

**NWX-FDA OC**

**Coordinator: Susan Chittooran  
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Operator: Welcome and thank you for standing by. At this time, all participants are in a listen only mode until the question and answer session. At that time, if you would like to ask a question, please press Star then 1 and record your name when prompted.

Today's conference is also being recorded. If you have any objections, you may disconnect at this time. Now I would like to turn the conference over to your host, (Christina Clefane). Thank you. You may begin.

(Christina Clefane): Thanks, (Givana). Good afternoon everyone and thank you for participating in today's call. My name is (Christina Clefane) and I'm from the FDA's Office of Health and Constituent Affairs and I'll be moderating today.

Thank you so much for attending to discuss the seventh and final major rule under the FDA Food Safety Modernization Act, the attentional adulteration rule.

Today I am joined by Dr. Stephen Ostroff, the incoming deputy commissioner for the Office of Foods and Veterinarian Medicine, Dr. Susan Mayne, director

of FDA's Center for Food Safety and Applied Nutrition, and Dr. Ryan Newkirk, policy analyst and FDA lead for the rule.

We will be taking your questions at the end of the call but for now let me turn it over to Dr. Ostroff to get us started.

Dr. Stephen Ostroff: Well, thank you very much and thank you for joining us either this afternoon or this morning, depending on where you're located. I would say that every week at FDA is atypical but this one is especially atypical in that it's the week that contains several lasts.

And as was mentioned, it's kind of a week of sevens. First, this is the last week that Mike Taylor will be serving as the deputy commissioner for foods and veterinary medicine at FDA and it's a post that he's held for the last seven years.

Second, as was just mentioned, we're releasing the seventh and the last of the major foundational rules for FSMA and I think that there's a certain elegance in the symmetry of those two statements because Mike Taylor, more than anybody else, is so closely identified with FSMA.

And I've often referred to him as Mr. FSMA, and after all, it was Mike that championed the need for the changes in FSMA. He was there when the wall is being developed, when it was being passed by Congress and when it was being signed into law by the president in 2011.

That he has been a continuous presence throughout the process of developing and writing the implementing regulations. And so he was there while they are being developed, while they were proposed, and in for instances, when they were re-proposed and now that they've been finalized.

And he's also been the one that has been the cheerleader that's been making the case that the impact of FSMA can only be realized if there is adequate funding to be able to implement FSMA in the way that it was designed in order to maximize and reap the public health benefits that not only congress but also the public expects.

So I think that without question, Mike will be leaving on a high note with the satisfaction of seeing the last of the major rules brought across the finish line on his last week at the agency.

In this particular rule relates to prevention of intentional adulteration of the food supply. And you will be hearing more about the details of this rule by the next couple of speakers.

And I think it's important to point out that you shouldn't think of the foundational FSMA rules as being seven standalone regulations because clearly they work together as a unit from farm to table in the same way that all of our various stakeholders which have helped us so much in developing the regulations have to work together to produce safe food.

These rules are the basis for building a new food safety system that's focused on preventing problems upfront rather than waiting for outbreaks or illnesses to occur.

And they will also work to strengthen what is becoming an increasingly global and complex food system and will guarantee the equivalent safety levels of food whether it's produced within or outside of the United States.

They will only succeed based on high levels of compliance on the part of regulated industries. Partnerships were crucial to the success of the rulemaking and they will be even more crucial during implementation.

And as we stated before, we're fully committed to providing the technical assistance, the training in the guidance that's necessary to assure our partners in implementing FSMA that they know what to expect and how to do it.

So please take advantage of those implementation tools and please provide feedback to us in terms of what's working well and what may not be working as well as anticipated as we go forward.

I will say that getting to this point where we're issuing the final rule took a tremendous amount of work but it's also important to point out that this doesn't get us to the finish line. It gets us to the starting line because that's exactly where we now are as we will move into the implementation phase of the seven foundational rules.

Before he turned it over to Dr. Mayne, I think that I would be remiss if I didn't think, in addition to Mike Taylor, all of the other people at FDA that have worked so hard over the last few years to put these rules in place and to produce them.

This hard work, without question, fundamentally changes the food safety paradigm in the United States and in many other parts of the world and it clearly changes that paradigm for the better. And I think that that's the ultimate reward.

