

FOOD AND DRUG ADMINISTRATION (FDA)  
PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

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A P P E A R A N C E S

CHRIS WALDROP

Senior Public Health Educator, Division of Public  
Health Informatics and Analytics, CFSAN, FDA

TRACEY FORFA

Deputy Center Director, Center for Veterinary  
Medicine, FDA

KRISTIN McNAMARA

Program Manager, Office of the Associate Commissioner  
for Regulatory Affairs, ORA, FDA

CINDY KRUGER

PepsiCo

MATT BRAUNER

National Customs Brokers Association

ERIC MOORE

Testo

ALEX MENDES

PepsiCo

OSCAR GARRISON

United Egg Producers

BOB BAUER

Association of Food Industries

SHELLEY FEIST

Partnership for Food Safety Education

JULIE MCGILL

FoodLogiQ.

JOY DZIECH

Blommer Chocolate

MELODY GE

Corvium, Inc.

A P P E A R A N C E S

JEFF ACKER  
Dairy Farmers of America

CALVIN GUYER  
QualiTru Sampling Systems

ARNIM VON FRIEDEBURG  
CMA Global Partners

DAVID CROWNOVER  
Self-Employed Food Safety Consultant

RANDY QUERRY  
American Association for Laboratory Accreditation

KARIL KOCHENDERFER  
LINKAGES

KRISTIN SPOTZ  
GMA

KARIN HOELZER  
The Pew Charitable Trusts

EVA HURT  
Nestlé USA

CHERYL ENLOW  
Renaissance Food Group

LISA LUPO  
Quality Assurance and Food Safety Magazine

AGENDA

Simultaneous Breakout Sessions Block #2  
Eisenhower Room: Food Safety Culture

Facilitators:

CHRIS WALDROP

Senior Public Health Educator, Division of Public  
Health Informatics and Analytics, CFSAN, FDA

TRACEY FORFA

Deputy Center Director, Center for Veterinary  
Medicine, FDA

KRISTIN McNAMARA

Program Manager, Office of the Associate Commissioner  
for Regulatory Affairs, ORA, FDA

P R O C E E D I N G S  
SIMULTANEOUS BREAKOUT SESSIONS BLOCK #2  
FOOD SAFETY CULTURE

MR. WALDROP: Okay everyone. Thank you very much for joining us. This is the Food Safety Culture section.

You've arrived at the right place. Thank you for making the long trip down the hallway and you found us.

UNIDENTIFIED SPEAKER: Secret location.

MR. WALDROP: Yeah, yeah, shows that you're dedicated and you really care about this so that's great. So again, my name is Chris Waldrop. I'm a senior health public educator with the Center for Food Safety and Applied Nutrition. And joining me, we have Tracey.

MS. FORFA: Tracey Forfa, Deputy Director of CVM, Center for Veterinary Medicine.

MS. MCNAMARA: Kristin McNamara, Program Manager, Office of the Associate Commissioner for Regulatory Affairs.

MR. WALDROP: And we have also Johanna Dubay. She is a strategic planning analyst with the Office of Food and Veterinary Medicine. She'll be taking notes so that we can make sure we capture everything that was said here today.

So again, thank you all very much for joining us in the Food Safety Culture section.

We've put this together, as you guys know from the first section, is that we want your input. We want to hear what you have to say and your feedback and input.

As part of the food for thought document that's in all packets, the back of that is the food safety culture piece. That was some work that was done internally, some just brainstorming, just to kind of get some ideas flowing and give you all something to react to or some way to kind of, at least, get some ideas out on the table. But not of those are policy or endorsed by FDA, but is really just a way to kind of get the conversation going.

So we really are looking for your input to --

on how and what challenges that we see and we all face in food safety culture, how FDA can be a part of that and can support the work that the stakeholders are on doing on food safety culture and so we're looking forward to your input.

So we don't have time to go around and get everybody's name and where you're from, but just as a show of hands, who all is here from the food producer manufacturer side? Okay, great.

What about other parts of the supply chain? Retail? Or distribution? Or -- okay. Excellent.

Consumer representatives or individual consumers? Great.

Researchers? Academia?

What about other government agencies?

Media? Anyone from the media here? Okay.

And what about other -- anyone from any other stakeholder group I didn't call yet? Okay. Great.

