

UNITED STATES FOOD AND DRUG ADMINISTRATION

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

DATE: October 21, 2021

TIME: 11:30 a.m.

LOCATION: Remote Proceeding
U.S. Food and Drug Administration
White Oak Campus, Building 31
10903 New Hampshire Avenue
Silver Spring, MD 20993

JOB No.: 4840365

REPORTER: Terrell Lee
Capital Reporting Company

A P P E A R A N C E S

Mark Abdoo

Associate Commissioner for Global Policy and
Strategy

U.S. Food and Drug Administration

Kari Barrett

Public Engagement Team Lead

Communications and Public Engagement Staff

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

Susan Berndt

Deputy Director, International Affairs Staff

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

Mary Cartagena

Retail Food Policy Team Lead

Office of Food Safety

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

Fabio Miranda da Rocha

Public Health Officer, Food Inspection Department

Brazilian Health Regulatory Agency - ANVISA

A P P E A R A N C E S

Laurie Farmer

Director, Office of State Cooperative Programs
Office of Regulatory Affairs
U.S. Food and Drug Administration

Michael Kawczynski

Project Manager
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Andreas Keller, PhD

Director, Multi-Commodity Foods
Office of Food Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Glenda Lewis

Director, Retail Food Production Staff
Office of Food Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

A P P E A R A N C E S

Sharon Lindan Mayl

Senior Advisor for Policy

Office of Food Policy and Response

U.S. Food and Drug Administration

Judy McMeekin, PharmD

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration

Akira Miki, PhD

Director, Food Inspection and Safety Division

Pharmaceutical Safety and Environmental Health

Bureau

Japan Ministry of Health, Labour and Welfare

Julie Moss, PhD

Director, International Affairs Staff

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

Julie Pierce

Director of Openness, Data and Digital

Wales Food Standards Agency

A P P E A R A N C E S

Georg Schreiber, PhD

Director, Department of Food Safety

German Federal Office of Consumer Protection and
Food Safety

C O N T E N T S

	PAGE
Greeting & Housekeeping Items	
Kari Barrett	9
Day 3 Public Meeting Overview	
Andreas Keller, PhD	11
Opening Remarks	
Judy McMeekin, PharmD	14
Mark Abdoo	20
Session 6: International Regulatory Perspectives on E-Commerce and Food Safety:	
Regulatory Framework and Oversight	26
Moderator: Julie Moss, PhD	
Panelists:	
Akira Miki, PhD, Fabio Miranda da Rocha,	
Julie Pierce, Georg Schreiber, PhD	
Discussion	44
Open Public Comment	54
Moderator: Kari Barrett	
Panelists:	
Sharon Lindan Mayl, Glenda Lewis,	
Mary Cartagena, Laurie Farmer, Susan Berndt	

C O N T E N T S

	PAGE
Daily Wrap-Up	
Andreas Keller, PhD	85

P R O C E E D I N G S

MR. KAWCZYNSKI: All right, and welcome to the "New Era," -- here we go, "The New Era of Smarter Food Safety Summit on E-Commerce." I'm Mike Kawczynski. This is our third day of this wonderful event.

Today I'd like to, you know, once again remind everybody that you can submit written comments, and we highly encourage it. You'll see the link below, and I don't expect you to memorize all of that. But what I do expect is that if you look in the description right on the YouTube page, you can see that link and you can provide comments at any time. Also we'd love for you to -- if you do want to tweet or share information about this socially, use our hashtag, #smarterfoodsafety.

Now we will have a -- today's Q&A will be a little bit different. But we do want you to submit your questions again during that portion to our smarterfoodsafety@fda.hhs mailbox. So please, like I said, any question you may have, please submit them.

Now to talk about you, the people that are

participating, and again, each day we've been watching our numbers climb as this event has been shared around the world and the different industries that have been participating. Right now as we speak, 44 countries initially participated. Now we're up to 49 countries that have participated. And we've had more than 8,000 individual participants each day or overall. So I can't thank you enough for joining us and also for sharing this.

So please, if you're interested in the whole series, you can go to the FDA YouTube site or go to our webpage, again, at New Era of Smarter Food Safety Summit on E-commerce, and all the videos and content will be shared there.

So at this time I'd like to hand it over to my colleague, Kari Barrett, who will be the moderator, or co-moderator for today. Kari, take it away.

GREETINGS & HOUSEKEEPING ITEMS

MS. BARRETT: Great. Thank you so much, Michael, and good morning again to everyone. And as Michael said, this is our third and final day of the summit.

Today we are going to focus on perspectives of e-commerce and food safety, ensuring business-to-consumer e-commerce models produce, sell and transport safe food. And we'll be doing this by inviting in a number of international speakers, our government partners from around the world. So it's a very exciting day, a little bit of a different twist.

And again, I'm Kari Barrett, and co-moderating along with Michael. And we have really covered so much ground over the last two days, and today will be no exception to that.

So again, we want to, as Michael said, remind everybody, we're really excited about your written public comments and also want to remind you on our website there is a one-pager on how to submit comments if you're unfamiliar with the process. It gives a docket number as well as the date for when comments are due. So again, I just want to let you know that reference is there.

And at this time, I'm going to hand the program over again to our summit host, Andreas Keller. Andreas, if you'd like to take it away?

DAY 3 PUBLIC MEETING OVERVIEW

DR. KELLER: Thank you, Kari. And welcome to all my colleagues around the globe. It is a pleasure to be here in this third day and final day of our summit. And as my colleagues said and mentioned, there is much more to come today, and specifically we'll talk about international topics in B2C e-commerce.

I want to take a little time to recap -- to capture what we talked about yesterday when we heard how important and valuable it is to work together in ensuring the safety of foods produced and sold through B2C e-commerce. Each of the sessions involved industry, consumers and regulators. They gave specific insight and perspective on the work that could be done to improve the safety of foods produced, delivered through B2C e-commerce and where we are having a positive impact already.

Some highlights from yesterday and very worthy to mention are we had an overview of how FDA, USDA, state and local partners oversee B2C e-commerce and the challenges and opportunities they face, the

importance of collaboration among federal and state and local regulators, the need to have flexibility in any new standards which might need to be developed due to constant change of food delivery models and the need to foster innovation, the differences in how animal food is regulated and what that could mean to animal food sold and delivered via B2C e-commerce, the need for accessible and accurate labeling information of food sold via e-commerce and how technologies such as artificial intelligence and temperature sensors can help ensure the safety of foods sold through B2C e-commerce.

All of us might think more about the constantly evolving landscape of B2C e-commerce and the opportunities we have to work together and collaborate to ensure the safety of foods. As noted previously, today we will immerse ourselves into the international regulatory approaches used by B2C e-commerce and foods.

Our lead speakers this morning will explain and share their perspectives on how Brazil, Germany, Japan, Wales and the United States of America manage

international regulations on e-commerce and food safety.

Our first speaker this morning is Dr. Judy McMeekin. Dr. Judy McMeekin is the associate commissioner for regulatory affairs in the Office of Regulatory Affairs at FDA, also known as ORA. She oversees approximately 5,000 ORA staff stationed in the United States and around the world.

As the FDA's lead office for regulatory field activities, ORA is at the forefront of protecting public health for today's complex global regulatory environment. ORA partners with FDA product centers throughout inspection, criminal investigations, compliance, enforcement, import operations, field and laboratory operations, among other areas. Before joining the FDA, Dr. McMeekin worked for the United States Pharmacopeia and served as a clinical pharmacist in several health systems.

Following Dr. McMeekin, we will hear from Mark Abdoo. Mark Abdoo is the associate commissioner for global policy and strategy at FDA. He provides executive oversight, strategic leadership and policy

direction to FDA's global operations, trade and diplomacy activities and engagement with international stakeholders expanding the reach of FDA's global agenda in sustainable and measurable ways. Mr. Abdoo joined FDA in 2013.

Prior to joining FDA, he served as senior advisor for food security and agriculture economics at the U.S. Agency for International Development, also known as USAID, and he was the director for global health and food safety at the National Security Council staff at the White House.

