FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC MEETING

DRAFT GUIDANCE: MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION

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C O N T E N T S

P R O C E E D I N G S

MS. BARRETT: All right. Well, good morning again. And I appreciate your patience. And we will go ahead and get started with our program today.

So I want to welcome everybody to today's FDA Food Safety Modernization Act Public Meeting focused on the Draft Guidance for Mitigation Strategies to Protect Against -- to Protect Food Against Intentional Adulteration.

My name is Kari Barrett. I am with our Center for Food Safety and Applied Nutrition on the Communications and Engagement Team and I've helped facilitate a number of these FSMA meetings. And I see familiar faces. I know a lot of you have worked very hard on this particular issue of intentional adulteration. So we appreciate your time this morning.

I want to thank everyone who is on the webcast as well. We have quite a large audience tuning in that way. So thank you.

Before we get started with our public meetings, we always have quite a few housekeeping announcements. So let me run through those fairly quickly. All of you should have received a meeting folder that has the agenda. It has the biographies for our speakers. So when I introduce them, I'll just really gives names and titles since you have the background. There's also a document in there about how to comment on this particular guidance -- although I'm sure all of you are familiar with that.

You also -- for those on the webcast, you should have access to the same materials. You can find them on the FDA Foods landing page if you haven't already received them. We will also have a number of PowerPoints that will be used today, and it will be posted to the FDA website. Sometimes that takes a couple of days. It could be as soon as this afternoon or it could be a few days. So check back to the website if you don't see them just right after this

meeting.

Also, if there's any media or press here who hasn't registered, if you could just see the folks at the registration desk to let them know you're here. For individuals who have signed up to give public comment, this is when we offer towards the end of the meeting an opportunity to read a formal statement for the record. We don't have a lot of people signed up to do that. So if you hadn't signed up previously but that's something of interest to you, you can see again the folks at the registration desk. They'll get you in touch with Juanita Yates.

And if you are signed up to give public comment, during the break you can also check in with Juanita Yates -- again, she'll be by the registration desk -- just so she can give you a little bit more information about that process and, you know, ideally where to sit as we get started with that.

Also, today since we do plan to wrap up early this afternoon, we haven't built in a lunch time. We do have a long break later this morning for half an hour. We have a cafeteria that's located as you come in the front entrance of this building, so during the break if you want to get a snack or a beverage. Just keep in mind there's not going to be a time set aside for lunch. The downside is you can't bring that back into this room. So again, allow yourself a little time for that if you -- if that's something you'd like.

Restrooms, as you leave this auditorium and you go in the hallway, they're on the right. Across from the restrooms, we do have a room that is available as sort of a break room if you do need a place to go and conduct some business during the break. That room is 1A002. And again, that's open for anybody who would like to utilize that space.

Phones. If again you can just silent your phones, it's always appreciated. Exit signs, something you should always be aware of whenever you're at a -- in a public space. So please take a

look and note the one nearest to you.

A reminder that this meeting, as I noted, is being webcast. It's also being transcribed. We will publish the transcription. That usually does take a few weeks. So again, you can check on our website to see when that comes up.

And also, a reminder: for any public meeting, there shouldn't be any expectation of privacy when you're in a public space. So we always want to remind people of that.

And then, if you have any general questions, something that we haven't addressed with these housekeeping notes, again the folks at the registration desk are happy to help you with anything you need. So feel free to reach out to them.

And so with that, that doesn't include the housekeeping. So now let's get into the interesting part and start our program. I do want to introduce our first speaker, Dr. Susan Mayne, who is our -- Director of our Center for Food Safety and Applied Nutrition, and welcome her up to the podium to welcome you to this meeting and to provide some opening remarks. Dr. Mayne?

DR. MAYNE: Thank you, Kari, and good morning to everyone. It is my real pleasure to welcome you here to CFSAN today to participate in this really important public meeting.

And in today's meeting the topic is the Draft Guidance for the FDA Food Safety Modernization Act Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration. And that's a mouthful, so we most commonly refer to it as the “IA Rule.”

The U.S. has one of the safest food supplies in the world, but our foods are potentially vulnerable, not only to unintended contamination, but also from intentional adulteration. While the likelihood of an intentional adulteration event such as a terrorist attack on the food supply, while that likelihood is low, the potential public health consequences and the associated economic impacts are

significant.

In recognition of the consequences of such events, Congress mandated in FSMA that FDA require the food industry to identify and protect against hazards that may be intentionally introduced to food to cause widespread harm or death, including by acts of terrorism.

Protecting the food supply via food defense activities is not new. Industry and government have worked under a voluntary program to protect the nation's food supply for years. Many companies have already made significant efforts to reduce their vulnerabilities under this program and many of these actions can help them meet the requirements of the IA Rule.

Because this is the first time industry is being required to take a preventive approach against intentional adulteration, there are some areas where additional measures will be needed, mainly because of the rule focuses on the inside attacker.

Extensive analysis shows that some of the most significant risks are posed by an attack perpetrated by someone who has legitimate access to a facility, perhaps an employee. However, some of the food defense measures that facilities have been taking, such as installing perimeter fencing and implementing visitor protocols, focus on thwarting an outside threat. These measures may not address the full scope of risks.

So the rule requires facilities to look specifically at how vulnerable they are to inside attacks, identify strategies to protect against them, and check to ensure that those strategies are working.

Because the IA Rule includes some new areas for industry, we've looked to key lessons learned from our collaboration with industry partners and we have engaged in substantial dialog with stakeholders. This includes over 15 years of working with industry and academia to conduct food defense vulnerability assessments, collect and analyze data, and identify

mitigation strategies. We've also spent over 15 years consulting with the intelligence and law enforcement communities to better understand threats to the food supply.

All of these efforts have provided important insights into the scope of the threats, the potential public health outcomes of an attack on the food supply, and have informed the development of the rule, associated guidance and training tools. We have continued to collaborate with stakeholders since finalizing the rule in May of 2016 and in preparation for the first compliance date in July of this year.

But the path here has not always been smooth. Stakeholders have raised some concerns related to IA Rule compliance. One of the biggest themes of concerns we've heard is that stakeholders believe there will be significant compliance cost associated with this rule. This theme has been raised to us in numerous ways, including some requests for more flexibility in order to comply, the ability to count some existing protective activities towards compliance, and estimated costs.

We are committed to making implementation for industry as practical and flexible as possible while also achieving the goal of protecting public health. We've taken the concerns we have heard seriously and have incorporated stakeholder feedback when and where we are able, including in the final rule, the draft guidance, and training materials and tools.

We are confident that by utilizing these resources, industry will find the costs associated with implementation to be manageable and that high rates of compliance will result in a better protected food supply.

Part of our commitment to a continued dialog with stakeholders is this public meeting here today. Today we will be discussing the chapters of the draft guidance that are currently available. You'll hear from some of our intentional adulteration working group members about draft guidance chapters on food

defense plans, vulnerability assessments, mitigation strategies, food defense monitoring, and education, training and experience.

The group will highlight how we've incorporated industry feedback into those draft guidance chapters. You will also hear about significant flexibility we've built into the rule requirements and how some existing activities can contribute towards compliance. The team will also discuss updates we're making to the popular food defense plan builder software tool, one of the tools industry asks about often.