I would also like to thank all of you who are on the phone who are stakeholders for sticking with us and for your input throughout the process and your commitment to implementing these rules in a very effective way.

So with that, when I'm going to do is turn it over to Dr. Susan Mayne, who is the director of our Center for Food Safety and Applied Nutrition.

Dr. Susan Mayne: Thank you, Steve. As Dr. Ostroff mentioned, the rule released today is the seventh and final major rule under FDA's Food Safety Modernization Act which is aimed at preventing food safety problems throughout the food supply chain.

Let me be clear what we mean by intentional acculturation. In the context of this rule, it means deliberate contamination of food and those who want to hurt many people.

That said, an event in which the food supply is adulterated with the goal to cause wide scale public health harm, including acts of terrorism, is unlikely. However, in the event that it occurs, intentional acculturation could have devastating consequences for public health.

Such an event may also result in widespread public fear, loss of public confidence in the safety of the food and the ability of government to ensure food safety and significant adverse economic impacts including disruption of trade.

That's why today's final rule is focused on the steps companies need to take in order to prevent intentional acculturation of the food supply. In order to protect food from such destructive acts, there needs to be a shift in approach from the safety standards established in the other FSMA rules.

Rather than targeting specific foods or hazards, this rule requires mitigations of risk reducing strategies - mitigation, sorry - or risk reducing strategies for processes and registered food facilities that are most vulnerable to an intentional contamination event that could hurt a lot of people.

We've established that the highest risk of intentional adulteration is from an insight attacker. This conclusion is based on FDA's interaction with the intelligence community and vulnerability assessments conducted in collaboration with the food industry.

The requirements of the final rule take this into consideration. Under the new rule, food facilities, for the first time, are required to complete and maintain a written food defense plan that assesses their vulnerability to intentional adulteration where the intent is to cause wide scale public health harm.

The plan also requires facilities to identify and implement mitigation strategies to address these vulnerabilities. They will need to establish food defense monitoring procedures and corrective actions and verify that the food defense system is working.

The final rule also includes requirements related to training as well as requirements for records. FDA proposed the intentional adulteration rule in December 2013.

The changes in the final rule are largely designed to provide either more information where stakeholders requested it or greater flexibility for food facilities in determining how they will assess their vulnerabilities, implement mitigation strategies and ensure that the mitigation strategies are working as intended.

Prior to developing this role, we have worked with others for a number of years to protect the food supply under voluntary program. FDA partnered with the Federal Bureau of Investigation, the US Department of Agriculture, the Department of Homeland Security and other federal, state and local government and industry partners to assess the vulnerability of the US food supply and to identify strategies to reduce these vulnerabilities.

We've incorporated that experience and knowledge into key requirements of the final rule. The final rule also takes into consideration more than 200 comments submitted to the docket.

The FDA included a number of exemptions, most notably based on business size. Since this rule is designed to reduce or prevent acts intended to cause wide scale public health harm, the requirements apply to larger companies whose products reach many people and where intentional adulteration what have a larger impact.

The final rule does not cover activities of farms although further considerations will be given to the possibility of requiring mitigation strategies to restrict access to (milk on) dairy farms in a way that is appropriate and practical to require.

The FDA will continue to work with key partners to protect the food supply. For activities on dairy farms in particular, the FDA will be working with the National Conference on Interstate Milk Shipments, the Federal State Collaborative Programs for Milk Safety along with other stakeholders in developing strategies to protect milk from intentional adulteration.

We recognize that food defense may be new to many in industry and additional time may be needed to learn about intentional adulteration and the requirements of this rule.

Therefore, in the final rule, we have extended compliance dates by an additional two years for each business size. The largest businesses will need to comply in 2019.

With regard to implementation, the FDA is committed to working with both industry and our government and international partners to ensure effective implementation of FSMA's new food safety and food defense laws.

Implementation of the intentional adulteration rule and all FSMA final rules will absolutely require partnership, education and training. The FDA and others are working on valuable tools to make compliance with the final rules easier, such as training courses and our technical assistance call center.

So that briefly sums up this new final rule and I'm going to turn the call back over to (Christina).

(Christina Clefane): Thank you to all our speakers. Now I'd like to ask the operator to open the phone lines and provide instructions for our callers on how to ask a question. Just a reminder to please state your name and the name of your organization prior to asking your question. Operator.