I will now turn the program over to Dr. McMeekin and Mr. Abdoo.

OPENING REMARKS

DR. MCMEEKIN: Hello, everyone. Welcome to day three of our New Era Summit on E-commerce. It is my honor to represent the Office of Regulatory Affairs, or ORA, the FDA's lead office for all regulatory field activities. We handle a range of mission critical work including inspections, investigations, sample collection and analyses, examinations of imported products, recalls and

enforcement.

The FDA supports retail food protection in many ways, including the development of the FDA Food Code and the Voluntary National Retail Food Regulatory Program Standards. We also provide technical assistance, standardization and training to our regulatory partners who are so important in our mission to protect public health.

We all know the COVID-19 pandemic has required us to do many things differently. But through it all ORA has been on duty ensuring the safety of food, drugs and medical products. We've continued to conduct mission critical and prioritized inspections, make decisions on imported products, conduct sample analyses in our laboratories and provide technical support to retail food regulatory partners through our retail food specialists.

We've also seen the pandemic change how consumers behave and how industry operates. So we've taken steps to adapt. We have seen a significant transformation in the area of retail food. Updated approaches are needed based on the demands placed on

the supply chain from marketplace imbalances to a rise in e-commerce. We are especially interested in stakeholder feedback on the regulatory oversight for the last mile of retail.

Without our federal, state, local, tribal and territorial partners, as well as trade associations and industry, we cannot fully achieve our mission to protect public health. This is especially relevant since we work with our state, local, tribal and territorial partners through cooperative programs to ensure the retail sector is regulated consistently across the nation.

It's important to stay nimble to ensure a strong food safety system and, in collaboration with our partners, keep all Americans safe during any crisis.

This is why the FDA developed the New Era of Smarter Food Safety Blueprint, which outlines a path forward and builds on the work we've done through the Food Safety Modernization Act. In February of this year, ORA launched the second phase of the agency's artificial intelligence seafood pilot program as part

of the New Era of Smarter Food Safety to leverage the use of machine learning. This is especially important since the U.S. imports about 94 percent of its seafood supply. Artificial intelligence will help quickly identify imported products that may pose a threat to public health.

Looking at more traditional business models, ORA is firmly committed to investing in New Era's modernization efforts to help ensure the safety of foods sold at restaurants and other retail establishments. This includes supporting our state local, tribal and territorial partners through our retail flexible funding model. The model is a cooperative agreement program that reinforces our efforts to modernize the nation's retail food protection program under the New Era initiative.

We're also very proud to be part of the Retail Food Safety Regulatory Association Collaborative which aims to leverage the resources and strengths of national retail food safety associations to advance retail food protection and reduce foodborne illness. Members are the Association of Food and Drug

Officials, the National Environmental Health Association, the Conference for Food Protection, the National Association of County and City Health Officials, the Centers for Disease Control and Prevention and the FDA.

The New Era elements of smarter tools and approaches for prevention and outbreak response includes domestic mutual reliance which enables the FDA and states with comparable public health systems to work with and rely on each other for a safer national food supply.

We are seeing more and more collaboration with the states and sharing of information. A strong regulatory partnership model is critical to protecting the public, particularly during these unprecedented times where consumer behaviors have changed. And while we've continued our oversight duties, there's no doubt that the pandemic has impacted our inspectional work.

In the spirit of transparency for our partners and the people that we serve, in May we released the Resiliency Roadmap for FDA Inspectional

Oversight Report. The roadmap, a result of collaboration between ORA and our FDA colleagues, details the pandemic's effect on our inspectional activities for each regulated commodity and our plan for a more consistent state of operations. It also shows how we're addressing postponed inspections based on risk.

Recently we've been able to complete more than 3,600 previously postponed surveillance assignments. Inspections will always be an essential part of our operation. But we've also learned during the pandemic the value in the multiple approaches available to us to assess safety, quality and compliance.

For example, in addition to enhancing our partnerships, we're using voluntary remote regulatory assessments. Overall we've heard positive feedback from firms, and we look forward to exploring this approach more. I'd also like to thank the firms that participated in the remote regulatory assessment human foods pilot.

The current challenges have presented

opportunities to reassess how we work. We'll continue to invest in collaborative efforts to achieve our shared goal of protecting the American people. We look forward to our continued work with you.

Thank you again for your leadership and partnership and shared commitment to public health.

MR. ABD00: Good morning, good afternoon and good evening, depending on where you are in the world. I want to extend a warm welcome to the many international attendees participating in our virtual summit and to especially thank the five international regulators who agreed to carve some time out of their busy schedules to join today's panel discussion. Our conversations over the past few days have given us an opportunity to examine both what we are doing and what more we might do to enhance food safety in the rapidly expanding business-to-consumer e-commerce food market.

As a point of reference, online food ordering, meal kits and delivery services take in around \$100 billion a year worldwide, and demand is still growing, according to McKinsey & Company.

Since e-commerce powerhouses exist throughout

the world, today we are turning our focus to get an international perspective on retail food safety. In particular we'll be hearing about what approaches regulators in Japan, Brazil, Wales, Germany and Canada are using to oversee the business-to-consumer e-commerce businesses engaged in producing, selling and transporting food.

Identifying opportunities for enhanced food safety in new business models and other forward-thinking approaches embodied under the New Era Blueprint have one goal in mind: bending the curve of foodborne illness. But given today's interconnected supply chains, the United States can't achieve that food safety goal alone. After all, 13 percent of the total U.S. food supply comes from other countries. And the market share from imports is higher in certain product categories such as fresh fruit, vegetables and seafood.

I'm sure many of our international colleagues who are here today confront similar or even more complex food supply chains. And with new technologies that facilitate direct-to-consumer purchasing of food

from anywhere in the world, additional challenges are emerging. FDA believes that ensuring food safety is not only a domestic imperative, but a global imperative.

Several years ago, we asked the World Bank to put dollar figures around the impact of unsafe foods on the global economy. In a 2018 report, the bank concluded that unsafe food undermines food and nutritional security, human development, the broader food economy and international trade.

Looking at the effects on low and middle-income countries, the bank estimated that foodborne disease was responsible for total productivity loss of \$95.2 billion each year and the annual cost of treating foodborne illness was \$15 billion a year for those countries.

However as the international community adopts the four core elements of the New Era Blueprint, traceability, smarter tools and approaches for prevention and outbreak response, fostering food safety culture and retail modernization including ensuring the safety of food produced and delivered

using new business models, we believe substantial progress will be made in strengthening food safety practices around the globe.

Since FDA rolled out its New Era Blueprint, we've been hearing about public and private entities throughout the world that are engaged in a variety of initiatives that are intended to move towards a smarter food safety future. Although these initiatives go beyond today's topic of e-commerce, they're important to mention because they show the number of people across the globe who are thinking about new ways to improve food safety.

In June, we launched the New Era of Smarter Food Safety low or no cost tech-enabled traceability challenge. This NoLo challenge, as it's been called, was designed to innovate cost-effective ways to track food from source to table. Better traceability helps us to respond to food outbreaks more quickly and therefore protects more consumers from illness. To our surprise and delight, our 90 contest submissions came from many countries.

We believe that by getting creative, as we

did with the NoLo challenge, we will create a more digital, traceable and safer food system. It will be a system that advances food safety, better prepares us for unexpected events that could put it at risk and overall improves the trust consumers and the United States and all over the world have in us, whether we're regulators or private industry to ensure safe food for themselves and their families.

This summit focuses on food sold directly from businesses to consumers using e-commerce. As we will learn today from our regulatory colleagues, this is a topic that crosses borders. We want to learn as much as possible to determine the best way to keep consumers safe, whether they order their food from a shop nearby or from sources around the world.

FDA will be collaborating with the international community over the next few years to build awareness about this issue and our broader New Era vision. Our intent is to lay the foundation for strategic engagement that will advance food safety priorities in the United States and across the globe.

