Transcript

FDA Public Meeting: Challenges and Solutions in Lot Level Food Traceability

Date: June 15, 2026

OPENING REMARKS

MODERATOR (Kyrese Johnson, Health Scientist, FDA Public Engagement Staff):

Good afternoon, and welcome to the Food and Drug Administration's public meeting on the challenges and solutions in lot level food traceability. I'm Kyrese Johnson, Health Scientist with the Public Engagement Staff at the FDA, and I will be moderating today's session.

This meeting is a part of a series of engagements being held in accordance with the directive from Congress and the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs and Extensions Act of 2026.

The FDA final rule on requirements for additional traceability records for certain foods, known as the Food Traceability Rule, requires persons who manufacture, process, pack, or hold food on FDA's Food Traceability List to maintain and, in some cases, provide to their supply chain partners key data elements for certain critical tracking events in the food supply chain. The requirements in the rule will allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

For today's program, we will first hear from Donald Prater, DVM, Acting Deputy Commissioner for Human Foods with the FDA. Next, we will listen to an FDA presentation by Katherine Vierek, Acting Director, Office of Surveillance Strategy and Risk Prioritization of the Human Foods Program here at the FDA.

After the presentation, we will move to the public speaker portion of our meeting, which is divided into two segments. The first segment will include our first set of 20 presenters, followed by a ten-minute break. After the break, we will hear from our final set of 18 presenters.

The purpose of today's meeting is to give the public an opportunity to share information on implementation of the Food Traceability Rule and areas of remaining concern, specifically as they relate to lot level tracking and flexibilities for compliance.

We opened registration for participation in this public meeting on April 22nd, and received a robust number of requests to speak today. I am pleased to announce that

everyone who registered and confirmed to present at this meeting has been given a four-minute speaking slot.

I would like to remind everyone that the docket for public comment on the challenges and solutions in lot level food traceability remains open until 11:59 p.m. Eastern Time on July 15th, 2026.

And now I have a few general announcements to go over before we begin. Excuse me. In addition to the hundreds of people we are expecting today to attend today's virtual session, today's hearing will be recorded for our speakers. Please be mindful of all of your fellow presenters' time and do not go over your allotted four minutes. We have an ambitious agenda today with nearly 40 speakers, and must stay within the time limitations in order to end on time.

I will call on speakers in the order that is posted on our website. Please pay attention to the slides and be prepared to begin your presentation before your time slot, so that we do not lose valuable time between presentations. If a speaker misses their slot, we will call on them again at the end of the segment.

If you have not concluded your remarks by the four-minute limit, I apologize in advance, but I will interrupt you and ask you to stop. And I want to remind everyone that your comments and presentations today will be included in the public docket. If you run out of time and don't get to complete your remarks, please submit any additional information to the public docket for consideration.

And with that, I'd now like to introduce FDA's Acting Deputy Commissioner for Human Foods, Donald Prater. As Acting Deputy Commissioner, Doctor Prater leads the agency's human foods program, overseeing all FDA nutrition and food safety activities. In this role, Doctor Prater exercises authority over all human food program entities and operations, including resource allocation, risk prioritization, strategy and decision making, policy initiatives, and major response activities involving human foods. Doctor Prater also oversees food resources in the agency's Office of Inspections and Investigations.

Prior to this role, he served as the agency's Principal Deputy Associate Commissioner for Food since 2024, and was previously Acting Director of the FDA's Center for Food Safety and Applied Nutrition, a role he took on in 2023. He adeptly helped lead the Center during a time of transition, prioritizing nutrition and the safety of the food supply, dietary supplements, and cosmetics, while helping to re-envision the organization.

Toward the end of Doctor Prater's remarks, he will turn the program over to Katherine Vierk, Acting Director, Office of Surveillance Strategy and Risk Prioritization of the Human Foods Program at the FDA. Katherine is the Acting Director for the Office of Surveillance Strategy and Risk Prioritization in the Human Foods Program at the FDA.

As Acting Director, she oversees three divisions dedicated to leading the Human Foods Program's overall surveillance strategy, development, oversight, and associated activities to assess the overall state of the food supply. The office also provides the overall risk-informed framework to inform recommendations and decision making for Human Foods Program priorities. She brings more than 25 years of experience working at the FDA in the areas of foodborne outbreaks, traceability, epidemiology, adverse events, and data analytics. Currently, she leads FDA's traceability rule writing efforts.

We will now hear opening remarks from Doctor Prater.

FDA OPENING REMARKS

Donald Prater, DVM, Acting Deputy Commissioner for Human Foods, FDA:

It does give me great pleasure to welcome everyone to today's public meeting on food traceability. As many of you know, I have spent a great deal of my career dedicated to advancing food safety, and I deeply understand the value of regulatory action in protecting public health. By the same token, I also very much appreciate the impacts new requirements can have on our regulated industry. For regulation to be meaningful, it must be practical for the regulated industry to implement.

Our goal today is to hear stakeholder feedback on lot level food traceability efforts and implementation challenges that our industry faces in this area. We're interested in hearing about the challenges and potential solutions for satisfying the Food Traceability Rule's lot level tracking requirements. The Traceability Rule, as you all know, is designed to prevent and reduce exposure to foodborne illness by enabling FDA and the food industry to take action more quickly.

Let me say this plainly: the U.S. food supply is among the safest in the world, and that is a sincere thanks to everything that you do. But we can make it safer and healthier, and we need your help. Lot level tracking will enable more rapid tracing of contaminated foods, allowing FDA to find the source of that food faster, narrowing the scope of recalls and removing affected products from the supply chain quickly. This can help prevent additional foodborne illnesses and deaths in the event of a foodborne illness outbreak.

We recognize that this rule has introduced an unprecedented need for communication and coordination among our supply chain partners. Much of implementing the Traceability Rule has been an iterative process. Over many years, we've engaged with the industry both domestically and internationally through roundtables, webinars, meetings, and other discussions to help support implementation of the Food Traceability Rule. We developed communication materials, templates, and supply chain examples to

help industry understand the rule, issued numerous FAQs, and drafted Q&A guidance to address specific questions we received.

We remain committed to this engagement as we work through the remaining challenges to implementation. I'm certain that with partnership and dialogue, including today's meeting, we will help ensure regulated industry is well positioned to implement the Traceability Rule. Industry is always innovating the way food is grown, stored, packed, and shipped. Our children don't know what summer fruit is because they have access to fresh berries all year long — just as an example. We can thank an incredibly innovative supply chain for that. FDA's duty is to protect the public health, and we must keep pace with industry's innovation.

Together, we have an opportunity to apply a creative mindset to identify possible additional flexibilities to address industry's implementation challenges, while also protecting consumers and maintaining the public health benefits of the rule. Given the complexities of lot level tracking requirements, Congress recognized the importance of FDA engaging quarterly with regulated entities, and today's meeting reflects that commitment. We continue to dedicate significant resources to industry guidance, tabletop exercises, and small business technical assistance to help support efforts of covered entities, including farms, restaurants, and retailers in order to comply.

Together, we will ensure that our food safety regulatory infrastructure is modern, technology-enabled, and science-driven to protect public health and earn the confidence of the American people every day. Americans deserve a food safety system built for the 21st century.

I hope you all had a chance to review FDA's food traceability discussion paper that we released to support this meeting, and to further dialogue with stakeholders and advance progress towards successful implementation. If not, please take a look and submit feedback to the docket on areas of interest. FDA has raised a number of questions about various potential flexibilities, and we need constructive solutions to advance our shared goal. We know there's work to do. We also know that faster identification and rapid removal of potentially contaminated food from the market will result in fewer foodborne illnesses and deaths. We're grateful for your participation in today's meeting. Thank you for your continued support and commitment to our shared goal of ensuring food safety.

So with that, I'll now turn it over to Katherine Vierk, Acting Director of the Office of Surveillance Strategy and Risk Prioritization and the lead of our traceability efforts. Katie, over to you.

FDA PRESENTATION

Katherine Vierk, Acting Director, Office of Surveillance Strategy and Risk Prioritization, Human Foods Program, FDA:

Thanks, Don. Welcome, and thanks for joining. Today's a public meeting. I am going to start with a brief background of the Food Traceability Rule, and then provide a few updates and discuss why we are here today.

Background on the Food Traceability Rule

The Food Traceability final rule establishes new record keeping requirements for persons who manufacture, process, pack, or hold certain foods — those on a list called the Food Traceability List. The additional record keeping requirements are necessary to help FDA rapidly and effectively identify and remove potentially contaminated food. The final rule covers the entire food supply chain, including retail food establishments, restaurants, and farms, and applies to domestic firms as well as foreign firms producing food for U.S. consumption.

The Food Traceability List

The rule applies only to foods on the Food Traceability List, or FTL, including foods containing listed foods as ingredients, as long as the ingredient is in the same form as what appears on the list — for example, fresh or fresh-cut. If you look on our website, you'll see descriptions for each commodity, including examples of foods that are and are not considered part of certain commodity designations on the Food Traceability List.

Critical Tracking Events and Key Data Elements

Critical Tracking Events, or CTEs, and Key Data Elements, or KDEs, are the foundational framework of the rule. The Food Traceability final rule identifies the key points along the supply chain where it is most important to collect traceability information. These are called Critical Tracking Events, or CTEs, and include the points where food is harvested and cooled; initially packed for raw agricultural commodities; first received on land from a fishing vessel for seafood; transformed; shipped; and received. At each CTE, we are requiring traceability information essential to understanding what happened to the food at that point. These are the Key Data Elements, or KDEs. This approach standardizes traceability information across the entire food supply chain. Importantly, the records required at the CTEs would need to contain and link the traceability code of the food to the other relevant KDEs.

Traceability Lot Codes

An important part of the rule is the requirements related to traceability lot codes. A traceability lot code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source. This is similar to what industry currently refers to as a lot or lot code. TLCs can only be assigned or

changed when the following occurs: initial packing of a raw agricultural commodity; first land-based receiving of a food obtained from a fishing vessel; transformation of a food; or when receiving food from an entity. Once a TLC is assigned, the TLC must remain unchanged and pass through the supply chain unless a transformation event occurs. The TLC source is the physical location where that TLC was assigned. Having these two pieces of information — the TLC and the TLC source — will allow us to jump more quickly to points where the food was handled and where contamination could have potentially occurred.

Compliance Date Update

The original compliance date for all entities was January 20th, 2026. Recently, Congress directed FDA not to enforce the rule prior to July 20th, 2028. FDA intends to comply with this congressional directive. The final rule to codify this compliance date is currently under review at the Office of Management and Budget. This provides industry with additional time to coordinate effective implementation of the rule and collaborate as needed on tracing systems. Consistent with our approach for other physical rules, the FDA intends to take the approach of educating before and while we regulate. This may include providing fact sheets and an opportunity for firms to ask questions about the Food Traceability Rule during routine inspections under other FDA regulations. We also want to support widespread compliance by making sure that covered entities have the information needed for the successful implementation of this rule.

Training and Outreach

We are pleased to share that the Food Traceability Rule industry training, developed in conjunction with the Food Safety Preventive Controls Alliance, has been finalized and published. The Lead Instructor and Participant combo courses have already been scheduled and are in person, but virtual delivery is being considered. The training is broad to cover many different sectors and foods, so it is not specific to any one area. This course will be translated into Spanish as well, but timing is to be determined. Please see the speaker's website for more details related to the participant course and for lead instructor applicants.

Also, as part of the 2026 appropriations bill, Congress directed FDA to conduct a tabletop exercise involving producers, distributors, retailers, and technology partners to test traceability readiness. FDA has finished those exercises and issued a public report on the outcomes of those exercises just last week.

FDA has also updated its Frequently Asked Questions on the Food Traceability Rule to provide greater clarity on a number of topics, including the traceability lot code source reference, food traceability plans, and intercompany shipments. In addition to these items, we have two items under review at the Office of Management and Budget: an

enforcement policy document for small retail food establishments and restaurants, and the compliance date extension that codifies what Congress directed as the compliance date of July 20th, 2028.

Purpose of Today's Meeting

Today, we are here as a continuation of our ongoing engagement with stakeholders on the rule. FDA was directed by Congress to discuss challenges and solutions with lot level tracing and identify potential flexibilities — specifically to engage quarterly with regulated entities, and within 180 days of the enactment of the Continuing Appropriations Act, to provide recommendations for additional flexibilities. We recognize Congress's desire for FDA to be transparent with stakeholders about this process, and specifically about where things stand. Approximately 180 days after enactment of the Continuing Appropriations Act, one goal of the discussion paper that we released prior to this meeting is to provide this transparency.

Stakeholder Engagement

Over many years, we have engaged with the industry both domestically and internationally through roundtables, webinars, meetings, and other discussions to help support industry as they implement the Food Traceability Rule. We have developed communication materials, templates, and supply chain examples to help industry understand the rule, issued numerous FAQs, and drafted Q&A guidance to address specific questions we received from the industry.