Operator: Thank you. At this time, if you would like to ask a question, please press Star then 1. Be sure your line is unmuted, and record your name when prompted. If you wish to withdraw your question, please press Star 2. Again, to ask a question, please press Star 1. One moment while we wait for questions to queue.



(Christina Clefane): While we're standing by for questions, I'd like to note that we will be hosting a Webinar covering this topic on June 21 at 11:00 am Eastern time. To have the presentation, you can dial into 888- 946- 6302 and the passcode would be 3811136. To find out more about this Webinar, please visit [www.fda.gov/fsma](http://www.fda.gov/fsma) - F-S-M-A. Operator, we'll take our first question.

Operator: The first question comes from Erik Lieberman your line is open.

Erik Lieberman: Hi, I had - this is Erik Lieberman with the US Food Imports, LLC. I had a question. The proposed rule makes a distinction between acts of terrorism and acts of disgruntled employees.

And I'm looking at the final rule, and it looks like we really don't have that distinction anymore. The final world basically requires facilities to focus on preventing attacks that could cause wide scale public harm whether or not there from terrorists are disgruntled employees.

I'm wondering if you can discuss that further, the difference between the proposed and final in terms of how the rule approaches disgruntled employees. Thank you.

Dr. Ryan Newkirk: Sure, Erik. That's a great question. This is Ryan Newkirk with FDA's food defense team. You are correct. In the proposed rule we did differentiate acts of terrorism, acts of disgruntled employees, consumers and competitors and also economically motivated adulteration.

Economically motivated adulteration is considered and is required - those considerations are required in the PC rules. As you also noted, the final oral includes consideration and preventive measures for acts intended to cause wide scale public health harm.

When we were going to your comments for the final rule, there was a little bit of confusion and potential overlap between disgruntled employees and terrorism.

We still continue to believe and the statute directs us to do so, to cover those points, steps are procedures in the food supply chain that are at highest risk of potential adulteration. In considering the spectrum of risk for intentional adulteration, it was those acts intended to cause wide scale public health harm.

Mostly those acts could be considered a terrorist attack on the food supply, but if a disgruntled employee, consumer our competitor changes their motivation and wants to cause an act of wide scale public health harm, the requirements of the rule would also significantly minimize or prevent those acts. And furthermore, we do intend to publish guidance on this matter that addresses more specific details for the topic.

Erik Lieberman: Great. Thank you.

(Christina Clefane): Thanks for your question. Did you have any follow-up to that?

Erik Lieberman: I think that pretty much addresses it. I mean, basically it's - the focus is on wide scale public harm regardless of whether or not an employee - or a disgruntled employee is involved in a terrorist network.

I mean, if someone wants to hurt lots of people, even if they're acting alone, that's something that needs to be contemplated in accordance with this regulation.

Dr. Ryan Newkirk: Absolutely, Erik. Yes.

Erik Lieberman: Right. Good. Thank you.

(Christina Clefane): Thank you. Operator, we'll take the next question and please remember to state your name and the name of your organization prior to asking your question.

Operator: The next question comes from, I believe, (Arkana Patel). Your line is open. (Arkana), please check your mute button. Your line is open.

(Arkana Patel): Yes, so the rule demands that personal (unintelligible) appropriate training. So I want to understand what is appropriate training. And similar to the preventive controlled rules where we have the - a clear understanding about the preventive controlled qualified individuals, is there something for this rule also?

Dr. Ryan Newkirk: Yes, thank you for your question. So we very strongly feel, and this was something that was also coming out of the public comments from almost everyone, that training is a key part for an adequate food defense posture for facilities covered by the rule.

Appropriate training, we will designate a number of different areas that are required training, both in food defense awareness, so what is food defense, why is it important?

As well as certain areas for writing and creating the food defense plan. Some of those areas include how to conduct a vulnerability assessment as well as what needs to happen when you're be analyzing the food defense plan.

We do have a definition of qualified individuals. The gist of that definition is that individuals need to be qualified through a number of different ways - either training, education, experience or a combination thereof.

(Arkana Patel): Yes, thank you.

Dr. Ryan Newkirk: Thank you.