FDA will engage with international food

safety stakeholders by working with foreign regulators and industry stakeholders through capacity development efforts such as training and webinar series, conference participation and public meetings on particular topics like this one.

We've opened a public docket for this meeting, and we urge all of our stakeholders, including our international stakeholders, to provide us with information and insights by submitting written comments to the docket about business-to-consumer e-commerce. The docket will remain open until November 20th. We will use this information from the docket, from the meeting and from all of our engagements to determine our path forward.

We aim to cooperate with our colleagues, not only providing information but seeking input on other systems, approaches to risk management, regulation and enhancing food safety practices so that together we can all bend the curve on foodborne illness. Thank you.

MR. KAWCZYNSKI: What a pleasure to hear from our FDA senior leaders, Judy McMeekin and Mark Abdo.

Thank you so much for helping us kick off the third day of our New Era of Smarter Food Safety Summit on E-commerce.

At this time, we will now turn to our international regulatory panel with Julie Moss as our moderator. Julie, take it away.

SESSION 6: INTERNATIONAL REGULATORY PERSPECTIVES ON E-COMMERCE AND FOOD SAFETY: REGULATORY FRAMEWORK AND OVERSIGHT

DR. MOSS: Good afternoon. My name is Julie Moss, and I'll be moderating today's panel session titled "International Regulatory Perspectives on E-commerce and Food Safety: Regulatory Framework and Oversight."

I'm the director for international affairs in the FDA Center for Food Safety and Applied Nutrition, where I am responsible for international engagement activities involving the safety of imports and export of foods and cosmetics, as well as global nutrition issues.

As a reminder, the purpose of this summit is to engage with stakeholders like yourselves and invite

input on various topics pertaining to the implementation of core element 3.1, new business models and retail modernization of the New Era of Smarter Food Safety Blueprint. 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 foods sold through new e-commerce business models.

It's my pleasure to moderate the next panel session. We are fortunate to have with us some very accomplished panel members from around the world. For this particular session, we prerecorded all the presentations and follow-up Q&A.

Our panelists for this afternoon are Dr. Akira Miki, with the Ministry of Health, Labour and Welfare in Japan; Mr. Fabio Miranda da Rocha, with the National Health Surveillance Agency, or known as ANVISA in Brazil; Ms. Julie Pierce, with the Food Standards Agency in the United Kingdom; Dr. Georg Schreiber with the Federal Office of Consumer Protection and Food Safety in Germany. You can find more information about these panelists in the bios

document on the FDA New Era Summit website.

As background on this specific panel, all parts of the world are experiencing an explosion of business-to-consumer food shopping practices similar to the United States. I did some research and wanted to share a few statistics.

Analyzed by geography in 2020, China represented the world's largest online food delivery market in revenue. The United States ranked as the second largest market. India is the third largest globally, with the United Kingdom and Brazil following. I'll note that the Asia Pacific region not only accounts for the majority of worldwide sales, it also is seen as an innovative hub, pointing the way forward for other regions of the world.

In my research, I've found that China, South Korea, Japan and India were cited as top markets in that region. For the European region, Belgium, Germany, France, Italy, The Netherlands and the UK were top markets. It is expected that Germany will triple its e-commerce food market in the coming years and the UK is expected to maintain its high ranking

globally.

This international panel will begin to inform us at the FDA about the regulatory e-commerce considerations by other countries of the world. They have a wealth of food safety oversight, data sharing experiences and knowledge about trade and the commerce of safe food. I suspect we'll learn a lot.

With that, let's get started with our first panelist. He is Dr. Akira Miki. He is the director for the Food Inspection and Safety Division within the Bureau for Pharmaceutical Safety and Environmental Health in Japan's Ministry of Health, Labour and Welfare. Over to you, Dr. Miki.

DR. MIKI: (In Japanese)

DR. MOSS: Thank you, Dr. Miki. Our second speaker is Mr. Fabio Miranda da Rocha. He is a specialist for the Health Regulation and Surveillance Unit at the National Health Surveillance Agency, also known as ANVISA, in Brazil. Welcome, Mr. Rocha. Over to you.

MR. DA ROCHA: (In Portuguese) Thank you, everyone.

DR. MOSS: Thank you, Mr. Rocha. Our next speaker is Ms. Julie Pierce. She is the director of openness, data and digital, director for Wales and director of science, evidence and research, all with the Food Standards Agency in the United Kingdom. Ms. Pierce, welcome, and over to you.

MS. PIERCE: Hello. I'm Julie Pierce. I'm the director responsible for science, information and Wales at the Food Standards Agency in the UK. Now we recognized the increased in e-commerce for food a few years back. First of all we started to see the food aggregators, Just Eat, Deliveroo, UberEATS, new, but similar to each other. We then saw the rest. Many more were appearing, from big to small.

So we could see we were looking at something different. But really were they food businesses just wrapped in a digital coat or something else? Were they more or less risky? Did our existing controls apply? And how should we respond? And then could we even see these digital businesses operating?

Then the pandemic hit, and the whole thing became bigger, changing faster as businesses

themselves pivoted from physical to online, as people left the jobs they could no longer do and came into a sector that was apparently easy to enter. So we commissioned some research to understand the market and how it was evolving. We wanted a taxonomy to understand the shape and nature of these businesses.

They weren't all the same. But were they built from the same building blocks, and what was common to all of them? Fundamentally food is being bought and sold and supplied to the consumer. But what is different? And I think for me seeing the platforms was key, and they were starting to stand out as being different.

There were many small micro businesses and also there were the big traditional physical retailers. And they were starting to move in to have an online channel. But these big digital platforms were different. And then are these digital platforms themselves all the same or no? And we begin to see again those that are focusing on food delivery, but also the big marketplaces that are selling foods that have a much, much wider offer.

So what is the impact on the food ecosystems? What have been the shared characteristics or themes that we're drawing out? We're seeing tech businesses entering the food world, native tech companies that don't know or don't want to know about food or food safety.

We're seeing the supply chains being rearranged. There's no need to keep the existing supply chains if they're not working for them. It's easy to switch. We're seeing online as default businesses, businesses that really only optimally operate as online. We're seeing lots of information on the supply chain, lots of data about the businesses themselves but also the whole of their supply chains.

We're seeing increased interconnectedness of the businesses and the ecosystems they generate around themselves. We're seeing ever adapting business models. Just because they can, they will change. They'll extend out and start to operate in new areas really quickly and just as quickly they might pull back if it's not working for them and they're not making money.

We're seeing bundling and unbundling of business process steps. The classic shape of the businesses are changing and changing repeatedly. We're seeing the faster emergency of new businesses and the changes of those businesses and sometimes the demise of them as well just as quickly.

We see decreased visibility of business identity often and that unbundling might include unbundling of the ownership of the business from its brand or maybe the creation of dark kitchens where it's just really not clear at all who owns or operates that dark kitchen.

And then finally, seeing private standards setting. Though many of the businesses do have standards, they create them. They may be standards of their own making or they're using ours. We think it's great.

So overall as we sit back and look at what we've learned, what is the real risk? And I think we can say it's not as great as maybe we feared when we went into this. A large number of businesses, many of them are very small, and so the scale of risk is low.

And most actually do want to do the right thing. They just want to find an easy way to learn and to do it quickly.

And the big platforms themselves often will help to get the smaller businesses to do the right thing through the application of their own controls of the provision of information and support to the business that they've listed. They want them to succeed.

So we are not done. We are not done at all. We continue to add to our understanding as to what is happening in this fast evolving sector. But we haven't created new regulation or legislation. We're using what we already have. But we're getting more confident in understanding and seeing the businesses that they're operating.

And the big challenge that we face, as I said, is with the digital platforms, those platforms that assert they are not food businesses, taking no responsibility for the safety of the food being sold by the other businesses that use them.

So maybe in a little more detail, what are we

doing? We're trying to be where these digital businesses are, seeing the world through their lens, understanding how they operate and how we can get them to operate to our standards. We first try to get them to do the right thing. So maybe for themselves, monitoring what they've got going through their platform, whether it's food products or businesses they're listing and quickly removing the unsafe and risky food and tracing it back to root cause.