In addition to our regular engagements with industry in 2026, we are engaging with stakeholders quarterly as directed. The first engagement was a small group discussion held in March, and the second session is being held today as a public meeting. More engagements will be announced as they are scheduled. We are planning for a next meeting in September. We want these engagements with regulated entities and other interested parties to be as productive as possible, so that they can inform our development of any additional flexibilities we ultimately offer for satisfying the Food Traceability Rule's lot level tracking requirement.

Discussion Paper

FDA has heard from industry on the need for flexibilities related to the rule, and has issued a discussion paper ahead of today's meeting. We wanted to capture what we've heard and raise specific questions so that we can better understand the proposed flexibilities from industry. But we also want to ensure we don't lose the public health benefits of the rule. So hearing from stakeholders on our specific questions will help us as we consider potential flexibilities.

The discussion paper describes potential flexibility topic areas. I highly recommend that you read it, as there is a lot in there. Please also note that the order in which the topics are listed is not meant to represent a prioritization or a preference for any topic. Today's meeting and subsequent discussions will inform our consideration of any flexibilities we may propose. Comments are open through July 15th. You don't have to comment on everything — just what's important to you.

While this discussion paper does not reflect an exhaustive list of potential flexibilities that FDA would be willing to consider, we wanted to capture areas where we had the most questions. I also want to note that the topics presented in the discussion paper may or may not be included as final flexibilities, and we want to provide all stakeholders with an opportunity to actively engage with FDA on these topics. We therefore invite and encourage all interested parties to submit feedback on this discussion paper to the docket on the areas of interest within the discussion paper.

Just to be clear, as we have received several questions on this: this dialogue today, future quarterly engagements, and feedback submitted to the docket will help inform final decisions on the scope of additional flexibilities. The discussion paper is not a final decision. FDA will communicate its decision on additional flexibilities once a decision is reached. Firms meeting the conditions for flexibility may nonetheless elect to comply with the underlying rule requirements. Our intent is to issue additional resources on the flexibilities as soon as possible.

Thank you, and we look forward to hearing today's comments.

ORAL COMMENTS — SEGMENT ONE

MODERATOR (Kyrese Johnson):

Thank you, Doctor Prater and Katherine, for your presentations. We will now move to the oral comments segment of our agenda. As a reminder, each speaker will be recognized for four minutes to present. First on our agenda is Maria Cristina de Souza Silva.

Maria Cristina de Souza Silva:

Good afternoon. My name is Maria Cristina. I am an animal scientist. I'm from Brazil, and I'm so happy to be here to speak with you today. I work in Brazil with regulatory affairs, supporting animal feed and pet food companies with product compliance, manufacturing regulations, and international trade. It is truly a privilege to be a part of

this discussion, especially because lot level traceability has become increasingly important in global food systems.

From my experience, I see traceability as much more than a regulatory requirement. In fact, it is one of the most important tools that we have to strengthen food safety, improve supply chain transparency, and support international trade. This becomes even more relevant in sectors where supply chains are highly complex and products often involve different and multiple ingredients, suppliers, and transformation steps. In many cases, ingredients move across multiple countries, and we have this in human nutrition too. Maintaining clear records and strong traceability systems is essential.

The system that we have here is the Ministry of Agriculture regulatory framework, and manufacturers already work with practices such as batch indications, production records, supplier qualification, and quality control systems. This helps us maintain accountability and improve efficiency whenever quick responses are needed. But at the same time, as international trade continues to expand, the importance of traceability grows as well, and helps companies and regulatory authorities make faster and more accurate decisions, while building trust between companies, partners, and customers.

This is exactly where international collaboration becomes especially important. Even though countries may have different regulatory systems or structures, we often share the same goal: protecting food safety, ensuring product quality, and improving transparency across supply chains. At the same time, I believe that practical implementation is challenging, especially in high-transformation product sectors where supply chains involve many combinations and several steps, which can make lot level traceability significantly more complex, particularly when transformation events occur and a new traceability lot code must be assigned.

Continuing dialogue between regulatory authorities and industry is fundamental to finding systems that are both effective and practical. Finally, I would like to thank you again for creating this space for discussion and for bringing together different perspectives on such an important topic. Thank you very much for your time.

MODERATOR (Kyrese Johnson):

Thank you for that comment. Can we please advance the slide to the oral comment presentation? Thank you. Next, I would like to call up Julie McGill to speak for four minutes.

Julie McGill, Chair, AIM North America Food Supply Chain Workgroup; Board Member, AIM North America:

Thank you so much for the opportunity to speak today. My name is Julie McGill. I am the Chair of the AIM North America Food Supply Chain Workgroup, and I'm a member of their board. AIM North America is a not-for-profit association enabling the cooperation, development, and standardization of automatic identification and data capture, known as AIDC technologies.

The FDA's continued commitment to technology neutrality preserves innovation and choice while simultaneously elevating expectations for data accuracy, interoperability, and system reliability. The FDA has made significant strides in supporting the food industry with the release of the FSMA Food Traceability Rule training for the food industry, and this marks a meaningful transition point in the implementation of Rule 204. This signals the FDA's progression from regulatory definition toward operational execution. We would like to thank the FDA, FSPCA, and all of the contributors who helped create the training curriculum. This educational program will benefit all stakeholders in the food industry.

AIM also strongly supports the collaborative approach which industry workgroups have taken to understand traceability challenges, and we encourage the use of global standards to help level the playing field for all trading partners. A wide range of solutions — including GS1-128 barcodes, 2D symbols, RFID, vision systems, temperature sensors, scanners, and traceability platforms — are being deployed to address Rule 204 compliance by enabling data capture, improving accuracy, auditability, data sharing, and consumer safety. These are not theoretical capabilities. These are operational realities for many companies today.

Discussions should no longer focus on whether lot level traceability is possible. It is possible. The challenge is implementation maturity, operational alignment, and change management — change management across highly complex supply chains. Change is hard, but it is achievable when industry and regulators work together around realistic operational models, technology neutrality, and shared data standards. The future of food traceability will not depend on one technology or one approach, but on the collective commitment to building systems that are accurate, scalable, and capable of protecting public health. And with that, thank you.

MODERATOR (Kyrese Johnson):

We appreciate your comment. Next, I would like to call Renee Tan to speak for four minutes.

Renee Tan:

Thank you. My name is Renee Tan. Our family has a controlling interest in a distributing company that is a wholesale convenience distributor operating ten distribution centers, supplying approximately 20,000 SKUs to 8,500 convenience stores in 34 states. To provide a sense of scale, our company is the third largest convenience distributor in the United States by geography. I also have a Bachelor of Science degree in packaging engineering from Michigan State University's School of Packaging, established in the 1950s. MSU's School of Packaging is the first and oldest packaging program in the world.

Based on my background in food packaging, there is a real need to focus food traceability on the very source of the product, which is usually the manufacturing plant or food processing facility where food products are created and packaged. Moreover, the method used to trace food products needs to be feasible.

As was cited by Ms. Vierk, on June 4th, 2026, the U.S. House of Representatives passed a 2027 appropriations bill which included funding for the FDA. The House report on the bill stated the following quote: "Food Traceability Rule Implementation. The committee encourages the FDA to continue working with stakeholders to ensure feasibility of traceability code requirements, interoperability of traceability, and successful implementation of the rule across the food supply chain." Unquote.

For some 70 years, food manufacturers and processors have imprinted basic traceability information — including the lot, the assembly line, and a time stamp — on food packages. This imprinting on product packaging was instituted to trace a product if contamination occurred in a manufacturing facility, or if people became ill and the source of the suspect product needed to be located.

I can appreciate the fact that food production has become more complex over the past seven decades, and I respect the process that the FDA is pursuing under the Food Safety Modernization Act to trace high-risk food products through the food supply chain. At the same time, I believe there is a fundamental and feasible method to trace food products, to simplify the process, and to expedite traceback investigations to protect the food supply chain and consumers. That method has been utilized since the 1950s.

As the Convenience Distribution Association and the Minnesota Wholesale Marketers Association are proposing, food manufacturers should imprint the traceability lot code, the traceability lot code source, and the product expiration date on case labels, inner packs, and individual product packages. To follow through on the new U.S. House recommendation that the FDA focus on feasible methods to trace food products, this method is feasible because it has been time-tested for seven decades. Being able to visually determine the lot code and lot code source on product packaging — whether the product is stocked on a warehouse shelf, on a store shelf, or in a restaurant's food

storeroom — would enhance the industry's response to a manufacturer's food recall notice or expedite an FDA food traceback investigation.

With my background, I'd like to be a resource to the FDA in the event the agency needs to collaborate on implementing the food tracing rule. Please let me know if I can be of any assistance. I greatly appreciate this time, and thank you for listening to my comments.

MODERATOR (Kyrese Johnson):

Thank you for that comment. Next, I would like to call up Mark Coast to speak for four minutes.

Mark Coast, Founder and CEO, Blockchain Agricultural Solutions, Inc. (BKS):

Oh, thank you for having us on. I'm Mark Coast, the founder and CEO of Blockchain Agricultural Solutions, Inc., or BKS, and we're a service-disabled, veteran-owned small business. We've been working on this problem for quite some time. We're partnered with Amazon Web Services and ESRI Geographical Information Systems.

A little history: after the 2018 Farm Bill, we started working on a track-and-trace cultivated controlled substances software system, which ultimately was patented a couple of times over. For example, the first patent was "Methods and Apparatus for Performing Agricultural Transactions." What's critical about that is we incorporated critical tracking events into the software. We also added the Food Traceability List as an expanded module of our software, and in recent days, because of the rescheduling of cannabis from Schedule 1 to Schedule 3, we've had that modular component to it. But where I'm going with this is that we currently have software that addresses all the needs that have been mentioned previously, including lot tracking, critical tracking events, and key data elements.

The platform is called the Aggregated Compliance Blockchain, or ACB. ACB is a regulatory software system and a common operating platform for commercial and government entities alike, so that they have a common exchange of data and information. What makes this interesting for us is that we also incorporate telematics into the system. We have onboard sensors which include temperature and humidity throughout the movement of the product. As a matter of fact, you could go from harvest all the way to sale and we would have all the data — temperature, humidity, vapor — whatever you would need to track that. And since we could do it on such a difficult product as cannabis, we were able to expand it. If we could do cannabis, we could certainly do cabbage.

One of the things that we looked hard at is that farmers and fishermen are not programmers and shouldn't be expected to develop track-and-trace software. So we took that on and developed it. I know the USDA estimated annual cost for small family farms to be about $4,700 annually, which eats into their revenue pretty significantly. So we're trying to get it out to them for less than $500.

What's impressive about our software is that we already bring in the key data elements and the critical tracking events that we've previously had to deal with in chain of custody. All the nomenclature and everything is set up in the FDA's format using their terms. This is critical because we've done everything with a unique nomenclature, which includes the states, dates, and times. We also pair it with universally unique identifiers, which is the hash that goes into the blockchain. So we have a system that is completely up and running. This system also includes everything from combining, processing, and derivative lots, creating them, and putting them into the immutable ledger. And since it's geographically driven, you can see immediately where the origin of the product is. I just wanted to make you aware of that. Thank you for the time allotted to present this.

MODERATOR (Kyrese Johnson):

We appreciate your comment. Is Elisabetta on the call? If so, could you please raise your hand?

[Pause — no response from Elisabetta.]

If Elisabetta returns, we will have her present at the end of the segment. Next, we will move on to Katherine Cahill. She will speak for four minutes.

[Brief technical delay.]

Katherine Cahill, Cahill Consultants:

Got her. Sorry, guys. Katherine Cahill, on behalf of Cahill Consultants. Thank you so much for the opportunity to speak today. Cahill Consultants is a woman-owned and operated regulatory, compliance, and product safety consulting firm. Professionally, over 35 years, I have deployed over 6,000 recalls on behalf of clients on a global level.

I'm really happy to be here today, and I just want to look at something slightly different than some of the other speakers talked about, and that is really the legal requirements that our clients are going to be subject to once these traceability requirements go into effect.

From that perspective, I think a lot of our folks are worried about two things. First is that Congress has specifically directed the FDA to prove that any new lot level tracking which is mandated results in a net positive for society overall. So, particularly in the implementation stage, I think what our clients are looking at is: what are the transparency requirements going to be on behalf of the FDA? We do recognize and we are thankful for the information that you have presented to date. But some of the things that we're considering — if we look at the flexibility that you talked about earlier in the presentation — specifically, monetizing public health imperatives, which would cause a public health benefit that the FDA is going to have to approve by establishing the total number of foodborne illnesses, hospitalizations, and potentially deaths that this new regulation would prevent. This should be tied to deploying faster recalls. How is the FDA going to accomplish this directive? And what is the process that the FDA is going to use to measure this? In other words, what our clients are looking at is: if this is a requirement, how are we going to give you input into this particular piece of it?