Through our collaborative efforts, we have produced a significant amount of resources. However, we have not yet issued all draft guidance, training or tools. Because of this, some stakeholders believe they need more time to comply with the rule.

We have received requests for a one-year extension for the initial compliance date for the IA Rule. Stakeholders requested the extension because they felt compliance requires a substantial investment beyond existing food defense practices, and noted yet to be released guidance chapters, training and tools.

We recognize that the IA Rule is the first of its kind and it is new territory for both FDA and for industry. We also recognize the rationale for preferring to have the entirety of the guidance, training and tools available prior to the initial compliance day.

We have weighed this request against the importance of the public health protections embodied in the IA Rule; the prolonged period of time since publication of the final rule, which we note will be 3 years, in May; and the status of rule associated guidance, training and tools.

Upon careful consideration, we have made the determination not to change the rule’s compliance date. This is consistent with our actions on other FSMA rules. But we have heard your concerns and are addressing them as follows. First, since the

finalization of the rule, we have prioritized the topics about which industry was most concerned and incorporated those topics into the first two installments of the guidance that are currently available.

In collaboration with the Food Safety Preventive Controls Alliance, these topics have also been prioritized, incorporated into multiple online training courses that also are currently available, as well as in-person vulnerability assessment course that will be available starting in May.

We recognize the importance to industry of having access to the final portion of the guidance that is not yet public, the last training course, and other technical assistance materials noted in the request.

Second, in order to allow you time to become familiar with the forthcoming materials, tools and trainings, and because the IA Rule represents new regulatory territory for all of us, we will begin routine IA Rule inspections in March of 2020.

Third, when we begin inspections in March of 2020, our overarching approach will be similar to that of the other FSMA rules. We will educate while we regulate.

Specifically, for the IA rule, our initial routine inspection activities will consist of a straightforward food defense plan quick check conducted during routine food safety inspections. During these quick checks, we will verify that the facility has satisfied the basic requirements of the rule.

In closing, we remain committed to protecting public health and ensuring a safe food supply while working with industry to implement this important and necessary rulemaking. We look forward to hearing your thoughts and comments at today's meeting. Thank you.

MS. BARRETT: Great. Thank you very much, Susan. Thank you. We'll now bring up members of our intentional adulteration food defense team. They're

going to come up individually, but I'd like to introduce them as a group. They will cover some background on the rule as well as Chapters 1 and 2.

So the folks that you're going to be hearing from in our next segment include Dr. Ryan Newkirk, who is the Senior Advisor for Intentional Adulteration in our -- again, our Center for Food Safety and Applied Nutrition, which is also known as CFSAN here at FDA; Julia Guenther, who is a Policy Analyst on the Food Defense and Emergency Coordination Staff, Office of Analytics and Outreach at CFSAN; and Captain Jon Woody, who is the Director of the Food Defense and Emergency Coordination Staff in our Office of Analytics and Outreach again at CFSAN.

So we're going to start with Ryan, who is going to give some background. And then the team will cover again Chapters 1 and 2.

DR. NEWKIRK: Thanks, Kari. And thanks to Dr. Mayne for those opening remarks. It really -- she's done a great job at kicking off what we've been looking forward to for quite a while now, the public meeting on the revised draft guidance.

So we thought in this first section of the subject matter material what we would do. We know folks have been tracking the IA Rule from proposal to finalization to the draft guidance, also tracking the alliance courses and the tools. But not everybody has been tracking them at the same level or for the same amount of time.

So we'll provide just a very brief background of the rule, just a few slides -- a few brief background slides on the overarching guidance. I'll hit on some details later. And then we'll start to bring up some subject matter experts to go into further detail for the chapters that are currently out in the revised draft.

So starting really at kind of a very high level. When we're out talking about intentional adulteration, most folks have a pretty good sense of what that is. But there are some folks that they're

working in the food industry, they're working to make healthful and safe food, but intentional adulteration, the term and/or the idea of somebody doing something to food on purpose to cause harm is a very foreign idea that doesn't sometimes register.

So why are we focused at the agency in protecting food against this type of adulteration? Well, there's a lot of information out there that leads us to make the conclusions, to make the determination that a potential intentional adulteration at particular points in the food system can cause significant health sequelae. A lot of people can become ill; a lot of people can potentially die.

One can quickly get to the point where if that starts to happen -- we all depend on food, we all eat. That could cause widespread fear in the public. If you don't know that your food is safe, if you think that you're going to be eating food that's intentionally adulterated or feeding that food to your family, that will cause a significant amount of fear.

There are also modeling studies and other information available that speaks to the devastating impacts, economic impacts of something like an intentional adulteration on the food supply. Not only would this be economic impacts for health sequelae, but also secondary and tertiary impacts, so impacts on the food system, impacts on the national infrastructure.

Loss of public confidence in the safety of food and effectiveness of government. Of course if there's a large attack on the food supply, people are going to question food safety: "Is this safe for me and my family to eat?" And we've seen in numerous instances around the globe where if there's a large health event, that the population in those countries very much start to question the effectiveness of certain parts of their government.

Disruption of trade of course can also be an important effect of intentional adulteration. We grow

significant amounts of food. We export that. We buy that. We trade that. If there's a large-scale intentional event, of course trade will be disrupted. So that's kind of the setting for why we take protections against intentional adulteration very seriously.

So moving into the background slides for the Intentional Adulteration Rule from the Food Safety Modernization Act, or FSMA, there were seven foundational rules. This is the last rule that was finalized. At a very high level what this rule does is establishes requirements to prevent or significantly minimize acts intended to cause wide scale public health harm, such as a terrorism attack on the food supply. And I'll talk about what we mean by wide scale public health harm later in the day.

We get a lot of folks asking us questions: "Okay, I got it. Do I have to do anything? Am I covered by the rule?" Basically, you are covered if you are required to register with the FDA under the Federal Food Drug and Cosmetic Act, Section 415. Another way to say that is that if you are a facility that manufactures, processes, packs or holds human food, you are covered by the rule.

As with the other rules, if you are covered, there are exempted activities. And Julia, when she gets up here in a few minutes, she'll highlight these -- the details of some of these exemptions.

Requirements of the rule. The main requirement of the rule is the writing and implementing of a food defense plan that has five sub-requirements of that rule. Vulnerability assessments are when facilities identify their most vulnerable points. Mitigation strategies are when facilities identify and implement protective measures to reduce or minimize those vulnerabilities. Monitoring, corrective actions and verification are a combination of requirements that ensure those mitigation strategies are doing what they are supposed to do.

There are reanalysis requirements, five

triggers there. Triggers for certain parts of the food defense plan or the entirety of the plan. Training requirements and records requirements.

So today what we are going to focus on are the vulnerability assessment component, the mitigation strategies, the monitoring, and the training.

Compliance dates: let's start with the bottom bullet first. So large businesses that are not exempt have 3 years from the finalization of the rule, effective date of the rule to comply. So that compliance date is coming up, July 26th of this year. Small businesses have an additional year to fully comply. And very small businesses have 2 years in addition to comply with a modified minor documentary requirement, which Julia will talk about it in her slides.

