience levels and possibility when deliveries are coming in, and just the ability to oversee the operations and the demand for the increased drive-through operations or the online ordering.

So, yeah, I can definitely see where there are challenges across the board with that and how that could lead to food safety issues as well.

CATHY FEENEY: So, one of the things that we've talked about too is to put a plug in for our culinary school, Johnson & Wales University, you know, the concept of having on-call workers.

So, maybe students could fill in some of the gaps, because they just can't do it with the staffing shortages without really, severely either limiting the days they can operate or the menu, you know?

And so, this might be something that they could do to just get them through this. And hopefully things will improve with -- I did hear recently that the

driver situation will not get better and could get worse, and I thought, "Oh, my God, it's not short-lived like I was hoping."

So, there are going to be issues with staffing for a while I think, and so if we can be really creative and help industry, you know, find solutions.

LAURIE FARMER: And I think that's a really important point, Cathy. This is not short-lived. Also, what's not short-lived is this continual increase of people using these platforms to order online.

And so, we're talking about ways that we can support that. You all have -- the last two years have been crazy, right? So, thinking about that, can you share any lessons learned that others can benefit from?

HEATHER BUONOMO: Well, I can start.

I was just going to say for our lessons learned, I think it -- and I'll just continue my torch with education and collaboration, is this year has been crazy and I think that all of us have experienced so many changes, temporary regulations, permanent regulations, modifying how we do illness investigations,

you know, some of our departments being responsible for COVID investigations, some not.

And so, really I think just lessons learned are be flexible, have some grit, and collaborate, you know? Don't be afraid to reach out to other agencies and see what they're doing. Don't be afraid to reach out to industry and ask questions. See how they're adapting to this, engage with them.

We can learn from their practices and they can learn from our food safety knowledge. I think that we're such one big, a little bit dysfunctional, food safety family, and that you know, we all need to just collaborate and rely on each other, and we're so much stronger when we do that.

GALEN BAXTER: And I'd like to piggyback on what Heather said about collaboration, because one of the things that helped us tremendously was not only sitting down talking with the industry to figure out how we can get them to be able to operate within our current rules and regulations, but another side of it, too, was in Fulton County, our biggest city here is Atlanta, obviously, and just sort of that disconnect between

departments, a lot of times when we would get these large ghost kitchen design ideas where they were going to go into an old warehouse, they may present, you know, what they're going to do to the building department as one thing, but then we wouldn't find out about it until later on the back end when, you know, some work may already be done.

So, just that reaching out to the building department to let them know, hey it doesn't say restaurant, you know, on the plans, but any kind of food operations at all, if we could just be in on the beginning part of that, we could save industry tons of headaches down the road if we have an opportunity to at least be able to speak to them on the front end about what they're wanting to do and to make sure that, you know, we have an understanding of what their goal is.

So, that was really helpful for us as far as overcoming some of those challenges.

CATHY FEENEY: One of the lessons that we learned was to really work with our cities and towns to identify the location of some of the unlicensed vendors and then reach out to the unlicensed purveyors and ask

them what they want to do and try to work with them to find something that will work for them.

You know, maybe it's a commissary that's close by. They actually help with marketing, they help with the labels, they teach food safety classes, so you know, if we can hook them up with somebody like that, it really works well for them. They become legitimate, you know, their business grows. We've had that close collaboration with the cities and towns. Of course, Rhode Island's small so it's a little bit easier, but we have 39 cities and towns and that's really who we collaborate mostly with.

The other thing is, we've come up with an interactive website on how to start a food business, so it actually -- and we did it in conjunction with our Department of Business Regulation and also with Commerce and ombudsman really helped guide the person through all the different areas including who they contact at town, who they contact at the Department of Health, how to get the application, what they have to do for plan review, what the minimum requirements are.

So, it actually walks them through those

steps. Additionally, we've actually put a resource library on our website with all different food safety documents and we had them translated into six different languages, so I think that's been really helpful, too, to guide industry and help them.

HEATHER BUONOMO: To tag onto your languages, one of the lessons learned that we had this year -- and I love, Cathy, how you've reimagined, you know, the way that you're putting your information out there. I think that's huge and I think a lot of people had to do that this year.

One thing we learned is as we switched to that virtual platform is we were able to actually reach a lot more people in different languages. So, using some of the platforms, whether it's Zoom or Teams, they all have translation baked into it, and so, you can provide a presentation and it can be translated into a variety of different languages for people to hear and see while you're presenting live.

And so, it just allowed us to reach that many more people with our food safety messaging, and that's been a huge lesson in again lemonade for us.

LAURIE FARMER: And who would have guessed, you know, this lemonade coming out of endless Zoom meetings, right? I love that, though. You're reaching -- we're reaching more people this way.

I know we miss each other but wow, these platforms are allowing us to reach so many more people. And what I'm hearing is I'm hearing real collaborators with a willingness to support innovation as partners. And this is -- this is a really foundational evolution for regulatory, and it means you're -- moving out of the inspection mode so much and moving into public health partners, public health coaches. I really, really like what we're talking about.

So, Heather, you touched on this a little earlier and it was about training and outreach you're doing for industry and consumers. Can all of you expand a little bit about what you're doing there?

HEATHER BUONOMO: Sure. So, we're doing training and outreach in a variety of different ways. We do -- on an annual basis we do outreach sessions to all of our different programs. Some have been in person. Some have been virtual. Looking forward to

getting back to a regular cadence with that.

But we also go out and do outreach in communities at different associations or business groups, whether it's a chamber of commerce or restaurant association or the Kitchenistas, whatever that group is, we try to get out to them as well.

We've done outreach, you know, inside of a mobile food commissary. We'll go to you, but again, like, similar to Cathy, we're trying to make sure that we're reinventing and getting that messaging out there.

Something that we're working on right now is also recording food safety videos that we could then post online for folks that aren't able to make it. So, how great would it be if you're looking to start a new mobile food business and you can go to a video on our website and get all of that information on how to start a business and be able to have that translated as you're watching it live so it's in, you know, any of the languages that you need that are preferred for you.

So, those are just some of the methods that we follow here.

CATHY FEENEY: I think one of the things

that we do, too, is especially if it's an unlicensed, you know, vendor, maybe operating out of the house, try to explain to them what the risks are that they might not even realize and also the liability, and then let them know that we're willing to help you do it the right way.

So, we work a lot with our commissaries in trying to kind of coordinate those partnerships so that we kind of get them in touch with someplace that's actually close to them and convenient so that they can work with them. So, I think that's really helped a lot, too, you know? I think those are all different things that we have to do to collaborate, and I also think that we have to just really be open to learn what it is they're trying to do, because every one of them is different.

The models are so unique. It's just not one thing anymore, and it's growing and it's here to stay. This is what the consumers want, and I think this is what the industry wants to do safely, and that was obvious from the first day, but we want to really help them do that.

GALEN BAXTER: And just really quickly for us, you know, we're lucky we have two in-house educators that do monthly food code sessions for the industry around the area and as an open forum for the public to ask questions.

LAURIE FARMER: Great. Yeah, so helpful. Lastly, I want to ask you guys, what would be the most impactful actions or approaches that should be taken to improve your jurisdiction's effort to advance public health in the e-commerce area?

HEATHER BUONOMO: I'll jump in. I'm not shy to start for what I would love to see, is the California call to action. You know, for me it's engaging, engaging and starting more and having more conversations with e-commerce partners, whether that's industry, whether it is regulators, just working together to advance food safety.

I think we need to have more of those conversations, and I think we need to go further with some of our regulations to really encompass some of the food safety, and so, I'd love to partner with industry to really, you know, co-create and co work on together

what those regulations could be to make this new world that we live in of e-commerce for food just a safe place for everybody.

CATHY FEENEY: So, I also -- I worked on the Council for Food Protection Direct to Consumer Delivery Committee, and a guidance document was developed that Don Schaffer will talk about next, but I think if we could use some of that information and develop something specifically for industry, I think that would be super, super helpful.

And state's been really good, and local, about sharing documents, and I think that's what we need to do, is to really collaborate amongst ourselves so that we can give them the very best product that will be most useful to them and help them succeed.

GALEN BAXTER: I echo what they say. You guys took it out. No, it's good. I agree 100 percent. I think that's a good approach.

LAURIE FARMER: Very good. Very nice call to action there, you guys. I appreciate that. Well, we're going to move into our Q and A session now. So, I want to thank the panelists for providing really

such insightful input. You know, if you have questions and you're in the audience, we want to hear from you. So, e-mail your questions to smarterfoodsafety@fda.hhs.gov. Some of you guys submitted questions when you registered, so we have some of those, and we're also looking at live questions in the chat.

So, I will go ahead and get started. I'm seeing some of the questions here, and let me see. All right. The first one -- let me start. We'll just continue this conversation as we have been.

What are the labeling and labeling standards/requirements for foods produced, manufactured, and sold through business-to-consumer e-commerce business models, and do they differ in any way from foods generally?

CATHY FEENEY: So, I can address that. What we require for packaged foods is the same as what's in the FDA Food Code. So, if the food is packaged, it's not being handed directly to the consumer so it has to contain label information with ingredients and allergens.

HEATHER BUONOMO: And similar here in California, if restaurant food is going out via e-commerce or third-party food delivery, there wouldn't be labeling requirements, but things such as cottage food operators who make baked goods and things like that at home, similar requirements, ingredients, allergens. But additionally, it needs to be labeled to state that it's made in a home kitchen.

GALEN BAXTER: And going back to earlier where I was mentioning how Georgia's set up, that aspect of it for any manufactured foods or cottage foods falls under the Georgia Department of Agriculture with their labeling requirements, but from our side, under the local health department, if it's coming out of a restaurant, there's no requirements for labeling for, you know, food that's been ordered online.

LAURIE FARMER: Okay. Thank you for that.

CATHY FEENEY: There need to be some kind of notation on the label or on the package that says keep refrigerated if it needs to be refrigerated, because people might not readily know that. I go back to

the example of the raw juices, you know, people might not realize those need to be refrigerated and kept refrigerated.

LAURIE FARMER: Yeah. You know, I'm reminded of those that use a lot of these platforms, are younger and may not -- may need a little more instruction. I think it's all a very helpful reminder to everybody.

Another question that came in, how do state and local regulators currently identify social media businesses which only advertise their products on social media outlets but which might otherwise not be licensed or registered with any given jurisdiction?

HEATHER BUONOMO: This is another challenge and that's a tough question. Definitely in California this is a challenge for us. We actually played with and looked at a social media aggregate that scans for words such as vomit or illness or things associated with food, and then we reach out via that platform and provide, like, try to trace it back to where that person got their food and then reach out to that food vendor and provide some education, outreach,

try to get them under permit.

But it's really staff-intensive. So, how we're doing it right now is just through response to complaint. And so, if we do receive a response to a complaint, we will go out to that home or to wherever to try to track down that unpermitted vendor that's selling through an online platform like social media.

CATHY FEENEY: Yeah, I just want to follow up on what Heather said, too, because I think that industry really wants a level playing field, so a lot of the complaints we get are from industry, because they feel like it's not fair and it's not fair if they have to meet the minimum requirements and somebody else doesn't.

So, they'll show us different snapshots of Facebook pages and things like that. We also get consumers who do that, and you know, we talked about the restaurant industry being really short-staffed, but so are regulators, so we don't have the bandwidth to be able to monitor social media, but we do get the complaints and we do follow up that way.

GALEN BAXTER: Same here. It's

complaint-based response.

LAURIE FARMER: Well, right, the resource-intensive part that all of you mentioned is the difficulty here, and you just don't have time for folks to be looking for that, so it has to be a complaint-based system currently.

One of the questions that came in the chat is really focused on I would say meal kits, meal kit companies in general and how they're covered within your state.

They're wanting to know inspectional and regulatory coverage. So, I would just ask that each of you go through that and how that works in your state.

GALEN BAXTER: So, for us here, you know, again, going back to the different agencies that cover the different responsibilities, the meal kits, those kind of things fall under the Georgia Department of Agriculture, so it wouldn't fall on our side.

HEATHER BUONOMO: And in California, it's the California Department of Public Health who oversees those manufacturing and processing warehouses that would be assembling the meal kits. And so, they do permit

them and go out and inspect them, and they have that over --

CATHY FEENEY: So, in Rhode Island, you know, if they were located in the state, we would inspect the facility, but I see that as a gap because a lot of them are crossing state lines and the food's being delivered to our state, but we really don't have jurisdiction because it's coming from another state and we don't even know about it most times unless we get a consumer complaint.

LAURIE FARMER: Another question that's in the chat, and I'll just mention that this afternoon Glenda Lewis will be moderating a session on federal perspective, but somebody asked about what role should be played at the federal level versus the state, local, tribe, and territory level.

And I'll start by the federal level. You know, we provide guidance with the food code, and Cathy mentioned the conference with food protection direct to consumer guidance document that was developed that will be discussed at the next panel, so those are guidance documents that we provide through state and locals, so

that is a role the agency is playing.

You know, this is about a conversation about those roles as well, right? So, I'd like the panelists to talk about their thoughts here on their roles and then what role they would like to see the federal government play as well.

HEATHER BUONOMO: So, in California, because we do have the California Retail Food Code and you know a federal regulation on food safety would be a challenge here, but where I really would like to see more done from a federal perspective is on the guidance that you're talking about and on the information that comes out.

To have it come out quicker and to have it from a federal perspective and these trends be addressed, I think that in the world of the internet and Google, we're seeing trends, not so regionally anymore, but we're seeing trends throughout the whole country.

And so, how can we, you know, use federal government and at the federal level look at, evaluate, and address things to be innovative from the top down and be innovative and ahead of these trends and working

with the industry to provide that guidance so much quicker and have it be consistent, right?

The trend is going to be similar everywhere, so how can we find that common thread? That's what I would love to see and work on at the federal level.

CATHY FEENEY: Yeah, I agree. I think that the biggest problem is it's interstate commerce a lot of times, so you know, we only go as far as our boundaries and then we also have to reach out to other states.

Many times we have to find out where the location of the commissary, or food manufacturer is. So, maybe FDA could help with that. We do contact our FDA retail food specialist Tom Nerney with questions. He will probably kill me for this, mentioning his name, but I wouldn't blame him if he changed his phone number because we call him all the time. He's so, so helpful and he gets right back to us.

But you know, that's always, you know, super, super helpful and several partners help us with consumer complaints. But you know, in Rhode Island, we

had to develop special regulations basically for temporary events and mobiles for food trucks, because they're so unique, and so maybe we need to do something along those lines with these type situations too just so we could have some parameters on how to deal with this and how to inspect them.

GALEN BAXTER: I would say from my perspective just, you know, continue with working with the state because, you know, I know states differ in the types of, you know, socioeconomic neighborhoods that exist, and just from -- in Georgia alone, I mean, we have -- the State of Atlanta and then we have the rest of the state, and it is completely different in the operations all within the same state boundaries.

So, just really, you know, working with the state locally to find out what their local challenges are and helping, you know, to address those issues is where I think it would be the most beneficial.

CATHY FEENEY: And I think even like -- I don't know if anybody's looked at the (indiscernible) resource page, but the states actually do post all their, you know, best documents so that we can all share

those things and also share them with industry, so that's another avenue to get the best information out there.

LAURIE FARMER: Oh, great, and we'll be hearing from AFDO in the next session, so nice plug. Thank you for that, Cathy.

So, as we close the Q and A session, I'd just like to ask if you guys have any closing remarks that you want to make, and this is about getting people thinking about what they -- what feedback for the docket, you know? And so, really what would you like to share here as your closing remarks?

GALEN BAXTER: I'll jump in first on this one. So, what I would like to say first of all is thank you for the opportunity to have such a diverse, you know, group dealing with different challenges that we've had, and this -- I think an important thing is, you know, now that I have Heather as a contact, whenever we get these innovative things that come to Georgia, I've got somebody to call now.

I think that's very beneficial, is reaching out to your, you know, your peers across the

state lines, across the country, whatever, just to kind of get feedback from them on, you know, things that you may be seeing that come into your neck of the woods that you're not used to seeing.