Secondly, and probably the most important, is measuring the burden to industry against flexibilities. The FDA contrasts the public health and saving lives against the total estimated capital, technological, and labor costs incurred by the approximate 325,000 foreign and domestic establishments that could be affected by this rule. So what our clients want to know is: how is the FDA going to accomplish this, given all of the recent headcount losses that the FDA has encountered? Will there be oversight on behalf of the conclusions that are made by the FDA? And how can industry continue throughout the process to give input to the FDA, specifically as it pertains to an already highly burdened supply chain and skyrocketing costs of current groceries? We are concerned with how those prices are going to affect the consuming public and, quite frankly, their businesses.

Additionally, we also believe that AI might be used to cheat. When we look at other regulations that have been deployed — specifically for seafood hazards — we saw more regulatory compliance in the area of seafood, but we also saw a lot more fraud. So the question is: how is the FDA preparing to monitor situations that arise because companies, foreign or domestic, may use AI to cheat when it comes to actually deploying the new requirements? Thank you.

MODERATOR (Kyrese Johnson):

Thank you so much for that comment. Next, we will have Frank Zoli, if he's on the line. Will you raise your hand?

[Pause — no response from Frank Zoli.]

Frank, it doesn't look like your name is in our participant list. We will again move him to the end of the segment. Up next is Laura Rich.

Laura Rich, Vice President of Regulatory and Technical Affairs, Consumer Brands Association:

Hi. Good afternoon. Can you hear me? Okay, great. Thank you. So good afternoon. My name is Laura Rich, and I'm the Vice President of Regulatory and Technical Affairs at the Consumer Brands Association. Consumer Brands champions the industry whose products Americans depend on every day and advances consumer choice through transparency. We represent more than 2,000 iconic brands spanning cleaning and personal care to food and beverage products. Beyond our presence in almost every home, the consumer packaged goods industry is the largest domestic manufacturing segment by workforce, supporting more than 22 million American jobs and contributing $2.5 trillion in economic impact.

Consumer Brands advocates for uniform, workable, and durable regulatory frameworks that are informed by risk-based science, promote consumer choice, and build customer trust across the sectors we represent. Food safety is at the core of our members' operations.

I want to thank FDA for hosting a series of public engagements on the Food Traceability Rule to better understand concerns and to explore options for regulated entities with the rule. We share FDA's commitment to providing consumers with safe foods, and are supportive of its efforts to enhance food safety. We also appreciate that FDA has made strong efforts to provide clarity and outreach on the rule, including by publishing the draft guidance, "Questions and Answers About Requirements for Additional Traceability Records for Certain Foods," which we commented on last month, and by continuously updating its FAQ page, including as recently as last week. Regarding the FAQs, FDA's recent updates included creating a more simplified approach regarding intercompany shipments and the use of corporate headquarters as a traceability code source reference. These updates will enhance efficiencies, protect public health, and reduce the risk of record keeping errors. So thank you for that.

As we discussed in our comment letter to FDA dated September 8th, 2025, we believe that FDA should implement flexibilities to ensure that entities, including manufacturers, are not required to engage in de facto case level tracking. We appreciate that FDA references this topic in the discussion paper entitled "Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot Level Tracking Requirement" that was released on May 27th. However, the discussion paper does not specifically reference manufacturers. We appreciate that the discussion paper was not intended to reflect an

exhaustive list of options for flexibilities, and we intend to provide written feedback in response to those questions that appear to be most relevant to our members.

For example, the questions for stakeholders in the section entitled "Reasonable Range of Traceability Lot Codes for Distributors Shipping to Retailers" appear to be relevant. This is because manufacturers should be offered the same flexibility as distribution centers to ensure that it is applicable to the entire supply chain. That said, we would be interested in understanding if FDA has additional or different questions in connection with these flexibilities for manufacturers, including large manufacturers. Getting this guidance will allow us to sharpen our potential responses and provide more useful information to the agency.

Thank you. And I have an example I can quickly provide if that would be helpful. I know I only have 30 seconds left.

[Brief pause.]

Okay, so I guess I can keep going. So one example we wanted to provide for your consideration is that some large manufacturers run continuous operations that generate a mixed pallet at the end of the shift. This mixed pallet contains one item, but this item is associated with different lot codes. For example, there could be five cases associated with one lot code and 45 with another. Industry's preference would be to put all 50 cases on one pallet. Keeping the cases separate because they have different lot codes would take up more space both in the warehouse and on trucks, which in turn drives up cost. That cost could ultimately result in higher prices for consumers. I can see that my time is up, but I would be very interested in getting FDA's feedback on this. Thank you.

MODERATOR (Kyrese Johnson):

Thank you for your comment. Up next is Thomas Bryant.

Thomas Bryant, Convenience Distribution Association (CDA) and Minnesota Wholesale Marketers Association (MWMA):

I am Tom Bryant with the Convenience Distribution Association and the Minnesota Wholesale Marketers Association. Thank you to the FDA for conducting this listening session.

Last week, CDA and the MWMA submitted a detailed memo to the FDA titled "Each: A New Flexible Option." Each is a very significant issue. A case of a product can contain one kind of "each," known as an inner pack, which is a box that holds a certain number of individual packages of a product. A second kind of "each" is an individual package of

a food product. Eaches are contained in 60% to 90% of shipments by distributors to convenience stores, and in more than 50% of shipments to restaurants. There are significant challenges for tracing products at the each level, and tracing eaches would require a significant amount of time and labor. However, there is another flexible option to support effective food recalls and food illness investigations, not only at the lot level but at the each level.

According to a report by Michigan State University, the foundation of this flexible option has been utilized by manufacturers for 70 years and involves the printing of the lot code and expiration date on product packaging. The flexible option that we propose involves manufacturers and processors printing the TLC, the TLC source, and an expiration date on case labels, inner packs, and individual product packages. While the final rule does not require these KDEs to be printed on packaging, printing the TLC and the TLC source on labels and packages could prove to be an effective method to expedite recalls and tracebacks.

A manufactured food recall notice usually contains the brand name of the product, the TLC, and the expiration date. If the TLC is printed on the inner pack and product package, then distributor, retail, and restaurant employees only need to visually check their inventories to quickly identify and remove any product with the matching TLC.

Regarding a traceback investigation, health departments utilize several methods to trace a contaminated food product to its origin. One method is to ask consumers who became ill for receipts from grocery stores. A second method is to access grocery store loyalty programs to track purchases. Third, during interviews with individuals who reported foodborne illnesses, health officials may request a survey of individuals' pantries and refrigerators for food in packages. In this third method, a food package with the TLC and TLC source imprinted on it would give the FDA the information to immediately alert distributors, retailers, and restaurants, and then go to the manufacturing facility to investigate possible contamination. If a food package is not found, but the interviews disclose the store where the product was bought by the consumer, investigators can visit the store and survey the same product on the store shelves. While the TLC may be different, the product should have the same TLC source imprinted on it, which would allow the investigation to focus on the manufacturing facility and expedite the process.

Importantly, this new option also aligns with the goals and underlying principles of Section 204 as follows. First, the goal of expediting food recalls and tracebacks. Second, the principle under Section 204(1)(F) to minimize the number of different record keeping requirements for companies that have more than one type of food — that would include distributors, retailers, and restaurants. Third, the principle under Section 204(d)(1)(G) that, to the extent possible, the FDA should not require a business

to change processes to comply with traceability requirements. And significantly, fourth, the bill report issued by the U.S. House of Representatives just recently on June 4th, 2026, which states that the FDA needs to continue working with the industry to ensure feasibility of tracing options. Our option has been in use for 70 years and meets the feasibility requirement. Again, thank you for allowing us to speak today.

MODERATOR (Kyrese Johnson):

We appreciate your comment. Thank you. Next, we will hear from Alex Caldea to speak for four minutes.

Alex Caldea, Founder, Dil Dil Inc.:

Hello. Thank you for the invite. Really appreciate it. So I'm Alex Caldea. I founded Dil Dil Inc. We do food labeling compliance solutions for operators across the UK, the U.S., and Canada, and we usually sit on top of the point of sale or the systems they already use. We handle the label at the point where the food gets prepped, packed, or sold — things like ingredients, allergens, lot codes, barcodes. We're used right across the board: service stations, stadiums, fine dining, quick service chains, and these sorts of places. And we're still walking into places doing this by hand — handwritten labels, spreadsheets, sticky notes on the prep fridge. So we've seen similar situations across different operations, but it's kind of the same problem at the core.

Because we see the print step, we see the operator on the floor — the actual moment the food gets made and labeled. So I see where lot level tracking happens, or where it doesn't, many times. And I've noticed it doesn't break at the big manufacturer. Usually the upstream is fine and the food arrives lot-tracked and the data is fairly clean. It breaks at the counter. So a deli or a café takes ten lot-tracked ingredients and makes a sandwich, and it's a critical tracking event. And right now it gets recorded mostly by hand, if it gets recorded at all. And these are places with high staff turnover and line cooks who are really, really busy during peak times. Accurate lot records from scanning don't always take place.

So my point is about flexibility. The fix is not recording less, but it's letting the record step happen when it realistically can. And there are two moments. The first is receiving: when a delivery arrives, someone checks it in — a manager or a shift lead — the calm moment of the day. The lot gets captured there, either scanned off the box or pulled straight from the supplier where they send the data — one person, one time per delivery. And the second moment is the print. So every time someone makes a product, they print the label — or handwrite it, but ideally they would print it. The print step is the

actual timestamp. The system already knows the recipe, the time, and the location. So it locks the transformation automatically and carries through the ingredient lots that were captured at receiving. So every label leaves a digital footprint of what was made, when, and where. And that line cook doesn't record anything — it just happens when they print.

The print becomes the record that stays with the operator. And honestly, for most of these operators, it's more of an upgrade than a burden because they're usually using paper for logging ingredients. We've built this — capturing the lot at receiving and inheriting it at the print step — and it's running live in multi-site operations. So just to close: the point of the rule is pulling the bad product fast and preventing illness. And from what I see on the floor, that's reachable for small operators when the record gets captured where the work already happens — at receiving and at the print step. So I just want to share that as you look at flexibilities. Thank you so much.

MODERATOR (Kyrese Johnson):

Thank you for that comment. Next slide, please. Next, I would like to call up Shaun Murphy to speak for four minutes.

Shaun Murphy, Vice President, Doyle Sheehan:

Hello. Thank you. My name is Shaun Murphy. I am the Vice President at Doyle Sheehan, a distribution company with warehouse locations in Idaho and Montana. Our company distributes food products, snacks, beverages, and grocery items to convenience stores throughout Idaho, Montana, Washington, North Dakota, Oregon, and Wyoming.

From a distributor's perspective, food traceability needs to start at the source and will only work if food manufacturers and food processors assume the primary responsibility for labeling their products, because they are the only segment with the scale, control, and resources to implement Section 204(d) effectively. Manufacturers create product identity and control the assignment of traceability lot codes along with all other product data, while wholesalers focus on logistics and efficient product flow throughout the warehouse. In short, traceability cannot be re-created downstream in a warehouse, but must be engineered at the source.

As a distributor, we purchase products from hundreds of food manufacturers. It is important to recall that Section 204(1) of the FSMA law states that, to the extent possible, the FDA should not require a facility to change business systems to comply with FSMA record keeping requirements. To trace food products from hundreds of

manufacturers would require significant upgrades to platforms and internal operations for receiving, stocking, picking, and shipping the regulated food products. This, in turn, will have an unintended consequence of reducing product flow through distributor warehouses. The result is that our company may be faced with no longer shipping food products to low-volume convenience stores, which could increase food insecurity in rural areas.

Despite what some in the industry may believe, many distributors lack advanced warehouse inventory management systems capable of tracing hundreds of different food products. To update these software platforms would be contrary to the underlying principle of the Food Safety Modernization Act — that companies should not necessarily be required to change their business systems to comply with the law. We have looked at other proposals, such as scanning every case, developing a range of lot codes, and the transformation model. But these concepts would also require significant upgrades and software platforms at a high cost, and likely would not address the challenges of mixed pallets and eaches.

Rather, Doyle Sheehan supports the flexible option being proposed by the Convenience Distribution Association and the Minnesota Wholesale Marketers Association to have the manufacturers and food processors imprint the lot code, the lot code source, and the expiration date on case labels, inner packs, and individual product packages. This option is feasible, and it would enhance the food recall and food traceability process, because the availability of the lot code — and in particular the lot code source — would provide the FDA with the physical location of the plant or processing facility where the product was made or packaged. This, in turn, should allow the agency to more rapidly go to the source of the product and find the origin of contamination. Again, I'd like to thank the FDA for conducting this listening session on Section 204 of the Food Safety Modernization Act.