Now, moving into guidance and kind of a high-level overview of guidance before getting into some of the details. Dr. Mayne noted multiple times we've had substantial interaction with stakeholders. And this predates FSMA. Under the voluntary program, we've worked together very well to protect the food system. Lots of history of positive food defense collaboration. Have learned a lot from that collaboration. We've also had significant dialog with stakeholders since the publication of the final rule.

As Dr. Mayne mentioned, we've heard a number of concerns or uncertainties, with the biggest one being a theme of concerns related to compliance cost for the rule requirements. Dr. Mayne hit on some of these as well. But we've heard concerns about cost from multiple perspectives, including the need for more flexibility in order to lower cost, including the ability to count some existing measures to lower costs. We've also had some very detailed industry-generated estimates for compliance. And then we've also heard some concerns about potential paperwork burden.

So I'll echo Dr. Mayne's important talking points here about we've taken this dialog very

seriously and we've incorporated that feedback from stakeholders into not only the final rule, also the draft guidance and some of the tools and trainings that we're putting out.

I think the most important thing that we can say before getting into the details is that the agency is committed to making the implementation for industry as practical and flexible as possible coupled with our very important goal to achieving public health protection.

Public health protection also incorporates the scenario of highest risk or highest vulnerability for intentional adulteration. And again, as Dr. Mayne mentioned, that's protection against the inside attacker.

The revised draft guidance has also -- we've taken the opportunity to include some addressing of misconceptions that we've heard, and we'll note some of these as we go through the remainder of the day. One of the most important that we've heard -- and this has been a theme that we've heard as we finalized the rule and have drafted the guidance that's currently public -- is that "not one size fits all". And we absolutely agree. We've built what we think is significant flexibility into the requirements and we expound upon that flexibility in the draft guidance.

A note here on food safety and food defense when implementing requirements for both. We've heard that some stakeholders in industry have concerns that implementing food defense requirements conflict in a negative way with worker safety and food safety. So the previous commissioner, Dr. Gottlieb, wrote in a blog and we also have a statement in the revised draft guidance that when it comes to that, food safety and worker safety take the priority.

However, we feel that flexibility for the intentional adulteration rule is to the point, to the degree that there should not be conflict when implementing intentional adulteration rule requirements with food safety requirements and of

course keeping workers safe.

So these next few slides are just highlights of some examples of what we've heard from stakeholders and how we've incorporated those into not only the final rule, but the revised draft guidance.

So let's start with the vulnerability assessment requirement and the revised draft guidance chapter first. There are a number of approaches that industry can take to conduct a vulnerability assessment. We've written three in the draft guidance, and you'll hear a lot about these three today: key activity types, three fundamental elements, and the hybrid approach.

Beyond that, you'll hear Jon talk about -- in the three fundamental elements, element one is where we require industry to estimate public health impact of an intentional adulteration event. In that element, there are three different approaches that industry can choose from to estimate public health impact.

Also, for the three fundamental elements, there are some scoring flexibilities, which we'll give you details about that. There's writing explanations requirements, which include a lot of flexibility for industry. We've heard that some of the revised draft guidance has significant amount of detail. Stakeholders are concerned about that level of detail. You have the flexibility to include that or much less. And we've incorporated a number of statements in the guidance that do address that.

Beyond the vulnerability assessment requirement, there's examples of flexibility in the other requirements, mitigation strategies, which Colin will talk about. This, in my mind, is the requirement that is most flexible for industry. Industry can choose which mitigation strategies--or combination of strategies--work best for them at their vulnerable points.

Colin will also talk about phrases that industry has raised to us about facility-wide security

measures and existing measures and how there's degrees of flexibility in those two things.

For food defense monitoring, I'll talk about the potential to incorporate monitoring responsibilities into existing worker responsibilities. There's the potential to leverage food safety activities when you're conducting your food defense monitoring activities. And we'll talk about exception records. Jon will also talk about the flexibility in the education, training or experience requirements as well.

Beyond flexibility, because we have talked with our stakeholders about more than flexibility, are other important issues. One important one that they've raised is uncertainty related to the inside attacker. This is, as Dr. Mayne noted, a new area for a lot of our stakeholders. Folks that brought to the table uncertainties in how to appropriately consider the possibility of an inside attacker when they're conducting their vulnerability assessment. They've also brought concerns about how to protect against this type of intentional adulteration when they're identifying and implementing mitigation strategies. So there's information in the revised draft guidance about both of those. Colin and Jon will talk about those.

I've touched on this briefly already, concerns about very costly mitigation strategies and costly monitoring activities. A few examples of how we've addressed this in the guidance. We do not expect facilities to completely reengineer their entire facilities as a mitigation strategy. We do not expect the hiring of additional employees for the sole purpose of monitoring other employees for compliance with the intentional adulteration rule. You can build monitoring responsibilities into an existing employee's existing responsibilities. And then I'll talk more about exception records.

So let's move into the meat and potatoes of the guidance. So when the guidance is all public what

it will consist of is 10 chapters with four appendices, and we're publishing that in three different installments.

We published the first installment in June of last year, the second installment in March of this year. And what we've done, because these chapters are tightly related, intricately related, we've combined the first installment with the second installment, and that's what we call the revised draft guidance.

An important piece to note here: we changed very little information from the first installment when we incorporated it into the second installment. The information that was changed is highlighted by brackets and/or footnotes.

Another thing that's important to note before we get into the details of the chapters is, we have written these chapters again with stakeholder input and incorporating that feedback when and where appropriate through the lens of compliance being risk-based, practical and flexible.

So this is a bit difficult to read, but for those that will be downloading these slides afterwards, you can kind of blow this up. This is the table of contents for -- when all of the guidance will be public. There are some superscripts 1, 2 and 3. Those indicate when these chapters were installed -- published, which installment was published.

So I'll highlight those three installments for you. The first installment, again, this is published in June of last year. Some background information. The key activity type method in the vulnerability assessment chapter, chapter 2. Chapter 3, mitigation strategies. Chapter 4, food defense monitoring. And then we start an appendix or templates for your -- putting together your food defense plan there for your voluntary use.

Second installment. This is the new information that was published in March of this year. We've completed the vulnerability assessment chapter. We've added two more options that Jon and I will talk

about later today.

We've also included a chapter on education, training or experience requirements. We've completed appendix 1, that food defense template chapter. And we added a new appendix, appendix 4. This appendix has in-depth examples of how to conduct a vulnerability assessment using the three elements and an example on how to conduct a vulnerability assessment using the hybrid approach.

Again, just a quick note on appendix 4. We have heard some uncertainty, some questioning about the details in that appendix. So we have taken the approach that we're outlining our thinking from how you go from step 1 to step Z so you can see each of those steps. Again, you have lots of flexibility in what you include in your written explanation, in your written food defense plan. So we do ask that you pay particular attention to some of the footnotes in the tables in the appendix. There's lots of flexibility in those small footnotes there.

The third installment which we are working on, which is not yet public, will consist of the remainder of the guidance, that's food defense corrective actions, verification, reanalysis, records. And there will be two appendices: one dealing with content of FDA's mitigation strategies database, and the other dealing with information for very small and small businesses.