Well, you will have a chance -- if you have comments, you'll have to chance to state your name and where you're from so we'll get to know. Please do that as the mic gets passed around.

Also, please keep your comments brief. We have a shorter period of time this afternoon than we did this morning, so we're going to have to kind of move pretty quick through these questions.

Be respectful of others and apologies if we have to kind of cut short the conversation to move on.

Please keep in mind that this an opportunity for all of us to kind of talk together, but there's still an open public docket connected to this meeting. So please do submit your comments, your thoughts, your ideas to that docket because we'll take what we hear today as well as what's in that docket and bring it back in the agency for our consideration for moving forward and eventually take all those ideas and put them into that blueprint that was discussed earlier.

So again, we're talking here about food safety culture. Frank talked about food safety culture equaling behavior. This is really the hard stuff, so I'm glad you guys are here and ready to dig into that hard stuff.

I think we'll start off with our first question. Looking at what are the most significant actions that FDA can undertake to foster and support the development of food safety cultures globally.

And Kristin will walk around with the microphone, so just raise your hand. She'll get her exercise in after lunch.

MS. MCNAMARA: Yeah.

MR. WALDROP: And she'll be able to take your answers and then Tracey will mark down some of the key themes that she's hearing as we go through the questions, so open that up.

MS. FORFA: I really just want to clarify that this the morning session, but we are looking forward to add to that.

MR. WALDROP: So don't feel -- you don't have to read that. You don't have to memorize it. We really just, you know, that's just to kind of give you a sense of what was talked about, but certainly, you know, we want to hear what you all have to say and we'll take all that down as well.

MS. MCNAMAARA: We recognize this first question. It's in the back page of your left-hand pocket of your folder, is very FDA focused. Because the first brainstorming was FDA only, so we talked about what actions FDA could undertake to foster food safety culture globally, but you all tell us what you think.

And then we want to move on and here what your challenges, changes, desires are.

So what do you think FDA could do? You heard some ideas this afternoon. Most of this afternoon, was just do it. Get that data. Use it, small data. Come on guys, it's there. What do you think?

Hands up. Yep, please say your name and your affiliation. Thank you.

MS. KRUGER: Sure. Hi, I'm Cindy Kruger with PepsiCo. So and this is something that someone at FDA gave me the idea of it, but I think it's great.

I guess because I'm a company, I think about investigators and I think about FDA's role in enforcement and how can they go from a check the box

approach to enforcement to looking for food safety culture. And I think that that's really something FDA can really tangibly do.

And in part, you know, how are your investigators financially incentivized, this is something we think about with our plans. How you do you incentivize people so that they're incentivized to look for corrective actions, that they look for improving the food safety culture at a plant and suggestions of improving culture opposed to the I gotcha moment and these are the 18 things that I want to cite you for.

And I think that's a real challenge to the agency and all of us to figure out how to do better in that response. I think --

MS. MCNAMARA: Thank you.

MR. WALDROP: Great thanks.

MS. MCNAMARA: So not just a check list, not just a compliance check list, but how do we affect your behaviors and get you to have it incorporated?

State your name.

MR. BRAUNER: Matt Brauner. I'm with National Customs Brokers Association and there's two existing bits of information or things. The first one is the food facility registration. That could be strengthened by asking some additional questions on not just whether the food is stored ambient or dried or whatever. You could ask a few more questions on that, a thing that's already in existence, already out there, you don't have to recreate something.

The other one is the FSVP, the Foreign Supplier Verification Program. There is some audits being done on that, but it's seems to be fairly limited and certainly the foreign suppliers are not fully aware. There should be more outreach to those foreign outfits.

And, you know, they're listed out there. You should have names and addresses that have already been given to FDA, but I think there's a fairly small audit percentage.

MS. MCNAMARA: So both food facility registration and FSVP in our databases, making sure

that those folks really are, I'll just use the word, behaviors, like Frank used, really having behaviors expected of them.

Say your name and affiliation.

MR. MOORE: Eric Moore. I'm with Testo. I would actually welcome the FDA's involvement with a study that NC State is doing that is using or evaluating food safety management technology platforms to evaluate the effectiveness of this system to evaluate if a culture is in place, less so on an audit basis, more so on a daily operational perspective.