And they can do that quickly. They've got the data to be able to do that fast. Or maybe we want them to take off those businesses that have got a low food hygiene rating score. So they shouldn't be working at all. they shouldn't be in operation, and often those big platforms will take them out much more quickly than we can. We're giving them relevant, easily consumable guidance for them to use and to share with the businesses they list. It's digital first.

We're monitoring the market. We're automatically scanning the main platforms to see businesses that are operating but not registered.

We're also using image recognition that see businesses that display a food hygiene rating, but don't really have one.

We're also helping consumers complain to those businesses. Often they feel impenetrable. They're happy to sell to you, but it's really hard to complain when something goes wrong. And that's both for the consumers themselves, but also the local authorities that are enforcement partners. So we're creating standard APIs that will be easy for these big digital platforms to use. So there's no excuse. It'll be easy for all parties to use the same API.

Now we think that we should not do this alone. We see that some of these platforms are super powerful. They're operating in many other sectors beyond food and working hopefully with many other regulators and also in other jurisdictions. This isn't just a UK thing. And so we're hoping that all of the regulators that need to regulate these big players need to be aligned to make those changes happen. And that is a challenge.

But there is something working for us. There

is an emerging safety tech market that's been developed for other online harm. And we're looking to see whether we can repurpose that technology and reuse it to see food safety risk.

Now we do see the importance of international alignment of these platforms, alignment of the regulations and the standards that they should be operating to. There is food being imported using these big platforms as the vehicle. We can see that. And with other subsectors, we see that alignment as valuable for the regulator, business and consumer.

And we at the FSA also wish to share what we've know, what we've learned and also some of these tools that we've developed that might help all of us along this journey. Thank you.

DR. MOSS: Thank you, Ms. Pierce. Our next speaker is Dr. Georg Schreiber. He is the head of the Department of Food Safety within the Control of Food, Feed, Cosmetics, Consumer Goods and Tobacco Products Traded on the Internet, all within Germany's Federal Office of Consumer Protection and Food Safety. Over to you, Dr. Schreiber.

DR. SCHREIBER: Ladies and gentlemen, first I would like to thank FDA for giving me the opportunity here to present how we do e-commerce control in Germany and what challenges we are facing.

In Germany, we have 400 district, and each of them has a competent authority which is responsible for food control. So they are doing the inspection of the food businesses and they are enforcing food law. And they are organized in 16 federal states. We call it in Germany Länder, 16 Länder. And these Länder governments, the Länder ministers are actually responsible that in their territory the food law is enforced. So we have a very federal structure.

But in the case of e-commerce control, we decided in Germany in 2013 to create one central unit -- the name is G@ZIELT -- who is doing the internet searches for all of these 400 competent authorities. And they are doing it not only for food, but also for feed, for cosmetics, for consumer products, for tobacco. We have meanwhile a unit who does searches for pesticides and control of pesticides and we are talking also about currently to control also the trade

of pets, yeah?

So we do centralized searches in order to avoid double or multiple work. So, and secondly, by organizing all this, all the work in one central unit, we can concentrate the expertise. So these people in this unit, they have special hardware, special software of course and they have meanwhile a lot of skills to do internet investigations.

So what are our achievements? In the European Union, and so in Germany, each food business operator has to be registered with its competent authority. And we are now -- we are since years now, we are enforcing that on the internet. So we are working together with our central -- federal central tech office which runs 24/7 a web crawler which is looking for e-businesses.

And of all these data of all business, we can extract -- we have the ability to extract the food businesses, the e-food business and together with the competent authorities, we are checking whether they are registered or not. We are informing also the big marketplaces, the platforms, Amazon, eBay, Alibaba

Group and so on, if a product is offered on their marketplace which is a risk to the health of the consumers or which are misleads the consumers. So we are informing them and then under EU laws they become responsible if they do not act immediately. So they have to remove these products from their website.

Thirdly, we have in the European Union we have the request that all the information which is normally on a food package, mandatory way, so it's mandatory to put this information on a food package, this information has to be put also on the website where the product is offered. And so the consumer can have access to this information before the purchase is made.

We have also under EU law, we have the possibility to close websites. Of course this is always the last measure. So we use this measure, this power if traders are not responding. So if they are in a third country, for example, if they are outside of the EU and they are not responsible to our requests, then we can close their websites if they offer unlawful products. And we have also the power

to sample online without identifying us as a control authority. So we can buy products and use them as official samples. And we can do that not only for all the food chain products, but also for consumer products. This is of course very important achievement.

So, but besides all these achievements which we made during the past years, we still face a lot of challenges. And so we are quite happy that the European Commission has put forward a proposal for a new law, the Digital Services Act, which gives much more responsibility to the marketplaces in order to make them offer lawful products on their marketplaces and remove the unlawful products.

And in these discussions we are requesting from the food side that these marketplaces are checking whether the e-food business operators which are on their platforms offering products, whether these are registered. So this should be the task of the platforms. And it should also be the task of the platforms to inform the public if a noncompliant product has been offered, so noncompliant with our

legal requirements.

Secondly, very important, we request the cooperation of the payment service providers and the logistics companies because some of these companies are cooperating with us and some not. So on logistics companies, if we are doing online purchases, then we need not only a mutual credit card. We don't need only a mutual email address. We need also a mutual delivery address in order to not be identified as control authorities.

And -- request a legal basis to make them cooperating. The same is true for payment service providers. We have from time to time we have traders who are hiding, who are offering by purpose unlawful products. Sometimes they are in third countries, sometimes in the EU, sometimes in Germany of course. And of course our unit has the means to find them but not in all cases. And in these cases, we need the cooperation of the payment service providers to give us the correct address of these traders in order to put measures on them.

And finally what we are requesting is the

legal basis to search in general on the internet without being identified as a control authority, so not only buying products anonymously but also doing general searches, and this is particularly important for social media.

So what do we do with the consumers? Of course we inform the consumers how to shop safely on the internet, yeah? We have on our website, we have a little shop, a kind of shop where we make them aware where are the challenges, where are the points, where they should be particularly careful. And we have also put this information in paper and we do annual reports and we of course try to distribute it at any occasion where we meet consumers.

In the same way, we are informing the traders. We have put in simple language the main requirements and the main obligations of traders. We distribute this information via our website of course but also we send it to the trade association, and we have given it to the marketplaces in order to give them the possibility to put this information on their website.

In the European Union, the European Commission has a unit which quite a number of inspectors who are checking the EU member states whether -- the competent authorities of the EU member states, whether they are able to transpose and enforce the EU food law. And so member states are constantly checked. This is a standard process since many decades.

But now the European Commission has also started to do this on e-commerce controls. They started in 2017 with fact-finding, with fact-finding missions. And now they announce audits and they will check how the EU member states do the control on the internet.

And finally I would like to mention CODECS. CODECS has also started with sysop check on their agenda and we are appreciating that very much. And we are contributing there on the CODECS level actively. Ladies and gentlemen, thank you very much for your attention.

DISCUSSION

DR. MOSS: Thank you, Dr. Schreiber, and

thank you to all of our panel members. It was intriguing to hear how all of you are addressing business-to-consumer food safety oversight in your own countries.

So let's start the panel session. I'm going to pose two additional questions to each of you today. Here's the first question. What regulatory and compliance challenges exist with respect to your current regulatory structure for business-to-consumer e-commerce businesses that sell human food? And in addition, what regulatory approaches have been effective?

I'm going to start off with Dr. Miki. Over to you first.

DR. MIKI: (In Japanese)

DR. MOSS: Thank you, Dr. Miki. Let's go to Mr. Rocha.

MR. DA ROCHA: (In Portuguese)

DR. MOSS: Thank you, Mr. Rocha. I'm going to tag Ms. Pierce next. Over to you.

MS. PIERCE: So the main challenges that we're facing in the UK relate to those businesses that

do not see themselves as food businesses. They say they're not selling food. They are simply platforms, and they have no responsibility whatsoever for the businesses that they list or they work with.