I think that's going to be very, very beneficial going forward, so I just want to say thank you for that.

CATHY FEENEY: And Galen, I want to say thank you to you, because we just showed your presentation on ghost kitchens to our staff. Our training officer, not even knowing that I was (indiscernible) Lydia Brown is our training officer, she actually showed it to all our staff last Friday. I said okay, so well, I'm going to be (indiscernible) with Galen, and you know, they really enjoyed it, so I thought that was super, super helpful, and I think the more we can share the better.

It also make sure industry knows we have our good listening ears on, and you know, we want to help. We know that this is what the consumer wants (indiscernible) wanted to be able to do it safety and help them do it safety.

HEATHER BUONOMO: And I couldn't agree more, the collaboration on this team and this panel has been incredible, and I'm so thankful for the opportunity to be able to speak here today and be a part of this panel.

You know, I've been raising my food safety nerd flag a lot lately, because it's just so exciting and invigorating to talk with other food safety professionals and collaborate, and you know, just engage with each other on these common challenges that we're having and how to address them.

So, I think that my final thought for the day would really just be for all of us to challenge ourselves. You know, when there is something new and innovative that comes up that we've never seen before, rather than looking at the regulation and saying, no, we can't do it, challenge ourselves and say how can we do this, how can we make this work, how can we make it safe while still, you know, allowing this new innovative idea to move forward.

What do we need to change, who do we need to engage with to maybe make some changes in our codes

or regulations to move it forward and just, you know, that culture of courage and innovation, I challenge you all to just take that away with you today.

LAURIE FARMER: Excellent. Excellent closing remarks, and I just -- this was really fun. You know, I really have enjoyed each of you. It was an engaging discussion. I've enjoyed this session and hearing your experiences and perspectives. It's -- and how you're implementing and how you're thinking outside the box, I really, really appreciate the dialogue in support of what we're trying to do here in food safety and the new era of smarter food safety.

So, I want to thank the panelists. I want to thank those that are participating. Again, I'd like to remind folks to submit your thoughts and feedback to the docket. We do want to hear from you. So, thanks again, and I will pass it to Mike to take us to the break.

Thank you, panelists.

CATHY FEENEY: Thank you very much, Laurie and Heather and Galen. It's been great.

GALEN BAXTER: Thank you.

MICHAEL KAWCZYNSKI: All right. Thank you all, and at this time we are going to take a quick, 10-minute break so everyone can stretch their legs. So, thank you, and we will be back shortly.

(Recess)

KARI BARRETT: Welcome, everyone, to session four, State Associations and Public/Private Partnerships, Perspectives on E-Commerce and Food Safety, Food Safety Concerns and Regulatory Challenges.

So, welcome back again from the break. Wow, what an engaging panel we just had. That was such a great dialogue. Loved all the themes of partnership, support for innovation. You could see these folks were really looking collectively to problem-solve and learn from each other. I loved those last words about culture of courage.

So, what a dynamic panel we just had and one to look forward to. Again, we're staying with the state theme, and this time we're bringing up our state association representatives as well as public and private partnership representatives.

And as Laurie mentioned before, Laurie

will also be moderating this current panel. So, Laurie, let me give it back to you.

LAURIE FARMER: Well, welcome back, everybody. We met at the previous panel. My name is Laurie Farmer, FDA's Director of the Office of State Cooperative Programs. Our next panel is titled State Associations and Public/Private Partnerships, Perspectives on E-Commerce and Food Safety, Food Safety Concerns and Regulatory Challenges.

If you're just joining us, this summit is about engaging the stakeholders and to invite input from specific core element 3.1 new business models and retail modernization of a new era of smart food safety and blueprint.

I encourage all of you viewing to actively be thinking about comments to submit to the docket as well as questions for the panelists during this session.

We intend to use the information resulting from the public meeting to determine what actions, if any, should be taken to help ensure the safe production and delivery of foods sold through new e-

commerce business models.

We're building on the previous state and local panel. You heard about specific regulatory jurisdiction challenges, gaps, barriers and recommendations for a path forward in this e-commerce space. We will continue our discussions related to food sold through business-to-consumer e-commerce, but we will be focusing on national leadership in the following areas: best practices in guidance documents, sharing of information, nation perspective of regulatory caps and how to address moving forward, recommendations to facilitate stakeholder engagement, and the use of best practices while allowing for innovation.

Today we will be talking with three very accomplished people who represent food safety professional associations and academia. I want to thank the panelists for their preparation and willingness to participate in a more coffee-talk conversation format for continued audience engagement.

Your panelists, as you see on the screen, are Steven Mandernach, Executive Director of the Association of Food & Drug Officials. Hi, Steve.

STEVE MANDERNACH: Hello, Laurie.

LAURIE FARMER: Palak Raval-Nelson, Director of Environmental Health Services, Philadelphia Department of Health, who is also representing the National Environmental Health Association. Palak, welcome.

Donald Schaffer, distinguishes professor from Rutgers University and also chair of the Conference for Food Protection Direct to Consumer Delivery Committee. Welcome, Don.

DONALD SCHAFFER: Hi Laurie.

LAURIE FARMER: So, we're going to go ahead, and these panelists have a wealth of information that they're going to share today, so let's get started.

In considering national leadership in the e-commerce business-to-consumer space, please individually share your background and history in the area of food safety. Let's start with APDO, Steve.

STEVEN MANDERNACH: Sure. Well, once again, thank you for the opportunity to participate in this discussion today. It's an exciting topic that I think all of us in the regulatory field have been

dealing with.

This week, I've actually been with a group about food service operators all week, and it was the -- probably the number one concern they raised during our conversations with them, was really food delivery and how do we manage food delivery, how do we regulate it, and how do we ensure the food gets to the consumer in a safe manner.

So, it's fascinating that this is not just amongst the regulatory community we're having these discussions every day.

Here at APDO, we've been engaged in this issue for a long time. I think the challenge we've all faced is there's not a lot of consensus on how to handle food delivery operations. We go back in history, you know, and I know we heard some of this yesterday. Traditionally, these were relatively limited, often non -- or shelf-stable products that didn't have a lot of issues -- potential issues, and then we got some really big players that were doing, you know, meats and those sort of things. We -- but now, it's everything as was noted on the earlier discussions and it's much more

challenging.

One of the things that was noted on the previous discussion by -- as they were discussing meal kits, meal kits are a very challenging area for us all, because we walk into a meal kit operation, it does not feel like a retail food operation where probably it technically falls. It feels like a large-scale manufacturing operation.

And probably in all honesty, the manufacturing regulations might better fit to that type of operation than the retail food code, so that's one area we've been in a long-time discussion with FDA about where do these fit, how should these work, what are we doing to do well in those.

Another thing I think that we've been in this constant discussion of is how do we get the regulatory work done in a timely manner. I know we've heard this on other panels, too, but one of our big challenges is we get something out across the country, broadly implemented, and then we try to do a regulation after the fact.

Well, by that point, there's going to be

hundreds if not thousands of different methods of regulating and taking and putting, you know, the genie back in the bottle is a little bit more challenging to do and to fix and to move toward uniformity nationally, so that's something that we're naturally very concerned about.

What we've been doing at APDO is really working with FDA partners and talking about some of these regulatory challenges we see at the state and local level. We've also been doing lots of webinars to educate.

You know, in all honesty, most of us didn't understand the food delivery services and what they were doing, what precautions they were taking, et cetera, and it varies across the delivery services, so given some of that ability to get out there and understand that better, what they were doing, was a huge things.

Those webinars are all available online, so if you haven't had an opportunity to look at them, please go ahead and take a look, but you know, that's really kind of where we're at.

The other thing that we've been talking a lot about was something we mentioned earlier, the social media sales. Social media sales are really challenging for lots of different reasons, and frankly many of those are very -- can be very dangerous products that require pretty intense food safety protocols in order to maintain them in a safe manner.

We've had several states that have been out there trying some methods there, but in all honesty, a lot of those social media companies have been less than cooperative and very challenging to work with as the states identified problems they were not very interested in helping find a solution.

So, I think that's an area that we all need to work together, and hopefully perhaps the FDA can work with that also. With them providing that marketplace, there should be a responsibility there to also ensure that things have been appropriately regulated for safety.

With that, I think that gives you a beginning answer, Laurie.

LAURIE FARMER: Okay. Thank you, Steve.

Next, let's go to Palak.

PALAK RAVAL-NELSON: Hi, there, everybody. Thank you so much for including me on this panel. I really appreciate the opportunity to talk to everyone.

As Laurie mentioned, I'm not only representing NEHA, I'm also representing the Philadelphia Department of Public Health. I've been the Director for Environmental Health Services within the City of Philadelphia for 11 years, most notably last year, the COVID year, and I started out as a sanitarian working in the field and I've worked extensively with my federal partners as well as NEHA.

So, I really have the added fortune of representing both NEHA as well as the city of Philadelphia and Department of Public Health, and NEHA has been working as has -- does not have a full position on e-commerce but has been providing multiple trainings and seminars regarding e-commerce and ghost kitchens and really working with locals and state officials to work on getting maybe -- you know, it's always, you know, innovation leading regulation unfortunately.

So, NEHA has been working with state and locals, and while there's not an official policy, they've been really working to provide seminars and educational opportunities.

Within the city of Philadelphia, we have been working with incubator kitchens for years now worried about food allergens and having kind of a kitchen-share model. So, there have been different groups, and we try -- I try to lead with education and then regulation, so the carrot and the stick model, and so we try to really encourage folks to let us know what's going on.

That model did assist us during the pandemic because there were less people hiding what they were doing. They were more willing to ask questions, and we were one of the only agencies that physically showed up to work and answered our phones even during the shut-down.

We did it all COVID safely obviously, but -- so that it was very interesting because while everything else could be shut down, as I kept reinforcing to my colleagues, everybody has to eat, and

if folks are unable to maybe cook at home because they don't have the means or the items, at least they can get delivery.

So, it was more now -- you know, during the pandemic it was very important to ensure food safety for all aspects and I'll stop there.

LAURIE FARMER: Thank you, Palak. Now, let's go to Don.

DONALD SCHAFFER: Yeah, so I've been involved in this area for a little while. You'd heard Bill Holman talk yesterday about the research that he was involved with. I was part of that team. My lab led the Rutgers microbiological sampling part of that effort. I was also involved in the first Conference for Food Protection Committee that worked in the 2016-2018 time period to develop that first bit of (indiscernible) mostly on mail-order delivery and less on third-party delivery services.

And then I had the privilege of sharing the committee that drafted the 2018-2020 guidance, and that guidance was finally approved when we had our 2021 conference for food protection which was of course

delayed because of the pandemic.

I should also add that I've been doing some food safety consulting in the area of risk modeling for a number of big players who are looking to use the best science and risk-assessment approaches to manage food safety for their business.

LAURIE FARMER: Awesome, great. So, thanks for setting the foundation as we move into our conversation. I'm feeling an echo. I don't know if y'all are hearing that.

Don mentioned the CFP Direct-to-Consumer Delivery Committee. Let's next expand on national guidance documents and best practices documents. You know, you guys are the national leaders here. Can you talk about those guidance documents and best practices documents that you had been involved in, how people can get access to those, what is involved in those documents? I'd like Don to go ahead and build on what he was already talking about, if he can.

DONALD SCHAFFER: Sure. So, I'll talk just briefly about the 2018-2020 document, and so the charge to that committee was basically to identify

current recommended practices and existing guidance documents that relate to the shipment directly to a consumer of perishable food items and then also to expand that existing guidance document to also cover the topic of safe delivery of food by third-party delivery services.

And so, in going on with that charge, we were charged to revise the guidance document for mail-order food companies. We were specifically directed to look at proper packaging, temperature control during shipping, return of compromised and abused products, and other food safety-related topics and then also include information on food safety training, specifically focusing on third-party delivery services, and then information for all food delivery practices.

And let's see. What else do I want to say? I want to say -- well, I will have to acknowledge that the wonderful committee that worked with me, we had 18 voting members, we had 25 at-large, non-voting members, we had eight more federal consultants or other representation from AFDO or the CRP council chair and vice chair.

We met literally every two weeks as a full committee plus dozens of sub-committee meetings. If you had to total it up, it would be hundreds of person hours.

We had volunteers on the committee from all of the big players that you would expect, many of whom -- many of these companies are also represented here at this -- at this e-summit.

So, just a really, really wonderful group. We -- the document as it currently exists has a new -- we -- one of the things that we did when we updated the old document was we created a section for foundational concepts in terms of regulations or risk management that relate to both mail order and third-party delivery and then -- or as we call it now direct-to-consumer guidance.

And so, there's still a substantial portion of the document that focuses on direct-to-consumer guidance. There's about 12 pages of the document focusing on that. Only about 6 pages -- I say only -- but 6 pages of good content on third-party delivery service guidance, and that was really -- that

was information that had to be written brand new from scratch, and fortunately we had a really dedicated subcommittee that took that on and gave us some great draft language to react to.

And then, another substantial portion of the document are the appendices. We've got eight pages of appendices covering food regulations, other resources, trading standards, imported food issues, etcetera.

And so, yeah, this is -- this is -- there is no current CFP committee focusing on this, but maybe we'll have a charge to reconvene a similar committee to update the guidance. This is a -- as many speakers have noted, this is a very rapidly evolving area, and I think we need -- we need to keep our fingers on the pulse of what kind of guidance is needed.

LAURIE FARMER: Thank you, Don. And if somebody's wanting to access that guidance document that you referenced, how would they get to it?

DONALD SCHAFFER: Yeah. I don't know if it's been formally posted as guidance on the CFP website, but it was an issue that was discussed in

council 3, and so, if you go to the CFP website, if you go to the 2020 meeting which was held in 2021, you look for council 3 and just look for the right words there, follow those links through -- it's not a short, easy-to-remember URL, but you can find it on the CFP website.

If anybody is having trouble finding it, by all means reach out and I'll send you -- I'll send you the link, but it's relatively easy to find.

LAURIE FARMER: Excellent. Thank you for that. Anyone else, guidance documents and best practices?

PALAK RAVAL-NELSON: I think for us, you know, NEHA has several guidance documents specifically that they are more like the virtual seminar that was provided for ghost kitchens and what to do. They've also been working with NSF and other kind of commercial partners to think about, you know, what are the best type of -- besides (indiscernible) this model and transport, right, we also need the -- from a food safety standpoint the innovative equipment and supplies to do this transport and to hold the temperatures and to, you know, have items and equipment that is tested and tested

by performance standards such as (indiscernible) you know at the national -- with the (indiscernible) or NSF.

And locally, we've been doing a lot of guidance through communication via e-mail. We adopted several regulations and amended our risk-based inspection approach and inspection report to add local city ordinances as they pertain to e-commerce. It was kind of fast and furious, but COVID was what it was. It still is, but last year, we did what we had to and tried to move as progressively as possible so that we could regulate things and put them on our inspection report so it would allow our staff to conduct education out in the field and allow the establishment owners to know what needs to be done in writing.

LAURIE FARMER: And Steve, anything you want to share on best practices and guidance documents?

STEVEN MANDERNACH: Well, I will share on this question and then skip the next one. We've been doing a lot of posting of information on our website under the resources section in addition to three webinars, one on the Amazon effect and other trends in the U.S. food industry, a 360 approach to food delivery,

and a long -- and a discussion on food delivery during a worldwide pandemic, so all three of those have a little bit different approach but all of those are available via the website and on YouTube, so those would be three great resources to take a look at.

LAURIE FARMER: Excellent. Thank you.

And I heard Don say when we -- when we're talking about stakeholder groups, you know, retail is an immense stakeholder group. Don talked about so many involved in the development of the guidance documents through CFP, that forum, and Palak mentioned partnering with equipment folks, so NSF, the standards group, ANSI, so the engagement of stakeholders, how have you been inclusive of your conversations and getting their perspectives as you move forward?

PALAK RAVAL-NELSON: So, I mean, I can kind of speak to it from -- I mentioned NEHA's role of engaging locals and you know county health departments and state, and during the pandemic, throughout the pandemic, we continued with our big city calls with the environmental health services directors of the big cities and NEHA took a really -- and has and is taking a lead

role on that to get us all involved and to give us a forum to talk through emerging issues on a monthly basis.