MR. WALDROP: And that's under -- ongoing at NC State right now?

MR. MOORE: It is.

MR. WALDROP: Okay.

MS. MCNAMARA: Thank you, okay. We're going to take maybe one more in this question and then keep moving because we do have less time this afternoon. Thank you.

MR. MENDES: Very fast, Alex Mendes with PepsiCo. Maybe going a little broader is what are the behaviors that identify a culture? Because I think we're all diving in on elements of it. Otherwise, it's very hard because it will vary one company to the other.

MS. MCNAMARA: Thank you. So what are the behaviors that really do make a food safety culture happen? Any burning desires, last desires?

So we wanted to shift gears on the second question away from what actions FDA could take to how can FDA support and encourage companies in development of food safety cultures food supply chain?

So kind of building off of what Alex just said. You've got the behaviors that make food safety culture happen. How can FDA support companies in doing this? Yes.

MR. GARRISON: Oscar Garrison, United Egg Producers. A couple of things that as a farmer cooperative we could have some support in is, you know, we saw the slide this morning on how local is growing. Well local tends to be your smaller producers. And that's where the culture tends to

break down.

So maybe some partnerships there that can build upon what we're doing with our larger members, but where we can also get it out to the smaller producers out there, some of which aren't even regulated.

When you look at the US egg industry, if you've got 3,000 or less birds out there, you do not fall under the FDA egg safety rule. So you got 50,000 or more, you got 50,000 and less and then you 3,000 and less that really, they have the ability out there to make a lot of folks sick day in and day out because they're dealing with your farmers' markets, your specialty restaurants, and others.

So even though that we, you know, you see a few illnesses that are multi-state outbreaks that FDA investigates, but when you see what's associated with egg consumption out there, CDC reports many more of those and those are really all focused on those smaller entities out there. So if you want it truly all the way through the supply chain, we've got to address those smaller producers out there.

And kind of tagging on to that, when you look at that from a farm to fork perspective, then that consumer education aspect there and a partnership through many different facets of that, is going to be huge. Because as a, you know, as a producer that produces a raw agriculture product that's designated to be cooked, what we see out there is that the consumer doesn't know what they're doing as far as proper cooking, proper handling, cross contamination. We can do everything within our hen houses and get that number way below 1 in 20,000, but all it takes those one or two instances within those households and we're still going to have the foodborne illnesses. It's not going to go away.

MS. MCNAMARA: Thank you very much. So, yeah, we heard the data this morning from Pradeep, 500,000,000 growers, small farm holders, 80 percent of product. And to the point that we just had, you got the small growers you have to educate, you got the consumers you have to educate. What else?

People we haven't heard from. Yes.

MR. BAUER: Bob Bauer, Association of Food Industries. A couple things come to mind. We deal only with imported foods and I have, for years, been trying to get FDA to participate in some foreign trade shows and never. There are some huge shows. I was at one last week with 170,000 people. So there are opportunities out there to reach thousands of people at one time that I don't think the agency is doing enough on.

And the other word -- I'm having a little bit of a problem with the word culture, even, because you're dealing with people in other cultures, it almost sounds like that you're coming down and speaking down to them. Don't adapt our culture. It might just be schematics. Whatever, I'm just having a hard time. I can't give you an alternative right now. Nothing's coming to mind either, but just, you know --

MS. MCNAMARA: Thanks. Thanks for that. And think about Frank, this morning, used the word behavior almost synonymous with culture. If we're talking food safety behaviors throughout the supply chain, that might make it a little bit different. Yes.

MS. FEIST: I'm Shelley Feist with the Partnership for Food Safety Education. I don't have an action per say, but to me this is about values, your fundamental values and acting on your values.

And so, in that way, I'm not sure what FDA can do other than maybe set a good example and maybe we do some positive deviance where we really show the companies that have done this and what are the values behind it which are clearly about protecting public health and having not be front of mind as opposed to, again, compliance. There's some good (inaudible) here about that. It's not about compliance.

MS. MCNAMARA: So if I'm just hearing correctly, proactive, identifying the good players, the good actors, the good stories to tell?

MS. FEIST: Yeah, giving them a platform to tell their story and to talk about how they were able

to work in this -- creating values within their company that make everyone wish to be active and comply.