MODERATOR (Kyrese Johnson):

Thank you so much for that comment. Next, I would like to call Jim White to speak for four minutes.

Jim White, President, Ancestral for Food; Co-Founder, Track Key Traceability Platform:

Good afternoon. My name is Jim White, President of Ancestral for Food and co-founder of the Track Key Traceability platform. We support traceability implementations across the food supply chain, including producers, aggregators, distributors, manufacturers,

food service, and retailers. I would like to share observations from our implementation experience regarding lot level tracking and compliance flexibility.

Primary source providers have one critical advantage in the tool for implementation: they are the non-contingent creators of the first traceability lot code. Unlike distributors, manufacturers, retailers, and food service operators, they do not have significant supplier dependencies for lot identity because they are the source of the lot. This matters because lot integrity is easiest to establish where the lot is created.

Our experience with farms, cooperatives, wild-caught seafood operations, aggregation facilities, and first packing operations suggests that smaller and mid-sized primary source providers are often more prepared to comply with lot level traceability than many stakeholders expect. These businesses typically have fewer critical tracking events, simpler operations, and fewer legacy technology constraints. Whether harvesting produce, landing seafood, or aggregating products from multiple producers, the operational tempo associated with Rule 204 record keeping is often manageable. A producer may move large volumes of products in a day while generating only a small number of critical tracking events.

The most important step in preserving lot integrity is creating an accurate digital record at the source and linking that record to a properly labeled physical package. The digital and the physical supply chains meet at the label.

Finally, we recognize concerns regarding lot level tracking in high-volume distribution environments. In our experience, many distribution and retail challenges are supplier dependency challenges before they are technology challenges. As a result, compliance at the source can often be achieved through straightforward labeling and record keeping processes, without extensive automation or major operational disruption. We have also observed that digital record keeping creates benefits beyond compliance. These businesses gain better visibility into inventory, production activity, customer requirements, and business operations. When source labeling is done correctly, every downstream participant benefits: distributors receive more consistent inbound product, manufacturers simplify transformation tracking, and retailers gain greater confidence in lot level visibility during recalls, investigations, and regulatory requests.

Our biggest concern is awareness. Working with SGS, we continue to observe low awareness of FSMA Rule 204 requirements among many primary source providers, particularly outside the United States. We also encounter confusion caused by uncertainty regarding enforcement timelines and conflicting advice about whether the rule will actually be enforced. Our remaining concern is that importers operating under FSVP are often the closest U.S. trading partner to foreign suppliers, and many domestic producers receive information through USDA programs, extension services, commodity groups, and cooperatives — and they're not receiving effective communication about

the rule. Exploiting these existing communication channels could help improve awareness where traceability begins.

Once products are consistently labeled and lot information is standardized at the source, the remaining challenge becomes an operational one that can be addressed through process design, automation, inventory controls, and scanning technologies. Thank you for the opportunity to comment.

MODERATOR (Kyrese Johnson):

Thank you. We appreciate your comments. Next, I would like to call up Jacob Bonner to speak for four minutes.

Jacob Bonner, Food Comply:

Hi. Thanks for having me. Good afternoon, everyone. My name is Jacob Bonner, and I'm here representing Food Comply, a digital food safety compliance platform designed to make regulatory compliance practical and achievable for food businesses of every size. Food Comply helps dozens of food businesses with their HACCP, BRC, and ISO 22000 compliance by replacing paperwork with digital checklists. We offer features including supply management, document management, automated order preparation, mock recall exercise simulation, and custom dashboards to trend any data you want in real time. We are a full food safety management system built for the modern food business, but today we would like to speak specifically about lot level traceability and how we've approached solving it.

After months of dedicated research specifically focused on helping businesses navigate FSMA Rule 204, we have built a custom traceability workflow directly into our platform. Rather than simply logging data after the fact, Food Comply allows businesses to predefine their critical tracking events and key data elements based on their specific operation. For example, if a process involves first receiving, followed by cooling, freezing, production, and dispatch, you would build that workflow once, and every time a new lot enters your facility, the system automatically generates a linked traceability chain tied to that specific lot number. From that point on, every step must be completed in sequence. If any key data element is missing, even if a single step is skipped, our dashboard flags it immediately. You always know exactly where every lot stands, and nothing can fall through the cracks.

This means that when the FDA requests your traceability records, the data is structured, complete, and ready to export, grouped by individual lot numbers. We built this because we believe lot level traceability should be a natural part of how food businesses already

operate, not a separate compliance burden layered on top. Food Comply allows you to bring everything together in one place. Through a combination of all of our features, you are able to receive all key data elements from suppliers, complete lot level tracking through every stage of your unique process, and provide all key data elements to your customers. Using this, you are able to simulate in-depth mock recalls for any product at any time.

Food Comply is an intuitive, adaptable, and accessible solution for all your food safety and traceability needs. The platform allows you to edit your custom checklists and workflows at any time, ensuring that we remain a tailor-made solution for anyone. So if you're looking for a digital food safety solution specifically to help you with Rule 204 compliance and much more, visit us to book a demonstration at www.foodcomply.com. We look forward to contributing to the ongoing conversations on practical traceability solutions. On behalf of Food Comply, I'd like to thank the FDA for organizing this meeting and for having us contribute, and also to the FDA for their ongoing efforts to ensuring that food safety is held to the highest standard possible. Thank you very much for your time. Have a good afternoon.

MODERATOR (Kyrese Johnson):

Thank you so much for your comment. Is Jessica Moreno on the line?

[Pause — no response from Jessica Moreno.]

Okay, we will circle back if Jessica comes on the line. Next, we will move to Allison Aja to speak for four minutes.

Allison Aja, FPI, Inc. (Foundation of Purposeful Production):

Hello. Are you able to hear me? Yes. Okay. Hello. My name is Allison Aja with FPI, Inc., which is the Foundation of Purposeful Production. We are a faith-based nonprofit organization committed to providing churches and their congregations with transformative business opportunities, shining a spotlight on God's gifts provided within them, and building community and church. We have faceted onto ourselves now manufacturing, and we provide consultation services specifically for companies such as Gathered By, for example.

So I just want to start off by saying that the information that has been provided thus far has been so very informative, and I look forward to hearing the remaining speakers as well. So thank you.

The U.S. has long been a global gold standard for food production, but a profound transformation is happening right now in our domestic markets. Our consumers are no longer just eating to live, but eating to heal. They are treating food as medicine, actively tracking the direct links between specific ingredients and chronic pain, inflammation, and autoimmune wellness. This cultural shift demands absolute transparency. When we explicitly trace allergens and eliminate unlisted fillers that trigger adverse reactions, we aren't just checking off a legal box, but we are restoring the immutable bond of trust between the manufacturer and the American household, as well as beyond.

But transparency requires operational precision. As a manufacturer operating right at a critical midpoint for food production, I know that traceability cannot just be treated as a post-production afterthought. If a contamination or raw material failure occurs, we must have traceable data points to nip it in the bud instantly. Waiting until a product hits retail shelves or consumers' plates risks devastating public health consequences and catastrophic financial loss.

However, shifting to continuous digital tracking alters production output. If we force a rigid, one-size-fits-all implementation even overnight, we risk severe supply chain deficits and inferior product substitutions. With the July 2028 FSMA Rule 204 enforcement timeline fast approaching, we need smarter, forward-thinking solutions. Blanket enforcement will break the supply chain. Instead, our immediate priority must be to target high-risk areas: first, onboarding up-and-coming manufacturing entities with foundational tracking tools on day one; and second, intensely auditing facilities that have triggered a Class I recall within the last 12 months. By prioritizing these high-hazard sectors and newer operations, we allow veteran manufacturers the necessary operational runway to transition without halting the public food supply, while immediately fortifying our vulnerable nodes.

So essentially, to turn this vision into a reality, we must address the financial and operational friction of this transition. I propose a cooperative framework where the FDA partners with certified third-party consultants to streamline technical implementations for emerging brands, mitigating initial overhead fees. I definitely look forward to 2028 as a historic opportunity to build a faster, safer, and entirely transparent food ecosystem, which is very important for us, the U.S., and beyond. Thank you.

MODERATOR (Kyrese Johnson):

Thank you for your comment. Next, we will hear from Roselle Garbarek for four minutes.

Roselle Garbarek, Gravitas Consulting:

Hi, my name is Roselle Garbarek, and thank you to the FDA for including me in this public meeting. I work with Gravitas Consulting, which provides food safety and quality assurance consulting services mostly to medium-sized companies. That being said, there are some challenges in food traceability for these companies — they have limited technical expertise as well as limited resources in terms of implementing or utilizing automated systems. But what I'd like to do for this meeting is share two examples that may add some food for thought.

The first that I've encountered is imported cheese that's purchased from a distributor. So if you're doing a hazard analysis, the individuals or the key manager at the plant may not necessarily know what the hazards are. So I'm thinking and considering: should a distributor also conduct the hazard analysis that they can pass on to their customers? Because the information — for example, GFI reports — may not be available to the client, or there may be a requirement for a Certificate of Analysis. So in essence, there is missing information not only on traceability because of the multiple lots sometimes, or even missing manufacturing dates on the packaging material, in terms of assessing the hazards of the ingredient being utilized in a food that may receive a transformation, or may not, and may rely on cooking or any heat treatment by the customer.

The second example I have is on produce. As you may be aware, there is 21 CFR Part 114, which is the CGMP. Many of those ingredients from a manufacturer or even a commodity are considered a raw agricultural commodity. But when you do the hazard analysis, the requirement of the regulation is only for refrigerated temperature if there's no heat treatment. So I'm wondering if it should be considered that, in addition to those two parameters, the chemical disinfection process be made a requirement in terms of ensuring that not only refrigeration and temperature will prevent the growth, but that you have a step in the process that will actually inactivate the pathogens, which could likely be brought in from the commodity ingredients such as peppers and tomatoes.

The other thing I want to mention is culling. It is a practice in the different sectors, but this has to be evaluated because there's a secondary market for the culled foods. So how would they assign a TLC? Would they combine two TLCs that had been assigned to the previous product? So I'm just bringing this to attention. It's more of a challenge than a solution, but I appreciate the opportunity to speak in this meeting.

MODERATOR (Kyrese Johnson):

Thank you so much for that comment. Next, I would like to call Liz to speak for four minutes.

Liz [surname not provided], GS1 US:

Good afternoon. My name is Liz with GS1 US. Thanks for the opportunity to be with you today and share our perspective about Rule 204 on behalf of our 300,000 member companies.

The use of GS1 standards is critical for FSMA Rule 204 compliance, as the regulation fundamentally requires end-to-end traceability, structured data capture, and rapid information sharing across the entire food supply chain — capabilities that GS1 standards uniquely enable at scale. The GTIN, or Global Trade Item Number, was developed over 55 years ago to uniquely identify products and powers the UPC barcode. Barcodes are scanned over 10 billion times each day globally, enabling global commerce and product movement throughout the supply chain. Today, GS1 US serves member companies across food service, grocery, apparel, general merchandise, healthcare, and other sectors. Our role is to bring industry together through voluntary, consensus-based, competitive collaboration to solve supply chain challenges.

FSMA Rule 204 is an interoperability challenge across the food supply chain. Companies must be able to capture and share key data elements connected to critical tracking events, and provide that information to FDA quickly — often within 24 hours. That requires a common language. GS1 standards provide that common language. They help trading partners uniquely identify products, locations, and events in a consistent, structured, and machine-readable way, irrespective of any specific or proprietary technology solution. GTINs identify products, Global Location Numbers, or GLNs, identify locations, and Electronic Product Code Information Services, or EPCIS, provides a standardized framework for sharing event-based traceability data — the what, when, where, and why of product movement.

Without a common data model, trading partners may be forced to translate and reconcile data across multiple formats, increasing cost, complexity, and potential for error. With open, technology-neutral standards, industry can reduce fragmentation, improve data quality, and support faster traceback and recall response.

While FSMA prohibits FDA from prescribing specific technologies for the maintenance of records, a system of standards is not a specific technology. Standards ensure consistency and interoperability throughout the supply chain, while technology enables the use of those standards and makes them usable at scale. Standards do not depend on any single technology. The same GS1 standard can be applied across multiple technologies, and as technology evolves, the standards remain constant. This consistency provides a common data language that can be shared throughout the supply chain, ensuring interoperability and supporting compliance with Rule 204.

FDA has already recognized the value of this approach in another regulated supply chain. Under the Drug Supply Chain Security Act, FDA released guidance that GS1 standards and EPCIS are an appropriate, globally recognized standard for interoperable data exchange. That precedent demonstrates how open, consensus-based standards can support regulatory goals while allowing companies to use a range of technology solutions. To continue supporting Rule 204 implementation, clear alignment with established open standards such as GS1 standards can help reduce uncertainty, prevent fragmentation, and accelerate consistent adoption across the supply chain. GS1 US stands ready to continue partnering with FDA and industry to make Rule 204 implementation efficient, interoperable, and effective. Thank you.