Locally, we involved our industry partners, so not just the food industry but also our other city departments, so the Department of Commerce, the corridor managers who often know, you know, what's going on at the neighborhood level that we may not know about, and also our Department of Licenses and Inspections. And believe it or not, as food delivery moved outdoors, food pickup and delivery moved outdoors, and with outdoor dining and outdoor pickup, it posed a host of temperature challenges for folks and it posed other such challenges.

So, our streets department within the city was also involved, because you could imagine the amount of traffic and congestion that would be created, and then the associated food safety challenges, because if the food orders are sitting on the side while they're waiting for pickup, then you have significant issues with temperature -- potential temperature abuse and food safety issues, and given the fact that, you know, we

were all inundated with COVID, the last thing we wanted in our city was to also have a massive food-borne illness outbreak, so we were very watchful of not only surveillance data about food-borne illnesses but also working with the industry and the other departments to create systems so there was easier pick-up and easier, you know, transport and maintenance of food safety temperatures.

LAURIE FARMER: And I would just say that's really innovative thinking. We like to call Palak "Positive Palak." I think Don gave her that nickname during one of our (indiscernible) prep sessions, but you know, really thinking outside the box and thinking about different departments in your city, you know, this is because of COVID you're really having to think of it, so really thinking about -- and I know you're a big systems thinker, Palak, so it's about looking at the system and what other information others might have that can improve the prevention of food-borne illness, so kudos to you.

You guys heard from the previous panel about their jurisdictional challenges. When you look at

this from a national perspective, what gaps, if any, do you perceive in the existing regulatory structure?

DONALD SCHAFFER: Well, I'm going to be really interested to hear what is going to happen in the panel after this one where we hear from our federal -- our federal partners on this. I'm very curious as to what the regulatory structure is that we're going to regulate these companies.

You heard Professor Holman say yesterday that the -- you know, the company turns the food over to the FedEx, UPS, or USPS, and it's not in their hands anymore, right? And so, how does that get covered under a regulatory structure?

I -- we had some -- I had some -- we had some really interesting conversations as we were preparing for this meeting, and Palak shared some of the work that she's been doing with her team there in Philadelphia to locate these businesses. I still remember when we were meeting as a committee to develop the guidance document, I asked one of these local regulators, well, how do you find these companies that need to be regulated? And her answer blew me away. She

said we go on Facebook, right?

That can't be -- or maybe it is, but that doesn't seem to me like a very good way to find businesses that need to be regulated, figuring out how to search for them on Facebook. Maybe that's -- maybe that's an interim strategy, but I can't imagine that's a long-term solution, especially if, as we've heard earlier, that sometimes these companies, these social media companies, are not really interested in helping, right?

And so, I -- and the other thing that I think about with this issue is -- and we grappled with this as does the CFP committee, the -- this area, this business area, evolves so rapidly, and you hear from Professor Holman, right? Five hundred companies and 100 of them had churned through, right?

Well, what about different structures? There were business structures that aren't even the ones that exist now. Whatever regulatory structure we end up putting in place or we end up -- you know, I -- again, I really want to hear from the lawyers to say, well, okay, yes, this is legal to regulate under this law, it has to

be flexible enough that as the space continues to innovate, that we are able to regulate it and assure safety, at the same time not spiteful business innovation, and so balance the need -- those needs.

It's going to be -- anyway, you know, ancient Chinese curse, may you live in interesting times. It's going to be interesting times in the coming years and decades.

PALAK RAVAL-NELSON: And you know, Don, you have to use Instagram and Twitter if you really want to get to them, and you have to pretend to be (indiscernible) too. No, I'm only kidding. That was a joke. But no, it is -- it is sometimes that's what we ended up having to do unfortunately, is learn about these things by creating accounts, believe it or not, and pretending to be, you know, interested parties and do some, you know, detective work similar to the police -- police would do.

DONALD SCHAFFER: But has -- Palak, has it moved to TikTok yet? That's what I want to know.

PALAK RAVAL-NELSON: Yeah, my TikTok video will be releasing. I'm doing it with Laurie. The

lovely Laurie.

STEVEN MANDERNACH: Well, there's a couple other things that I might want to mention, Laurie, here is I think that the challenge we all face is the clear standards for third-party delivery.

When we were -- previously when the restaurant was responsible for the delivery, it was one thing. We knew what the standard was. We knew who was responsible. But I'll tell you, I sat at an industry group yesterday and they argued over who had the liability for the food delivery service, and it's fascinating.

And the question of training and who's responsible for that, can anyone actually train, and I know that there's been some of those discussions, that really needs to be dealt with.

The other thing we need to think about is perhaps the traditional definition of deciding where the line is based on whether it's going to the consumer directly is not the right line anymore. Maybe we really need to look at what is the practice that's happening and what is the appropriate regulation for what we're

doing.

I think a good example is, you know, when you hit a 100,000 square foot facility that's assembling food kits or distribution facility, that may not be the best thing to try to regulate under the retail food code. There are better methods to do that and that work more -- better with that area.

So, I think we have to get a little bit different. The other thing I'm going to say, and this is really challenging for a regulator to say, but we might have to get less specific.

We have created a very specific food code. The problem is with a very specific food code, we have no ability to adapt. There is some beauty when you think about some of our other regulations that are a lot less specific, the GMBs or the Good Agricultural Practices. They allow for that adaptation so we don't need to be continually amending the regulations.

I'm afraid with, you know, basically a four-year cycle to get something in the food code, by the time that's happened, it's all out there, and you know, trying to put -- to fix it is not going to happen.

So, we probably need to think about that, and I know those are challenging things to think about, but we may just have to think differently, and I guess the other piece of that is I'm afraid that no state or local government's ever going to get Facebook or other social media companies that are out there selling these goods to the table.

That might be one that we need to rely on the federal leadership to get them to the table and help generate the understanding of what's going to happen with those areas.

So, those are just a few things that come to mind that I just think we can do better and we have to do better for the consumers. Their expectation is that this is not what's happening and the answer is we don't know who regulates oftentimes, but that's not what they expect and frankly that's not fair to them.

PALAK RAVAL-NELSON: And to your point, I just want to add one other component, so first of all, I agree with you. We -- you know, as we were -- as this was a moving target of food safety locally, we did come up with guidelines instead of regulatory and

regulations, so as things changed we could be agile. I've been doing a lot of database development, so I learned the word agile.

You know, it's always good to learn new vocabulary. And then the other piece that I want to kind of bring up and that I think is very important, right, is consumer education, because there are a lot of folks that don't understand why certain things are important in food safety, you know, why is it important that -- you know, that my food didn't get here hot? Does it mean that I have to just reheat it or could it mean that it's going to make me sick?

So, leading with food -- ultimately leading with consumer education and just making it very quick and easy so we're thinking about the, you know, two-minute YouTube videos or even, Don, to your point, TikTok that say, oh, you know, if you get this food that's -- feels cold out of temperature or -- you know, this is the difference between the spoiled food and food that's going to make you sick, what to look for, because at the end of the day, while as regulators we're trying to fill this gap of creating regulation or

guidance or working with nationals in the industry and social media and everything, if we pump out education to the end user or the consumer and let them know what to look for then we will impact, I believe, ultimately food safety and prevent some food-borne illnesses that would otherwise occur, because a lot of times people don't understand that and again, my biggest concern during the pandemic was, you know, having things inundated with our food-borne illness numbers going up. And so, thank goodness that didn't happen, but I think that's the other big piece, is educating the consumer and being agile with our kind of guidelines and documents.

STEVEN MANDERNACH: So, Laurie, can I just add on thing on the consumer education?

LAURIE FARMER: Uh-huh. Absolutely.

STEVEN MANDERNACH: That is awesome. The Partnership for Food Safety Education, who I know I think is speaking later today or tomorrow, has done a phenomenal job in this area, in developing some resources for the end consumer. We're very pleased that AFDO was one of the -- was the first funder of that activity and one of the lead funders overall of that

activity, but it was something our regulatory community thought was so important that we wanted to put our money where our mouth was and help get that message out there to the consumers.

And we're very excited about their work, and I hope you all get a chance to see more of it in their presentation.

LAURIE FARMER: All right. Yeah, Britney was on yesterday and she shared that.

STEVEN MANDERNACH: Oh, yeah, sorry.

LAURIE FARMER: And she recognized you guys, so you know, good work and good partnership together. You know, I appreciate that Steve and Palak just talked about, you know, allowing for innovation as we think about regulation, allowing for flexibility, right?

You know, we talked about the previous panel, about how government's a little bit behind and we're always trying to catch up. And so, you know, I want to talk about that a little bit more, about do you have recommendations of how -- you know, what we hear from the industry in retail is they want to see uniform

structure, and so do you guys have any recommendations on uniform national retail structure for these business models and thoughts on implementing those?

STEVEN MANDERNACH: Well, I'm happy to start on that one. I think one of the things that we really have to start thinking about is how can we exercise some of the pre-existing, regulatory jurisdiction that FDA has in some of these areas?

As you might recall, there is a Food Transportation Act that actually is quite broad, but the regulation greatly limited FDA's authority. The law didn't. Maybe there's some ways that we can use that act in a better way to actually, you know, set the parameters nationally for the large, multi-state companies and do something there.

Another thing to think about is how do we create safety standards that are easily identifiable for the consumer so they know if their product has been tampered with or has been temperature abuse.

I just read some interesting research that suggests one out of four delivery drivers says they've eaten part of a consumer's food from the

delivery. That's amazing to me. I have -- of course I guess maybe it makes sense, but you know, shocking. That tells us our tamper-evident packaging is not working. We need to do something better there, but on the other side, we don't want to inhibit the ability to have quality products coming out at the same time.

Some of the challenges that, you know, industry is really facing is any packaging during COVID times is challenging in the first place but finding the right packaging for the right items is very challenging because each one has some different qualities and I know someone like Don would know that far better than I do.

But I think that's something we also have to think a lot about. If you were going to ask me what keeps me awake at night, particular as it relates to food delivery, is intentional adulteration. We would not figure that out in a quick timeframe no matter how good the local agency is, and particularly with many of these delivery drivers.

I'm just thinking of the Philadelphia area where I live, you know, they're driving across jurisdictions every two seconds in some spots, and I

know they do a fantastic job in the region, but how would -- you -- it would take days for things to get across to everyone understanding, oh, we all have the same issue going on, you know, and that's just one small -- one metro area. Imagine what it's like in other places. We've got to do better there and really figure out some ways to be more effective there.

I think that really gives you some ideas of some of the areas I think we can do well on. The other thing is, I think the regulation can help drive and reduce price on some of these safety majors.

I mean, think about this. There are some really cool temperature strips that have been used in some of the perhaps more expensive products that show tampering. I see it all the time in pharmaceuticals as they're shipped, et cetera, and we seal those to a point where they really are effective in your -- you know, your dinner tonight or other things.

So, those are just a few things to think about, but I definitely think we've got some research partners in the packaging and food safety industry that can help us there and great researchers like Don that

can do amazing work there.

LAURIE FARMER: Others ensuring uniform national regulatory structure. Any thoughts?

PALAK RAVAL-NELSON: So, I think just playing off of Steve's comment, I think one of the ways of potentially doing this, and having been in this field for a long period of time and thinking about when we've had interactions from the feds and local levels and jurisdictional counties and everything where we've been successful, I think back to the papal visit that Philadelphia had and our democratic national convention and the RMC where, you know, it was multiple federal agencies and then localities. It was Montgomery County, Buck County, Delaware County, Philadelphia County, and you know, the feds took the lead, and it was an amazing experience because we would have these calls and these discussions and all of us were, you know, measuring and surveilling the food-borne illnesses within our different systems and hearing that information with each other.

When we worked on the food code with the FDA, the local standardization process, and we conducted

an enhanced uniformity training from standardization within our local government, it was yet another experience where we met in groups and talked through, you know, what are specific challenges to our jurisdiction and how can we capture those while we can meet the standards that are ongoing.

And you know, we were -- we were pretty successful with those things. There were organizations such as our Central Atlantic State Association of Food and Drug Officials. I mentioned, you know, NEHA and working with our partners. I mean, NEHA is a true leader with all of this stuff with innovation and everything, and just -- and it's a virtual world, so in some ways it's a bit of a challenge because I don't recognize people when I meet them in person, because I'm not used to the screen not being there, but it also affords us the opportunity to maybe do more and get connected, you know, from all over the country and all over the place and really get ahead of this or think through the innovations.

So, there are ways of doing it. I think that there have been models that have been proven

successful in the past. So, thinking through what those models were and how we can adapt and adopt those models and then maybe build in the industry and others, you know, researchers and groups to come up with agile regulations that can be changed and manipulated so that they're keeping up, you know, with the innovations.

LAURIE FARMER: And there's that word agile again. You know, I'm thinking about -- you were talking about these models where I think we've seen best practices when we come together as a regulatory community, and you know, I personally experience these national security events working with states, locals, feds, and how it's all one team focused on the prevention of food-borne illness and contamination.

And then you talk about your experience with coming together on the adoption of food code and really bringing in the industry as well, and so, it's so important, what you're talking about, Palak, as to the true partnership.

So, you guys being the national food safety leaders, we're moving into your call to action. So, what do you see as key areas to address moving

forward?

MS. MURRAY: Well, I think one area, and we heard it mentioned yesterday as well, and maybe even earlier today, is this trade-off between safety and sustainability, right? Like, everybody wants their foods to have minimal amounts of packaging, but it's the packaging that keeps the temperature control, right? And so, how do you -- how do you deal with that? And then -- or you can say, well, we'll have reusable packaging. Well, now you've got cross-contamination issues that you've got to manage on that packaging.

And so, looking at all of these trade-offs I think is a challenging area, but what I would say in terms of a call to action, you know, I would like to see whatever comes forward to be risk-based, right?

And so, what do I mean by risk-based? Well, so it's not -- it's not centered on the hazard, Salmonella in chicken, let's say. It's what is the risk that you'll get cross-contamination from this chicken or what is the risk that you'll promote Salmonella growth in this piece of chicken or what have you?

And so, the idea that, yes, foods should

be stored at 40 degrees Fahrenheit, but is -- if it's stored at 42, is that the same as being stored at 72? I don't think so, right? They're both out of compliance with the code, but one is much riskier than the other.

And so, I'd like to see us take a more risk-based approach and then realize that these are -- these things are not happening in a vacuum. We're always making trade-offs, right? We're making trade-offs with sustainability. We're making trade-offs with cost. We're making trade-off with convenience, and so trying to navigate that world is going to be challenging, but I think, you know, from my point of view it's about the science, and it's about trying to use a risk-based approach wherever we can.

PALAK RAVAL-NELSON: And you know, to play off of what you're saying, Don, it's almost like using the (indiscernible) -- applying (indiscernible) to this new e-commerce system, you know? The analysis -- the hazardous analysis of the different critical control points and establishing that, and then to your point on sustainability, you know, one of the biggest concerns as an environmental health director, food safety is one of,

you know, four program areas and NEHA is a national environmental health association, so we're concerned about overall environmental health as well and sustainability and packaging has been a big deal for us.

And in the city, we've partnered with some local food establishments and Circle Philly and other groups to figure out how we can reduce waste, and so we're in the process of filming. We have a great internal filming system, so we're filming some videos on innovation of how to use reusable, to-go containers, but to make sure that they're safely washed and reused and we're going to be doing some consumer education videos as well as training for our staff so they're well aware of what to look for, and then overall for the industry and how they can do this so that we're not producing excess waste as people continue to, you know, order the food.

So, you know, that's -- the food safety piece is very big, but I also have to be mindful of the overall environmental health piece.

STEVEN MANDERNACH: So, there's one other science here that's a soft science, and I'm going to

call it political science. I think during COVID times, we've recognized how important political science sometimes becomes in public health.