MS. MCNAMARA: Got it. So the leadership led, values driven.

Yeah, okay. Coming over here.

MS. KRUGER: Yeah, so -- Cindy Kruger with PepsiCo again. I guess some of these comments are making me think, you know, so the agency provides sort of a stick to inspire good behavior, but how can you put sort of the shining model out there too, which is what Alex was referring to. And I think that would be helpful.

There hasn't been a lot of work -- you know, when you tell people you should have good food safety culture, what does that mean? Does it mean you have videos for employees to watch? Does it mean you do a certain amount of training? Does it mean you have a presentation to your board every year or do you have someone on your board, you know, who's responsible if you're a big company? What does it mean if you're a small company? I think that a lot of people need it broken down a little bit more to be honest. And it does roll up to do you have the right values? Is it part of your company's core values and corporate statements when you're training people and stuff like that?

MS. MCNAMARA: So modeling and best practices. We also heard this morning folks saying make sure everyone at every level of the organization knows the behavior, the food safety behavior they're responsible for, that they have to do, so somehow figuring out how to communicate that. Yes.

MS. MCGILL: Yeah, you just took the words out of my mouth, yep. This is Julie McGill. I'm from FoodLogiQ. We're a SAS-based traceability software company.

You took the words out of my mouth. What we often see when companies are implementing a traceability implementation is, you know, it has to have top down support. Everyone has to understand what this is all about and if they don't, there is a

breakdown. You know, someone might call in, a supplier might call in to their restaurant operator and well, what's this program all about and then someone says oh, you know, I'm not familiar with that. You don't have to do it. It's like it has to be part of their culture.

And, you know, certainly looking at it from the FDA standpoint. You know, I've had companies say we're not doing this until it's mandated. And, you know, I don't think we want to get there as an industry. We don't want to get to that point. We want to be part of the solution, but part of the solution is companies doing exactly what Cindy just talked about which is it has to be part of the company's culture. Everyone has to understand.

And if you drive that to your training partners in the supply chain, then you're pushing it outside of your four walls. So it has to be a collaboration, but everyone has to be working from the same playbook and I don't think we've talked about that yet as having common goals and objectives for this culture piece.

MS. MCMANARA: So actually making those cultural -- the common cultural elements throughout your supply chain so evident that people know what they have to do and then just do it.

Somebody's hand -- yes.

MS. DZIECH: Joy Dziech with Blommer Chocolate. This comment is going to lead into the next one, so I guess I'm double dipping.

I think it's really important that we talk about why. Why do we have the rules that we do? I guess I would ask the FDA to do the same, to make sure that we understand where the regulations are coming from, not just because we said so. Right? Because I get that question a lot with our employees. I don't like to have, you know, just because the crazy red head said so, I use that line a lot. But, employees at all level of the organization need to understand why are we asking them to do what we're asking. These are professionals from the front line to the boardroom. Everyone needs to understand in order to

get on board.

I don't want a culture of compliance. I want a culture of commitment. I want them doing it because it's the right thing to do. And for me to get that, it needs to be because they understand why and they can get on board especially because, and I say this all the time, people eat this stuff. My kid, even though she's 25, is my baby and I give her this chocolate and if you mess with mama bear's baby, it's going to get ugly. Right? So whatever my hook is, whatever your hook is, to me, that's part of our culture and for me to get on board with FDA regulations, I've had to understand the why.

MS. MCNAMARA: Thank you. Very articulately said.

We have two more over here and then we're going to have to move on to our next question. Thank you.

MS. GE: Thank you. This is Melody from Corvium. I think what FDA can help is recognition of, may partner with GFSI with their unannounced audit, because now more and more people are signing up for unannounced audits and then there even willingness who have they have selected site, that they're unannounced all the time.

So I remember at that time back then, we we're talking about unannounced, we say crawl before walk, walk before run. So although we -- the first initial we started with unannounced audit is like we want to make facility audit ready 24/7, but the reason why we wanted them audit ready is because we want to build in this habit for their operations.

So once the habits grow in the facility, then eventually it will grow. So I think it could give a little bit credit for those facilities selected unannounced audit during the GFSI certification.

MS. MCNAMARA: I like the idea of partnering on unannounced. Thank you.