Now that is I think a difficult area. And so at the moment we're trying to make the most from the regulation and the legislation we already have. And to date, that has proven its worth. I think we're also very open to the other regulation and policy leaders or tools that we've got in the toolbox, so working with businesses, persuading them to do the right thing, maybe calling out publicly where we think their behavior is inappropriate.

They really do not want to lose customers. They really do not want to get a bad name in the marketplace for those people they're selling to. So I think we're also mindful of the power that we've got in the influencing approach rather than pure regulation. And then if we did step into that wider legislative arena, it takes a long time to make changes there.

We are very mindful in the UK that we

probably need to work with other regulators. At the moment in the UK, we have a bill going through Parliament about online harms that doesn't address food safety as being one of those harms but maybe we can use that to get big businesses to change their behavior and maybe apply a similar sort of approach to food safety in the same way they do in other types of online harm.

Now I don't think I'm being overly optimistic in that because again these businesses, what do they want, they want a level playing field. And if they've got to do something, they want to do it only once. So if there are these online harms over here and they're obliged to do something and respond, we say, ah, well, it's relatively easy to apply the same sort of approach to food safety.

So that's the sort of approach we're taking. And again, that's why we're looking at some of the food safety tech that's being developed to again say it's being used over here. You understand how it works, what it can do. So maybe we just extend it and apply it over here. So that's the sort of approach

that we're taking.

DR. MOSS: Thank you, Ms. Pierce. Let's go to Dr. Schreiber. Over to you for final words on question one.

DR. SCHREIBER: So for us in the European Union and of course in Germany, it is very important that the e-businesses comply with the whole law, with the whole food law which we have on the EU basis and on the national basis.

And this is irrespective whether they are trading within the EU or whether they are situated in a third country and then supplying their products to EU, to German consumers. So even if they are in China or in U.S., they have to comply with EU and national law if they want to put their products on the German market, if they want to supply the German consumers with their products.

So this is very important for us. And this is actually the case also for the stationary trade. So what we are demanding is the same requirements for whether -- it's the same requirements for online businesses as well as offline businesses. So we don't

want a discrimination or we don't want advantages for one side or the other side. We would like to have the same requirements for all the businesses, whether they are offline, whether they are online, whether they are in the EU, whether they are outside of the EU. That should be the same. And this is very important for us. And in order to achieve that, of course we need strong e-commerce control.

So we requested the legal basis to sample online for official sampling. And finally we got the legal basis. We can buy products on the internet and without identifying us as a control authority. And we can treat these products as samples, as official samples. This was very important for us.

But we are still facing a lot of challenges. So on the marketplaces, we have of course a lot of products which do not comply with the law. And of course we are checking. But we cannot check the whole internet. So what we are requesting is that the marketplaces take much more responsibility.

So if they see that a product is not complying with legislation, they shouldn't put it on

the marketplaces. And with new law, we make them -- we will make them much more responsible as it is today. The same is true for payment service providers.

So in general, internet services providers, what we are seeing is that some -- quite a lot of internet service providers are cooperating with competent authorities because they want to make money. They don't want to have problems with control authorities and enforcement authorities.

But some do not. And for -- in order to make them all cooperating with us, we need a legal basis. And we are working on that in the European Union, and I am very sure that we will achieve that quite shortly. Thank you.

DR. MOSS: Thank you, panelists, for your responses to my first question. With this area of food purchasing being relatively new, we all have much to learn, don't we? Let's move on to question number two, and here it is.

What administrative, regulatory and compliance challenges exist with respect to businesses

that sell animal food or pet food through business-to-consumer e-commerce as compared to being sold business-to-business or in traditional retail settings?

For question number two, I'm going to mix it up a bit and go in reverse order. Dr. Schreiber, you're up.

DR. SCHREIBER: For us, again, it's the same like with food. We are requesting that internet feed businesses respecting the EU laws and the national laws. So they have to respect it in the same way as stationary businesses doing.

And there is -- the challenges is mostly on pet food because the business-to-business trade, these are large quantities and they are -- I mean, this is normal business. but more and more feed for pets are of course offered on the internet. And so our focus lies on these products.

And of course we again, like with food, we are checking whether they are complying with the feed legislation. And we are again -- we don't want that -
- the e-feed businesses have an advantage over the

stationary business. They all have to respect the full spectrum of legal requirements. And in order to enforce that, we have special programs in Germany where we check special food for all these pets.

So this is an ongoing process, and we have annual programs where we focus on certain products. And we are checking them. We are buying these products on the internet. We are checking them in the laboratories and then we of course enforce in this way feed law also in the internet. Thank you.

DR. MOSS: Thank you, Dr. Schreiber. Let's go to Ms. Julie Pierce. All you.

MS. PIERCE: Whilst we in the FSA are responsible for what we would feed, animal feed, this isn't an area we've explored. We've prioritized food, human food and have seen that as being the biggest growth area. Now that therefore means that we haven't been particularly looking into this area. So I'm not aware of there being any particular growth or even significant risk.

Saying that, we probably need to do more work to understand it and I would also hope that many of

the monitoring and technology tools we've developed for the other types of digital platform and human food, I see no reason why it shouldn't be applied equally to feed.

DR. MOSS: Thank you, Ms. Pierce. Mr. Rocha, you're up next.

MR. DA ROCHA: (In Portuguese)

DR. MOSS: Thank you, Mr. Rocha. And lastly, Dr. Miki, over to you for last words on this question.

DR. MIKI: (In Japanese)

DR. MOSS: Thank you, Dr. Miki, for closing out question number two. I appreciate the time our panel members took to participate and share their knowledge with us today. This concludes our panel session.

If this panel session spurred an idea or a comment, I encourage anyone in the audience to submit a comment to the docket or to the FDA website associated with our New Era for Smarter Food Safety Summit.

Again, thank you to my esteemed regulatory panel members that joined me from Japan, Brazil, the

UK, Germany and Canada. Hearing your experiences and perspectives about business-to-consumer e-commerce is incredibly useful as we move forward in this dialogue about new business models and retail modernization. All of us at the FDA really appreciate your participation today.

At this point in the agenda, we have a short break. My colleague, Kari Barrett, will return to reopen the meeting for open public comment when the break is over. Thank you.

MR. KAWCZYNSKI: Thank you, Julie, and thank you to all of our international regulatory panelists. We're now going to take a 15-minute break. And when we return, I will hand it off to my colleague, Kari Barrett, who will guide us through the open public comment portion of the agenda.

(Off the record)

OPEN PUBLIC COMMENT

MS. BARRETT: Well, welcome back, everyone, to the New Era of Smarter Food Safety Summit on E-commerce: Ensure the Safety of Foods Ordered Online and Delivered Directly to Consumers.

We are now at the part of our agenda where we're going to take open public comment. Hi. Hi, again. This is Kari Barrett, a co-moderator. And just as we have over the last two days, we are now transitioning to the public comment session where we do have a panel of government agency subject matter experts who will listen to prepared stakeholder remarks that are offered during this time.

So I want to welcome today's public comment presenters. We have a group here with a number of international perspectives. So we're very excited to hear all of our speakers today and to bring that aspect into the public comment process.

As we have noted the other days, all of our commenters will have five minutes to present their remarks. And before we get started, just as we have, we do want to introduce our panel of FDA experts who will be listening to these public comments.

And so Sharon Lindan Mayl, I'd like to start with you.

MS. MAYL: Thank you, Kari. Hello. It's a pleasure to be here again. I am Sharon Lindan Mayl.

I'm senior advisor for policy in the Office of Food Policy and Response which is in the Office of the Commissioner, and I manage cross-cutting policy initiatives and currently serve as the lead for the implementation of the New Era of Smarter Food Safety Blueprint. Thanks. Thank you.

MS. BARRETT: Yeah. Thank you, Sharon. And Glenda Lewis, we'll go to you.