So with that, I'm going to hand it over to Julia to start to talk about some of the first guidance chapters.

MS. GUENTHER: Good morning, everyone. So I get the pleasure of starting you off with the first chapter of guidance, which is the introduction chapter. As you can imagine, it's kind of the high overview, key points of what we will cover in the guidance. There's a section on the purpose of guidance and outlines the different components within the IA Rule that we will cover in the different chapters of the guidance; the purpose, as Ryan had

mentioned, the scope of the rule as well as compliance dates that are included in the rule.

In addition, there is a list of glossaries of terms and abbreviations that we use throughout the guidance. That list includes both the definitions that are in the CFR at 121.3, as well as other terms that we use throughout the guidance. So we thought that it was important enough to list them in the introduction section. Some of those examples are the food defense qualified individuals, the three fundamental elements, and the key activity types. And then there's a list of acronyms that we use throughout the guidance.

Lastly, in the introduction section, we go through the list of exemptions. And the exemptions include an exemption for very small business. And there's a full definition of what a very small business is, but in general it is a business that has less than $10 million in annual sales for human food. And again, there's a full definition of very small business in the CFR as well as in guidance. And we will be issuing an appendix that will help businesses calculate whether they are a very small business for the purposes of the IA Rule.

Very small businesses are exempt from the full requirements of the IA Rule, except they do have the requirement to maintain and keep records that prove that they are exempt, that they are a very small business. And upon request by the FDA, those companies are required to provide that documentation to prove their status.

There's some activities that are exempt from the IA Rule, and that includes the holding of food, except for holding of food in liquid storage tanks; packing, repacking, labeling or relabeling of food or the container that directly contacts the food remains intact; activities or farm that are subject to the FSMA produce safety rule; manufacturing, processing, packing or holding of animal foods; alcoholic beverages at certain facilities.

And this last exemption is very nuanced and there's a full appendix that's a reference to the final rule that talks about this last exemption, that is on farm manufacturing, processing, packing or holding by a small or very small business of eggs in shell other than racks or certain types of game meats if such activities are the only activities conducted by the business subject to Section 418.

Of course that's a mouthful, but again it's very nuanced. And if you believe that you might fall under this exemption, I would suggest that you go back to the preamble of the final rule and read through the write up there as well as the appendix that is a reference to the final rule.

So that was the introduction section or chapter. And in chapter 1, we introduce the food defense plan. This is the first time I think we've described what we mean by a food defense plan. That is a set of written documents that is based on food defense principles and incorporates a vulnerability assessment, includes mitigation strategies, and delineates food defense monitoring, corrective actions and verification procedures to be followed.

A food defense plan, as Ryan outlined earlier, must include these components, and that's the VA, mitigation strategies and explanations, food defense monitoring, corrective actions and verification procedures. And the owner, operator, agent in-charge of the facility must sign the food defense plan upon initial completion and any reanalysis of the food defense plan.

In section B of chapter 1, we talk about individuals that might be helpful to include in your food defense team to help develop the food defense plan. There are special qualifications for food defense qualified individuals. These are the individuals that must do or oversee the development of a food defense plan, conduct a vulnerability assessment, identify and explain mitigation strategies and perform the reanalysis. So the food defense

qualified individuals must do or oversee those four activities.

Other than that, there is flexibility as to who you might want to include in the food defense team. In the guidance, we provide some suggestions such as personnel from your site security, maintenance; some food production folks, including equipment experts who might have detailed knowledge of how a piece of equipment works; sanitation personnel; your food safety QA/QC folks; individuals from engineering, purchasing; your human resources folks that work on hiring and firing of employees; and others that might contribute to developing the food defense plan.

As Ryan mentioned, there is great flexibility in the Food Defense Plan. We do not have a standardized or a required format for the food defense plan. As long as the required components of the food defense plan are in the document or documents, FDA does not prescribe a specific format or organization structure for the food defense plan. We do, however, provide sample worksheets in appendix 1 to help you get started on how you might want to organize your food defense plan.

As Ryan mentioned, later today I'll be walking you through the food defense plan builder version 2. And that, again, is a voluntary tool. But it basically helps industry with organizing the content within their food defense plan.

Another section that we talk about in chapter 1 is how often you might need to change the food defense plan, modify the food defense plan. And a full discussion of the reanalysis requirements will be in chapter 7 that's forthcoming in installment 3. And again, reanalysis is required every 3 years at a minimum. But there are additional triggers and circumstances under which a food defense plan needs to be reanalyzed.

And lastly, in this chapter, we talk about maintaining the food defense plan. The food defense

plan itself is a record and therefore is subject to the records requirements of the IA Rule. The owner, operator or agent in-charge of the facility must sign the food defense plan upon initial completion and upon any reanalysis.

And lastly, in this chapter, we talk briefly about the sensitive nature of the food defense plan. As you can imagine, with the vulnerability assessment information as well as mitigations and the other required components of the food defense plan in a document, we understand and suggest that you -- that facilities adequately protect the food defense plan, as well as any associated records and documents. And more information about how to protect that information and why you might want to protect that information will be forthcoming in chapter 9 of the guidance in the records chapter.

So moving on to chapter 2. This is the lengthiest chapter within our guidance. And that is the vulnerability assessments to identify significant vulnerability and actionable process steps. So I'm just going to go through kind of the overview and touch on key activity types, and then I'll pass it on to CAPT Woody to go through the individual sections of the vulnerability assessment chapter.

We talk about the purpose and scope of the vulnerability assessment; that is to assess each point, step or procedure to identify those points at highest risk or those with significant vulnerabilities. And those are the actionable process steps. So those are the steps that you would then need to implement -- identify and implement mitigation strategies for monitoring, et cetera.

The scope of the vulnerability assessment includes only those points, steps or procedures that are related to manufacturing, processing, packing or holding of food. So the non-food related points, steps or procedures such as your HR procedures, mail handling procedures, utilities and other processing aids that do not come in contact with the food or do

not end up in the food do not need to be included in your vulnerability assessment.

Some folks will note that, you know, if they start with the same process flow that they have for HACCP or for their food safety plan, that the actual steps that you need to assess in a vulnerability assessment for the IA Rule might a subset of those. So looking at your full HACCP flow diagram, you might not need to assess every single point, step or procedure in that HACCP flow diagram for the purposes of the vulnerability assessment.

In the guidance, we do talk about grouping of products. And the example that we use is, if you're producing yogurt in multiple flavors with fruit add-ins, for example, strawberry, raspberry or blueberry, you don't necessarily need to conduct a full vulnerability assessment for every single one of those lines. What you can do is group those foods into one vulnerability assessment and call that yogurt with fruit add-ins. Of course that is not the only example of how you might group foods, but that's just one that we provide in the guidance to kind of explain that concept of grouping.

The vulnerability assessment requirement requires that for each point, step or procedure a facility must consider at a minimum these three fundamental elements: the potential public health impact, degree of physical access to the product, ability of an attacker to successfully contaminate the product. And that's elements 1, 2, and 3 that you'll hear about later.