MR. ACKER: Thank you. Jeff Acker with Dairy Farmers of America. So Joy, I agree 100 percent on what you said, but I think to move forward with the behavioral changes, right now the industry -- the food

industry views the relationship between regulatory and the manufacturers as less than collaborative. It's very adversarial and therefore will not get passed that until regulatory and the manufacturing community work collaboratively either through trade associations or directly.

So my company has offered, and FDA has accepted numerous times, to go in and learn about our products and industry so they can train the next bunch of people. And that comes with a dual-edged sword. It's like we want to educate them, but then they're going to be in our house and you're always worried about them being in your house.

And so it's got -- we've got to somehow tear the barriers down in order to advance behavioral changes, start with don't always look to be punished, look to be collaborative.

MS. MCNAMARA: Excellent. Thank you. Thanks Jeff.

So that's a perfect segue to the very next question. So what are the obstacles to creating food safety culture, so obviously the lack of collaboration, a perceived adversarial relationship, obviously an obstacle? What other obstacles? FDA side? Any side throughout the supply chain, what do you all face that are your challenges that we haven't even touched on, you haven't heard today? You need to make sure somebody here knows that there is an obstacle that just wasn't even mentioned. And you've heard a lot.

I'm going to somebody who hasn't had a hand up yet if I -- if there is anybody. Yep.

MR. GUYER: Calvin Guyer with QualiTru Sampling Systems. I think maybe take a lesson from some other industries like the FAA. Pilots are incentivized to note an error that they personally made and they log those in various systems, other pilots read those and hopefully somebody doesn't make the wrong -- the same error.

I think I'll go back to Jeff's comment. It's a bit adversarial if you admit an error, then you get this big stick coming after you from regulatory

agencies, fines, more audits, intrusion as opposed to collaboration, so.

MS. MCNAMARA: Thank you. So obviously having an obstacle to overcome being when you identify an area that you don't know enough about, don't know how to do, you need to train on, you don't want to get whacked for it. You want to have some bandwidth to work on it.

What else? What are other obstacles? Yeah, okay. Can I come back to folks who haven't had their hands up, yes. Go ahead. Say your name.

MS. GE: Thank you. I'm Melody from Corvium. One quick comment is the size of the companies. That's a lot of times I found its obstacles especially for the public. People think food is a very easy business to enter. So there are a lot of entrepreneur and the challenges that they have, the understanding of the culture they have is tremendously different as PepsiCo like global companies, so that's the biggest obstacle in my experience.

MS. MCNAMARA: Thank you, absolutely. We've heard a lot today about the small farmers' markets where the chefs get all their food and do those folks really have the same food safety culture?

MR. VON FRIEDEBURG: Hi, I'm Arnim von Friedeburg, CMA Global Partners. One of the biggest obstacles might be money because culture changes require coinication. Coinication requires budgets to make coinication happen, pay for the media and with limited funds, the FDA maybe hem strung. So it may require a certain set of budget to create that culture without the stick, but with carrots.

MS. MCNAMARA: Absolutely. And remember we're talking about changing human behavior. Behavior at FDA, obviously behavior at other places, that is always the most heavy investment.

Name and affiliation?

MR. CROWNOVER: David Crownover. I'm just a self-employed food safety consultant soon to be with AIB International.

This gentleman actually brought it up earlier and its culture, different cultures. If we're talking

the supply chain, we're not just talking right here in the states, we're talking about global. And, you know, when you're talking about changing behavior, behaviors are wildly different from, you know, this country to the one just south of us or just north of us. And so making certain that there's that understanding of the cultural differences and the behavioral impacts that has on that for something as simple as washing your hands.

MS. MCNAMARA: Absolutely, thank you.

Right back to you. There is a hand I haven't seen before. Yes.

MR. QUERRY: Randy Querry with the American Association for Laboratory Accreditation. I would encourage that the FDA adopt or encourage the adoption of ISO standards, the global standards. They offer requirements for quality policies and when we go to conduct an assessment on site, we're not just meeting with the upper management, we want to see that that management system has been implemented at all levels throughout the organization. So we're interviewing and reviewing records and watching tests being performed at the bench level. So that's important. Thank you.

MS. MCNAMARA: Absolutely. We heard that earlier. ISO standards, in other words consistency across all kinds of -- standardization across all kinds of regulatory authorities, countries, systems would be a huge boom.