MS. LEWIS: Hello, everyone. It's also my pleasure to be with you today. I'm the director for the retail food protection staff within the Office of Food Safety in FDA's Center for Food Safety and Applied Nutrition.

And I'm responsible for oversight of the teams that develop national policy for retail food safety and also policy for the interstate travel program in regards to interstate travel conveyances. Thank you for being here today.

MS. BARRETT: Yeah. Thank you, Glenda. And Mary Cartagena?

MS. CARTAGENA: Hi. My name is Mary Cartagena, and I work for 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 policy documents, such as the FDA Food Code, the Voluntary National Retail Food Regulatory Program along with other retail policy documents. and I look forward to hearing the comments today.

MS. BARRETT: Great. Thank you, Mary. And next we'll go to Laurie Farmer. Laurie, welcome back.

MS. FARMER: Thanks, Kari. It's a pleasure to be here. I'm Laurie Farmer, the director of the Office of State Cooperative Programs. My responsibility in FDA is around field programs, strategic direction and retail food protections, mollusks, shellfish, sanitation and Grade A milk safety. Looking forward to the comments today.

MS. BARRETT: Great. Thank you. And I want to welcome a new subject matter expert to our panel today, and that is Susan Berndt. Susan?

MS. BERNDT: Thanks, Kari. It's a pleasure to be here and join this panel. My name is Susan Berndt. I'm the deputy director for international

affairs staff at the Center for Food Safety and Applied Nutrition at FDA. I support the center's mission to protect and promote public health by providing leadership and guidance on international activities and initiatives across CFSAN.

MS. BARRETT: Great. Well, thank you all and thank you for joining us, and we look forward to hearing from our public commenters. So at this time, the FDA group, we are going to turn our cameras off. And I will call up each commenter, and again there'll be five minutes.

And our first commenter is John Spink, Michigan State University Food Fraud Prevention Academy. And John, thank you for joining us again this afternoon.

DR. SPINK: Thank you. First, these comments are my own and not of my institution or of anyone else. Thank you for the opportunity to comment here today, and I commend FDA for taking the step to first 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 within the Michigan State University Business College. And my supply chain management role includes overseeing the content and instruction of our introduction to supply chain, and that supply chain management scope includes the type of foundation setting that you're addressing in this meeting.

My food fraud prevention and supply chain management roles are especially applicable to this meeting since you are first looking for system weaknesses that builds upon my product fraud research and research of others. You're starting with a food supply chain mapping to look at the big picture, and then you're conducting risk assessments to identify the problem areas before considering any regulatory gaps.

Your meeting can create a foundation for all of us to build upon and the foundation can identify the areas of concern and the most efficient role for each food safety chain partner.

The FDA is taking a proactive first step aligned with standards such as ISO-31000 risk management and that's establishing the context and following ISO-9000, quality management and ISO-22000, food safety management. The next step is to gather incident information, to conduct risk identification before considering the risk assessment models that you would use or even assessing those models.

Those key steps include supply chain mapping to identify how product flows and who handles the products. This provides the information to conduct a criminology type hotspot analysis to look at those problem areas. These are important steps to prepare for conducting that actual risk assessment. And by taking these steps, we can usually break complex systems into many pretty simple maps.

After seeing the meeting announcement, we mentioned the meeting in blog posts and one thing led to another and we just published our sixth follow-up report. You can find these on our website or posted on LinkedIn, and we will also submit these in the written comments.

We went through a lot of the different concepts and background and basics, and the most recent document includes a list of terms and definitions such as ghost kitchen and dark stores. It was interesting to start listing the terms and mapping the supply chain. And we check on covering different attributes of the overall food supply chain map.

We also provided a link to a shared document where stakeholders can comment or edit the glossary itself.

Your meeting has created encouragement for this type of foundation setting, and good luck and please feel free to contact me or us to know if or how we can help. I can be contacted at foodfraudprevention.com, and with that, I'd say thank you. I guess, the end, of my presentation.

MS. BARRETT: All right. John, thank you so much for your comments. And we'll now go to our next public commenter, which is Amit Kheradia. Amit?

MR. KHERADIA: Thank you, and -- yes. Thank you, and good afternoon. My name is Amit M. Kheradia, education and technical support manager for Remco

based in Zionsville, Indiana.

We supply high quality sanitation and material handling tools such as brushes, brooms and shovels to our North American clients in the food manufacturing, retail and food service sectors. We're now part of a Denmark-headquartered company, Vikan, a leading manufacturer of hygiene cleaning tools with a global presence in over 90 countries.

This association has greatly enabled us to offer world-class support to our clients through color-coding solutions, hygienically designed tools, hygienic zoning tool management, 5S and other best in class sanitation recommendations.

Our focus in this area becomes crucial since we estimate about 1 in 3 food recalls in North America are directly related with improper hygiene, cleaning, sanitation and material handling practices within establishments. As industry representatives, we are highly supportive of the FDA's New Era of Smarter Food Safety Initiative such as this retail e-commerce summit.

I'd like to state five key issues or points I

believe the FDA may need to address in their B2C e-commerce model deliberations that may have been covered in this summit in one form or another.

The first issue is we need clarity on compliance status of retail e-commerce ordered foods on possibility that delivered products should pass from one state to another having variable public health regulations. Such variability poses two additional risks. Product might be compliant yet not safe or product might be safe yet not compliant.

Whether B2C companies need to comply with federal regulations or public health regulations of the client's location or the latest food code or whether uniform adoption of food code by states may resolve this issue are some questions to us.

The second point regards closely reexamining risks associated with e-commerce ordered and delivered foods. They cannot be equated with the manufacturing facility because clearly the scenario has changed. We now have a largely uncontrolled, unchartered territory that changes with each online consumer transaction with a different food safety risk portfolio and an

assortment of delivery loads that may pose multi food safety challenges. Here FDA could provide risk-based food safety plan development guidance to cater for such complexities.

The third issue is about establishing virtual and sustainable food safety controls. Technological innovation and consumer expectations outpacing regulations is a reality. So controls may get reassessed with every change. Many feel regulations are best left at minimum barebones since the onus should lie more with industry and their partners to design better controls.

Moreover we also need robust controls whose effectiveness should remain unaffected by such market changes. FDA, with the help of stakeholders, can support industry in the development of stronger controls in part by offering nonbinding recommendations.

Fourth point, employees working across e-commerce food supply chain need to be motivated through continuous awareness education, training and refresher update modules, hence communicating with

clear, bitesize effective training modules especially for players in this last mile delivery becomes clear. However considered the varied demography of players that belong in third-party organizations and them having different skill sets may create hurdles. Again here FDA and stakeholders can help address such barriers to education and training.

And finally, fifth issue, how can we encourage customers at the last mile delivery to provide feedback on food safety issues in the best possible way. Are our online communication systems designed to effectively capture, analyze and relay actionable information to the supply chain players in the spirit of fostering continuous food safety improvement?

Thank you for the opportunity to comment. This concludes my remarks.

MS. BARRETT: Thank you so much for your remarks today and for joining us. We now will go on to our next speaker, and that is Sharmeen Khan. Sharmeen?

MS. KHAN: Hi. Good afternoon, everybody.

Thank you so much for allowing me to give my comments today. So my name is Sharmeen Khan. I'm the founder and chief marketing officer of OpsSmart Global. We are a food safety and traceability company, and we are also one of the proud winners of the FDA traceability challenge that ended last month. So we're super excited about that.

And so I'm going to comment a little bit from the tech perspective of how we see a business-to-consumer partnership forming in the e-commerce space. We believe that it's really important that FDA mandate some sort of a serialization similar to what the pharmaceutical industry has.

We feel that it's very important to create a food safety code, per se, so that when you speak of the segments within the e-commerce food market of meal kit delivery, grocery delivery, prepared food delivery, we feel each of those segments needs to be assigned a code.

We feel that every provider, every company within that segment needs to have their own code as well. So when a meal kit is delivered to the doorstep

of a consumer, they have a barcode at their hand so if they open that package and they have an issue with that package for any reason, there should be a code ready for the consumer to scan and let the FDA know that there is a problem with that particular meal kit. And what this does is it removes all sorts of fraud.