The VA requirements also include the consideration of an inside attacker, and that consideration needs to be taken into account when you're assessing all three elements. It's not a fourth element. It's when you're assessing all three of the elements you must consider an inside attacker. And lastly, there has to be a written explanation at each point, step or procedure for why that step is or is not an actionable process step.

Similar to the food safety plan and the PC guidance, we include some preliminary steps that a facility might want to take before conducting a vulnerability assessment. These are not required. But they are just some suggestions of how we might start if we were conducting a vulnerability assessment at a facility.

The first step is to assemble a food defense team. As I mentioned earlier, there is great flexibility here. Other than the food defense qualified individual requirement, you can include anybody you would like at your company. Or if you choose to include outsiders like a consultant or a trade association assistant, they may be a part of your food defense team to help you with some of the technical expertise.

The second preliminary step is to describe the product. This does not have to be lengthy at all. Again, this is a voluntary step here and it's really just to help you kind of identify what product you're assessing. Especially, if you're grouping products, it's good to know in your food defense plan, "well, I'm doing this vulnerability assessment for these groups of products and that includes X, Y and Z." So that you make sure to cover all the products that your facility makes.

We recommend that you develop or use an existing process flow diagram. As I mentioned, you can start from your HACCP plan -- or flow diagram if you have one, or the flow diagram that you've already created for your food safety plan. And again, because of the scope of the vulnerability assessment, not every single point, step or procedure in a HACCP or a food safety flow diagram may need to be assessed for food defense.

And the last preliminary step is the describing of process steps. Again, this is completely voluntary and there's great flexibility here. It really is just suggestions for identifying and writing down "at this process step, this is what

happens." It's a short description that might include things like "the food here is manually handled" or "this is a completely enclosed system" -- "it's a high traffic area" or "it's out in the corner of the facility in a dark room or a dark area."

So this is just descriptive information about the process step that would help when you're conducting the vulnerability assessment and when you're doing the assessment of the three elements or the key activity types. And also it will help greatly when you're identifying mitigation strategies for that process step. Again, this does not need to be lengthy at all. It's just a suggestion that you jotted down some information about that process step and the characteristics of that process step.

Ryan mentioned the different methods that we have included in guidance for conducting a vulnerability assessment. There's flexibility here, in that you can choose the method that makes sense for your facility or your company based on considerations such as time and resources available and the level of specificity that you like to include in your vulnerability assessment.

There's a key activity types approach, which I'll touch on, the three fundamental elements and then the hybrid approach, which is just a combination of the key activity types and the three fundamental elements.

So section C of chapter 2 talks about the key activity type method. This is the -- probably the most high level, quickest method to conduct a vulnerability assessment. And the benefit is that -- companies have found that they need fewer resources and fewer experts for food defense in order to conduct a vulnerability assessment using the key activity types method.

There are four key activity types, and they are the general categories of manufacturing and processing that we have identified as most vulnerable regardless of the commodity that is being assessed.

And how we came up with those four activity types is over the past 15 years, we have conducted more than 50 vulnerability assessments in collaboration with our government partners, academia and with great support and help from the food industry.

In looking at the vulnerability assessments that we've conducted, we did a further analysis of those vulnerability assessments and we found that regardless of the food that's being assessed, we found that there were process steps that generally ranked high and being the most vulnerable. And so we saw consistently that these similar process steps were always ranking high in our vulnerability assessments. And when we looked at those process steps, we were able to come up with these four general categories under which those process steps fell under. And so, therefore, those were the four key activity types that we came up with. Those here are the bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, and mixing and similar activities.

Some of the kind of common threads between all four of these key activity types is that in general the contaminant if added at one of these steps can be uniformly mixed. And also, many of these process steps that fall under these key activity types include a large volume of food.

So when identifying the actionable process steps using the key activity types method, you would assess each point, step or procedure to determine whether they fit within a key activity type.

The example that we use in guidance I believe is for peanut butter. And this is an excerpt from that example. Part of the flow diagram here, where we show that steps 11 and 10 here, mixing all ingredients and grinding, would fall under the key activity type of mixing and similar activities.

And so what you would do is take your flow diagram of the food that you are assessing and look at those points, steps or procedures that, you know,

involved -- that are within the scope of the vulnerability assessment and map them to the key activity types. Does this map with at least one of the four key activity types? And if it is, then it's an actionable process step. If it's not, you can check that off your list and simply write in your explanation "this process step does not fit within one of the four activity types," and then move on.

So that's the benefit of the key activity types method, is that it is quicker and easier because all you're doing is looking at all your process steps and mapping them to one of these four key activity types.

And again, we'll go through later kind of the hybrid approach, where you start with the key activity types and then continue further analysis of the three fundamental elements. And we'll talk about why you might want to do that.

And now, I'm going to pass this on to CAPT Jon Woody, who will go through the vulnerability assessment using the three fundamental elements. I believe he and Ryan are going to tag team this hefty, hefty chapter.

CAPT WOODY: All right. Well, good morning, everybody. Before I just jump into the three fundamental elements, there are one or two points I wanted to make, because we're about to transition into some fairly weedy details. And so I just wanted to kind of provide a little framework for this particular discussion.

And so the background is that I've been working on food defense vulnerability assessments here at FDA for the past 13 years. I led many of the assessments that Julia referenced, and it was a great opportunity to interact with the food industry in particular.

And one of the things I learned by working industry is that the vulnerability assessment is really what I call a means to an end. The process is meant to get you somewhere. It is a tool to help you

make a decision. And that decision is: for the points, steps and procedures that I'm evaluating, processing steps as I'll sometimes refer to them, do I have a significant vulnerability or do I not -- do I have a significant vulnerability or do I not? Where I have a significant vulnerability, that of course is a defined term in the IA rule. There I have an actionable process step. There I must identify and implement mitigation strategies, manage them and keep records. Where I don't, I don't, period.

And sometimes I bring that up -- it might seem very apparent to all of you in this room and on the phone, but it's amazing when we start to get into the details of these things, sometimes we get lost, we lost sight of the bigger picture that we're trying to get somewhere.

And with all due respect to folks who love doing vulnerability assessments, most of the people that I interact with are trying to understand how to get to that point most efficiently. Because you could spend the rest of your career conducting vulnerability assessments. My guess is most in industry, here and on the phone don't have the time or the resources to do that. And so what it's meant to do is help you to prioritize: where do I focus my resources as it relates to vulnerabilities in my operation?

That's the first thing I would say. The second thing is relative to the requirements of the vulnerability assessment -- and both Ryan and Julia kind of touched on those requirements, the elements, the considerations of an insider, explaining your decisions and keeping records.

But we are not telling you what vulnerability assessment method to use. That is up to you as a company to make those kinds of determinations. What we have provided in the guidance are some options. Julia talked about one of those: the key activity type approach.

The key activity type approach, FDA has come out and said it's an appropriate method 1 for

conducting a vulnerability assessment because those results are derived from vulnerability assessments that we've done in collaboration with industry, those assessments included the three elements and consideration of an insider. Therefore, it is an appropriate method.

And as Julia highlighted, it is a very simple, straightforward, quick, clean method -- it is meant to be. But I think of these methods as existing along a spectrum. That's at one end of the spectrum, key activity types. As I said, quick, clean, efficient. There are pros and cons to that. One of -- those are some of the pros. The con, the drawback is it does not allow the level of tailoring and specificity that some facilities would want. Where you have a key activity type, it maps through a process step, there I have an actionable process step, period, in its simplest and most concise form.