What else? What other -- what's a huge benefit that you would just love to see, an obstacle removed that would change -- be a game changer for you and make the world different?

A hand in the back? Yep.

MS. KOCHENDERFER: Karil Kochenderfer for LINKAGES. Building on the last point about ISO standards for lab certification or lab, the biggest obstacle I hear and see across the industry is redundancy in standards whether for food safety management or food safety certification or for traceability. There are global standards that exist. They are ISO standards 22000. They are consistent

with the lab standards. They are consistent with other standards. They are consistent with what the rest of the world is doing. They are being used at the local level. They're used in Canada and Mexico.

Why recreate the world when you have a workable standard based on Kodak standards that recognized by the WTO that works? Let's get the redundancy and inefficiency out of the system rather than create more with new standards.

MS. MCNAMARA: Thank you very much.

I'm going to come to one more and then we are going to move on to our next question. Thank you.

MR. BAUER: Hi, Bob Bauer, Association of Food Industries. Just building on the standard, but coming from a different angle, creating more standards of identity for products would be helpful because, and in particular for product where there is a Kodak standard, you know, I know of two products our members deal a lot in, we've been trying for 20 plus years to get standards of identity and no action has been taken in the three or four times each is petitioned.

It would be so helpful if FDA, since it participates, it approves, and accepts the Kodak standards for those two products, and the industry is backing them, why can't US create a standard identity for these products? I think more standards would be good particularly for some products.

MS. MCNAMARA: Thank you. So standards of identity as another example of eliminating redundancy and having one standard.

So our next question is changes. We said in the question in your booklet, changes that FDA can and should take in how it approaches food safety to place further emphasis on prevention, but not just FDA. I mean if there were other changes, we want to capture the universe here, changes emphasizing prevention.

You heard Natalie from Dole, the last speaker on the panel just now say you cannot measure prevention. She talked about the return in investment they'd had across all kinds of things in their organization of doing the simple system that they began to put in place with blockchain.

What else? What other prevention measures would you like to see would make a real difference?

MR. GARRISON: There's two key things out there and it's Oscar Garrison from United Egg Producers.

We need to see the baselines come back, the old baseline studies that basically tells the industry what's coming at them next. We hear our rules set up for salmonella enteritis. Our last two outbreaks have been with Oranienburg and they've also been with Braenderup. And where did those come from in the continuum? It's something that in the risk assessment was not identified.

The second one is the development of alliances out there for training programs where the industry and regulators train together and that also includes farm visits.

I've been a big proponent -- I was a regulator for 20 years in the State of Georgia, past president of the Association of Drug Officials and it was a hard sell to my members, but we open up three of our farms a year to Jerry Ramirez and the Egg Safety Group to come out and actually do training of the FDA inspectors on those farms.

And it is a full blown -- it's a no penalty inspection unless egregious violations are found. But they're pulling drag swabs, they're doing everything they would normally do. And when they leave that farm, those samples go in the trash.

But until you get those inspectors out on your farms and give them the opportunity to see what you're doing, how you do it, and so when they come out in pairs of twos or threes to actually do the inspections and know the culture, know what they're looking at, know that is a feed mill that's sitting over there next to the birds that's got to feed 2 1/2 million birds that's on site there, it has made a major difference in the quality of inspections that we're getting day in and day out and the cooperation we get from the agency.

MS. MCNAMARA: Thank you very much. A collaboration, you used the word alliance, but

collaborations on training so you agree on what a good inspection is, consists of, what to look for and those behaviors. Again, use the word in your mind, behaviors for cultures. What are those behaviors of prevention that need to be somehow adopted?

MS. KRUGER: Well, this is really simple, but the FSMA guidance --

MS. MCNAMARA: Say your name and affiliation.

MS. KRUGER: Oh, I've said it three times, Cindy Kruger with PepsiCo.

And I'm kind of on this theme, but we're missing like ten chapters of the FSMA guidance. We haven't had a single revision that has responded to industry comments re-released. You know, the agency wants to really help us in how we can, you know, do better than -- get it out.

MS. MCNAMARA: Got it.

MS. KRUGER: Oh, wait, wait, wait, and work with us out with open for comment.