(Christina Clefane): Thank you for your question. Operator, do we have any other questions?

Operator: The next question comes from (Curtis Anderson). Your line is open.

(Curtis Anderson): Yes, this is (Curtis Anderson) of (Seymore) Milling. We are in the flour milling industry, specifically wheat flour. But my reference to - are my question is in reference to the exception of farms and, indeed, the - except for the dairy farms and dairy industry.

Is there any thought of application of that type of philosophy to other commodities like the wheat farms, the flour industry including other grains, those types of products, if you will, or commodities and respect to the widespread affect that they could have?

Dr. Ryan Newkirk: Sure. Thank you, (Curtis). Again, this is Ryan Newkirk with the Food Defense Team. We have, through our years of working with industry, identified that there are certain processes, steps are procedures that drive vulnerability. For those, they occur for the right scale public health harm, will occur in manufacturing and processing settings.

For those facilities that are required to register with FDA through Section 415 of the Food, Drug and Cosmetic Act, those are the facilities that are required,

then, to comply with this rule if they don't fall under an exemption. The exemption does apply to activities occurring on produce farms, and to just clarify, just a note, there are no requirements for dairy farms either.

(Christina Clefane): Did you have a follow up to that, Mr. (Anderson)?

(Curtis Anderson): No, very good. Appreciate it.

(Christina Clefane): Excellent. Operator, do we have any other questions?

Operator: Currently there are no questions in queue. As a reminder, if you would like to ask a question, please press Star then 1.

(Christina Clefane): Okay, and while we wait for the next question, I'll just remind you, that the Webinar to discuss this rule more thoroughly will be on June 21 and we're working to schedule more Webinars and meetings around the country to meet our stakeholders - meet with our stakeholders on this rule. We look forward to discussing this implementation with you.

Operator: Okay, we do have some questions in queue. The next question comes from (Jason Bashour). Your line is open.

(Jason Bashour): Hey, Ryan, thanks for your work with this. Really excited to get through the rules. Still reading it, although we just got the heads up on the call about a couple of hours ago so I haven't gone through the whole thing.

Response 105 talks of the establishment of the intentional adulteration subcommittee within the (unintelligible) (preventive) controls alliance but it doesn't identify industry stakeholders. It talks about industry associations. So

are you seeking or will there be input available from actual industry owner operators (or are) just those (associations)? Thank you.

Dr. Ryan Newkirk: Thank you, (Jason), for that question. It's good to be speaking with you. We have just recently, and we're very excited to be able to share this, have stood up the intentional adulteration subcommittee within the Food Safety Preventive Controls Alliance.

Part of that standing up of the committee is an initial activity of funding the committee and establishing ground rules and also looking for committee members.

So those particular activities, some are underway. Some are not. I believe the focus is on associations. But if you could please submit your question through the technical assistance network, we will also be able to get you details about that.

(Jason Bashour): Great. Thanks much.

Dr. Ryan Newkirk: Thank you.

(Christina Clefane): Operator, we'll take the next question.

Operator: (Carlos Cortez), your line is open.

(Carlos Cortez): Good afternoon, everybody. (Carlos Cortez) with (Mondelieze) International. My question comes through if the FDA will recognize any of the international standards that are currently established that some multinationals have potentially using already including the direction of many other mitigations that are in effect based on the rule?

And that's a two-sided question. It's also the outreach of the audit of international locations, (what is costs to) food defense? What is the plan to work outside of the US and Canada when it comes to the audit piece? Thank you.

Dr. Ryan Newkirk: Sure. Thank you, (Carlos). To take your first question about recognizing international standards, we do recognize that our - there (are) great work being conducted and being done through some of these international standards that include particular details on food defense.

We did receive a number of comments asking your exact question. I can tell you that we can't recognize the standards as 100% equivalent in compliance with the rule.

But what I can tell you is that we do feel that a number of these standards include activities that will reduce vulnerability of such entities to intentional adulteration. Also, related to this, in the final rule, we have included in the regulatory text the allowance for existing records.

So there could be the potential, and this needs to be considered on a case-by-case basis, that records that these facilities are using under the International Standards could have components that do require - that you comply with the rule. I believe that answers your first question. Your second question, could I ask you to repeat it please?