I think one of our giant challenges is when we fail to regulate early, the political science gets involved and it becomes much harder to regulate later, and we need to learn that at all levels, the state, local, and national level, that at some point we're going to -- you know, as an industry becomes more organized, they carry the clout to exempt them from everything, and we're seeing that across the country if you look at some of the food freedom, the cottage foods.

There's a national organization that's seeking to legalize home restaurants across the country right now. Those sorts of things, you know, are getting more and more organized, and I think that's a big concern that I have going forward.

One other concerns is a labor concern, so in talking to a lot of the third-party delivery companies, I often hear we can't require our independent contractors to take training. Well, I've seen some deal with it through incentives. That's great. But I'm

going to take a step back here. I think if we're going to bring, you know, an independent contractor into a brand, there are some ways, and I know the IRS regs, but it might be time to have a conversation with the IRS about what are the real limits on third-party contractors? Because I do think there needs to be some mandatory training on certain base elements for all of these delivery folks and that just has to be part of the system.

And it's not huge. I mean, it probably could be done in five minutes or less, a simple sort of training, but it needs to happen and there needs to be those reminders and cues, and there is a responsibility at the corporate level to do that work.

And I know I'm probably going to be unpopular with some of our industry colleagues by saying that, but I just think that's the first step of the puzzle is we can't expect the delivery driver to know about safe temperatures if we never talk to them about it.

And just saying, well, they should want to learn about it, well, that's not going to get us

there and the foods will become increasingly complex and challenging over time, and frankly, the distances will probably become further as we look at things like drones and other things, too.

I'll stop -- I'll stop talking about the other science, though --

PALAK RAVAL-NELSON: And -- no, no, and I think I -- what I -- what I want to say to that point is it's really important, and I was talking with Doug Farquar at NEHA, and what I said to him, it's really important for us not to wait until there's a massive food-borne illness, so -- you know, and I gave him the example in Philadelphia where several years back unfortunately we did have -- our powers had been limited and we did have, unfortunately for the food establishment, 100 attorneys that got food-borne illness at the establishment.

And so, then -- I know. I was like -- and so, then it was, well, you know, why didn't you -- they had all these failing inspections. Why didn't you take action? And our response was we've been trying to take action. We've been -- and all of a sudden we were

relegated with more authority and more prompt action, so we were not waiting for an establishment, you know, to get to court.

And with that, though, we've established the metrics, because our goal is food safety, so we have the carrot and stick approach which is, you know, if you are in compliance with your annual inspection and we're not seeing you, then you're not going to be charged a fee and you're not going to be closed.

So, it's a balanced approach, but I agree with you, I don't want to wait until there's a massive, food-borne illness.

LAURIE FARMER: Exactly, and you know --

DONALD SCHAFFER: But if there is, let's hope it's lawyers, right?

LAURIE FARMER: We do have a lawyer on the panel.

DONALD SCHAFFER: Not really. Not really. (Indiscernible) lawyer.

LAURIE FARMER: So, you guys, let's close our last question with talking about engagement. You guys are representing national groups, and let's talk

about moving forward. What are your recommendations of best approaches to facilitate stakeholder engagement? We know there's a vast stakeholder group. How can we get them engaged in best practices that have been identified while also allowing innovation?

DONALD SCHAFFER: Well, I mean, I'm really interested to get to the questions, because I think that's a great way to get engagement, but I'll say I think we're -- having this e-summit is a great place to start. I'm going to continue to be involved in the CFP process. I'm going to continue to talk to, you know, folks in the food industry that are getting into this space or that are in this space and want risk-based advice.

So, you know, those are all the things that I'm going to keep doing.

PALAK RAVAL-NELSON: Agreed.

LAURIE FARMER: Okay. Anything else? Any closing comments before we go to Q and A? I know you're excited about the Q and A, so we can go to that. Okay, I'm getting the head nod, so we're moving to Q and A.

I want to thank all of you for your attention. We're moving into the live Q and A. You can send your questions to smarterfoodsafety@fda.hhs.gov. We'll be looking for that.

We'll continue in this format that we're doing right now where we're just engaging and talking and we will talk through the questions as they come through the chat.

So, looking on the chat -- we lost Don. Maybe he'll come back. There he is. One of the questions that I'm seeing is how should any perceived gaps in the existing regulatory structure be addressed? Anything specific? We've talked a bit about that, but is there anything more that you want to share as we wait for additional questions to come in?

DONALD SCHAFFER: Well, I'll just say that the good companies out there are the ones that are thinking about this already, and what worries me is companies that are just getting into the business. Again, as Bill Holman said yesterday, all you really need is a website and access to a post office, right, and you too can give people food poisoning through the

mail.

But it's -- yeah, so it's really, you know, like I said the big companies, the names, the people that are on this panel, you've heard -- you heard yesterday about all the great programs that they have. Those are not the ones that worry me. What I worry about is the -- you know, the smaller operations, which I mean, they had every right to be in business, too, but we just need to make sure that they get the help and the training that they need, you know, before we have a regulatory structure, right? Because it's going to take us a while to get to that structure that we need.

PALAK RAVAL-NELSON: I think from my perspective, I'll be very interested to see, you know, the overall capacity of questions that the e-summit has and working backwards from those questions to figuring out do we want to, you know, work -- partner with innovation? Is it temperature test strips that are the issue or is it training for the transporters or is it training for the food safety industry, or is it the -- you know, how do we get everybody to come out and talk to us outside of social media?

So, really looking at the questions and really asking, you know, FDA to take the lead and incorporate the rest of us with, you know, NEHA and AFDO and the research folks like Don and others and say, okay, here are all the question. What do we want to -- what -- you know, what are the similarities? What are the outstanding issues? And then from that, kind of doing almost a needs analysis and then reforming groups to see where the gaps really are, you know?

STEVEN MANDERNACH: I agree completely with Palak. I think that's a great place to start. I think the other thing to think about is we have the classic challenge in the regulatory community as this is the way we've always done it and this is who traditionally has the responsibility.

This is an opportunity to rethink. I'll give you a non -- a different example here. Who would ever design the egg regulatory system in the way we've done it today? I think this is an opportunity for us to think about these new business models and how could we design it in the right way versus within the structures we've created right now.

Because if we do that, we're going to end up with something a lot like the egg regulatory system, which if any of us try to map it, it confuses all of us that kind of understand it, not to mention the producers, not to mention the folks that get sick.

We don't need that sort of system. We need it to be clear and have clear lines of authority, et cetera. And it might be a reality that we need to go back and ask for some changes in the FD&C Act, which is scary. I will tell you, very scary when you ask for a law change, but maybe that's what we need to do on some of these things to make it effective.

The other challenge we're going to face is information sharing, particularly if the federal government takes a leadership role in any of this, there are restrictions to when they can share -- particularly FDA can share information upwards or downwards with the state and local folks that may be doing the actual work.

That creates a huge issue. You know, we have to really think about that. For example, let's say we get a consumer complaint in Philadelphia and some of the new -- some of the current information-sharing

interpretations would prohibit giving all the information that Palak needs to investigate that complaint on the retail food establishment. We've got to deal with those challenges immediately. Those we really can't wait on.

The last thing we want is to not be able to accurately and fully investigate an illness or a complaint that we're getting, so those are just a couple things that come to mind for me.

PALAK RAVAL-NELSON: I think, you know --

DONALD SCHAFFER: So, Steve, does that mean you're in favor of a single food safety agency?

STEVEN MANDERNACH: That's a great question. I think -- I think I can see merits to a food -- single food safety agency, but I'm not saying I'm in favor of it. There are advantages and disadvantages to everything.

PALAK RAVAL-NELSON: Spoken like an attorney.

LAURIE FARMER: Exactly. That's exactly what I was saying.

PALAK RAVAL-NELSON: You know, I think

the other -- to your point, Steve, I think the other big thing is that we want to also use -- not only think outside the box -- you're spot on because that's what I found myself doing a lot because there were a lot of sleepless nights and I was really concerned about what was going on within our city last year.

Not that I'm not concerned now, but it's a little different, and one of things that we did was we used innovation and we used communication, and we stopped the way we were communicating because as good regulators we have documents and we have guidelines, and they're all written out and spelled out and -- but nobody wants to read, you know? It's like Don mentioned, the average attention span is a TikTok video, honestly.

And if the information -- I'm not going to let Dynamic Don live that out, so you know, and the -- and the thing is that, you know, if we provide and communicate information in innovative ways, our industry folks, the drivers, all those folks that you were talking about, they may not have time.

One of the things we realized during the

pandemic was that folks don't have time to speak with us between this hour and this hour, so we then started providing information and making it accessible so that they can review it when it was necessary for them to review it.

So, really, you know, to your point, we should reevaluate where we are and take the -- you know, in public health I learned from CDC crisis is opportunity, and that's where we are. We are in that place of public health where crisis can be opportunity to really reevaluate and make better.

DONALD SCHAFFER: Another thing to answer that, Palak, one thing that I would -- and I'm playing a small role in inviting you to come speak to our New Jersey IAFF affiliate in February, but I think the lessons that you learned, that information -- I'm sure you're doing it already, but that information needs to be captured and shared with other jurisdictions so people don't have to reinvent the wheel, like, oh, look what they did in Philadelphia, right?

Is there something in what they did there that we can now apply and innovate in terms of what

we're doing, you know? I mean, I think that there's a real benefit there.

PALAK RAVAL-NELSON: Absolutely.

(Indiscernible) -- no, I'd be happy to share, and you know, that's one of the reasons why I'm so glad to have the connection and to represent NEHA today and to have the connection.

STEVEN MANDERNACH: So, one other thing that --

LAURIE FARMER: Did we lose you, Steve? We can't hear you.

STEVEN MANDERNACH: I think I'm still here on audio. I think I lost video for a second. I apologize.

LAURIE FARMER: Okay. Got you.

STEVEN MANDERNACH: But one other thing I was just going to mention, and I won't worry about figuring out the video while I'm talking at least, to think about is, is there a way that with these -- you know, particularly with third-party deliveries, there's a lot of information technology -- information behind there.

Do we -- can we regulate in a non-traditional manner? Truthfully, you know, when you think about where the risks are on extended time frames, I can give you a pretty good guess at when we're probably having extended time frames from delivery in our neighborhood and it's probably from, you know, 3:30 until 7:30 or 8:00 at night is when the -- you know, it -- just due to traffic and such. It's very hard to make a traditionally quick delivery. Can we look at those sort of time frames and see what's falling outside the norm? What are the things that they're doing? Are there ways that we can ask for reports or information versus actually go out and look at a delivery driver and look at those individual records.

We have to be smarter and work in a smarter manner than what we've probably done in the past.

LAURIE FARMER: And I think COVID has made us all kind of rethink how we do our jobs, right? What are the real essential pieces of what our function is and to reinvent ourselves and the delivery of that, so I think it's really important.

Palak mentioned, you know, it's really important to see what the questions are and responses are, and you know, we're going to have responses that come from the docket and you discuss the gap analysis, and so, you know, I see that occurring, you know, to see what is outstanding.

We've talked about some of that gap analysis. This panel is an opportunity for you guys to share the level of engagement that you'd like to see for the future. You know, once we leave here, what do you want to see happen? What do you want your level of engagement to be?

So, I'll stop there --

PALAK RAVAL-NELSON: Well, I think for me --

DONALD SCHAFFER: Well, this is -- no, go ahead, Palak.

PALAK RAVAL-NELSON: No, I think for me, I mean, making the connection with Don is really important. I'm looking forward to working -- you know, starting at the local level and really working where we're -- and then reconnecting with Doug Farquar and

NEHA and Dr. (indiscernible) to see what information and the lessons that we've learned locally that I can share nationally, and then really, Laurie, going back to yourself and the FDA, just being here. And as you all would like me to take part in any sort of review of questions or gap analysis or share any information that we have, you know, I will gladly share that and be a part of the discussions and figure out and move forward as we reinvent the system.

DONALD SCHAFFER: Laurie, I'll just add, we're going to keep doing research in this area, right, and this -- I get ideas -- new ideas for research projects all the time. I also know that Bill Holman would be very happy with me if I actually finished the draft of the student thesis that came out of the work that is still sitting on my desk and languishing there.

There's no shortage of opportunities to engage, and there's lots of opportunities for creative research and also creative outreach, and it's just a matter of, you know, balancing all of those opportunities amongst all the other wonderful opportunities that we all have every day.

STEVEN MANDERNACH: So, Laurie, I think when we're implementing (indiscernible) we did a great job of engaging stakeholders clearly and often throughout the process to make sure we got closer to the right regulatory answers.

And while I understand that's difficult sometimes with some of the federal restrictions, advisory committee acts, et cetera, you know, that can be challenging, I think this is an area that we're going to no matter what we do end up with cross-regulation and multiple levels involved, and if we don't do that successfully, we're going to have a giant challenge.

The other thing I would just note is I'm not sure that we can wait for two, four, six years to take something through the conference for food protection if we decide the food code is the right direction. I think that's -- that is part of what's getting us into these continual situations, is the extended amount of time it takes to adopt or to make a recommendation and get it adopted, (indiscernible) some of these things just out of control by the time we get them adopted and regulate them, so that's another little

piece to recommend.

But I think (indiscernible) we did a great job of engaging folks early and often. If we can figure out a way to model that process and use it again, we would be in a great spot.

LAURIE FARMER: Great feedback. And you know, I just want to say, these panels are so great because they -- these panelists become resources to each other. They're resources for you, so I know the panelists are going to kill me, but I know -- I want you guys to reach out to them. These are the experts. They're here.

And you know, it's been a pleasure having you guys. This is a really fun session for all of us to engage and discuss, and I want to thank the audience for your participation. It's been really helpful dialogue as we really think about implementation of new business models and retail modernization as we implement the new era of smarter food safety.

Again, I want to remind folks to submit your thoughts and feedback to the docket. That's going to be essential. We really want to hear from you. So,

thanks again to the panelists. It was great fun. Appreciate your time and effort, and I will hand it back to Mike for the break. Thank you.

PALAK RAVAL-NELSON: Thank you.

DONALD SCHAFFER: Thanks, Laurie.

MICHAEL KAWCZYNSKI: All right. And thank you, everyone. So, yes, we will now take a quick break, and then when we come back, we will hear from our next speaker, and then we'll -- so, thank you, and studio, take us to break.

(Recess)

KARI BARRETT: We now have a guest speaker from USDA, Sandra Eskin, who is the Deputy under Secretary for Food Safety at the U.S. Department of Agriculture.

Sandra, it is such a pleasure to have you here today. You are well-known I'm sure to most of our audience in your role as a food safety advocate over the years, and certainly in your current position as well as in the work that you had done previously, (indiscernible) as well as in the produce safety project.

So, it's really a delight to have you, to hear from USDA, and at this time I'd like to turn it over to you to hear your remarks, so thank you so much.

SANDRA ESKIN: And thank you, Kari. It's great to be here. Again, I am the Deputy under Secretary for Food Safety at USDA and I'd like to commend FDA for convening this summit on such an important topic.

It's actually very much preferred or I say always a lot of fun to be the one delivering opening remarks before a panel session. Since I get to ask a lot of questions, I don't have to answer them. The panel does.

So, I appreciate that many of those questions I'm going to go through right now are ones that have been asked throughout the meeting so far and will be asked through tomorrow.

I think that hopefully asking them more than once will prompt people to think about new ideas and novel approaches to handle this food safety issue. Again, in my role at USDA, I oversee the food safety and inspection service, or FSIS, which has regularly --

regulatory oversight for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled.

Since 1906, when the Federal Meat Inspection Act and the Pure Food Drug Act were enacted, certainly USDA has relied on traditional regulatory tools in overseeing the safety of meat and poultry products during slaughter and processing. Again, we rely on inspection, of course, but many other oversight and enforcement tools, testing, detention or seizure of products, et cetera, and FDA has many of those same tools.

So, of course, the question now is how can we in 2021 ensure that consumers are protected from food safety risks posed by foods sold online and delivered by other parties on many different platforms?

Again, in terms of traditional retail food safety, we all think of brick and mortar stores. We have relied on states and localities to oversee grocery stores, restaurants, in terms of food safety, with guidance from FDA through its model food code.