So that's at one end of the spectrum, okay. At the other end of that spectrum is the company that may say, "You know what? I'm not going to really focus on or use the key activity types. We want to, what I would call, start our vulnerability assessments from scratch. We want to use the three elements, we want to consider the actions of an insider, but we're not going to reference the key activity types. We believe that's going to provide us with the best level of specificity." And you know what? That's perfectly allowable by the rule.

Some companies have even already said, "You know what? We don't think the requirement goes far enough. We want to go above and beyond. We want to bring in other additional factors to help in our analysis." That's also allowable provided it doesn't fundamentally conflict with the information and requirements of the rule. Okay.

So those are the bounds of the spectrum. Somewhere in the middle, which we'll talk about later, is this hybrid approach, which draws some of the strengths of the key activity types in terms of its

efficiency, also draw some of the strengths of the three elements in terms of the ability to tailor an assessment. Okay.

So you as a company, by all means talk to your neighbors in industry, see what they're doing, see what best practices you can glean and garner from others in industry, absolutely. But at the end of that process and at the end of that fact-finding, you have to choose where do I want to be on that spectrum, what method do I want to use to help me get to that goal of identifying and distinguishing where I have my significant vulnerabilities. Okay.

So that's my little soap box. I just wanted to provide a little context before we jump into some fairly weedy details. Okay. This is what I was afraid of. I asked them five times before I came up "does the clicker work?" It works for somebody who knows how to use the clicker. There we go.

Okay. So the three fundamental elements that are -- you'll probably hear me refer to them as the three elements -- are the -- what we believe are the three most important, most critical factors to look at when conducting a vulnerability assessment. Why? Again, going back to all this work we've done with industry for 15-plus years under Homeland Security Presidential Directive 9, which Julia touched on, where FDA and USDA were directed to conduct vulnerability assessments and partnership with the food industry really with three overarching objectives: to identify vulnerabilities, identify potential mitigation strategies, and to identify research needs.

And through those many years of doing that, both FDA and USDA with kind of a consortium of federal agencies decided on using a method called CARVER + Shock. CARVER + Shock has seven attributes. I'm not going to go into what those attributes are. However, what we found through the process of using that methodology and the feedback we got from industry was, out of those seven attributes, three consistently

drove the results. Three of those seven attributes consistently drove the results. And those three attributes are: criticality, accessibility and vulnerability.

And if you look now at our three elements, guess where their origin comes from? You would say CARVER + Shock assessment, and you would be correct. So element 1, potential public health impact, maps to criticality. Of course we've refined it through the years. We've refined it further for the rule. Element 2, degree of physical access, maps to the attribute of accessibility. And element 3 maps to the attribute of vulnerability. Okay.

So that's the derivation, the genesis and the origin of the three elements that you find in the IA rule. So in other words, this has been field tested over the course of the last 15 years. We didn't just sit upstairs and pull them out and say, "Well, let's require industry to evaluate these things." They've been field tested for a number of years and really homed in and refined.

Okay. Before I get into element 1, how to calculate potential public health impact, there are two other factors that we talk about in the context to the rule. The first is a requirement, it's the requirement to consider the actions of an insider. And the second is this concept of inherent characteristics. And so I want to address each of these individually.

Okay. The first is related to an inside attacker. And I guess I want to make it clear first off that these are not individual factors that we are asking a company to decide whether or not they're real and true in their facility. These are assumptions that we have laid out. They've been assumptions for years and years in our vulnerability assessments specifically because the partnership we've had with the intelligence community and they're informing this discussion and saying the highest risk is associated with an inside attacker.

So these are four assumptions that we lay out in the guidance that says, "as it relates to an inside attacker, this is what we mean." And those four assumptions are: that the individual would have legitimate access to the facility, so they are an employee, a contractor or a visitor, authorized visitor. Anyone that I've allowed into my facility is someone who has legitimate access.

Secondly, they have a basic understanding of the facility operations. They may be able to identify a piece of equipment. They may not have intricate knowledge of the process, but basic knowledge. Third, they have the ability to acquire and deploy a highly lethal agent that's capable of withstanding the food production process. And we're not going to spend a lot of time talking about contaminants here today. But certainly there is a number of those that would fit that characteristic. And finally, they have the intent to cause wide scale public health harm. And we'll come back and revisit this concept of wide scale public health on.

So these are assumptions we lay out. And what you will find as you conduct a vulnerability assessment is that level of -- the determination as to -- the degree of access to the food that someone may have and their ability to contaminate the product may very well vary from process step to process step. For example, what you see at a receiving bay and what you see at a mixer may not be the same in terms of access, element 2, and the ability to successfully contaminate the product. That's why it's incorporated within the concepts of the elements. Okay.

The second of these is this concept of inherent characteristics. And this is a concept that has been a constant of our vulnerability assessments once again and it's looking at those conditions, activities, practices or characteristics that are integral to the operation of the point, step or procedure. "Integral to the operation of," okay, that's kind of the key concept.

The question that we like to say is: absent the existence of that inherent characteristic, would that process step function -- absent the existence of that inherent characteristic, would the process step function? The guidance -- we'll go through a couple of examples here. The guidance plays out a lot of different examples about what we mean by an inherent characteristic. So at the end of all this, it's something that's not easily altered, not easily changed. Okay.

So let's go through a couple of examples. Number 1, type and nature of equipment, is it enclosed. This really tracks with element 2, degree of access. Do you have an enclosed system, if it's a retort or a pasteurizer? If product is being transferred from one point to the next in an enclosed system, that severely lowers the ability to access that product, does it not? And so that is an inherent characteristic, just the way the system is designed.

Is it pressurized? Do you have a pressurized vessel? So if somebody tries to access that, they could experience bodily harm. They could have a real mess on their hands in terms of product if they're even able to access it because of the pressurization, inherent to the nature of the equipment.

The nature of the food itself. It's not specifically mentioned on this slide. Is it a liquid or a food? You'll notice from the key activity types that Julia listed that we made a distinction. We sort of highlighted liquid, right? So a distinction between a liquid or a solid food is also inherent to the process.

High rate of speed. The example we like to use here is conveyers. I like to talk about conveyers. Well, it's wide open sometimes in facilities. You can get access to that product, yes. But often times what we have found: the product is moving at a rapid rate of speed, so the ability to contaminate the product may be unlikely or impossible. And it may move through as a slug, you don't have a

mix going through. So conveyers is an area that often times you see product moving at a high rate of speed.

And I've already sort of touched on this, but product that's mixed thoroughly -- it's just make sense, you want something to be uniformly distributed throughout the product.

Worker safety mechanisms that are built in. If there is a worker safety mechanism that's built in and the piece of equipment automatically shuts down, that's inherent to the system, it's inherent to that piece of equipment.