(Carlos Cortez): Yes, it was based on the - for multinationals that have already engaged in food defense programs, how it's going to be the average of the FDA in regards to the audits or reviews that will be performed outside of US grounds.

Dr. Ryan Newkirk: Sure. So I can take the outreach piece first. We do have robust plans in place to conduct education, training and outreach for both the domestic and international audience.

Your - some of your questions I also believe could be asking about inspection and we are currently working through the best approach for inspection at this time and we will share that with you once it's finalized.

(Carlos Cortez): Thank you very much.

(Christina Clefane): Thank you. We'll take the next question.

Operator: (Clay Detlison), your line is open.

(Clay Detlison): Thank you. (Clay Detlison), National Milk Producers Federation. Dr. Newkirk, others, thank you for promulgating what was, I'm sure, very difficult rule to issue.

Generally, I think things look good. I appreciate the dairy farm process that you're going to engage with the (MCI MS). I think that's a good solution to that issue.

One question I have is, with respect to vulnerability assessment requirements, certain segments of the food industry, namely dairy, have taken a very hard look at our vulnerabilities over the years.

We've done many vulnerability assessments. Will dairy facilities be required to go back through that once again or can we rely on our past efforts in that area? Thank you.



Dr. Ryan Newkirk: (Clay), thank you. This is (Ryan) again. Excellent question. So a little bit of the response to the last question, I think, is appropriate here as well. In the proposed rule, we did not have consideration of the use of existing records.

In the final rule, there is allowance for use of existing records. However, specifically related to vulnerability assessments, from the proposed to final, there are new details that need to be considered, at a minimum, for an appropriate method to conduct a vulnerability assessment. So I would encourage dairy facilities to read through those particular details, look at their existing records and see if they need to update those in any way.

(Clay Detlison): Very good. Thank you.

(Christina Clefane): Thank you for your question. Operator, do we have any other questions?

Operator: There are no questions in queue at this time.

(Christina Clefane): Okay, while we give folks a second to - reminder to hitStar1 if you have a question, I'll go ahead and remind you that in your invite today we did link to the Federal Register notice with the rule, the constituent update and the fact sheet regarding this rule. So if you need those links, go ahead and check the invite that was sent out this morning. We'll take the next question.

Operator: Thank you. The next question comes from Warren Stone. Your line is open.

Warren Stone: Hello, this is Lauren Stone from the Grocery Manufacturers Association. I echo (Clay)'s sentiments. Thank you for promulgating this. I'm sure it was lots of work and it's a groundbreaking rule for the entire food safety community.

My question was on warehousing. I noticed the applicability portion of the rule says that it applies to owner operators, et cetera, they manufacture process, pack or (holds food), but then under the portion in 121.5B exemptions, it says it does not apply to holding food except liquid storage. Could you clarify that please? Are warehouses covered?

Dr. Ryan Newkirk: Sure, Warren. Thank you for your question. So the - you are correct in reading - your read of the exemption of holding of food is exempt except for holding of food and liquid storage tanks. So they warehouse is only holding food and not doing any other manufacturing for processing activities, those warehouses are exempt.

Warren Stone: Thank you for the clarification.

(Christina Clefane): Okay, thank you, Mr. Stone. Operator, we'll take the next question.

Operator: Erik Lieberman, your line is open.

Erik Lieberman: Will the agency hold a public meeting on this rule is they have for the other FSMA rules? I think that would be great if they decide to do so. Hello?

(Christina Clefane): Thank you for your question. Currently at this time, we don't have plans to hold a public meeting.

Erik Lieberman: Okay.

(Christina Clefane): But if you would like to submit your comments to us, we'll definitely take it into consideration.

Erik Lieberman: Okay, great. Thank you.

(Christina Clefane): Thank you. Operator, do you have any other questions?

Operator: There are no questions in queue at this time. If you'd like to ask a question, please press Star then 1.

(Christina Clefane): I believe we have time for about one more question. We'll give it a moment. Just as a reminder, the Webinar regarding will be Tuesday, June 21st at 11:00 am Eastern time. Do we have any more questions?

Operator: There are no questions at this time.

(Christina Clefane): Okay, great. Thank you so much for attending today and this will conclude our stakeholder call. Have a great day.

Operator: Thank you for your participation in today's conference. Participants, you may disconnect at this time.

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