Again, the federal agency's FDA and FSIS

ensure that the products are safely in our case slaughtered but in USDA and FDA's case processed in a way that ensures their safety.

So, what role should FDA and FSIS have in overseeing the safety, the safe transport and delivery of food provided through novel platforms? Of course, we know that the risk posed by food-borne pathogens can change on the journey from processing plant to restaurants, retailers, and homes. Those risks can be exacerbated if things go wrong during delivery and certainly cross-contamination is always a concern.

Okay, so then how do we know if the company that's shipping raw steaks to my house are ensuring that the steaks are kept cold throughout transport to minimize any safety problems or how do I know that the person employed not by a restaurant but by a third party delivery service has handled my take-out meal safely? And again, who should be responsible when food safety problems happen?

Again, in many cases, the services that deliver food to customers involve entities such as shipping companies or delivery drivers who have not

traditionally been focused on or trained in proper food safety and food handling.

There are so many important questions from a regularly perspective such as, again, who has the responsibility for assuring safety at each point in the delivery process? It may change.

Again, what happens if food is left outside a house on a front stoop and people wind up getting sick? And again, what is the role of e-commerce food sellers or even deliverers when there's a problem and a product has been recalled?

Again, because of the way that our food safety system is segmented amongst state, local, and federal agencies, there can be a portion of the continuum where oversight is fragmented or unclear, and I'm sure as I said earlier, there have been discussions about this already. I'm sure our next panel will be addressing this as well.

Of course, we have another element in here. We have contractual agreements between businesses such as online food sellers and delivery services. These can also add to the complexity in determining who

is responsible for food safety at every point.

Now, I will leave to my colleague Robert to discuss what FSIS is doing in this area in more detail, but I'm going to just throw out some more questions, because that's the opening commenter's prerogative.

How do we define a retail store, something FSIS is looking at and others are as well. Should these e-commerce entities be considered retailers? What are the requirements for businesses wishing to offer interstate sale of food products? What about those that want to cross state lines? Or for that matter, somebody (indiscernible) want to import products from aboard -- abroad. Again, in the case of an outbreak, how does FDA and USDA's ability to initiate a food recall or to detain misbranded, adulterated products apply to e-commerce operations and their contractual partners?

Again, I am sure that you will hear more on all of these in the panel that will soon follow. So, bottom line, American consumers should be able to trust that their food products are safe, again, in terms of

handling and consumption, and it shouldn't matter in theory if that product was purchased over a retail counter or with the click of a mouse.

Meetings like this will hopefully move us forward by working through some of these questions collaboratively. Again, I want to thank FDA for the invitation, and I look forward to this discussion, and I'm going to turn it back to you, Kari.

KARI BARRETT: All right, Sandy. Thank you so much for your excellent remarks today, and it's really been a pleasure to have you here.

So, now at this time we're going to go ahead and go to session five, which is the Federal FDA and USDA Perspectives on E-Commerce and Food Safety, Regulatory Framework, and Oversight.

So, we're going to continue our federal regulatory theme, and our next panel as noted is comprised of federal agency subject matter experts and thought leaders who will further expand on the theme raised at the summit and related to food sold through business-to-consumer e-commerce.

And this panel will be moderated by

Glenda Lewis, so Glenda, let me turn it over to you.

Thanks.

GLENDAL LEWIS: Thank you, Kari. Good afternoon, everyone. My name is Glenda Lewis and I'll be moderating today's federal regulatory perspective panel.

I'm currently the Director of the Retail Food Protection Staff and FDA Center for Food Safety and Applied Nutrition, FSAN, within their Office of Food Safety, and in this role I'm responsible for oversight of the team developing national policy for retail food protection as well as for the interstate travel program for interstate conveyances and policy for those conveyances.

As a reminder, the purpose of the summit is to engage with our stakeholders like yourselves and invite input on these various topics pertaining to this new business model, and as a reminder for those that -- or for those that may be just joining us, this core element looks to address how to protect these foods from contamination as these new business models emerge and change.

I encourage all of you that are viewing to actively be thinking about the comments you want to submit to the docket as well as questions for this set of federal panelists during this meeting, and again, you may submit questions to the mailbox at smarterfoodsafety@fda.hhs.gov.

We intend to use the information resulting from this meeting to determine what action, if any, should be taken to help ensure the safe production and delivery of foods sold through new e-commerce business models.

So, as I said, it's my pleasure to moderate this afternoon's panel, and we're fortunate to have with us this afternoon four very accomplished panel members. They have a wealth of federal regulatory experience and B to C e-commerce experience.

And what's listed in the bios is really just a snapshot. We appreciate them taking time to participate and share their knowledge, and our panelists this afternoon, as has been said are from FDA and USDA. We have Dr. Girvin Liggans. There's Jennifer Erickson, Dr. Claudine Kavanaugh, and Mr. Robert Bane.

Again, take a look at the information in the bios on the New Era Summit website.

Today, we've asked our federal regulatory panelists to discuss some topics related to foods sold through B to C e-commerce, and again, that refers to manufacturing, packaging, labeling, storage, and delivery of foods that are sold directly to consumers through commercial transactions conducted electronically on the internet.

We know yesterday we had some overarching themes in terms of the models themselves or any perhaps safety risks with foods associated with that and the type of delivery models. We've heard that both days.

We're going to talk about regulatory approaches to these foods including challenges and gaps and the labeling of foods sold through that. More specifically, we'll discuss federal regulatory perspectives on the B to C e-commerce on the regulatory structure and where current regulations and model codes fit in that existing regulatory structure.

We're going to talk about regulatory

challenges and opportunities ensuring the safety of food sold through B to C e-commerce business. We're going to discuss labeling needs and we're also going to talk about and touch on any differences between regulation of human food and animal food.

With that, let's get started. Our first speaker is Dr. Girvin Liggans. He serves as the Technical Lead for Retail Food Policy within the Center for Food Safety and Applied Nutrition, Office of Food Safety at FDA, and in this role he leads policy analysis and research initiatives for the development and evaluation of retail food safety policy.

I'll turn it over to Girvin.

GIRVIN LIGGANS: Well, thank you, Glenda, and good afternoon. You know, it's really a pleasure to be with you today and talk a little bit on perspectives related to retail food safety and this era of online platforms and e-commerce.

You know, I'll say from the onset, you know, I'm sure it's not at all lost on this particular audience that food affects everything, right? And more specifically, the quality and safety of that food is

literally tied to our individual well-being. And so, you know, we've talked about the importance of all the steps from getting food from its source to the end user are all going to be important.

And therefore, you know, we've called it by many names, that -- the process of getting food from the -- from the source to the point of sale has gone by many names, but one thing that we've consistently called it is this farm-to-fork continuum.

And you know, within this continuum, we've had two over-arching business models, right? And that's been kind of this business-to-business or B2B, and this business to consumer or B2C with business-to-business or the B2B sector supplying B2C or the business-to-consumer. So, we know and we've seen that this is generally on the B2B side in our producers, manufacturers, distributors, and when it comes to the B2C side dealing with that point of final sale, we kind of largely call that retail, right, or retail food establishments.

And this has largely been the case going back to the corner store area of the 1930s until now in

the online era that we find ourselves in. But as has been discussed over the past couple of days, there's a number of specific questions and concerns that are arising that we're trying -- looking at as challenges and things that need to be addressed.

And so, of course, as has been mentioned, it's very important to state that the retail sector for the most part is really regulated at the state, local, tribal, and territorial level, and FDA provides a model food code for adoption.

And what it really sets up is it's kind of FDA's best advice of a uniform system of provisions to address food safety in this particular sector. And it's existed in its purest form, as many know, since '93, but you can find different ordinances and guidelines and guidance stretching back to the '30s.

Now, one thing I always want to stop and pause and just make sure that I emphasize, and that is, you know, retail food establishments right now consisted of much more than just restaurants and grocery stores, right? Even now in this space we talk about prisons, we talk about schools, hospitals, mobile units, food banks,

you know, farmer's market, county fairs, and the list goes on.

There's a number that already fall in the retail food establishments, and so what happens when we think about this in terms of the food code, it becomes important because the food code really tries to take both a component and systems theory approach to the different processes that happen within the food establishment.

And so, with that in mind, it really tries to take a science-based approach to really addressing all of those things that would occur in the food establishment.

And so, this becomes important also because it is -- because it's updated every four years, it also tries to lean into being both adaptive and timely to changes that occur in the retail space.

(Indiscernible) been mentioned on previous panels, you know, that's both like a blessing and a curse, right, depending on what's happening, how much time it takes to discuss an issue, to get into the food code, to possibly adopted by, you know, a state.

There's a lot of time that goes in between there, but by working collaboratively with our state and local partners, we're able to try to do some things even outside of regulation to try to make an impact, and we'll probably talk about that a little bit later.

And so, all of this becomes important in this online era that we have with online platforms which really are these digital, you know, spaces that facilitate interaction between individuals. And as you can see by the definitions on the screen here for online platform and then e-commerce, the takeaway is that, you know, online platforms -- not all online platforms are going to include e-commerce, but all e-commerce is happening over an online platform, and that distinction becomes important because there's a number of food safety-related issues because things are always adapting that are happening online through a platform but not necessarily through e-commerce, like some of the things that are happening with some of the food donations and food sharing apps that are available today.

And so, what we know is that those have -
- that have traditionally been in this B2B space, right,

traditionally the business-to-business, are increasingly, you know, focusing more on going direct to consumer, right, and bypassing that initial relationship with the B2C or what we call the retail food establishments, right?

So, they're increasingly investing in that area, and so what we see is that both the direct-to-consumer and the B2C, the traditional retailers, have incorporated the e-commerce platforms.

And so, firstly, you know, there's questions surrounding, right, and I think I've heard it raised, you know, well how should those that are doing these various levels of B2C that were traditionally in this B2B space and who doing heavily into direct-to-consumer or D2C, how should they really be regulated? Should they be regulated more like retail?

And so, whether you're looking at that B2B space that is, like, I said, getting more involved in D2C or the traditional retailers, those B2C operators, you see a number of questions coming up in buckets but you definitely see in these areas, right? We talk about ordering, we talk about, you know,

production, and we talk about packing and delivery, right? And we'll talk a little bit specifically, but you generally see those three areas.

And this important, because one of the new things going on, or should I say New Era, but it has been around for a while when it comes to retail food establishments is this role of the digitally native brand or the digital company, all right, digitally native company.

And there's so many different nuances in this new space it becomes important really to distinguish, you know, what we're talking about and how these might cross-pollinate and the relationship.

You know, you have the usual suspects as you see here, right, restaurants, grocery stores. You've already -- you've had difficulty sometimes with people trying to track down illegal operations already. So, now in this digital space, right, which technically being digital native just really means that you started completely online, it doesn't mean that you haven't evolved into having a traditional brick and mortar but you started online, the thing to distinguish is that you

can be digitally native and vertically integrated, and that's where you start to get some different nuances, too, where the vertically integrated, digitally native, controls every aspect of that customer experience from start to finish so you get -- you get all these different variations of this, and of course would bring about its own questions and complications.

And that leads us to the big area of -- as I've heard a lot of discussion on so far and I'm sure we'll hear about it more, and that's this whole area of delivery, right? And we see -- it runs the gamut when it comes at what's being delivered. We've got the prepared foods, the grocery foods, and the meal kits.

But what we really see is this variation in the ordering, delivering platform, you know, and how it works, right? So, you've long had the traditional and you continue to have the traditional where a retail food establishment can take an order over the phone or, you know, online and they handle all logistics of delivery, right? I mean, this is something we've seen for quite some time in the industry.

And then of course you've got this

evolution of these aggregators they've been called where you've got an online platform that handles both the -- handles the ordering but the retail food establishment still handles all the logistics of delivery.

And of course, you know, where all of the innovation is happening and where it continues to grow, and that is, you know, on these online platforms that handle both the ordering as well as the logistics of delivery and all the different variations they're in, right, delivery only, package and delivery, and so on and so forth.

So, there are a number of things going on in that particular space. And so, this brings us back to those buckets that people have been -- like I said, have -- we've heard conversation about and we want to hear more about, and that is with the ordering aspect, we're hearing different things about, okay, well, what are the regulations, what should the regulations be?

And everything from -- I've heard, you know labeling, we've heard issues regarding, you know, what should be on the website itself. We talked -- you know, even talking about, and some states have already

moved on different aspects of taxing and things like -- of that nature, so it becomes very important for us to really kind of delineate what is a need and a particular issue in a given area.

And then of course production, and whether you're talking about the D2C or B2C, you've got issues and concerns about potential food safety challenges as well as what the current regulations are as well as what might the gaps be and what should be addressed, so I think it's very important for us to understand which buckets and delineate, and we really want to hear from all of our stakeholders about these areas and be very delineative.

And then of course the packaging and delivery, so there's issues not only of the regulations, the food safety, but also around liability. So, we're very interested in hearing more and discussing more about this.

And with that, I'll turn it back over to you, Glenda.

GLENDAL LEWIS: Thank you, Girvin. That is great information and we really, really appreciate

your insights on that. We'll talk more later toward the end when we get to questions.

Our next speaker is Dr. Claudine Kavanaugh, and she serves as a Director of the Office of Nutrition and Food Labeling within the Center for Food Safety and Applied Nutrition at FDA, and her recent activities include leading the (indiscernible) nutrition innovation strategy, restaurant menu and venue, and vending machine labeling, updating the nutrition facts label, and sodium reduction.

With that, I'll turn it over to Claudine.

CLAUDINE KAVANAUGH: Thanks, Glenda. I'm happy to be here to talk about food labeling (indiscernible). Actually, today I'm going to be focusing more on the labeling (indiscernible) for online grocery shop. So, before the pandemic, certainly were ordering their groceries online (indiscernible) what a great way to do it from the comfort of your own home and either have the groceries delivered to you or you do a quick pick-up at the retailer.

But the pandemic really accelerated the use of online grocery shopping. In 2020, the online

grocery sales grew 54 percent and it accounted for just a little over 7 percent of all grocery sales, and it's anticipated that online grocery sales will grow up to over 11 percent.

And interestingly, the trend of using online grocery shopping really cuts across all demographics. USDA expanded the ability to redeem SNAP as well as WIC benefits in most states.

The recent (indiscernible) survey has shown that younger consumers, African Americans, and parents tend to grocery shop online more than other groups.

So, this trend of, you know, purchasing your groceries online really can change consumer behavior indefinitely and makes it increasingly important for FDA to provide guidance regarding the food (indiscernible) that should be available to consumers at the (indiscernible).

So, the labeling requirement, there's a lot of mandatory (indiscernible) including nutrition information which we look at as (indiscernible) label, ingredients, declarations, as well as allergen

information.

(Indiscernible) must be provided under (indiscernible) labeling (indiscernible) Federal Food Drug and Cosmetic Act. The primary purpose of labeling is to provide consumers with information so they really can make informed decisions about what they eat and buy, and particularly the information on the nutrition facts label can really help consumers maintain healthy dietary practices.

So, we think this is important information for consumers to have. In 2007, FDA provided some information regarding online labeling in a Dear Manufacturers letter, and in that letter, we really (indiscernible) that in some circumstances, the information disseminated online by or on behalf of a regulated company (indiscernible) the definition (indiscernible) labeling under the act and is subject to the require (indiscernible).

We also have found -- we also really think labeling (indiscernible) truthful and not misleading. While FDA has recommended in the past that nutrition information be presented online similar to

FDA's regulations for consistency to kind of minimize consumer confusion, we do acknowledge that a lot of our labeling requirements really predate the online practices really people (indiscernible) utilizing (indiscernible) shopping.

So, one thing that we've noticed with, you know, online labeling, there really isn't a lot of consistency on -- in how the labeling information is being presented for food products. The -- there's a lot of -- it varies greatly between the different types of platforms, and sometimes it can be challenging to find the information.

And in preparation for this (indiscernible) I actually looked up online a box of cereal, (indiscernible) cereal that probably is in a lot of people's cupboards at home and wanted to look it up on (indiscernible) sites and find the nutrition information.

Happy to say that it was on all of the sites that we looked at; however, it really (indiscernible) to not being very consistent. Some of the sites the information was right there.