MS. MCNAMARA: Got it. Get it out and then let us opine. That's important too. Okay, yes.

MS. SPOTZ: Kristin Spotz from GMA and Cindy took the words out of my mouth about the guidance documents. I mean we talk a lot about small businesses and helping small businesses and fostering prevention. They have probably a lot of hard time reading the rule and understanding it. That guidance is key for them. The Cindy's of the world know what they're doing, but, you know, the smaller producers, you know, really need that guidance. So I can't echo that enough, is that prevention could really -- guidance.

MS. MCNAMARA: Thank you. Again, on the smaller growers and prevention and guidance, we heard that.

So any burning last minutes on this one because we want to open the floor up? I'm going to come to the back. We want to open the floor up to hear what else we haven't even thought about that you all think are really critical ideas.

MS. HOELZER: Thank you. Karin Hoelzer with The Pew Charitable Trusts and we've heard a lot today

already about root cause analysis and how important it is for prevention-based system. But I think really bringing root cause analysis back to behaviors. What are the behaviors that led to an outbreak? How does food safety culture intersect with an outbreak at (inaudible) so really trying to focus on that would be my recommendation.

MS. MCNAMARA: So especially in an outbreak situation, but root cause analysis and behavior modification, right? Not just behavior identification, behavior modification, actually making the changes.

So we've heard a lot about changes FDA needs to make, own that, hear that. Thank you.

What else? We'd like to go to changes -- other changes you think are needed, challenges you face.

We mentioned in our kind of, you know, document, consumer education. You know, other things that you think are part of this equation haven't been dealt with. It's food safety culture writ large if you will.

MS. DZIECH: Joy Dziech with Blommer Chocolate. Cindy's my new favorite person, just so you all know. I was with her in the previous session and just to get it on the record for a third or fourth time, we'd really like to see those chapters finished for preventive controls.

And in the previous session, Cindy mentioned also about environmental assessments and getting support and I guess collaboration on the idea that these are meant to be early warning systems and also verification that our systems -- our programs are effective not "gotcha and now you're in trouble for doing the right thing." Is that about what you said? Yeah.

We feel a bit crucified, perhaps, when our data is reviewed and we are in the process of investigating and tracking down and eradicating and that takes an effort and that is not something that is always quickly resolved. So it is a sensitive area when we document these things and it gives us pause

when we have to decide what to record and what not to record. I think it goes back to that comment someone made about maybe an adversarial -- maybe it was Jeff - - an adversarial relationship as opposed to working with the agency.

Yeah, and I would really like to have that collaborative and transparent relationship and I think a lot of us here would.

MS. MCNAMARA: So I heard of a big emphasis on the words work with. Work with FDA. And I will see, I mean we all heard Ian from the CDC loud and clear saying, you know, you're only as good as the data you have, but you also can't wait for perfect. And I think, you're right. You hit that balance.

MR. MENDES: I'll be succinct. Alex Mendes, PepsiCo. I think I want to be just provocative.

If you look at the Europeans, the way they are labeling products with the, you know, simple for the consumers. Green, yellow, red, so why can't we take that concept actually to show companies that they are doing best practice.

I don't think we do communicate well with the consumers and that will help the business tremendously.

I mean we have in this room a bunch of geeks. Everybody loves food safety here, right? No problem. No problem. Go back to your companies and then try to get everybody else on the same page. It's much tougher. If the pressure comes from outside, you'll be a lot more effective.

MS. MCNAMARA: Excellent idea. Green, yellow, red as a very simple, very simple indicator. I mean, again, rethink the world here for a minute. We're giving you carte blanche for the next couple of minutes.

Other challenges? Changes? Out of the world ideas? Yes.

MS. HURT: I'm Eva Hurt from Nestle and I was wondering if we have talked enough about the potential of public private partnerships in the food safety area, and in particular, when we talk about behavior and cultural change.

I think everyone -- we know that culture change is one of the hardest things to undertake in a large group or in a company or any other entity. So I just wonder if the FDA that has the head as the regulator and enforcer is really the best qualified single spokesperson for that culture change or whether it wouldn't more favorable to team up with multi-state corridor platform for example, so that larger companies, smaller companies could engage, but also reach out to their respective suppliers and as such to the whole eco system.