So when you get a Blue Apron box at your door, you know it is a Blue Apron box at your door, not someone who has chosen to replicate the box. This creates responsibility within the food supply chain, creates responsibility, removes fraud and, most importantly, it empowers the consumer and connects them directly to the FDA so that when that homeowner who opens that package scans the barcode, they can connect to the FDA and say there's something wrong, we need to return this.

And at the same time, FDA is immediately informed of a problem with that package and then they can reach out to the producer of that package and capture the challenge that they're facing on their production line and remove it or stop it at that point.

So that returns us back to the conversation of food traceability and recall management, which is intrinsic to the New Era of Food Safety. So it connects both e-commerce and food safety and the New Era all together by serialization, by providing responsibility and empowering the consumer at the same time. And we believe FDA has a responsibility to do that in order to keep the food system safe.

Thank you so much for my comments, and I will put myself on mute, I assume.

MS. BARRETT: Okay. Thank you for joining us and for offering your thoughts, and we deeply appreciate all of our public commenters for taking the time. We now will go on to our next one, which is Maria Jose Plana Casado. Maria?

DR. CASADO: Good afternoon, and good evening from Amsterdam. My name is Maria Jose Plana Casado, and I am assistant professor at the Wageningen University in The Netherlands where I teach European, U.S. and Chinese food law. At Wageningen, I carry out research on the regulatory challenges of the digitalization of the food system with a team of

colleagues leading food and environmental legal research in the European Union.

I am intervening here today to ask the FDA but also other regulators globally such as that of the European Union to launch a comprehensive review of current food laws and regulations to make sure that the rules are fit for purpose in online marketplaces enabling third-party suppliers to trade e-foods.

As I examine in my recent book titled "E-Food: Closing the Online Enforcement Gap," we need rules that take into account the particularities of online marketplaces because online marketplaces challenge longstanding legal arrangements in the U.S., in the European Union and abroad.

For instance, marketplaces are not legally responsible for mandatory information. The trader is under consumer law rules and under food law. But the private rules, marketplaces rules and their interface shape food information to a great extent.

I want to focus my intervention on one main additional concern, supplier volatility in marketplaces and its impact on compliance with legal

requirements. I will explain. In marketplaces, consumers have the choice of buying products from not only popular retailers but also from smaller disruptive businesses, home-based suppliers or even their peers.

This is due to the fact that platforms reduce market access barriers by providing anyone from anywhere with a ready-to-use interface to offer e-foods. But peers and micro businesses are often not aware of their obligations regarding food safety or food law and this generates novel safety and legal risks.

And the popup nature of others in marketplaces challenges enforcement actions to remediate noncompliance because too often with a problem arises, the supplier is no longer active in the platform.

Therefore it is necessarily to adopt measures to ensure that consumers know what type of suppliers they are buying from, and it is also essential that the new law assigns marketplaces obligations regarding the safety of the offers they facilitate.

Taking that into account, I am asking here today that regulators adopt rules ensuring the following. First, that consumers can clearly identify whether suppliers are a traditional retailer, a home-based supplier or a peer. Some big marketplaces voluntarily do so. But most providers don't.

Second, that there are clear rules determining the legal obligations on home-based suppliers and peer traders operating in platforms because those are operated in the space no longer protected by food law.

And third, regulators should require that platform design requires at least proof that the supplier has been registered as a business in order to use the platform, what's his legal name, what's his address, what is his contact info.

The law should also require that a platform's design ensures that e-food offers cannot be published without all mandatory information, even if the marketplace is not made responsible for its security.

And finally regulation should also ensure that platforms establish minimum standards for

delivery. All of this is necessary to ensure the new business models that consumer can take advantage of the possibilities of the platform revolution while ensuring the e-food market is a safe market. Thank you for your time.

MS. BARRETT: Thank you so much, and we appreciate your comment. And we will now go on to our next public commenter, which is Cori Muse. Cori?

MS. MUSE: Thank you. First, I'd like to thank you for the opportunity to speak on a topic that is very important to me as a professional and a consumer.

My name is Cori Muse. I am a scientist and the founder of Muse Food Safety Solutions. Food safety is my passion and my profession. I've been in the food industry over 14 years working and consulting in various roles.

Currently e-commerce encompasses three business models: historical retail establishments, food delivery services and food businesses that deliver B2C. It's important to distinguish the differences as the food safety implications differ

drastically.

Food delivery services are responsible for the transport of food from restaurants to consumer. The available time window for proliferation of microorganisms and introduction of other hazards is short, typically less than an hour.

Traditional restaurant establishments have limited onsite storage. ETS ingredients are delivered and utilized within a relatively short window. If the establishment is observing local food safety regulations, the window for proliferation is about six hours.

What should be defined as an e-com business model is critically different than the aforementioned. Some cook and package their finished products onsite while others receive ingredients portioned by hand or equipment and then distribute their product via commercial trucks.

These trucks range from private fleets to third-party carriers and in many cases are exempt from sanitary transport rules. Here the time window for micro growth is much greater, ranging from 24 to 85

hours or longer.

Typically the packaged food products are shipped on non-temp-controlled fleets and in many cases left on a consumer's doorstep for 8 to 10 hours. If this is Nevada in the summer, it could be over a hundred degrees.

As speakers have demonstrated, we have the data to show that if products are not handled appropriately, there are critical risks to the consumer.

E-com operations are more comparable to food manufacturers, and there is a full lack of federal oversight. They are regulated under local food codes developed for traditional establishments with significantly smaller windows for micro growth and food safety failure.

Dr. Hallman highlighted the lack of central registry to reference in the event of an illness outbreak and others highlighted it's been a complicated task to locate new businesses. It's important to highlight that Facebook is not the answer to this problem.

Because of the complexity of e-com business, there must be federal oversight through the appropriate authority. I urge regulatory bodies to require e-com businesses to register with the FDA and require shipment on carriers which fall under sanitary transport rules.

I further urge regulators to require scientifically validated temperature controls throughout the supply chain. Companies which are unable to scientifically validate their controls should be required to employ the use of continuous temp monitoring technology to ensure safety.

Since e-com are not currently regulated under FSMA, they're not required to have environmental monitoring for pathogens. This is a critical risk, as many businesses handle ready-to-eat foods such as leafy greens and raw produce. I urge regulators to require these e-com businesses to register with the FDA and require environmental monitoring for pathogens.

With no federal oversight in mind, I'd like to pose three questions to local regulators. How are

local authorities ensuring large volumes of protein are being handled appropriately? And how are local authorities ensuring seafood is being handled appropriately and packaging regulations are being observed? Finally how are local authorities ensuring that ready-to-eat ingredients are being appropriately classified, stored and handled?

It is paramount solutions are rooted in science and based on risk to mitigate these critical risks that inherently exist with these e-commerce businesses. Regulations for food delivery and traditional retail establishments are grossly inadequate and do not provide the necessary solutions for this rapidly growing business model.

I look forward to submitting additional written comments to supplement my comments today. Thank you for your time and allowing me the opportunity.

MS. BARRETT: Great. Thank you so much for your comments today, your oral comments, and we'll look forward to your written comments submitted to the docket. So thank you for taking the time. We will

now go on to our next public commander, which is Muhammad Shahbaz. Muhammad?

MR. SHAHBAZ: Hello. Good evening, from my side. My name is Muhammad Shahbaz. I am associated with Mawarid Food Company, which is based on Saudi Arabia. First of all, I would like to say many thanks and it's an honor and privilege for me to be part of this FDA New Era of Smarter Food Safety Summit on E-commerce, and many, many thanks for providing me this amazing opportunity.

I would like comment -- wide-ranging and catastrophic effects -- that has disturbed the global food supply chain and have damaging impact on food safety as well.

In this challenging time, the food industry come together and played wider role to ensure that food sector should remain open for consistent and unhindered production of food so consumers have continued access to safe, healthy and nutritious food during this pandemic.