MODERATOR (Kyrese Johnson):

Thank you so much for that comment. Is Nilu Corona on the line? Please raise your hand, Neelu Corona, if you are on the line.

[Pause — no response from Neelu Corona.]

All right. We'll move to Sarah Morris to speak for four minutes.

Sarah Morris, Senior Scientist, Institute of Food Technologists (IFT) Global Food Traceability Center:

Good afternoon, everyone, and thank you for the opportunity to comment. My name is Sarah Morris, and I'm a Senior Scientist with the Institute of Food Technologists Global Food Traceability Center.

First off, we want to say we appreciate FDA's willingness to engage with stakeholders on the challenges of implementing lot level traceability. As others have said, we know that maintaining lot level visibility through distribution channels can be challenging, especially when products from multiple lots are aggregated in storage or transit. So, as FDA considers potential flexibilities to ease those challenges, we want to encourage the agency to view them as transitional mechanisms towards full compliance, rather than permanent alternatives to lot level traceability.

The Food Traceability Rule established traceability lot codes, or TLCs, to reduce the time required to identify affected product during foodborne illness investigations and recalls. As such, any flexibility that relies on inferred, predictive, or potential lots should include guardrails that preserve those public health benefits. We recommend establishing a defined timeline for the use of such flexibilities, along with interim milestones that demonstrate measurable progress towards full lot level traceability,

because without a clear endpoint, temporary flexibilities may become long-term operating practices, which could potentially hinder the speed and precision that the rule was initially designed to achieve.

To support that progression, FDA can encourage standards-based approaches that reduce implementation burden while still improving interoperability. The Food Traceability Rule was structured in a way that is already compatible with established data standards like GS1 EPCIS — an open global standard that is specifically designed to capture and exchange traceability information across supply chains. The rule defines what information should be captured through CTEs and KDEs, while standards such as EPCIS provide a common framework for how that information can be organized and exchanged between trading partners. Notably, this includes support for a consistent way to identify traceability lots.

Industry stakeholders have long recognized the value and the need for a standardized TLC format that can be easily recognized and exchanged across supply chain partners, and implementing that shared format for a TLC is a very critical step in achieving lot level traceability in a way that's scalable.

IFT works to support this progress via the Global Food Traceability Center. GFTC has developed and continues to refine open-source tools and implementation resources that help both industry and regulators exchange standardized data more efficiently. And we know that many organizations are concerned about the costs and complexity of replacing systems or modifying existing ones. So our resources are designed to help organizations build on the systems they already have, without requiring major infrastructure changes.

In closing, we support FDA's efforts to identify practical solutions that acknowledge implementation challenges while maintaining a clear path towards accurate lot level traceability throughout the entire food supply chain. Thank you for your time and consideration.

MODERATOR (Kyrese Johnson):

Thank you, and we appreciate your comments. Next, I would like to call up Claudio Pinto to speak for four minutes.

Claudio Pinto, Principal, Key Channels:

Good morning — good afternoon. This is Claudio Pinto. I'm the Principal of Key Channels. We're a boutique processing software consultancy out of Walnut Creek,

California, and have been providing guidance and training specifically to seafood exporters in Chile.

Just some editorial and observational comments in regard to this. The supply chain revenue rails are clear for exporters, distributors, and retailers alike. What is not clear is the definition of the liability rails to establish financial or operational penalties beyond the U.S. border.

Much like Katherine Cahill mentioned earlier regarding the legal requirements, I say that there will be requirements as well. FSMA information requirements are sufficient on a recall basis, but they assume that the information stems from a regulated source of truth, such as an auditable ERP or audited legal statements. If it is just a spreadsheet put together manually upon request in response to a regulatory requirement to address data and information for lots as well as other transactions, the supporting information architecture should be persistent, immutable, and secure across the supply chain. We believe that the reporting requirements in terms of data limits suffice for now, but what is needed are further requirements making information secure and persistent in the process and data architecture of the providers, manufacturers, etc., and furthermore, that they be secured by trusted processes such as blockchain to expand trust and visibility of source and process of foods being imported and consumed in the United States.

The very absence of dynamic QR codes and supplier production catalogs clearly indicates a lack of investment in supply chain IT technologies. The architecture is available today to implement FSMA requirements. These tool sets — beyond Excel — must be made part of the regulation guidance: product information management, CXML, RTGS, GS1 systems attached to QR barcoding systems in an ERP are not rocket science and are available via open marketplaces to all stakeholders.

The existing rules and proposed changes should include the proposed data architecture and process improvements to expand visibility and the eventual trust that must be extended to the U.S. consumer. I would suggest the following be considered, in no particular order. First, engage vigorously with national regulators and/or national cooperatives to establish integrated, mirrored U.S. rules to local regulatory guidance and technical compliance. Establish them as regulatory nodes. Second, that a public-private program be implemented in which private consultancies and platform providers are authorized by the FDA to implement FSMA in collaboration with national regulatory agencies. I would point to companies in the tier-one space like Accenture, Deloitte, PwC, and others. Third, the most useful and best outcome is to consider the feasibility of creating a single platform for all stakeholders, moving from an in-house data architecture to a blockchain-secured data entry system in which data providers are legally responsible for the data, and data is available as needed to regulators with

persistent endpoints to each registered company. I would also suggest that the FDA work closely with the U.S. Department of Commerce, USDA, and the U.S. Treasury to create links between the transacting companies and their transactions. These sorts of data and information can be very useful for revenue and fraud surveillance. I think in order to fund these things, you need to tax imports and provide that for the infrastructure, and reduce tariff burdens for compliant national regulators. I work with companies like Ledger, Origin Plus, and MacRobert in order to achieve these ends. Thank you very much for your time.

MODERATOR (Kyrese Johnson):

Your comment is appreciated. Thank you. I believe Jessica Marino — are you on the line?

[Pause — technical difficulty with unmuting.]

Jessica, will you press star then six to unmute yourself for us?

Jessica Marino, Four Seasons Produce:

Hi. Can you hear me? Yes, now we can. There we go. Oh, thank you so much. My name is Jessica Marino. I am with Four Seasons Produce. We are a cold storage distributor and wholesaler of fresh fruits and vegetables. A significant portion of our inventory is on the FDA's Food Traceability List, and we are fully committed to the public health goals of Rule 204. And we are here today because the current lot level tracking requirements create real compliance challenges for operations such as ours — challenges that we believe can be resolved through practical, targeted regulatory flexibility.

As a cold storage distributor, mixed pallets are not an exception — they are the reality. Produce from multiple growers and multiple lots arrives, is stored, and ships together. Strict one-for-one lot compliance, as currently structured, would require a warehouse the length of a city block and an unlimited labor budget that no distributor in this industry possesses. We would also like to note that Section 204 prohibits mandating case level tracking, so we are left wondering how this level of compliance is meant to be achieved in a real-world cold storage environment.

Beyond the operational burden, forcing a single lot code match on co-mingled product actually misrepresents how product moves, potentially producing false precision that could slow an outbreak investigation rather than aid it. Compounding this, large retailers are now requiring that their suppliers upload traceability data into proprietary online

portals that cost thousands of dollars annually to enroll — an unfunded mandate passed down the supply chain onto small and mid-sized distributors who have no choice but to comply or lose the business. Make no mistake: these costs do not disappear. They are passed directly to the consumer at the grocery store. At a time when food affordability is already a concern for American families, FDA should be mindful that regulatory implementation costs have real-world consequences at the checkout line.

We are encouraged that FDA is actively evaluating practical solutions that reflect how our industry actually operates, and we strongly encourage FDA to formally adopt the stances it is currently evaluating. Specifically, we voice our strong support for two of them. First, we support allowing distributors handling mixed swap pallets to provide a reasonable range of potential traceability lot codes when individual case level scanning is not practical. A defensible range, documented and bounded by clear operational parameters, is more honest and more useful to an investigation than a single forced lot code on co-mingled product. Second, we fully support the agency's exploration of allowing warehouse management systems to use operational and historical data to infer TLCs as a step towards compliance. WMS already captures date, pick, slot, supplier, and shelf life data. This is the infrastructure needed to support inferred lot codes and exists today, and simply needs regulatory recognition to be put to work. Together, these two flexibilities would dramatically reduce the cost and complexity across the supply chain, and ultimately help keep food prices in check for consumers. This rule is designed to protect the public. We ask for clear, written guidance formalizing these approaches, and we're ready to work with FDA to define the parameters that make them operationally sound and fully accountable. And thank you. That's all I have.

ORAL COMMENTS — SEGMENT TWO

MODERATOR (Kyrese Johnson):

For this next segment, we will hear oral comments from 18 speakers. As a reminder, each speaker will be recognized for four minutes. Our first virtual speaker on the agenda is Tom Ragsdale.

Tom Ragsdale, Software Developer:

All right. Can you hear me? Yes, we can. Perfect. Well, as she said, my name is Tom Ragsdale, and I'm a software developer. When I first heard about this regulation, I started thinking about an app that I could write, and I'm just about finished with it. I'm writing an app that allows companies to easily conform to this rule. It's almost complete.

It'll be available on tablets, phones, computers, and servers, and the cost will be about $100.

Originally, I planned two versions of this app — one for wholesalers and the other for retail establishments. But since learning about a lot of issues that wholesalers are having to get resolved, I'm just working with the retailer version at this point.

Let me describe the sections of the app. There's a main menu with four sections: a section to add products, multiple ingredient products, and suppliers with contact information, as well as company contact information; a section to be able to edit this information; a section to add tracking data and key data elements required by the FDA; and one thing that I've heard talked about a little bit is that if that data were in a standardized format, I could have it entered just by clicking on a button and having that data come in without having to worry about what format it was in. Right now, I don't think there's a standard format. If it were standardized, it could be automated better.

Anyway, I've also included ad hoc transfers and emergency procurements in the app. That was discussed late last month and includes product quantity and unit measure, the supplier's address, and their contact information. There's a report section that allows you to see and print out all of the above, and also in the report section is the FTL view and plan.

The main feature that facilitates the ease of use is that the amount of typing required is set to an absolute minimum. And I have a video showing all of the capabilities and the ease of use of the app available, and if anyone would like it, they can contact me. My phone number is 702-704-9497, and my email is codacoders@yahoo.com. Again, my name is Tom Ragsdale. I thank you for the opportunity to tell you about this app.

MODERATOR (Kyrese Johnson):

Thank you so much for your comment. Up next, we have Manuel Arredondo.

Manuel Arredondo, Professional Chef:

Hi there. Well, thank you so much for giving me the opportunity to make some questions. Actually, I do have two questions. So I'm going to start with question one. My name is Manuel Arredondo. I'm a professional chef and I work with different groups and clients. One of the clients that I have is involved in exporting products from here, from the U.S., to Mexico.

My first question is: I know here on the U.S. side, Rule 204 applies to handling regardless of destination. But on the Mexican side, the entities that we have — like

COFEPRIS — require sanitary permits with lot-specific certificates and analysis, and SENASICA requires sanitary documentation and NOM-051, which requires Spanish language labeling with nutritional and warning information. My question is: is the FDA aware of, or is any work being done through the FDA's second-tier agreements and the food safety partnership to align our Rule 204 records — TLCs, KDEs — with what Mexico requires for import, particularly those lot-level certificates or the analysis? Is there a movement toward mutual recognition so that we are not maintaining two separate record keeping systems?

And the second question: I work with a lot of customers in the sports and entertainment industry — stadiums, arenas, convention centers — and they all operate with commissary kitchen models. A central kitchen receives bulk food ingredients — greens, tomatoes, melons, cheeses, everything — and transforms them into prepared items, mixed salads, sandwich components, then distributes them to satellite concession stands throughout the venue. The transformation triggers a new TLC linked back to the input TLCs from each ingredient.

My questions are: first, how does the new TLC need to be assigned in a high-volume commissary — per batch, per shift, or per product? Second, when the transformed item moves from the commissary to satellite concession stands at a different location but the same company and same building, does that count as a shipping and receiving CTE under the section, or is there a simplified treatment for intra-company transfers between one facility? Third, if a salad mix combines lettuces from three suppliers, do we need to track and retain all three input TLCs individually, or is there a practical threshold for the inputs in a high-mix environment? Finally, these venues run on event schedules that are not continuous operations — they are sometimes active only a few days a week or month with seasonal staff. How does that affect the record retention timing or the designated point of contact requirement? So, on the assignment and transformation, what else should venues like this be thinking about? Please let me know, and thank you so much for having me.

MODERATOR (Kyrese Johnson):

We appreciate your comments. Up next, Margaret Harden to speak for four minutes.