MS. MCNAMARA: Thank you, great idea. We also need to partner more widely and that's why we have you all here today.

MS. ENLOW: Cheryl Enlow, Renaissance Food Group. I'm in the fresh produce industry. And building on that, some of you may be aware of the romaine task force that was put together. And I think that's a good model where it was academia, the regulators and all aspects of the industry getting together to work on that problem. And it would apply to any of the things that we've talked about today.

MS. MCNAMARA: So a real-world example of this public private partnership that we're talking about, yes.

MS. FEIST: I would say I work in consumer education that evaluation is needed and I've never found funders that want to help support evaluation, so, invent in evaluation.

Shelley Feist, Partnership for Food Safety Education. Thank you.

MS. MCNAMARA: Thank you. Excellent ideas.

Others? We have a few more minutes before we go back to the open comments. Yes.

MR. GARRISON: You know we had a major lesson learned after our last large egg outbreak and the company involved, I went in and asked them, they said what can we do. And there was a big disconnect between getting the culture at the top and bringing it down and then getting it at the bottom and bringing it up.

So one of the things that that company

instituted, their chief operating officer goes around the country to all their different farms and visits their nighttime sanitation group at each one of those complexes a couple of times a year. And it doesn't seem like a lot, but for those folks on that clean-up shift, which is the hardest shift to actually get the labor to do, but it's the most important thing we do in those plants, day in and day out. But to let them know that the management cares enough to travel around to come out to bring them dinner, sit down with them, break bread, and let them know that what they're doing is sometimes the most critical part of that operation has really made a difference throughout that entire company. So just getting that involvement all the way through the system is huge.

MS. MCNAMARA: Thank you. We heard a lot about that. Actually in this morning, a number of people said, you know, when someone's feet hit the floor in the morning and they go into whatever their role is, a regulator in the plant, wherever, that they know their role. They know what they do, that their behavior matters in the food safety area.

What other burning last minute, brilliant insights that you want up here? This is your chance.

We also have the record you can report on online in the Federal Register and it's in your packet also, but anything you want.

Tracey's going to be up at the end of the day kind of reporting out from this whole breakout session, so if you want a key idea up there, you can insert it now.

Yeah, coming to you.

MS. HOELZER: Karen Hoelzer, Pew. As was said earlier today, one of the most motivating things for many of us hearing patient stories, hearing the people who have actually be infected by foodborne illness. And I wonder, going through my food safety training, I was never exposed to that. So I'm wondering if there is a role for bringing the patient's story, bringing that face more into food safety education to really create that culture of food safety.

MS. MCNAMARA: Thank you. Humanizing it and making sure that you get the person's face, the story behind the illness, behind the impact, so that really makes it come home, hit home.

UNIDENTIFIED SPEAKER: I just want to add to that. You know, we've tried to that, but it's hard for us to identify those people and so I feel like the agency with some funding -- I mean this is a very simple thing that could be done. You can get consumers with allergen stories, with pathogen stories that can be compelling training materials. And I keep repeating training, but I'm on a bandwagon.

MS. MCNAMARA: Training because it's behaviors. I mean that's where it all comes down to. Like a parent, right. Here we are.

UNIDENTIFIED SPEAKER: Yes.

MS. LUPPO: Hi, I'm Lisa Lupo with Quality Assurance and Food Safety Magazine and Stop Foodborne Illness does that. It's actually out on their website. They have a bunch of stories and so we've started doing it in the magazine now. In each issue, they give us one and we put it out there saying this is why and that's kind of the introduction we give is, here's why you need to do this.

So you can go to our website which we would love to have you do. Or, like because Let's Stop Foodborne Illness has a bunch. So it's something that FDA maybe could partner with them on and help get it out there because obviously it's not getting out there a whole lot. So maybe if FDA would partner with Stop Foodborne Illness that could help a lot.

MS. MCNAMARA: Excellent. We'll capture that. Stop Foodborne Illness as a platform. Thank you. Other last-minute burning desires?

So our job is to synthesize this, and as I as I said, Tracey will be representing this at the end of the day, but the record remains open and we'd love to continue to hear from you.

We appreciate it and you're return to the big room for the public comment session. Thanks.

MR. WALDOP: Thank you.

(Whereupon, the breakout session concluded.)