All you had to do when you -- I found the cereal was just scroll down and I could (indiscernible) information, the ingredients, allergen information, very easy to see. Others it was more (indiscernible) and you had (indiscernible) on it but very well able to find the information very quickly.

I will say on one site it took me about three or four minutes to actually locate any of the information, and I was definitely getting a little frustrated with that and I had to click probably about eight or nine (indiscernible) go through a series of pictures of people eating the cereal, a picture of the cereal in the bowl with milk and a spoon before I actually got to the (indiscernible) information.

So, I can definitely relate to the third bullet about consumers not really being (indiscernible) to identify or find the information quickly. And then another area that we're definitely interested in is the discrepancies between the labeling on food packages as well as one of the sites that I went to actually had a disclaimer about the accuracy of the information that they were giving online.

So, FDA is really interested in gathering more information from consumers and retailers to better understand the challenges about providing this (indiscernible) want to hear from the consumer perspective as well as the regulated entity (indiscernible) stakeholders.

So, really, we want to know what labeling information is really important for consumers to have access when they're doing their shopping, and do consumers really expect to have all of the labeling information online that is the same to the product label (indiscernible) or only certain elements.

Is the labeling information online consistent with what's actually on the label and how is the information presented? And I gave in my little scenario of looking at eight different sites, it varies a lot from having more information (indiscernible) what's helpful to consumers would be very helpful for.

And then looking at it from the regulated industry, is the labeling information provided online consistent with the actual product label that is purchased?

I do understand that it -- this is probably a little bit more challenging in the online environment as the manufacturers change their label or reformulated their products. And for example on the cereal if it changed and the nutrition facts label changed, when the retailers in their brick-and-mortar store -- they just put the new boxes of the cereal probably right next to the old ones and a person could pick those up and look at the information.

It's a little bit more challenging when they're making that change (indiscernible) when does it get changed in the queue and delivered to the person. So, we do understand there are different scenarios. I also want to take into consideration providing the (indiscernible) through different platforms.

Retailers have it, sometimes (indiscernible) using the phones, sometimes they're using websites on their laptop. So, the different (indiscernible) any challenge (indiscernible) providing the labeling information there. And what are some of the issues or limitations they have with their respective platform?

And again, how does the manufacturer and retailer of the grocery store really ensure that the information is accurate and up to date? We definitely understand some of the challenges but there are definitely safeguards and things like that that I think (indiscernible) can implement so understanding more about what's happening, very helpful.

So, we really encourage people to kind of think about the questions that we're asking, providing us more information so we can assess -- better understand the challenges of providing and doing the labeling information so we can provide further guidance to (indiscernible). Thank you.

Back to you, Glenda.

GLENDAL LEWIS: Thank you, Claudine. I appreciate so much hearing that information there. There's so many people interested in labeling and you provided us some really important things to think about, so thank you for that.

We'll hear now from our third speaker, Jennifer Erickson, and she serves as the Acting Director of the Division of Compliance in FDA Center for

Veterinary Medicine in the Office of Surveillance and Compliance, and this division helps regulatory policy, it supports field operations and protects public health using regulatory actions for animal food, drug, and device products.

And with that, I'll turn it over to Jennifer.

JENNIFER ERICKSON: Thanks, Glenda. So, yeah, today we're going to talk a little bit about animal food. There has been an increase in pet ownership and the sales of pet products including pet food and pet treats, using e-commerce platforms and the delivery of pet foods especially in the time of pandemic.

So, today we're going to highlight some of the differences and similarities between pet food and human food with respect to the regulatory framework, the types of e-commerce business models we're seeing, and food safety.

So, first I want to talk a little bit about some of the differences between the regulatory structure for animal food and human food retail

establishments. So, the first thing is that there's not an FDA retail food code for animal food retailers like there is for human food.

The FDA retail model -- retail food code only really covers human food under its requirements. And so, in practice, this means that animal food retail businesses including those that use the business-to-consumer e-commerce business models are regulated a little bit differently than our human food facilities both at the federal and state levels.

Because most of the pet food retailers are selling directly to consumers, they're going to actually be exempt from our food facility registration requirements as well as additional regulations for the preventative (indiscernible) animal food rule.

Who has to comply with that rule really depends on whether a facility has to register as a food facility. And the way that you determine that is, is that who -- who you're selling to. So, a business doesn't have to register as a food facility and meet the definition of a retail food establishment if they're selling more animal food directly to consumers which are

pet parents in the animal food world than they are to other food businesses.

So, because most of our pet food retailers, both the traditional brick and mortar pet food retail stores as well as our online pet food retailers, our grocery stores that sell both human and pet food and then, you know, some of our pet food manufactures that sell directly to their consumers and not to other businesses, they're not -- they're going to be required to follow the requirements of the Food, Drug, and Cosmetics Act and ensure that this food is not adulterated, but they're not going to be subject to additional requirements on the prevent of control for animal food rule.

Some of our businesses are going to be selling some of their animal food to other businesses as well as directly to consumers. And if they're selling more of their animal food to other businesses, they're going to be required to register as a food facility.

And examples of this would be our businesses that are pet food manufacturers and then sell some of their pet food directly to consumers but they're

going to -- they're selling more of that pet food to another business that's going to further distribute or sell it.

And so, these businesses are going to be subject to the current (indiscernible) manufacturing practice, hazard analysis, and risk-based preventive controls requirements that are in our (indiscernible) preventive control for animal food regulations. And so, we would routinely inspect these businesses under those requirements in addition to them also being subject to the Food, Drugs, and Cosmetics Act's adulteration provisions.

So, although the FDA Model Retail Food Code does not apply to animal food, we do have state regulatory partners with programs that are responsible for regulating animal food safety and then the laws and rules of their specific jurisdictions. But because there's not a model food code, some of the requirements are going to vary from state to state.

So, next let's talk a little bit about some of the trends that we're seeing as far as e-commerce and animal food. And generally, we find that

many of the trends that we see in human food often quickly become trends in pet food. And this of course has been true of e-commerce as well. We see a lot of businesses and marketing trends for pet foods that are similar to the business models on the human food side.

For example, some pet foods or pet treat manufacturers may market their products online and ship those products directly to consumers. And as Dr. Solomon mentioned earlier, we also see pet food now being carried by third-party delivery services. So, for example you can use a third-party app to order your pet food or treats and then have them directly delivered to you via that third-party delivery service.

And then, we've also seen a rise in digitally native brands that don't have a physical store for you to visit. Some digitally native brands specialize in pet food sales, that's the focus of their business, and then others have pet food sales as part of their many products offerings. So, a lot of similarities between human and animal food in this area.

So, finally, you know, as we're talking about the pet food sales and delivery models, let's talk

a little bit about food safety during these (indiscernible).

So, typically pet food can be thought of from a food safety perspective as falling into kind of three broad categories. Our pet foods that are packaged and shelf stable such as our dry pet foods and treats and those that are canned or pet foods that are refrigerated and frozen or have not been processed to be shelf stable, and then our pet foods that are sold in bulk and then packaged. So, for example, some stores have bands of pet treats or pet chews that you can kind of, you know, reach in and grab a few for your pets.

Each of these different categories poses different food safety considerations, especially during the last mile of distribution. Pet foods that are packaged and shelf stable are not likely to be impacted during the last mile provided that the packages are delivered in a way that doesn't interfere with that package entirety.

So, for example, the packages aren't getting ripped or wet or somehow damaged so that the contaminants could be introduced. Our pet food that

requires time or temperature control to prevent the growth of pathogens during that delivery process is going to need to be maintained at an appropriate temperature, both while it's being held prior to transportation and then during transportation.

And then our other category, the pet foods that are sold in bulk, you know, really, the key food safety thing to think about there is that they're held and transported in a way that they're not contaminated with any chemical, physical, or environmental pathogens.

You know, a few years ago we had several recalls of (indiscernible) pet treats that were contaminated with Salmonella and humans got sick from handling the pet chews in their home. These chews are sold in bulk and co-mingled during the distribution process.

And you know, bulk storage and comingling of product (indiscernible) result in some post-processing contamination of pet food with pathogens from the environment. So, in our physical retail stores, this might be introduced by, you know, people reaching

in, grabbing some pet treats and chews from a bulk bin.

Our current understanding is that most of our treats and chews that are delivered from, you know, an e-commerce type model are typically packages and may not be exposed to contamination from people handling them.

But if those bulk foods are being handled by employees prior to distribution, if they're being packed in boxes to be sent to the consumer, it's really important that those handling activities be conducted safely so that the pet foods and treats are not contaminated.

So, in addition to kind of these specific food safety concerns, all of our pet foods should really be handled in a way that's sanitary and protects the pet food from contamination.

So, you know, again, thinking about things like pest infestation and other just general goods handling practices for food. Many of these food safety concerns are really similar to the types of food safety concerns for human food that's sold and distributed through e-commerce models.

So, as we discussed earlier, many of our pet food retailers, whether they are traditional pet food brick and mortar stores or ones that fell primarily online, you know, because they're not subject to food facility registration, they're selling directly to the consumer, those pet parents instead of to other businesses, they're not currently subject to specific FDA regulations regarding food safety.

They still have that obligation under the Food, Drug, and Cosmetic Act to ensure that they're not adulterating their animal food or distributing an adulterated animal food but there's not specific regulations for them.

And so really, through this summit and the open docket, we would really appreciate comments that address whether additional federal food safety regulations are necessary to address food safety concerns for the pet food retail distribution both for traditional brick and mortar stores and for, you know, the various e-commerce and delivery models that we're focusing on in the summit.

In addition, you know, some of our pet

food retailers that fall through e-commerce are also manufacturers of the pet food. And you know, in the situations where they're selling directly to consumers and not to other businesses for further distribution, they too are going to be exempt from food facility registration and from (indiscernible) preventive controls for animal food regulation.

Again, they're still required to ensure that the food is not adulterated under the Food, Drug, and Cosmetic Act, but they're not specific regulations that are going to apply to them. And so, we would also appreciate comments that address whether these types of facilities should be regulated in a way that's similar to other pet food manufacturers including, you know, should they be required to register as a food facility, should they be subject to the preventative controls for animal food regulation, et cetera.

So, we really want to ensure that regardless of the sales model, regardless of, you know, who's doing the manufacturing of the animal food, how it's delivered, we want to make sure that at each step of the way that animal food is handled in a way that

results in a safe and unadulterated pet food and treat.

And so, that's really, you know, where we're hoping to hear a focus of comments from this process. Thank you.

GLEND A LEWIS: Thank you -- thank you, Jennifer. We all love our pets and it's truly interesting to hear about the animal food aspects of it so that we're sure to keep them safe. And now, our last speaker today is Mr. Robert Bane, and he serves as the Assistant Administrator for the U.S. Department of Agriculture's Food Safety, and Inspection Service in their Office of Investigation Enforcement and Audit.

And in this capacity, he leads the USDA FSIS Surveillance and Investigation Activities for incidents of food-borne illness outbreaks, recalls, natural disasters, and intentional contamination, and he oversees state and foreign audit programs and enforcement and litigation functions. And with that, I'll turn it over to Robert.

ROBERT BANE: Well, thanks Glenda. And I want to start out by thanking my colleagues at FDA for hosting this summit and for the invitation to join this

discussion. I really appreciate the opportunity to speak with you all today.

As Glenda said, I work for the Food Safety and Inspection Service, which is the federal agency responsible for the regulation of meat, poultry, and egg products intended for commerce.

Today I want to provide you with sort of an overview of the regulatory framework that we currently have in place for the production and sale of those products in the retail environment to include interstate transactions facilitated through the online platforms.

So, I'll start out by giving you a quick overview of how FSIS approaches its regulatory role in the slaughtering and processing arenas and then we'll work our way to the retail environment and e-commerce.

So, FSIS regulates the production of meat, poultry, and egg products for human food under the authorities of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

And these statutes require that meat,

poultry, and egg products intended for commerce be inspected and passed by FSIS. Now, for meat and poultry, that process begins at the slaughter establishments where FSIS inspection personnel perform animal ordinate post-mortem inspection on each and every amenable animal slaughtered for human food. We also conduct daily inspection at processing establishments that produce meat, poultry, and egg products for commerce.

FSIS has approximately 8,700 employees. Most of those employees are frontline inspection personnel that provide daily inspection service at over 6,000 meat, poultry, and egg products establishments across the country.

And each of those establishments has been issued (indiscernible) federal inspection and is assigned a unique establishment number. Now, federal inspected establishments are required to comply with sanitization performance standards and develop written food safety plans to include sanitization standard operating procedures and has an analysis of critical control point plans to ensure the safety of the products

that they produce.

Products produced under FSIS inspection are labeled with a mark of federal inspection and you'll see some examples of that mark in the lower right corner of this slide and that mark signifies their eligibility for commerce.

And there's no restrictions on the movement of these products through commerce. They can be sold to anyone in any quantity including through an e-commerce platform or through a traditional brick and mortar retail store.

FSIS also partially funds state meat and poultry inspection programs in 27 states. Those are the dark blue states on this slide. These cooperative state programs are authorized by the Federal Meat Inspection Act and the Poultry Products Inspection Act.

Now, an important distinction between federal inspection and state inspection is that meat and poultry products produced under a state inspection program are only eligible for distribution and sale within that state.

And that's a key point to keep in mind as

we get further into our discussion about retail sales and e-commerce. Now, some states do have a secondary cooperative agreement with FSIS to participate in what's known as the cooperative interstate shipment program or CIS.

Under this program, selective establishments are inspected by the state using regulations and methodology that are the same as those utilized as FSIS and establishments operating under a CIS agreement may apply the mark of federal inspection to products and shipments across state lines.

So, FSIS also performs the inspection of imported meat and poultry products, and only meat and poultry products that are produced in approved countries and foreign establishments are eligible for import into the United States.

FSIS only allows imports from countries that have demonstrated that they've implemented an inspection system that provides an equivalent level of food safety to that of our domestic system. And these foreign inspection systems are audited by our agency on a routine basis and each shipment of meat and poultry

from a certified establishment is reinspected by an FSIS inspector at an approved import facility.

The Federal Meat Inspection Act and the Poultry Products Inspection Act both exempt operations traditionally conducted at retail stores from routine inspection requirements. And so, that means that retail stores can prepare meat and poultry products for sale to the end consumer in normal retail quantities without a grant of federal inspection.

They aren't required to maintain (indiscernible) plans and SSOP's like federally inspected establishments. They are, however, still subject to the adulteration (indiscernible) provisions in our statutes.

Businesses that use an e-commerce platform can prepare meat and poultry products for sale directly to consumers under the retail exemption; however, in order to be eligible for interstate sales and shipment, those products must be produced from federally inspected source products.

And that's because the regulations don't include the slaughter of beef, swine, and other amenable

animals to the Federal Meat Inspection Act in their definition of operation traditionally conducted at retail stores.

While the Poultry Product Inspection Act does provide some limited exemptions for the slaughter of poultry, none of those exemptions allow for transactions and interstate commerce.

And as I mentioned earlier, state-inspected products are eligible for interstate commerce only. So, therefore if a business wishes to use an e-commerce platform to facilitate interstate sales of retail exempt meat and poultry products, those products must be derived from federally inspected source products.

Now, it should be noted that imported meat and poultry products from eligible foreign establishments that have been reinspected and passed by FSIS inspection personnel are considered federally inspected in this context.

While FSIS doesn't perform routine inspection of retail exempt facilities, retailers as I mentioned earlier are still subject to the adulteration

in the branding provisions of our statutes as well as certain recordkeeping requirements.

The acts do provide our authority -- or agency with the authority to access and examine the facilities and inventory of retailers and other firms that sell and transport meat and poultry products in commerce as well as the authority to exam and copy records and to collect samples in exchange for fair market values.

FSIS has compliance investigators located throughout the country that conduct surveillance activities at distribution centers, warehouses, transporters, retailers, and other firms to verify that meat, poultry, and egg products are from approved sources, that they're appropriately labeled, and that they're not adulterated.