The food regulatory authorities responded quickly and immediately and ensured that during the

pandemic, specifically -- promulgated regulations, developed -- specific operating procedures and best practices for food sector to keep them safe and healthy even during challenging time.

Nowadays we have seen most of the foods we eat are grown and manufactured in different places and different countries and being delivered to various places using e-commerce channels. Maybe these channels may be online shopping or home delivery. E-commerce provides consumers with greater choice and convenience and access to food products that they could not access through traditional way and traditional physical trade ways.

E-commerce can directly connect small and medium enterprises to the global market, allowing them to extend their sales beyond the limited geographical boundaries and to access small personal as well. Online ordering can be cheaper option as well. Therefore online ordering has become a favorable way for consumers to get their safe and healthy meal in very, very convenient way.

Here in Saudi Arabia, since the last couple

of years, we have seen record expansion in cloud kitchen concepts of selling of various types of food online. That has grown tremendously. It is awesome that online selling of food is growing. But we have to ensure that all food delivery aggregators are following food hygienic practices and delivering the food to consumers in very, very hygienic and safe way.

Once again, thank you very much for providing me this opportunity.

MS. BARRETT: Well, thank you so much and thank you for giving us your evening and calling in from Saudi Arabia. I know it's quite -- it's later there. And we so appreciate you joining us for the summit. We'll now go on to our next public commenter, which is Jeanne Duckett. Jeanne?

DR. DUCKETT: Hi. Thank you. My name is Jeanne Duckett, and I am chair of the board of directors for AIM North America. I'm chair of the AIM North America food policy group. I'm convener of the ISO WG8 AIDC and applications group. I'm the GS1 co-chair for RFID Gen2 B3 and my day job is understanding food traceability from fark to fork for Avery Denison.

Thank you for allowing me to add public comments during this amazing three-day event for the FDA summit on e-commerce. I've learned a great deal listening to the different perspectives from the presenters and the other commenters.

The COVID-19 pandemic has made it clear how essential the actions outlined in the Blueprint for Smarter Food Safety released in the summer of 2020 are for a safer, more resilient, sustainable, interoperable digital food supply chain.

Let's review the four pillars. First, new business models and retail modernization. That's the topic of this week's symposium, although the concept of new depends on your definition.

Communal kitchens or ghost kitchens were uncovered in the ruins of Pompeii and the very first pizza delivery is popularly attributed to Queen Margherita in 1889. After traveling to Naples, she requested food to be delivered to her room and pizza delivery was born. However it's more likely that food home delivery dates back as far as communal kitchens.

The new challenges for these communal

kitchens and third-party delivery services and e-commerce is proving the chain of custody. Simply put, the chain of custody is the unbroken path a product takes from the first stage in the supply chain to the end customer, including raw commodity materials, conversion, transportation, distribution and logistics.

Note that the physical product holder can be different than the product owner. Today a customer uses a third-party app or a webpage to purchase home delivery of food and becomes owner of that food. However they do not have possession of it. Third-party apps have proprietary methods of capturing this data. But the New Era pillar will be enabled through common access.

This brings us to our next pillar, enhanced traceability. There is a global interoperability model currently in use in the drug supply chain. And it's starting to emerge in food. Commenters have referred to it on each day. Let's look at what's required.

First you need definition. You need the

critical tracking events. These events flow nicely from the food process map required for hazard analysis. As discussed, that made its appearance in the 1960s. A common language builds common understanding. The common language is EPCIS, defined by the GS1 and ratified by ISO.

In the coming months, food safety experts will assist in defining these points for communal kitchens and delivery services. To cure access, this model is being developed by the Internet Consortium W3C as the centralized identification.

For the practitioner in the field, it's obvious that not all of this data is going to be stored in a single repository. This is neither practical or desirable. This centralized identification will enable permission to access to this data with verifiable credentials.

Provident certificate and sensor data, a common data which is needed for the verification of certification and evidence that hazmat controls were met. EPCIS Standard 2.0 is now in community review and this enables this data to be tied to the item

moving through the supply chain.

Building on this foundation, you'll see that the digital food supply chain rapidly emerging over the next decade with automatic exception handling based upon unmet control points, which brings us to the new culture of food safety and another emerging standard, GS1 digital link.

GS1 digital link is building upon all of the web-enabled references that have developed over the last decade from proprietary QR codes. The GS1 digital link is a structured way of web-enabling GS1 data such as global data model or EPCIS.

Imagine a third-party delivery service creating an EPCIS event that builds upon the previous events that an item was picked up and delivered to a consumer in an appropriate transportation environment with a tamper-proof label on it.

The GS1 digital link contained in a QR code on the package could not only tie the brand directly to the product and the consumer, provide verified nutrition and allergy information as well as maybe a coupon for the third-party delivery services.

Within this framework, you can educate while regulating. The GS1 digital link could link safe food handling practices. In the case of a recall, the GS1 digital link with verifiable credentials could enable the access to the unbroken chain of custody for the product for rapid traceback and trace forward.

To wrap up, we've discussed how global interoperable standards can enable the access of food safety information, allergens, nutrition facts, product handling and enabled third-party deliveries to offer value-add to both restaurants and consumers.

With interoperable traceability events, we enable the final of the New Era, smarter tools and approaches for prevention and outbreak response to enable that quick traceback. Thank you.

MS. BARRETT: Thank you, Jeannie, for both your technical remarks and I have to say I enjoyed your historical notes as well. So thank you so much for joining us, and I want to thank again all of our public commenters. That does bring us to the end of our open public comment session this afternoon.

And at this time, I do want to welcome back

our summit host, Andreas Keller. Andreas?

DAILY WRAP-UP

DR. KELLER: Hello, everyone. And thank you for listening to us throughout these three days. Dear audience, over the past three days, we learned so much about what is being done to help ensure the safety of food produced and sold through B2C e-commerce as well as thinking from many different perspectives on where potential regulatory gaps may exist and what opportunities exist to better protect consumers.

During today's summit sessions, we learned how some of our international food safety partner agencies regulate B2C e-commerce and the challenges they face.

The challenges that we face in the U.S. are similar to those faced by other countries, further highlighting the need to collaborate and exchange information about how best to ensure the safety of these foods and how to manage food safety problems once discovered and how countries provide executive oversight, strategic leadership and policy.

We have reached the end of our summit. It

has been an interesting and informative few days. I want to thank all of those that participated in this summit, whether they participated as panelists, submitted questions or just listened in to learn about the potential safety issues which attach to B2C e-commerce and foods.

While the summit is almost over, the dialogue on food sold via e-commerce will continue. As we have said throughout the summit, we intend to use the information resulting from the public meeting as well as all submissions to the docket which will remain open until November 20th 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.

We urge you to think about the issues raised over the last three days as well as those highlighted in the Federal Register notice and background materials for the submit that were posted on our website and provide us with any data and other information which you might have that can help us in our deliberations on how to improve the safety of

foods produced, sold and delivered through e-commerce.

So what are our next steps? As I said, FDA will be reviewing all the information we heard over the last few days, the public comments provided to us and other feedback received. We will work in collaboration with our state and local partners as well as all our stakeholders other than in the federal and U.S. so that we incorporate all international levels as well to continue the dialogue, follow up on discussions and potential other forums as needed to determine the path forward.

Please share the summit YouTube links for all three days with your peers and friends and you may also follow our progress at www.fda.gov/food/neweraofsmarterfoodsafety.

I urge you to sign up for the subscription service on our website so you can be kept up to date on all developments related to the New Era of Smarter Food Safety and learn of future opportunities to get involved.

We thank you again for your interest and participation this week. All of us, whether

regulators, industry, consumer groups or academia, share a common interest in ensuring the safety of food sold through e-commerce, and together we will work to protect consumers. We wish you an enjoyable rest of your day. Goodbye, and stay safe.

(Whereupon, at 1:57 p.m., the foregoing was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, TERRELL LEE, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that 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.

TERRELL LEE

Notary Public in and for the

STATE OF MARYLAND

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