Margaret Harden, Director of Government Relations, National Association of Convenience Stores (NACS):

Hi there. My name is Margaret, and I'm the Director of Government Relations at the National Association of Convenience Stores, or NACS. We represent an industry of

more than 150,000 convenience stores nationwide, and we're an industry of small businesses. Roughly 60% of convenience stores are owned by single store operators. These are true mom-and-pop businesses running on margins of about 2 to 3%, and our industry handles about 160 million transactions every single day.

I want to start by saying that our industry cares deeply about our customers. Our members are part of their communities. And for many rural and underserved communities, the local convenience store is often the most accessible source of food. These are community stores, and our customers are our friends, our neighbors. When there's a safety issue, our members want that product off of their shelves fast.

Our concern is that the Traceability Rule, as designed, doesn't reflect how food actually moves through the convenience supply chain. The clearest example of this is in the "each" problem, which is when a master case of a product is broken down into smaller units, referred to as "eaches." The majority of convenience stores are small-format and don't have the shelf space or the sales volume to buy full cases. So our distributors break down master cases and ship us the inner packs and individual units to our stores instead. Eaches are in about 60% to 90% of the shipments that our stores receive.

However, the problem we face is that the traceability data lives on the master case label. Once the distributor breaks that case down, the case and its label are discarded, and the key data elements are gone. No software platform fixes that. For retailers and distributors to recapture that data at the each level would require exactly what Congress said that this rule shouldn't do — requiring businesses to fundamentally change the way that they do business in order to comply.

That's why we support the solution put forth by the Convenience Distribution Association, which would require the traceability lot code, the lot code source, and expiration date to be imprinted on the eaches — so on case labels, inner packs, and individual packages. And then, perhaps most importantly, manufacturers have imprinted lot codes and expiration dates on food packaging since the 1950s. It works well with the recall procedures our industry has used for decades, because when a recall notice comes in, employees physically check inventory against the human-readable lot code and date, and they pull that product. FDA itself even left the door open to this concept in its response to comments on the original rule. So imprinting these three key data elements directly on food product packaging is a proven approach.

The risk of the current rule is that small businesses at the end of the distribution chain may be stuck with an impossible task of capturing and maintaining data that doesn't exist, that doesn't serve anyone, and the entities originally creating this data — manufacturers of these packaged goods — have to be required to do what is necessary to avoid that outcome. So between now and the July 2028 compliance date, we ask that the FDA work with us on this practical path. It will deliver faster, more accurate

traceability without burying the convenience industry and other small retailers and distributors in requirements that they cannot operationally meet. We appreciate the opportunity to provide feedback today and look forward to the rest of the town hall. Thank you.

MODERATOR (Kyrese Johnson):

Thank you. We appreciate your comments. Up next, I would like to call Stephanie Johnson to speak for four minutes.

Stephanie Johnson, National Grocers Association (NGA):

Thank you for the opportunity to comment on behalf of the National Grocers Association. NGA is committed to food safety and improving our coordination during foodborne illness outbreaks. We appreciate the FDA's continued engagement through the draft guidance and recent FAQs. Independent grocers continue to face significant implementation challenges, including lot code management, technology interoperability, record keeping costs, supplier communication, and regulation understanding. Additional clarification and practical flexibility are needed to ensure the rule reflects real-world retail operations and does not impose undue burdens.

On discussion questions related to eaches, NGA urges FDA to provide flexibility where cases are broken before shipment or receiving. This is especially important for smaller retail formats that have limited storage and rely on smaller or more frequent orders. Once the case is broken, the traceability lot code cannot appear on the individual item, making full lot code tracking difficult and impractical. You just heard this from Margaret as well. Flexibility on lot code management will be critical to ensure that small-format stores can comply.

On intercompany shipments, small grocers frequently transfer products between locations for inventory balancing, temporary shortages, or operational efficiency. These routine transfers should not automatically be treated like third-party commercial distribution shipments requiring full shipping and receiving CTEs. FDA should allow streamlined or modified record keeping when product remains within closely connected operational and traceability systems. For example, FDA should clarify that shared facility operators may rely on common inventory and receiving or transfer records where they support traceability.

On shipping for retail transformation, FDA should provide flexibility for retailers that prepare or transform food in retail kitchens and send limited quantities to nearby affiliated locations, often due to space constraints. Independent grocers may prepare

sushi, sandwiches, salads, or other ready-to-eat foods primarily for sale in one store while sending some product to another location. Maintaining full transformation CTEs for every retail kitchen item shared within an organization can be impractical. FDA should consider a streamlined approach where ordinary course records support traceability compliance.

Finally, NGA thanks the FDA for its extension to 2028. However, given ongoing operational, technological, and supplier coordination challenges, NGA continues to request an additional extension until 2032 for the independent grocery industry. Thank you so much for your time today, and we look forward to continuing to work with you on this rule.

MODERATOR (Kyrese Johnson):

Thank you for that comment. Next, I would like to call Andrew Kennedy to speak for four minutes.

Andrew Kennedy, At Foods and New ERA Partners:

Thank you for inviting me to speak today. I've been working in the traceability space for about 20 years, including a three-year stint with the FDA to help write the rule, and I really appreciate how this rule creates a language of traceability. Prior to joining FDA, when I tried to implement traceability systems, it was a challenge because every different supply chain wanted to kind of do their own thing. I think what the rule really does is craft that language that everyone could talk about. And you've heard today people using the language of the rule pretty easily. So we've gone from Katie having to explain the rule to now people actually using the terms very fluently.

So that being said, we wholly support at At Foods and New ERA Partners, which is dedicated to Rule 204 traceability technology solutions and consulting. Based on our experience going out to over 100 facilities over the last three years, we've seen real challenges — as you pointed out in the discussion paper — that mixed lots, co-mingling, and slots create a real challenge for distribution centers. So what you've brought up is allowing distributors to use inference. We wholly support that. At Foods developed a solution called Lot Code Assist, which is based on an inference method.

So we struggle with some of the questions that you raised in the discussion paper, and I want to use that as a framework for how we tackled some of these challenges. You asked about how do you share data with subsequent recipients if you infer multiple lot codes and you're not quite sure which lot code is the one you actually shipped. So you have to provide a list of lot codes that could have been shipped. What we do is provide

three different options. One is just a list of the lot codes without any weighting or values — just saying, for this shipment, these lot codes could have been shipped. A second is a weighted list, where you can say, for example, this lot code has an 85% likelihood of composing this shipment. So that way it gives you a sense of the most likely lot code to investigate. And third, for recipients that can't handle a list or a weighted list, if the flexibility is allowed for a new traceability lot code assigned by the distribution center, then we would pass the new traceability lot code and take all that inference data and store it as a transformation record internally. So the subsequent recipient would just get one lot code, and all that detail would be provided to FDA in the form of a transformation record.

But honestly, in most situations, this data is intended to be from a distributor to the final mile, but it's usually stored by that distributor on behalf of the final mile, because you're talking about mostly self-distributing retailers and large food service operations that store data for restaurants. So in most cases, that data will just be kept internally anyway and provided upon request to that final mile location.

Also, to avoid oversharing — one of the questions is: if you have too many lot codes, you can set, based on the weighting and the percentage likelihood, a threshold — a reasonable 1% or 5%, somewhere in that range — so that you don't end up sharing 50 different lot codes.

And then finally, the question about being a stepping stone: we see that the Lot Code Assist approach offers a stepping stone, because you can use the data to help improve the model over time and make the model better as a standalone option. Or secondly, the Lot Code Assist data that's provided can be used to improve other methods like RFID, barcode scanning, and voice picking, because it shrinks the universe of possibilities that those technologies need to choose from. But I know I'm a little bit over time. I just want to say thank you again for all the FAQs, the communications, and these public meetings.

MODERATOR (Kyrese Johnson):

Thank you for your comment. Next, we will have Celia Gonzalez to speak for four minutes.

Celia Gonzalez, Other Avenues Grocery Cooperative:

Hello. My name is Celia. I'm representing Other Avenues Grocery Cooperative, a small independent grocery store in San Francisco. So yeah, we've been trying to understand what this rule would mean for us and what compliance would look like in reality. And it's

been a little challenging. It's been a concern in a lot of the food circles and small grocer circles that I'm in.

And I think mostly I just have questions about the standardization — thinking about how we receive information from, you know, we work with big distributors, medium distributors, and have direct relationships with producers and farms. And understanding what that reality looks like. We're getting a variety of different information. Some of it is in paper — bills of lading or different printed communications — and also electronic information, online emails, and so forth. And trying to understand what the expectation is for standardizing all of that information, and how to file and have this information organized in a way that, if it were requested, we would be able to comply within 24 hours, as expected.

So yeah, just asking for more clarity and guidance around how to organize and what the expectations are for maintaining these important, traceable data points from a variety of different sources — small producers to larger distributors — and how do we integrate all that in a system that doesn't add so much more labor? Because we work on small margins and we're not a data entry business. So just thinking about the smaller grocers and producers on that end and what it would look like to integrate. And I appreciate some of the comments made by Stephanie Johnson and resonate with a lot of what was requested in giving a little bit more time to better understand what implementation would look like for small grocers. Thank you so much.

MODERATOR (Kyrese Johnson):

Thank you for that comment. I would like to call up next Sherry Jenkins.

Sherry Jenkins, Vice President, Paden Cold:

Can you hear me? Yes, we can. Awesome. Hello, everyone. I am the Vice President of Paden Cold, and we are a third-party logistics, multi-temp warehouse in Norfolk, Virginia. So we don't own any of our products — we handle them for our customers.

A lot of our products fall into the wholesale seafood sector. And seafood has been largely under-regulated compared to other industries until recent years. The seafoods that we handle vary widely from method of catch to processing facilities and procedures. So we see very different packing and labeling across the sector. Many of the products on the list that we handle come from Asian countries, and these products tend to have more uniformity in packaging and labeling overall, which is a plus.

However, the challenges I foresee with the ruling relate to the amount of intensive labor that will be required to separate these products by lot codes. For example, the fresh products we handle could have as many as 30 lot codes per item, and then multiply that by the number of items on the container, since these products are harvested and processed over many days. So all those days have different lot codes, and they all come from several different processing plants.

With the ruling, all these codes would need to be segregated by hand, and they are usually not separated by lot code and tend to lack organization on the ocean shipping containers. An import container that would typically take about four hours to unload by hand could end up taking 16 hours to unload — about four times as long — with the container free time being only two days. I foresee that the stress caused by time constraints could lead to mismatches and sorting by lot code. In addition, this puts excess risk to the product quality and safety while products are held on the unloading docks. It puts significant risks to supply chain mobility, lot trace accuracy, and product safety. The warehouse loses capacity, container availability decreases, distribution is delayed, costs increase throughout the industry, and efficiency is greatly reduced.

To make lot level traceability practical at scale, the solution must begin upstream with packers and processors overseas, including improved container loading, product and lot organization within the containers, and labeling practices that align with receiving operations and import shipping line requirements in the U.S. Thank you for the opportunity to speak, and we look forward to helping continue with the strong efforts to maintain a safe food supply chain in the U.S. and abroad.

MODERATOR (Kyrese Johnson):

Thank you for your comment. Next, I would like to call up Siobhan to speak for four minutes.

Siobhan [surname not provided], CEO, Produce X:

Yes, I'm audible. Good afternoon, everyone. My name is Siobhan, and I'm the CEO of Produce X. We build agentic AI solutions tailored for the fresh food industry, operating heavily on the front lines of the critical Texas-Mexico supply chain corridor.

I want to start by acknowledging the FDA's tabletop exercise report released last week. These exercises were essentially simulated fire drills for recalls, testing if a supply chain could produce an electronic tracking spreadsheet for a specific lot within 24 hours. The FDA's findings confirm what we see every day on the warehouse floor. Passing that fire

drill does not come down to heavy, isolated tech mandates. It comes down to proactive supply chain coordination.

Right now, the industry is trying to solve this by forcing top-down compliance networks onto the market. But lot level traceability is not a macro data problem. It's a localized facility operations problem. If we want pristine key data elements, we cannot rely on complex software that forklift drivers and warehouse workers find tedious. Compliance is won or lost on the facility floor. If receiving, processing, and HACCP monitoring are treated as separate, cumbersome chores required only for compliance, the traceability chain breaks before the fire drill even begins.

Our focus is entirely on facility operations, tasks, and standard operating procedures. As Jessica Marino mentioned previously, traceability shouldn't be an extra step. It must be a seamless, native byproduct of automated quality reports and daily management. When we equip workers with the tools that genuinely make their jobs easier, the required traceability data is generated organically. But building that right tool is only half the battle. The other half is adoption across a highly fragmented supply chain.