Compliance investigators have the authority to detain misbranded meat and poultry products in commerce and they investigate and document violations of the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act.

And depending on the nature and severity

of those violations, FSIS may elect to pursue enforcement action administrated in the civil and criminal arena.

The FSIS website has several resources that firms that are interested in operating under the retail exemption may find useful. The address for that website is www.fsis.usda.gov. The first document on the slide is for the livestock slaughter and processing exemptions, and it covers the personal use and custom exemptions in addition to discussing exemptions for restaurants, retail stores, and central kitchens, and it also explores some emerging business models for food and how FSIS regulatory requirements apply to those models.

The second document covers the various poultry exemptions and the limits on the distribution at those products and the third document provides guidance to retailers on best practices for controlling listeria monocytogenes in retail environments, record-keeping requirements for retailers that grind beef, and information on food-borne illness trace-back and more.

And then the last link takes you to important and export library which includes a listing of

countries and establishments that are eligible for importing meat and poultry products into the United States.

And with that, I'd like to thank our partners at FDA once again for the opportunity to be here with you this afternoon and thanks to all of you for your time and interest in this important topic, and I'll turn it back over to Glenda now as I understand that we have some questions for the panel.

GLENDAL LEWIS: All right. Thank you, Robert. We appreciate that and I would like to thank all of the panelists for providing such insightful input on these regulatory aspects regarding B2C e-commerce we've discussed today and really yesterday, how food -- how for several years now and especially during the pandemic there was an expansion of food sold through B2C e-commerce.

And one thing I want as a reminder as we go into the questions, you'll see on the screen it says smarterfoodsafety@fda.hhs.gov, so please submit your questions to that and we'll get started and we'll see them as we go through our session today.

So, looking forward to our discussion. But we do know that we've been shifting from traditional models. We've heard about that today, the B2C e-commerce model, and many of us are online today because of our individual and collective interest in how we and our families -- we see food as consumers when using B2C e-commerce and most of us, if not all, have certainly ordered through those platforms.

So, it really becomes a personal issue to us. So, now I want to pose a few questions for the panelists to answer. And here's the first question, and I would like to mention that each panelist will have an opportunity to answer these questions should they -- should they wish to do so.

So, what actions if any could FDA and USDA undertake to help B2C operators better understand existing regulations? And think about for example what actions, maybe a regulation or standard or a model practice or a technique. Is it training or outreach or guidance, or even revisions to the food code we've heard in the other panels (indiscernible) mention about the food code.

But what actions can FDA and USDA undertake to help me to see operators better understand existing regulations? Would anyone like to start us off?

ROBERT BANE: I'll start if that's okay, Glenda.

GLEND A LEWIS: Yes.

ROBERT BANE: So, I referenced some of the guidance documents that FSIS has posted on its website in my presentation and of course as new business models continue to emerge, it's always important for us to go back and revisit that guidance and update it to ensure clarity and how regulatory requirements apply to those new models.

And so, a couple of years back our agency released a guideline on determining whether a livestock slaughter or a processing operation was exempt from inspection requirements.

And in that document, they dedicated a section to emerging local and regional food business models where they address businesses like food hubs and online markets and home delivered meals.

So, I think that approach is a good starting point. But we also have to make sure that our regulations adequately address the operations that are being conducted by these emerging business models and that they continue to protect public health.

And for example, we've seen in FSIS increasing interest in the marketing of shares of live animals over the internet, and then slaughtering those animals under the custom exemption and shipping the resulting meat products to the -- to the shareholders. And so, that prompted a lot of discussion on whether FSIS should limit the number of individuals allowed to co-own an animal that's presented for slaughter under the custom exemption and whether rule making needs to be enacted to clarify the keeping requirements associated with those transactions.

And so, the agency put those questions forward at the recent meeting of the National Advisory Committee for Meat and Poultry Inspection, which has representation from the industry, consumer groups, academia, and other regulatory authorities.

We've also put forward questions to that

group on what types of situations may warrant allowing third parties to prepare meat and poultry products received from retail restaurant operations for delivery to consumers without inspection and whether rule-making should be conducted to address those situations.

So, we're continuing to evaluate the changing landscape to determine how our regulatory requirements fit into it and to make adjustments where necessary and communicate with our stakeholders about the challenges that we're facing and (indiscernible) currently stand.

GLENDAL LEWIS: Wow, that is fantastic, sounds like it's really, really busy. Did any of my FDA colleagues want to chime in here?

JENNIFER ERICKSON: Yeah, this is Jen from the animal food perspective. I mean, I think, you know, one of our challenges as we implemented (indiscernible) was that, you know, these were new regulations for animal food. We hadn't previously had regulations for pet food, and it was a challenge to help people understand who had to register as a food facility and who (indiscernible) subject to those requirements.

We've done a lot of work in updating some of our guidances like our food facility registration guidance to help provide some information out there in the world for people about where do these different businesses fall.

And I think we would, you know, really appreciate comments, you know, beyond that and what requirements applied to you, also, you know, what would be useful information for people who may not be subject to those requirements and are just subject to the food, drug, and cosmetic adulteration provisions, you know, what are the expectations for them? What are the food safety risks they should be looking out at? And you know, what kind of practices might they be employing to kind of mitigate those risks?

GLENDAL LEWIS: Thank you. Thank you.
Claudine, did you want to add something?

CLAUDINE KAVANAUGH: Sure, I just wanted to say about the labeling, so FDA -- a lot of our labeling (indiscernible) really pre-dates the onslaught of (indiscernible) grocery shopping that's been a more recent phenomenon.

So, we're really looking for -- trying to gather a little bit more information from stakeholders, particularly trying to utilize the information you're going to get from this meeting docket, to really just inform or understanding some of the challenges that people have with actually looking at labeling (indiscernible) online but also regulated stakeholders, how they have to provide the (indiscernible) as well.

So, we really (indiscernible) encourage everybody (indiscernible) docket to give us some feedback so that will really (indiscernible). So, we really appreciate -- I know a lot of this (indiscernible) more food safety focused, but I (indiscernible) labeling (indiscernible).

GIRVIN LIGGANS: I'll just -- let me follow up on a number of things that both Jen and Claudine said, because I think one of the things that becomes important (indiscernible) help is to really kind of get a little bit clearer on some of these terms, right? And how some of them are used interchangeably but mean something different and really try to delineate when we talk about something that's new how it really

relates to what exists, right, and what regulations currently apply to that so we can get clear on a conversation about what the gaps are or where the gaps may be. So, I think that's what they meant that it would be helpful.

And of course, we're looking for that and reviewing some of that for this summit, and I think those are some of the things that we need to continue to do, because on some levels we're running into a situation -- I'll just give you one -- where it -- e-commerce just by definition can just be a -- you know, a sales platform.

So much information (indiscernible) delivery in third-party delivers because they intertwine, but just like we had the early cash register then we had, you know, we've got coin operating things, (indiscernible) cash register, you know, credit card swiping, you know, now you have the ability to pay over an app.

Right, there's aspects that just relate to the way in which payment is made versus all of these other variations that happen whether it be it's someone

who is traditionally as I mentioned business-to-business or someone who's business-to-consumer and how it exists in this e-commerce space and how they're interacting.

So, I think some of that clarification over terms being clear on what exists versus what is new because it keeps evolving. So, to me it becomes extremely important to -- that people can clearly identify how does this differ and in what ways from what's already established and we understand that regulatory framework.

Think it helps people when they're -- wherever they are in that conversation and wherever they come in to kind of level-set. And so, that's one thing that I would just add.

GLENDAL LEWIS: I think that's a key point when you say level-set. Some of the conversations that our state and association partners (indiscernible) to have, you know, to come back together, have these technical conversations around that, and it's really looking at -- and we just have to understand those foundational pieces, right?

And you guys have laid out that this is -

- this is where we are, this is where we think we want to go, and how do you factor in new and evolving and innovative things that aren't even in yet, right? And to prepare for that. And that's what New Era is all about, taking us into at least a 10-year mark down the road. So, thank you for that.

GIRVIN LIGGANS: It's absolutely important, right, not to stifle innovation as at the same time we're trying to ensure, you know, food safety at every level, so absolutely.

GLENDIA LEWIS: Yeah. We also had a question about -- like to know, like, at a minimum -- and Claudine this will be for you -- for some of the labeling requirements in the B2C platform. Can you cover again some of what's there, what's kind of not there yet, what we're exploring, what we -- where we need some information.

Can you touch on that again, for us?

CLAUDINE KAVANAUGH: Right. So, we're actually very encouraged that that most on (indiscernible) certainly in grocery store settings or retailers are providing (indiscernible) so that's very

helpful. It's just that it's all in different formats, and as I discussed, all of that information is truthful and not misleading, and you know, we really are looking to -- all of our regulations really predate this kind of era.

We're trying to get more (indiscernible) through the docket to kind of engage so we're better information (indiscernible) and some of the challenges that companies and consumers might have with viewing this labeling information before we provide further guidance. So, we're really utilizing this (indiscernible) start to engage with stakeholders before we start rolling out or giving more information.

GLENDAL LEWIS: Thanks, Claudine. I have one more question. I see we're getting close to our break time, but just one more. The -- as a group, you all mentioned several (indiscernible) challenges in the federal regulatory landscape that present opportunities for exploration as well as innovation and as we seek what actions, if any, to take, this dialog is beneficial, and we know that much work remains.

But yet, there's some aspects that are in

place right now and to help control food safety risk. Can any of you tell us your thoughts on how existing federal regulations and model codes from USDA and FDA are helpful in -- for achieving safety (indiscernible) in food, in B2C e-commerce, or really controlling any risks that are encountered?

So, how are our federal -- how do you see the existing federal regulations achieving that? Anyone can jump in first.

GIRVIN LIGGANS: I'll jump in there. And at least from the reach-out perspective right, when it comes to the model food code, and as I mentioned before and as we all know here in this audience that, you know, it's really -- retail is really regulated at the state, local, tribal, territory level.

But through the FDA Model Food Code which we provide and it's -- you know, continue every four years to go through, you know, a collaborative process just to try to keep it up to date, you know, with current changes, I think, you know, one of the things to consider is that it really does try to look at specific components of different -- the intersection between

people, processes that happened with (indiscernible) establishment. So, there's a lot there when it comes to what's happening within a food establishment.

And as you can see, I think some of the things that as we venture into as it leaves the food establishment and the different players that may get involved, I think it's important to kind of think through some of the long-standing food safety principles that have been in place and how they need to apply, right?

Because there's an aspect of delivery that is happening that has happened for a long time. The difference has been that it's really been under the control in some form of the food establishment, right?

And now we've got this other piece that you have a third party. So, in a way, the e-commerce, a platform in and of itself, is -- it's important but you can almost remove that and just say even if people didn't have an e-commerce or online platform to do it, if an establishment delivers it to somebody else before it gets to the end consumer, what kind of concerns, food safety, you know, aspects do we need to be thinking

about?

And so, you know, I offer that because I think those, that type of perspective to keep in mind is important because the food code has a long-standing, you know, history of trying to provide, you know, solid science-based, science-informed provisions to regulate this space, but of course it's within the -- for the most part within the confines of the control of a food -- a retail food establishment.

So, great basis, but as we think about the evolution of these things, I think we need to think about how that basis might need to expand or just the principles need to be applied in this -- in this changing environment.

GLENDAL LEWIS: Right. Yeah, that's a good point. We know the food code has the basic principles of time and temperature control and prevention of cross-contamination, and you know cleaning and sanitization, and that stays the same across all of the new innovations that come in place and trying to maintain that food safety.

Thank you. Did anyone else want to weigh

in on that question? Not today. No takers. Okay.
With that, we will end our question and answer. I thank everyone for joining us today for the -- the federal panel, and I will hand it back over to Mike. Thank you everyone.

MICHAEL KAWCZYNSKI: Thank you. All right. All right. Well, thank you so much and we will now be taking a short little break. So, see you all in a few minutes.

(Recess)

KARI BARRETT: Well, welcome back everyone. This is Kari Barrett, and we are at the point now in our agenda where we go to open public comments. I will be moderating the session and we have a number of panelists. So, let's -- just as we did yesterday, let's sort of walk through what the process is.

With our public comments, we have a panel of government subject matter experts here to listen to the comment offered. We want to welcome everyone who has signed up today to offer public comment and we thank you in advance for the remark you have prepared.

Each of you has five minutes, and we do

have a number of commenters. I will call each person by name and that will start the clock for the five minutes. And so, with that, let's go to our panel and they can introduce themselves again. It's the same panel as we had yesterday afternoon, but I will start with Sharon Lindan Mayl.

Sharon?

SHARON LINDAN MAYL: Good afternoon, everyone. I'm pleased to be here again today to listen to the public comments session. I am Senior Advisor for Policy in the Office of Food Policy and Response in the Office of the Commissioner.

And in that role, I manage cross-cutting policy initiatives, and I currently serve as the lead for the implementation of the New Era blueprint.

KARI BERRETT: Wonderful. Thank you, Sharon. And Glenda, we'll go to you.

GLENDAL LEWIS: Good afternoon, everyone. Again, my name is Glenda Lewis and I'll -- and I'm happy to be here today. I'm the Director for the retail food protection staff within FDA Center for Food Safety and Applied Nutrition in the Office of Food Safety. And in

my role, I'm responsible for oversight of the teams that are actually developing national policy for retail food safety as well as for interstate travel conveyances.

Happy to be here today. Thank you.

KARI BARRETT: I'm happy to have you again, Glenda. We're keeping you busy this afternoon. So, thank you. Thank you for your time. Our next subject matter expert is Mary.

Mary, we'll go to you.

MARY CARTAGENA: Hi, my name is Mary Cartagena and I lead the Retail Food Policy team within the Office of Food Safety, Center for Food Safety and Applied Nutrition.

And I lead the team in development of retail food policy such as the FDA Food Code, the Voluntary National Retail Program standards among other retail group policy documents.

KARI BARRETT: Great, thank you Mary. Laurie Farmer, another person we're keeping busy today. Laurie if you would reintroduce yourself to our summit participants?

LAURIE FISHER: Thanks, Kari. I'm Laurie

Farmer, the Director of the Office of State Cooperative Programs and FDA. I lead strategic leadership in the areas of retail food protection, Mollusca and shellfish and grade A milk safety, and FDA field operations. So, looking forward to hearing the public comment today.

Thank you.

KARI BARRETT: Absolutely. And we had a great session yesterday and we have a great line-up right ahead of us. So, at this point, the FDA says we're going to turn off our cameras, we're going to go to audio, and as mentioned we are going to walk through the public comments.

All right. We'll begin with our first public commenter, which is Stephanie Harris, FMI, the Food Industry Association. So, Stephanie?

STEPHANIE HARRIS: Thank you, Kari and good afternoon. My name is Stephanie Harris, Chief Regulatory Officer and general counsel at FMI, the Food Industry Association.

FMI is the trade association that advocates on behalf of a wide range of members within the food industry value chain from food wholesalers and

suppliers to grocery retailers.

FMI strongly supports food safety compliance and sharing best practices in order to provide consumers with safe products and to protect public health. FMI members openly share food safety information to assist the entire industry with their food safety management programs.

We plan to submit more detailed written comments; however, there are several issues we think are important to raise at the summit today. First, food delivery is not new. There are many different models over many decades from pizza delivery, milk delivery, and even frozen products delivered directly to consumers at home. Consumer expectations and consumer satisfaction are at the root of this business model.

The market drives innovation because keeping customers is becoming more and more competitive. Because business models will continue to change rapidly due to technological innovations as well as consumer expectations, the FDA and other public health regulatory agencies should focus on outcomes that consumers receive safe food and not the process, how they receive it.

Since 2020, we have seen double-digit growth in online shopping with almost 90 percent of FMI member companies reporting the use of online shopping and alternative delivering methods for consumers.

Additionally, two-thirds of consumers report that they have shopped for food online.

Businesses will continue to respond to consumer demands and businesses will continue to innovate. There already is a strong legal framework ensuring the safety of foods delivered through new business models.