This doesn't just apply to equipment. A lot of these highlight that, but there's also scenarios around observation, level of observation. In the guidance, we talk about a number of people working in a process step. I think the example is they're working sort of assembly line style, shoulder to shoulder or across from one another at a step. That's inherent. It's necessary for the function of that step. That's different than "we're going to station the senior person at a step." It's a little bit different animal there and the guidance lays that out. Okay. What we're talking about here is required presence. The step simply wouldn't function if there's not several people working there. Okay.

So these are some examples of inherent characteristics that we outline in the guidance. Again, a lot of good information there with examples and so on about that, as well as some examples of non-inherent characteristics.

Okay. So with that -- so those are kind of the underlying principles to stepping into the vulnerability assessment. So let's transition now and talk about element 1. Element 1 -- I will tell you there's a little bit of math involved in element 1, and so we'll walk through some of this and give you a sense of how this functions.

The idea here is that for all of these elements, you're assigning a score -- and you'll see a table here in a moment -- you're assigning a score at

each point, step or procedure. And when we talk about estimating public health impact, there are three approaches for calculating that that we lay out.

Basically, we're looking at an approach where we're taking into account volume of food at risk. There's a second approach that talks about representative contaminant. And then a contaminant specific approach.

You do not have to use all of these. You do not have to use any of these. These are suggested approaches for getting at estimating potential public health impact, acute illnesses and mortality specifically. Okay. Or in the case of volume of food at risk, as you'll see in a moment, a proxy for acute illnesses and mortality. You don't have to do all of these approaches. Again, this is a buffet that you can choose from. Okay. So this is another way to build in that buzzword of flexibility that we seem to be using today.

For each of the three elements, there is a table associated with it in the guidance. I will once again point out these tables have as their origin CARVER + Shock. Okay. We did not miscount on the table. You see 10, 8, 5, 3, 1 -- "FDA can't account." No. It's an effort to remember the goal, identify significant vulnerabilities. That gap is to help industry more clearly see where that delineator is. That's why you have 10, 8, 5, 3, 1 in case anybody was wondering.

So for each of the elements, you will see an associated score that goes with it. This is the score in guidance for table 1. Again, you don't have to use this. This is an example that you may choose to use. Okay.

Basically, what the table lays out, as you see in each of the scores, potential public health impact, as I said, acute illnesses, deaths or both. Or as you'll see in a moment in the case of volume of food at risk, a proxy, servings at risk, if you don't want to delve into deaths -- estimating death numbers

or acute illnesses. Okay.

So let's talk about volume of food at risk first. This is a way to -- and by the way, what you see at the bottom, worksheet 1D, is the worksheet from the guidance associated with this that lays out an example of how to do this. I'll briefly walk you through this. So basically in volume of food at risk, you're using servings as a proxy for public health impact, otherwise calculated through acute illness or mortality.

The guidance lays out some examples about batch processes and making some assumptions about a batching operation versus a continuous flow operation. I won't get into the weeds of that. But there's some good examples in guidance that touch on that.

Basically, at the bottom of the worksheet what you have is the process step, the batch size, the amount of product either in the ingredient or the final serving depending on the product that you're manufacturing, a simple division calculation. And then you'll see an associated score from table 1.

One of the benefits of the volume of food at risk method that we've seen with -- not that we've specifically use this method in our vulnerability assessments. But as we started talking to industry about batch sizes and serving sizes, this is information that they just know. They're in operations -- they just know this information because they're dealing with it every day. So it's not information that's well outside their wheelhouse, so to speak, because it's often information that they have fairly readily available to them.

So in the volume of food at risk method, with the incredibly small worksheet that hopefully somebody can see -- it's the same worksheet I just showed from the last slide. Basically, you do a calculation again based on batch size looking at either amount of ingredient or product and then you calculate the servings per batch. And then it's a simple correlation over to the table that we showed you --

that I just showed you that's available in guidance. Okay. So it's just a match at that point.

So a little bit of math involved clearly. But once you get that, really the decision is made for you in a sense because it simply aligns to the associated score on the table. Okay. So that's volume of food at risk.

You're going to see this bullet point for each of the approaches I'm going to walk through. It's beneficial to include a rationale for how you came up with your calculation and so on. It's not required. The requirement is for an explanation associated with whether or not you have an actionable process step. But you may find that this is beneficial to keep some notes along the way as to the thinking and the rationale.

This is by far the simplest approach. As I said, it draws often from information that's readily available to the facility. But it may not provide the level of specificity that some of the other approaches do. Okay. So again, we're weighing pros and cons.

Okay. Let's talk now about the second approach, which is the representative contaminant approach. I will tell you in our vulnerability assessments, often through the years -- we've often settled on this concept of a representative contaminant for a number of reasons. The biggest reason is that when you start talking about someone acquiring and introducing a contaminant, a lethal contaminant into the food system, the universe of potential contaminants is much greater than what we see on the food safety side. And so trying to catalog the potential biological, chemical, radiological contaminants can be rather daunting.

And so through the years, we've often used a representative contaminant concept in our own vulnerability assessments. And so this approach is meant to provide more specificity than the volume of food at risk, but not go as far as the next method, which I'll talk about, which is contaminant specific.

The representative contaminant is not one contaminant. It is work that we've done with federal partners to identify real contaminants, these are all real contaminants. We've worked with them to identify a lethal dose value for that. So the lethal dose LD50 is the amount of contaminant sufficient to kill 50% of a given population. It's a very established scientific concept. So we peg the representative contaminant to LD50. And I'll show you what that value is here in a moment.

The benefits of this are -- there's a lot of talk about sensitivity of information and records associated with that, so we're not naming agents in this approach. You're using representative information, contaminant information provided by FDA in partnership with the work we've done with federal agencies. And you essentially use, as you'll see in a moment, the LD50 value that's been provided. You use a mortality rate. And you calculate then estimated number of deaths. The only focus is on number of deaths.

When identifying this representative contaminant concept, we very much factored in those assumptions for an insider. Okay. That this is a highly lethal contaminant that could survive the production process. Okay. And I'll talk about some strengths and weaknesses to that line of thinking.

Back to our handy-dandy worksheet. Again, this is also -- this is worksheet 1E in the guidance. It starts with the same columns that you saw for volume of food at risk. What it adds are essentially a couple of columns associated with mortality rate. Again, we'll peg that at 50%. That's a constant. You don't have to make that decision if you use this approach. And you'll see in column I, the representative contaminant dose is pegged at 40 milligrams per serving. Okay. And so you do the calculation in a similar fashion and you generate the number of potential deaths and you -- that goes -- corresponds to the score on the table that I showed

you a moment ago.

I will point out -- you'll notice on the right-hand side of this column, there's these element 3 calculations. Ryan will go into this more when he talks about element 3. One of the distinct value -- one of the distinct attributes of using the representative contaminant approach is it provides a level of specificity around the amount of contaminant that would be needed at the particular process step that you're evaluating. Volume of food at risk doesn't get you there. This does.

So when we're evaluating a step and looking at element 3, "can someone successfully introduce a gram," are we talking about a gram of contaminant or 10 pounds of contaminant -- that may make a difference in the evaluation you do for element 3. So there's I think a pretty valuable piece of information that is garnered by using the representative contaminant approach without going to the extent of contaminant specific, which I'll talk to you about in a moment.

I feel like I'm trying to sell you an approach here. I'm really not. I'm just trying to lay out the pros and cons of this, okay. So that's one of the benefits of that.