We know many small upstream growers and suppliers simply cannot afford expensive traceability software. That financial friction halts coordination in its tracks. To solve this, we champion a hub-and-spoke model. Mid-market distribution hubs and cold storage facilities adopt operational platforms to drive their own ROI and reduce defect rates because they get immediate value. They champion the system. Then we onboard their entire network of upstream suppliers and growers at absolutely no cost to these growers. By aligning the technology investment with the operational needs of the central hub, we empower them to bring their upstream network online. This completely eliminates the financial friction at the farm level and creates true vertical visibility.

As FDA evaluates flexibilities for the Food Traceability Rule, we believe a powerful avenue forward is through public-private partnerships. We encourage FDA to collaborate with frontline innovators to study these hub-and-spoke models in real-world environments. By exchanging ideas on what actually drives operational adoption on the warehouse floor, we can shape practical flexibilities together. When we foster true vertical visibility, lot level traceability ceases to be a mandate. It simply becomes the way business is done. Thank you for your time and thank you for having me here.

MODERATOR (Kyrese Johnson):

Thank you so much for that comment. Is Ramis Actor on the line? If so, can you raise your hand?

[Pause — no response from Ramis Actor.]

We'll move to the next slide, please. I would like to call up Derek to speak for four minutes.

Derek Hannum, Repository:

Thank you, and thanks to the FDA for the format and the public hearing and the opportunity to speak. I'm Derek Hannum with Repository. Repository is a supply chain data management company that has tracked food product shipments for more than two decades. In the last two years alone, we've created over 8.2 million traceability records for Rule 204 compliance using existing supply chain data alone — no case label scanning. But we acknowledge that challenges exist. I want to speak today to what is technically possible and operating today at scale to address the challenges.

But first, I'd like to share our perspective that traceability is becoming an industry-driven initiative. More than 80 retailers and wholesalers have publicly announced details on their traceability programs. Many are going beyond Rule 204, requiring more data than the rule requires and mandating traceability of all food items, not just the Food Traceability List. Suppliers with no items on the FTL are already complying with their customers' traceability requirements and sharing TLC data. This is non-enforced traceability, and it's happening today. Many retailers have set deadlines well ahead of the July 2028 enforcement date of Rule 204. But be clear about cause and effect: none of this momentum would exist without FSMA Rule 204. The rule created the impetus, and the momentum will continue to build if the FDA stays the course.

Technology is in fact solving the two most challenging problems of traceability. Problem number one: data accuracy. Error rates in supplier-provided records run as high as 40%, and traditional data sharing protocols like EDI don't detect those errors. Today, AI-driven error detection and auto-correction technology is working successfully at scale, catching and fixing those errors with no new work required of suppliers, wholesalers, or retailers. The second problem, and perhaps the most well-documented, is the challenge of DC outbound shipment lot code tracking. Outbound TLC tracking at the distribution center has been called the hardest mile to traceability, and for good reason — but it's not impossible today. DC outbound traceability KDE records are being created with no case scanning, using a deterministic, data-only approach with accuracy that rivals case scanning.

The word "deterministic" matters here. A deterministic record states which TLCs actually shipped to which store. Probabilistic models or inference models guess at what was shipped. In an investigation or a recall, a guess means either contaminated product stays on shelves or safe product gets destroyed. Technology exists to solve the big

traceability challenges, and it will keep advancing so long as the Rule 204 requirements are not diluted.

The FDA has heard that lot level tracking is too burdensome, especially for small suppliers. The argument is built on 2022 assumptions. Modern approaches extract traceability from data the supply chain already produces, with no new hardware and no new labeling lines. The burden case for weakening the rule gets weaker every year. The rule should not be watered down around technology constraints that no longer exist.

We have three requests of the FDA. First, no further delays — hold the July 2028 enforcement date. The industry has been given many years to establish traceability. Another extension rewards those waiting for a reason not to start, and penalizes the companies that have invested in good faith. Second, affirm to the industry that the rule is in effect now. The FDA should state plainly that it expects the industry to be building toward compliance today and not waiting to start in 2028. And finally, preserve deterministic lot level requirements. Don't compromise the rule to accommodate assumptive or probabilistic models that are inherently error-prone. Watering down the data standard would undermine the entire point of the rule, and it's unnecessary because the technology to do it already exists. Thank you.

MODERATOR (Kyrese Johnson):

Thank you for your comment. Next, I would like to call Tamara to speak for four minutes.

Tamara Henson, Russ Davis Wholesale:

Hi. Good afternoon, everybody. I am Tamara Henson. I am with Russ Davis Wholesale. As Stephanie, Jessica, and Margaret already stated, mine's going to kind of coincide with their statements.

Russ Davis Wholesale has been in produce since 1955. We are specialized in distributing both whole and processed fresh fruits and vegetables, as well as commissary items. Currently, we have over 300 SKUs and work with over 400 suppliers. We have two manufacturing facilities and five distribution centers. We are proud to partner with all of our retail and food service customers, and to create and deliver the best fresh food we can. We hold ourselves to a very high standard in food safety.

Some of our concerns and comments here: first of all, I would like to thank the FDA for taking steps to help prepare us for Rule 204. However, we would like to see more guidance regarding the unit or each-level traceability. Also, we would like to know how and if the government is going to aid small producers with being in compliance. And

then, as a company, we face the challenges — as everybody has stated — of the cost of being in compliance. We know we're going to have to update some of our systems. So those are the concerns we have around Rule 204. I would just like to thank you for the opportunity to make some of our comments.

MODERATOR (Kyrese Johnson):

Thank you for your comment. I would like to call next Jacob Moe.

Giacomo [Jacob Moe], Restaurant Operator and Founder, Safe Logs:

Hello. Can you hear me? Yes, we can. Good afternoon. I appreciate the chance to speak. My name is Giacomo. I operate a handful of restaurants and catering and event center facilities here in Minnesota, and I'm also the founder of a company called Safe Logs, which is a compliance platform that we're building for food service operators, which obviously, based on this, includes traceability. So I'm kind of looking at this from both sides.

Thinking as the operator who has to keep these records, I want to speak to kind of the last mile where this all ends. And I think the operator reality is kind of underrepresented. The restaurant is the smallest business, with the least technology infrastructure. And we're being asked to maintain the final step of the traceability piece. And if we're being honest, a lot of the existing things get skipped or not done. So the vision I think for this is it has to be incredibly simple, and it has to not require any work on the part of the staff member at that point.

I think, obviously, some of the grocers and other people have talked a lot about eaches and the challenges with that. Obviously in the restaurant industry as well, we see a ton of that. So handling all of those pieces is going to be very crucial.

But I think the biggest concern that I have is just: remember that any flexibility that's granted upstream transfers ambiguity down the line. Obviously, if a distribution center were to ship a reasonable range, then the restaurant has that record. But nobody really — we're just inheriting uncertainty. So whatever is granted and decided upon for the middle of the chain, just please keep in mind: what is the retail node expected to have? And is that good enough for actual traceback execution?

And that kind of ties into the last question that I have, which is: how exactly would this be enforced at that level — at my level? Obviously the 24-hour FDA request, but that usually comes during an outbreak traceback. Whereas our inspections come from state

level, county level. So are they going to be looking for any of that? It's kind of what I'm curious about, for both my restaurants and as we try and build Safe Logs.

And last, I think others have kind of touched on it too: just the data standardization. I think that's crucial in this actually being executed at the final restaurant level. And I think that's kind of all I have. I appreciate the time again. Giacomo, restaurant operator and founder of Safe Logs. I'll follow up in the written docket. Thank you for your time.

MODERATOR (Kyrese Johnson):

Thank you. We appreciate your comments. Next, I would like to recognize Luis Alfonso Garcia.

Luis Alfonso Garcia, Chief Commercial and Global Operations Officer, Salsa Vigil:

Yes, I'm here. Do you hear me? Yes, we can. Thank you. Hi, everyone. Good afternoon. I hope everything is going well today and that you're having a great week. My name is Alfonso Garcia. I'm Chief Commercial and Global Operations Officer at Salsa Vigil. We are a hot sauce brand with more than 75 years on the Mexican market, and we are currently expanding across the U.S. nationwide territory and some other country territories.

As everyone is mentioning, maintaining traceability for consumer product goods is a great challenge. However, specifically for us, it is a significant challenge since we are currently working with agricultural producers for ingredients like chili peppers and salt, which are part of our raw materials, which presents a greater challenge for us.

Nevertheless, in order to maintain good control and traceability with all the products, we are developing a great production batch system using our own in-plant factory laboratory, where we test every single batch of production. We are measuring the low acid control with the temperature and the water quality for every single batch. Consequently, since we are an importer of record for FDA purposes, we have a very detailed analysis for each and every single production run in order to comply also with the Mexican COFEPRIS regulations and the U.S. compliance records.

Additionally, we have put in place a production batch code for every single product. We have a barcode and the batch production lot printed on the bottle, on every single bottle, on the box, on the tray, and also on every single pallet, in order to ensure complete visibility for the distributors, wholesalers, retailers, and food service distributors. In fact, every single shipment running out of the factory is in our own lot control list, and also

every single bill of lading that we get from our U.S. warehouses to our customers is also detailed and registered one by one.

That said, we believe the ultimate challenge lies in the final link of the supply chain — to prevent the potential risk or the control of the inventories. So we need more control of the distributors, the retailers, and other food service operators that work appropriately with the warehousing, the batch logging, the first-in, first-out inventory management, and finally that the consumer — the final consumer — works appropriately and correctly at the point of consumption, whether at the restaurant or in the home.

We firmly believe that proper information management is the most important part of the foundation for the correct handling of product goods. However, another critical piece during the process is the product use and consumption, which remains outside of our control. Therefore, it falls upon all restaurants and all individuals using the products to handle them appropriately and in compliance with sanitary regulations. For this reason, we call on the state and federal authorities to raise awareness regarding the proper management of all human consumption products. Most importantly, we urge them to empower consumers to practice correct product handling, proper storage, and safe food preparation. This ultimate step is the final link to preventing potential risks to human health. Thanks, everyone.

MODERATOR (Kyrese Johnson):

Thank you for your comments. I would like to recognize next Drew Zebra.

Drew Zebra, Managing Partner, Totem Limited; Co-Lead, Supply Chain of the Future:

Great. Good afternoon. I'm a Managing Partner at Totem Limited. While I'm not here in an official capacity today, I also co-lead the Supply Chain of the Future — a pre-competitive, noncommercial industry collaboration. We have hundreds of participants across dozens of countries, and we work alongside folks like the International Fresh Produce Association and standards bodies such as GS1 International, ISO, and also UN/CEFACT. So I want to thank the FDA. It's also really nice to be in some good company — many colleagues and friends are speaking here today.

So I guess just before my remarks, I'd like to second a couple of things I heard from this circle of us, and also from Julie McGill of AIM: the industry capability really is here, and that shared data standards and technology neutrality will be absolutely essential to scaling this.

And I think the audience really knows what I'm about to say here, but it's important that Congress also hear that "a lot" is doing a lot of work in this rule. A lot can mean a harvest, a field, a shift, a production run, a repack. You can have two compliant firms defining lots completely differently. A lot code by itself is a local name and not an identifier. And so in the paper you had asked whether there is a data standard that industry should coalesce around. And our answer is yes — it already exists. GS1 identification such as GTIN for the product and GLN for the location or source, with the EPCIS event captures, handles the lineage through not just the supply chain, but also, importantly, transformation and aggregation. And as my colleagues mentioned, RFID, 2D, and IoT data carriers all make it possible to carry the full data set — and not just possible, but operationally sustainable. We're already using this. Moreover, standards such as the GS1 Digital Link extend this static data printed on labels to now linked, trusted data across the entire supply chain.

And on untrusted data, I need to address some guardrails — specifically for range-based or inferred lot codes. The guardrail I'd like to present here is verifiability, referencing the ASTM Committee E49, which has published a technology-neutral conformity assessment model. This has been developed in accordance with WTO guidance. And the same logic applies to traceability records. So when we think about flexibility, we believe that flexibility only holds when those claims can be independently checked. Flexibility without verification isn't flexibility — it's fragmentation. And fragmentation is a real risk.

Just last year, Totem, together with federal partners, the Fresh Produce Industry Association Collaboratory, ASTM, and GS1, facilitated a workshop at the World Trade Organization in Geneva, where the head of Technical Barriers to Trade plainly made the point that international standards on traceability exist, and they exist to keep markets from fragmenting. Food supply chains are global. And so if American flexibility drifts from the identification schema that the rest of the world is converging on, we don't reduce the compliance burden — we double it or more.

And so maybe to leave us on more of a positive note: how do we actually scale this? How does change actually scale here? And I feel that it's not by publishing a new standard and hoping — it's really leveraging those existing standards that I've mentioned. They were built by the people who depend on them. Growers, packers, distributors, retailers, and regulators were all in the room developing these standards before they were finalized. And it's that pre-standardization work that is a cornerstone of those standards — specifically GS1, ASTM, ISO, and UN/CEFACT. My co-lead Martha King at Supply Chain of the Future puts it best: you build the standard with people who depend on it, and it makes it workable for everybody. And so I really would encourage us to go back to those standards, because we would argue that it matters because the bar here isn't "practical" — it's "practicable." Practical means that it can work on paper.