This starts with the general prohibition on introducing or receiving adulterated or misbranded food in interstate commerce or adulterating or misbranding food. More specific details are found in the food code, the preventative controls for human and animal food regulations, and the sanitary transportation of food requirements to name just a few.

We encourage the FDA to carefully evaluate existing requirements and to exercise enforcement authority when appropriate before developing new, additional, or different regulations for new business models.

A strong starting point for education and evaluation should be a recently released document from the Conference for Food Protection titled Guidance Document for Direct-to-Consumer and Third-Party Delivery Service Food Delivery.

This was developed by a multi-disciplinary committee with NCFP and includes broad consensus of food safety and public health professionals. This document addresses issues like temperature control, packing, training, and other delivery considerations including allergens, traceability, and recalls.

The food industry is committed to food safety and extends food safety practices to their e-commerce business models. FMI members report having procedures in place to support food safety for employees performing tasks related to e-commerce including temperature controls and practices to prevent contamination.

The industry will continue to innovate while ensuring food safety is at the top of the priority list when serving customers day in and day out. I want

to end by noting that we encourage the FDA to continue to engage with the food industry and food safety professionals to obtain information and encourage the sharing of novel ideas and best practices that will help protect public health.

Thank you for the opportunity to provide comments today.

KARI BARRETT: Great. Thank you so much, Stephanie, and for giving FMI's comments this afternoon. We'll now go on to our next commenter who's Donna Garren with the American Frozen Food Institute. Donna?

DONNA GARREN: Thank you, Kari. Good afternoon. I am Donna Garren, the Executive Vice President for Science and Policy for the American Frozen Food Institute or AFFI. Thank you for the opportunity to share AFFI's perspective and insight during this summit.

AFFI is a national trade association that represents America's frozen food and beverage makers. Our members include farmers, fruit and vegetable growers, makers of prepared foods and compliers and distributors.

AFFI appreciates the opportunity to share with FDA our perspective on opportunities for the (indiscernible) to modernize its protection of the food supply.

AFFI and its members have a long history of advancing science and technology to achieve public health benefits, and we applaud FDA for proactively identifying the ways it can use new and emerging technologies and other tools to advance food safety.

During the pandemic, food supply chains were dramatically tested as Americans -- millions of American's relied on the food and beverage industry to keep shelves stocked.

The pandemic has permanently changed the frozen food industry through accelerated megatrends including the rise of e-commerce, new consumer behaviors, dramatic demographic (indiscernible), new technology, and (indiscernible) emphasis on sustainability of our food system.

The increased complexity associated with the rise of e-commerce brings about a greater question regarding the liability of stakeholders along the supply

chain and these uncertainties become more complex for cross-border transactions.

It has become more challenging to determine who is responsible for food safety incidences arising from e-commerce food transactions due to the increased number of stakeholders end to end.

Due to the explosion of e-commerce, AFFI has embarked on a journey with food safety and supply chain experts in our membership to develop frozen specific food safety best practices guidance related to e-commerce.

The changes of this working group -- the charges of this working group include, one, identify existing food safety guidance for the shipment of foods direct to consumers, and for the safe delivery of food by third party entity -- service entities like the CFP document that Stephanie just mentioned, and using these guidance documents to develop frozen specific recommendations for practices and procedures that maintain the safety and quality of frozen foods delivered directly to consumers.

Recommendations of the AFFI guidance will

address temperature control during shipping, receiving, and storage, use of proper and safe packaging, prevention of cross-contamination, food safety and regulatory requirements for third-party or independent distributors or sellers selling food products on e-commerce platforms, food safety training for direct-to-consumer entities to highlight category-specific food safety practices, and food production, distribution, and retail food service operations.

Two e-commerce related activity that present the greatest concerns from our members include, one, maintaining safe transportation temperatures throughout shipping and distribution, and two, selling of frozen foods without the knowledge of the original manufacturer on various digital platforms.

Examples of unsafe shipping practices include using our frozen products as a replacement for dry ice or gel packs during distribution. As it relates to selling the frozen foods without the knowledge of the original manufacturer on various digital platforms, many members have shared concerns about the potential loss of the chain of custody which would negatively impact

traceability and increase liability.

Moving forward, we do not expect the rise of food e-commerce to slow down any time soon. While we welcome this opportunity and growth, it is unavoidable that we will continue to see issues arise due to the lack of harmonized standards and regulations.

While regulatory gaps bring about food safety and quality challenges, we must be mindful that an over-regulation of the industry would ultimately affect consumers' accessibility (indiscernible) products online and pose a barrier to trade.

If the FDA decides to develop guidance or regulations related to e-commerce, AFFI would support efforts that focus on prevention, relies upon sound science to inform a risk-based approach and enhance traceability.

Using this practical approach in the development of policy will best ensure food safety and equality throughout the establishment of responsibilities and expectations of the multiple stakeholders along the supply chain of e-commerce activity.

Once our frozen-specific guidance is completed, we look forward to sharing with FDA and having ongoing stakeholder collaboration with the agency. Again, we appreciate the opportunity to provide comments during this important and timely summit on food safety and e-commerce, and this concludes my remarks. Thank you.

KARI BARRETT: Donna, thank you so much. And thank you for your verbal remarks this afternoon, and we'll look forward to AFFI's written comments to the docket. We'll now go on to our next public commenter and that is Jim Greene of Next Wave Advisors, LLC.

Jim?

JIM GREENE: Yes. My name is Jim Greene. I'm with Next Wave Advisors. I do independent technology consulting, in particular in the food safety and cold chain monitoring space. In my past, I've developed food safety solutions for major retailers.

I recently participated in the FDA's contest with (indiscernible) submitting their solution, and I strongly believe that the number one comment I would give is that we need to include the delivery

companies in the responsibility for monitoring food -- for food safety at least, you know, from a temperature standpoint being liable for that, because today what I'm seeing and observing is that liability is pushed back to the retailer or to the restaurant, which is totally unfair because those companies have no control over that delivery mechanism.

And yet, the technologies, especially after going through this traceability, they exist. And you know, AND I won't call out names, but personally, every major restaurant chain that I've dealt with, which is somewhere around 30 or 40 of them, have deep concerns about tampering and the reliability of the delivery companies to support this.

So, that probably concludes my comments. I really appreciate the opportunity to speak to you about this. I will say, It's validated by the number of return transactions where people are being refunded for, you know, receiving product in bad shape.

So, that's the end of my comments. Thank you very much.

KARI BARRETT: Thank you very much. I

thank you for taking time out of your day to offer public comments this afternoon. We'll now go on to our next public commenter, which is Rhonda Baines, DCBOH Environment Health.

Rhonda?

RHONDA BAINES: Good afternoon, everyone, and thank you for allowing me the opportunity to speak to the panel. I am currently an Environmental Health Supervisor within DeKalb County Board of Health with the Division of Environmental Health. My scope of responsibilities are to conduct regulatory inspections at local eateries within our jurisdiction.

My perspective is that strictly of a regulator. I also assist with interviewing complainants for food-borne illnesses and just general food safety issues.

Recently there has been an uptick in third-party delivery services being at the helm of some of these food-borne illness complaints. When I'm trying to do the trace-back to see what's actually going on with facilities, the operator of food service establishments regularly defaults to, well, it was

through this particular delivery service, so it wasn't my fault. But there is no way to identify who the delivery driver is and if they in fact had any part of whatever the complaint may have been.

I have witnesses first-hand while doing inspections delivery drivers from third-party services pulling up to grab food and they will have pets in the car, there will be kids in the car, and it's just overall they don't seem to have -- they don't have to abide by the rules set forth in the FDA Food Code that we try to enforce throughout our county, and that seems to create a shift in responsibility and accountability amongst the third-party delivery drivers.

Also, with the increasing boom of pop-up kitchens and ghost kitchens and mobile food service vendors, some of these people are coming in to share kitchen spaces and they're -- on their application with my office they are checking that they are caterers when in fact they aren't caterers. They're not necessarily using contractual obligations to prepare food, which is what a caterer's definition would be, but they are simply preparing food in shared kitchens and then

sending them out using these third-party services.

So, with the lack of regulation, we aren't really sure how to handle them or, you know, how to categorize them. So, it would definitely be beneficial to get a better understanding of what may persist in the future when it comes to third-party services, so we know how to either regulate or advise going forward.

Again, thank you for your time and listening to my comment and that concludes my input. Thank you.

KARI BARRETT: Rhonda, if you're still on, there is a quick question for you. There was a question of what county and state. You mentioned the county, but I think they were wondering what state you're in.

RHONDA BAINES: I'm in Georgia.

KIRA BARRETT: Okay. All right. Thank you so much and thank you for your remarks and for taking the time, and again, please do submit your written comments to the docket as well. Thank you.

We'll go on to our next public commenter.

That's Michael Prorock of (indiscernible). You'll have to say it for me, Michael, but I'm going to turn it over to you. Thank you.

MICHAEL PROROCK: Thanks so much and yeah, good afternoon. Happy Wednesday, I think. They're all running together these days with COVID. No, much appreciate the opportunity to speak, and we will obviously follow up with more detailed, you know, written comments, et cetera.

The primary item that I wanted to comment on was more on the data traceability side, and I think one of the key things that we should recognize is that by this migration over into digital delivery direct to the consumer, we're creating much more of an opportunity for direct to the consumer traceability that provides visibility back to point of origin.

And this is especially important when we look at cross-border deliver of foods. It's also well within the bounds of what the existing, especially major tech players support, right? When we look at large online retailers, you know, of any goods but especially those that are delivering foods via non-traditional

mechanisms that previously were used for books, et cetera, that tech capability is there, right, to provide that visibility there.

One of the traps, though, that we should be aware of is that it's very easy in doing so to create walled gardens of technology and silos of data if we don't focus on ensuring that open standards are used for how that data's interchanged and what formats that data's stored in.

In particular, I think there are great open standards such as verifiable credentials that are a W3C global standard that can be used for securely storing verifiable data, right, which is exactly what we're after from a traceability standpoint.

Ultimately, one of the things that stands also as an opportunity is to ensure that there is interoperability between multiple players supplying traceability needs into the food supply chain side of things, right, whether that's at the farm level, processor, first receiver, et cetera, all the way on up to the retailer.

And so, if we don't ensure

interoperability and open standards on how that data is interchanged, we're going to get into gaps like we -- you know, extensions of gaps like we have now where there's traceability in portions of the ghost system but not consistently across the board.

Ultimately, if we do go that route, that provides the ability to provide publicly testable compliance with those data guidelines. I think there exists the opportunity here because of the all-digital nature to move beyond Excel and (indiscernible) as is currently done now for a lot of that data gathering and exchange or even just handwritten on notebooks, right? Move that data out into these kinds of more modern standards such as verifiable credentials for this exchange of verifiable data.

Ultimately, one of the other things that needs to be accounted for so that we can provide visibility on contamination, allergens, other areas of concern, is that we do account for the combination of various items into a finished food product, right?

Today that can be difficult at times, but the technology exists to support solving, you know, that

traceability and combination, recombination, et cetera, all the way through.

If we do go down this route, it does create more importantly I think a model where we can shift from tracing the items back when a problem's detected out in the marketplace to a proactive detection and identification and the utilization of machine learning to predict where we may see contamination problems or spoilage problems, et cetera, that may cause a food safety issue in the supply chain.

Ultimately, I see this as a true opportunity to, you know, that can be leveraged to bring traceability back to the farm on all levels of items of, you know, food goods that are delivered to consumers, and I think that's important especially given the standing commitment from multiple parties and support via the new proposed traceability rule in another context to provide that level of traceability effectively for free such as our company is doing back to the farm should they need to support new guidelines in that aspect.

So, that's all I have today. Thank you

very much for your time. I look forward to continuing to see the outputs and the great work that you guys are continuing.

KARI BARRETT: Great. Well thank you so much Michael, and again, thank you for your comments this afternoon.

MAN 1: Testing, testing.

KARI BARRETT: We now will move on to our last public comment speaker today, which is John Spink, Michigan State University in the Food Fraud Prevention Academy.

John?

JOHN SPINK: Thank you. First, I must state that the comments are my own and not of my institution or anyone else. Thank you for the opportunity to comment here today, and I commend FDA for taking the step to first look and ask a lot of questions.

Everything I've prepared here supports the comments of the other presenters. I'm Dr. John Spink. I'm Director of the Food Fraud Prevention Academy. I'm also an Assistant Professor in the

Department of Supply Chain Management at Michigan State University within the business college.

My supply chain management role includes overseeing the content instruction of introduction to supply chain management. That's the basic course for all business school students. And that scopes includes a type of foundation setting that you're addressing in this meeting.

My food fraud prevention and supply chain management roles are especially applicable in this meeting since you are first looking for system weaknesses that builds upon my product broad research. You're look -- and other people's research. Second, you're starting with food supply chain mapping to look at all these relationships and all of these type of entities, and then you're conducting risk assessments to identify the problem areas before finally considering any regulatory gaps. Your meeting can create a foundation for all of us to build upon. And that foundation can identify the areas of concern and the most efficient role for each food supply chain partner.

The FDA is taking a proactive first step

aligned with standards such as ISO 31,000 risk management which is establishing the context following ISO 9,000 quality management and ISO 22,000 food safety management, and the next step is to gather incident information like you've heard about.

KARI BARRETT: John are you still there?

MICHAEL KAWCZYNSKI: It shows John's connected, but John did you lose connection? We'll give you a second here. It says his phone's connected. John did you mute your own phone? All right. We may need -- I think what we're going to do here quick is we may have to invite John back for tomorrow, Kari, just to be safe, okay?

KARI BARRETT: Okay.

MICHAEL KAWCZYNSKI: Because something may have happened on his end, you never know. So, again, we want to make sure that John has all the adequate time. So, Kari do you want to wrap up our open public comments?

KARI BARRETT: Yes, Michael. Let me go ahead and do that. So, excellent. We will certainly extend the investigation to John to join us again

tomorrow, and with that we will end our public comment session.

I do want to thank everyone who gave remarks this afternoon for being with us and we do look forward to your full comments noted to the docket. So, now at this time I'd like to welcome back our summit host, Andreas Keller, director of Multicommodity Foods, Office of Food Safety, FDA Center for Food Safety and Applied Nutrition, and Andreas will provide us closing remarks for today.

So, Andreas?

ANDREAS KELLER: Thank you, Kari. And while I -- again, I'm blown away -- we had another great day and experienced excellent presentations with information on the regulatory aspects of food sold via e-commerce.

These past two days of information has shown us how valuable it is to work together in this space. Each of the sessions from industry consumers, regulators, and public comments, perspectives that highlight the work to be done and where we are having positive impact already.

Today where (indiscernible) how it collaborates with state partners. The constant change of food delivery models and the regulations (indiscernible). Regularizes do not oppose innovation and -- as long as these innovations are done safely.

Pet food handling, regulations of compliance of pet foods delivered via B to C e-commerce, education collaboration between federal state, local, tribal, industry associations, social media, and virtual platforms selling food to our success, labeling information requirements (indiscernible) labeling requirements of foods sold B2C e-commerce and (indiscernible) allergens and ingredients, concerns (indiscernible) unlicensed businesses and how to identify and find them, need for best practices and guidance documents related to shipment of foods directly to consumers via B2C e-commerce.

We heard about model code -- food code and a changing landscape of food delivery. I really enjoyed the Q and A conversations we had today and open public comment we had and the (indiscernible) great solutions and approaches to improve food safety in the

B2C arena.

Tomorrow, so let me prep you for tomorrow. We will have another great day I'm pretty sure. It is our last day. We will add in the global perspective of our partners and colleagues around the globe. You definitely don't want to miss this.

We have speakers -- we have speakers lined up from several countries such as Brazil, Germany, Japan, and Wales.

For this, my dear public and all colleagues online, thank you very much and take good care of yourselves.

Good-bye.

(Whereupon, at 4:01 p.m., the proceeding was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, JANEL FOLSOM, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate

record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

JANEL FOLSOM

Notary Public in and for the

DISTRICT OF COLUMBIA

CERTIFICATE OF TRANSCRIBER

I, SONYA LEDANSKI HYDE, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which

this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

SONYA LEDANSKI HYDE