But practicable means that a packer can execute at 5 a.m. in the field, a receiving clerk can process it without a manual, and a small business can afford to meet it.

I think our time is about up. My last remark was just to simply say: we applaud FDA for shaping these flexibilities, and we ask you to honor and anchor them in these global identification and assessment standards. Thank you for your time. I apologize for going over.

MODERATOR (Kyrese Johnson):

Thank you very much. Next, we will hear from Katy Jones for four minutes.

Katy Jones, CEO, TrustWell:

Hi. Good afternoon, and thank you for the opportunity to speak. My name is Katy Jones, and I am the CEO of TrustWell. I have spent the last 11 years of my career helping to implement traceability with our customers through our software, Food Logic. To date, we have captured nearly 500 million critical tracking events across every single point in the supply chain. I really appreciate the FDA's continued engagement with industry as we work together towards successful implementation of the Food Traceability Rule.

I am going to use my time today to address two questions outlined in the FDA discussion paper — one related to inferred data and the other to data standards.

We appreciate the FDA's willingness to explore reasonable flexibilities. As we have implemented traceability over the years, we have learned that we can't shoot for perfection in the beginning, and we completely agree that some traceability is better than no traceability. However, any use of inferred or probabilistic lot codes should be restricted, as my colleague Drew mentioned, verified, and treated as a stepping stone towards whole-chain lot level traceability.

At its core, Rule 204 is about increasing speed and certainty. There has been traceability in the industry, and many have said that today. But I think we can all agree that we are not where we need to be. And as pointed out by Sarah Morris, Drew, and several other speakers earlier, relying too heavily on inferred data will not advance safety for consumers and will weaken the effectiveness of the rule. Probabilistic methods can be used to advance traceability forward, but should be kept to a threshold of low single-digit percentages, and documented lot level records should remain the gold standard against which all other approaches are measured.

As an example, if a retail grocer is only 80% confident that lettuce during an E. coli outbreak originated from a particular lot, that retailer is left with a difficult choice: either

recall more product that may not be affected, or risk leaving potentially contaminated product in commerce. Neither outcome advances the goal of Rule 204.

For my second point, the FDA should maintain flexibility in technology, but not flexibility in standards, and that data standard should be the GS1 standard. Companies should have flexibility in the systems, the software, and the processes that they use to comply with the rule. And trust me — as the CEO of a software company, I know that may sound unusual, but we believe that companies should have the flexibility to choose the software or the process that they go with. Innovation should be encouraged, but the FDA should remain and continue to remain technology-neutral. But from my perspective, a data standard is not a technology. A data standard is the underpinning of whole-chain traceability. It is the underpinning of data integrity and auditability, and is critical for success in traceability.

GS1 standards play a critical role in enabling interoperability and seamless information exchange across the food supply chain. And as we look towards the future, we see technologies such as AI and advanced analytics becoming increasingly valuable, but they will only be as effective as the quality and consistency of the underlying data. Thank you so much for the opportunity to speak today. I encourage the industry to continue working together, that we maintain the integrity of the Food Traceability Rule, keep the 2028 deadline in place, and continue to work together as an industry. Thank you.

MODERATOR (Kyrese Johnson):

Thank you. We appreciate your comment. Next, I would like to recognize Abdallah Rajab.

[Brief technical delay with audio.]

Abdallah Rajab, Head of IEEE Engineering, Ability Technology Company:

Can you hear me now? We can. Okay. Good afternoon. My name is Rajab, the Head of IEEE Engineering at Ability Technology Company, based in Jeddah, Saudi Arabia. At Ability Technology, we provide end-to-end solutions and tailored systems for fresh produce supply chains, covering everything from harvesting through the chain, transport, all the way to the point of receipt at restaurants and retailer locations. Our systems are currently deployed across agricultural operations and commercial facilities in the Kingdom of Saudi Arabia.

Today, I'm here to raise a challenge that we face daily in the field — one that I believe is shared by many operators trying to comply with lot level requirements. The Food Traceability Rule requires that key data elements, including the traceability lot codes, be maintained and passed forward at every critical tracking event in the supply chain. In principle, this is the right framework, but in practice there is a significant gap at the receiving end, especially at restaurants and food service locations.

This is a problem that we see each day. Fresh produce suppliers often do not provide lot numbers alongside their delivery receipts in a format that the receiving staff can easily capture and link digitally. When a restaurant receives ten to 15 or 20 deliveries at the same time in a single morning from multiple suppliers for fresh produce, the staff at the receiving dock are under pressure. They are making sure to check the quantities and the condition of the receiving goods and the quality, and asking them also to manually capture and link the lot codes from paper receipts from the suppliers to individual orders is creating a real operational bottleneck. The result is that the lot data either gets lost, entered incorrectly, or simply skipped, which breaks the traceability chain at exactly the point where it matters the most.

What we are calling for is greater standardization upstream — specifically requiring the suppliers of fresh produce to provide machine-readable lot codes, whether through barcodes, QR codes, or RFID tags, directly on the delivery documentation. This would allow IoT-enabled receiving systems — like the ones Ability Technology uses, and many other companies use — to capture and link the data automatically, without relying on manual data entry under time pressure by the workers. The technology exists, the infrastructure is ready, and what is needed is a clear expectation from the regulators that suppliers must deliver the traceability data in a format that receiving operators can actually use readily and easily, reducing reliance on manual IoT device entry.

So thank you for the opportunity to share this perspective. We are committed to making sure that food traceability is practical and scalable — not just in Saudi Arabia, but as a model for global food safety systems. Thank you for your time, and I appreciate the opportunity to share these considerations with the FDA. Thank you.

MODERATOR (Kyrese Johnson):

Thank you for your comment. Next, I would like to call Jonathan Sagar to speak for four minutes.

Jonathan Sagar, Senior Director for Federal Government Affairs, Western Growers:

Good afternoon. My name is Jonathan Sagar. I'm the Senior Director for Federal Government Affairs at Western Growers, a trade association of growers, packers, and shippers making up about half of the domestic production of fresh fruits, vegetables, and nuts. On behalf of Western Growers members, I'd like to share a few observations on Rule 204 implementation and potential flexibilities for domestic fresh produce upstream entities.

Important questions were raised in FDA's discussion paper, and we believe additional flexibilities may need to be recognized for upstream entities, which are often responsible for generating and maintaining traceability information. We encourage the agency to ensure that any flexibility is limited and reduces burden, while preserving accountability and data integrity across the supply chain, without disproportionately shifting traceability responsibilities to a single sector without corresponding investment by all entities in data quality, verification, and traceability systems. The FDA draft guidance should clearly identify and support practical approaches, including parameters for implementation of any flexibilities.

Growers, along with all others in the supply chain, have long been aware of the requirements of Rule 204, and as such, growers have invested heavily to prepare for the implementation date. Since the announced delay, growers have concerns with interoperability and reliability of traceability data received from suppliers. We see a need for more real-world testing leading up to the implementation date. Multiple buyer-specific platforms continue to create complexity and increase implementation costs.

Three areas of concern remain. One: the accuracy of lot level traceability data from growers who have not yet been involved in the Produce Traceability Initiative, and who rely on older systems. Two: the lack of standardization among data platforms. And three: the overall impact on food safety prevention, as more buyers are requiring data entry into data platforms that are not part of the current food safety and sustainability platforms, creating additional unnecessary burdens on growers.

To support fresh produce growers and shippers in this effort, we recommend the following. First, leveraging existing traceability systems and industry standards such as those that are part of the Produce Traceability Initiative. Many companies have already invested in PTI-based traceability systems. Building upon these existing frameworks can reduce implementation burden and support more consistent adoption across the supply chain by promoting interoperability among platforms. Second, for spot purchases, we ask for flexibility in data collection, especially as they are primarily needed during unexpected events. Fresh produce companies making a spot purchase should have the option to assign a traceability lot code, just like the approach used for other supply chain entities. Third, supporting pilot programs and phased implementation approaches that allow companies to test and validate systems before compliance is

required. FDA should take an active role in such pilots and assess its internal systems and processes. Fourth, providing best practices or recommended methods for sharing, receiving, and verifying traceability information across supply chain partners.

In closing, traceability works best when all stakeholder entities take responsibility, collaborate, and make appropriate investments. Thank you for the opportunity to share these concerns and suggestions, and we very much look forward to continued engagement on this issue. Thank you.

MODERATOR (Kyrese Johnson):

Thank you. We appreciate your comment. I would like to recognize Caitlin.

[Brief technical delay with camera.]

Caitlin Monahan, Whole Chain:

Hi. Good afternoon. My name is Caitlin Monahan, and today I'm speaking on behalf of Whole Chain, a verified, capable GDS and EPCIS-compliant, interoperable traceability solution. Whole Chain is a member of NFI's Rule 204 Traceability Workgroup, supporting industry's efforts to comply with the rule.

First, I want to thank the Traceability Rule team for their responsiveness and willingness to engage with us as we help our customers implement lot-based traceability in compliance with the rule. We know implementing interoperable, lot-based traceability is key to the FDA's public health mission, and the Food Traceability Rule is a foundation to get us there. We appreciate the opportunity to write comments on these challenges, specifically at the beginning of the supply chain where TLCs are assigned, to ensure that critical data is accurately and efficiently shared to and maintained by downstream supply chain partners.

As it currently stands, upstream processors assign individual production codes to lots and then fulfill orders for shipment. The shipment is packed with the production lots on hand, sometimes upwards of 50 per shipment or 100-plus for a container. Per the rule, those individual production codes or traceability codes must be received, maintained, and shared further down the supply chain. It is operationally and technically prohibitive for receivers — including, but not limited to, U.S. importers and cold storage operators — to systematically receive and manage plant-level production codes at the individual production lot level.

Both Whole Chain and NFI have proposed and discussed a solution with the agency whereby the TLC source applies a single traceability lot code to a single shipment at the

time of packing the shipment. FDA and partners throughout the supply chain would benefit from FDA's public concurrence on this practice. At the source, production code data will be properly documented and linked to the TLC in the source's records. From the buyer's perspective, the buyer will more easily and consistently receive production code data that can be directly linked to the internal lot codes assigned by 3PLs at receipt. The 3PLs will save time and money by not having to slot individual production lots into their facility, and curb the practice of granting the shipment receipt. Instead, the receiver will receive a single TLC that can be linked to the 3PL's internal lot code. The single TLC will link to the actual TLC source of the lot, allowing FDA to skip over the 3PLs during an investigation.

Downstream receivers could also implement this concept — maintain and share a single TLC, and by default a TLC source, per pallet or shipment, to help streamline capturing and sharing TLCs in their operations without guessing or estimating which lot code went where. From FDA's perspective, the integrity of the TLC will be maintained through the distribution chain and through 3PLs, because a single TLC per shipment is easier to manage and pass through, and critically, because the TLC is associated with the source key data element. FDA will still be able to bypass the 3PLs and quickly get back to the location where the contamination event could have most likely occurred in response to a whole-chain inquiry.

FDA stated that when a manufacturing facility transforms a product and packs it as part of the event, the processing and packing constitute one transformation event. However, it's important to note that the manufacturing and packing event often are separate and would be captured in the firm's records separately. Overall, and not explicitly stated, because the FDA confirms they consider packing to be part of the transformation event, the TLC source company assigning and sharing a single TLC per shipment is in line with the final rule as written.

It's also important to note that if supply chain partners are using an EPCIS-verified traceability system, FDA will have immediate access to the production codes when requesting records at retail, since FDA's BTS similarly uses the interoperable EPCIS format. Public clarification from the agency would help the TLC source companies come into compliance, allow 3PLs to save time and money in slotting, allow buyers to more easily link the TLC in the shipment to subsequent internal lot codes, and most importantly, get FDA back to the TLC source quickly and efficiently during an outbreak investigation. Thank you again for the opportunity to provide comment, and we look forward to continued collaboration with the agency to fully implement the final rule.

CLOSING REMARKS

MODERATOR (Kyrese Johnson):

Thank you so much for your comments. Thank you again, everyone, for joining us for today's discussion. I would like to remind everyone that the docket for public comment on food traceability remains open until 11:59 p.m. ET on July 15th, 2026. The webcast of today's hearing was recorded, and a copy of that recording should be available on our website by the end of next week.

Thank you again to all of our speakers, Doctor Prater, Katherine, and attendees for your participation and thoughtful contributions today. We appreciate the time, expertise, and perspective shared during this meeting — all in service to our public health mission. This concludes today's session. Thanks again.

[End of Meeting]