And finally, the third approach that you could choose from is that contaminant specific approach. A great deal of specificity to be gained here, but you have to understand what you're getting into. And we say in the guidance something to the effect of "really weigh the pros and cons before you just jump in to a contaminant specific approach." Maybe representative contaminant will suit your needs, maybe key activity types alone, maybe a hybrid approach. Really take a look and really carefully weigh the pros and cons to this.

Yes, you get a great deal of specificity. One of the things representative contaminant approach does not afford you, which this would, if you believe you have steps in your operation that could neutralize or eliminate perhaps a class of contaminants, you're

not afforded that level of specificity by using the representative contaminant. So a facility just needs to decide if that trade off and the extra time involved in theoretically listing out multiple chemical, biological and radiological contaminants and doing the requisite research to understand that information if that's worth, you know, the trade off there.

We would fully expect that the contaminants that will be chosen would at least have the level of toxicity as the representative contaminant. In other words, you can't just choose -- let's be honest, you can't just choose salmonella and say, "Ah, I got my biological contaminant." No, it's not what we're talking about here.

And the onus would be on the facility to have the expertise to do this. FDA is not going to be publishing a list of contaminants. I think we would all agree that's not a great idea. So the facility would be on the hook to do the research, to have the expertise to be able to do this.

And I would also add, getting back to safeguarding information, this is now the most concerning of this approach -- the approaches that we've outlined, right? Because now you have -- you've identified specific contaminants; you've lined those contaminants up to specific process steps in your operation. Again, companies just need to weigh the pros and cons of doing that.

Basically, in terms of the calculation, it's nearly identical to what I just showed for representative contaminant. But in this case, you would be listing out multiple potential chemical, biological and radiological contaminants for each point, step or procedure -- not just a global one, each point, step or procedure you're doing this evaluation.

Okay. I think I've touched on some of the points about this. The first sub-sub-bullet here "use the largest public health impact score." So if you're

looking at a range of, say, chemical contaminants, you would settle on the score that generates the highest public health impact. That's the recommendation in the guidance.

And of course, again, a great deal of specificity here, but just some pros and cons to weigh. Again, more calculations in volume of food at risk, a lot more specificity, quite honestly potentially a lot more work to be done here as well.

One of the things I didn't really touch on before is a number of the contaminants that we're talking about are a little bit more on the exotic side I think as the guidance refers to them. And so there are some data gaps associated with them. There's information that's not in the public literature. So those data gaps can be quite problematic. The threat landscape is not stagnant. It changes, it evolves. And so an individual facility or a company's ability to stay up-to-date on individual contaminants may be problematic as well. So again, carefully weigh pros and cons before just diving into the deep end here.

My last slide before I turn it over to Dr. Newkirk. There are two additional factors mentioned in the guidance that, again, a company may choose to incorporate into their element 1 calculations. And I'll quickly touch on these two. The first is end use of food.

This is particularly helpful for ingredient manufactures, I think. If you have an ingredient -- I think the example in the guidance is high-fructose corn syrup. And it talks about high-fructose corn syrup maybe that's going into a soft drink, high-fructose corn syrup that's going into a baked good. They may have differing amounts of that high-fructose corn syrup in those products. And so this allows a little bit more specificity.

If you know the end use of that ingredient, if you know 98% of our product, high-fructose corn syrup, goes to soft drinks, you can probably calculate the percentage of that ingredient in the product. And

that may, again, provide a level of specificity as it relates to the element 1 calculation going back to that worksheet.

The second one is consumer packaging. And this -- you'll notice in the volume of food at risk method or approach, it talks about servings being used a proxy, right? And so with the consumer packaging concept -- I think here we use a breakfast cereal example in the guidance. You may find that using servings may actually overestimate public health impact. So you may look at how many consumers do we have per a packaged unit.

And if you know -- again, if you know that information, if you know who you're selling your product to or what your product is and how it's packaged, this may provide a little bit more specificity for you relative to calculating volume of food at risk and even some of the other methods or other approaches.

So again, these are optional. No need to use them if they don't make sense for you. But that's a little bit more latitude -- I'll get away from the word flexibility -- a little bit more latitude that's afforded if you choose to use that. So with that, Dr. Newkirk.

DR. NEWKIRK: Thanks, Jon. So that was fairly math heavy. So if you like math, please focus on Jon's remarks. If you are not a huge fan of math, element 2 will be a little bit better read for you. And element 3 has a little bit of math depending on how you go about using it.

So element 2. Just a very quick reminder: this is the element where we talk about degree of physical access to the product. As Jon mentioned, for each of the elements in the revised draft guidance, how we laid it out, is in the beginning at a very high level we talk about what the elements are.

Then we provide the scoring tables with the description of each score, 10 being the most concerning score, 1 being the least concerning score.

And then we walk you through specifics of what the particular elements are.

There's some flexibility or I guess latitude I should start using -- as my boss said we should get away from flexibility -- so latitude with some of these requirements and how to go about complying.

So for the degree of physical access to the product, basically what we are asking industry to evaluate for each of the points they're looking at is -- pretty much boils down to some kind of barrier or a lack thereof. Again, a score of 10 for accessibility would be complete openness of the product, so an inside attacker can actually touch the food, all the way to a score of 1 for accessibility, basically there's no access to the product, there's no way an inside attacker can touch the food.

For elements 2 and elements 3, we've explicitly incorporated what Jon mentioned, those two overarching considerations: inherent characteristics as well as inside attacker. Those are explicitly included into the descriptions in the scoring table.

So we've done that. This is a bit hard to see. But this is a snippet of the scoring table for element 2. Here on the first row is a 10, the most concerning or the most accessible, followed by the bottom row--an 8.

In the middle column there, this is the description column similar to what Jon showed for public health impact estimations. But you'll see here that there's a lot less math and more words. So there's a number of factors in element 2 in each description for each particular score.

Again, probably not able to see most of this, but the first bullet in the first row talks about an inside attacker having access to the product. Again, what we're saying here is the attacker can actually touch the food stream.

Second bullet, there are no inherent characteristics. That would make access to the product difficult. And we go into a few examples here

for what we mean by inherent characteristics and closed systems, pressurized equipment, railing, worker safety features. Jon mentioned a number of these.

Important piece here for both elements 2 and elements 3 scoring tables, there's a small footnote, but a very important footnote at the bottom of these two tables, which basically indicates that not every single word in the description for, say, a score of 10 needs to happen at the point you're evaluating. So you're looking at a mixer and you're seeing what happens around the mixer, you're seeing the characteristics of the mixer. And if that lines up with the description column, you assign that score.

So if you're looking at a mixer and it's completely accessible, if the inside attacker can touch the food, there's no railings, there's no worker safety features, there's nothing, it's just open, you would assign a score of 10, because the description that we've included in guidance for a score of 10 basically matches or a number of the factors in the description column matches a score of 10.

So this is -- I said most of this already. But turning the scoring tables into actual assignment of a score, it is somewhat of a matching game here. You're looking at the description. You're seeing what's happening in your facility. If the description matches your circumstance, that's the score you assign.

Again, I will highlight -- and I'll do this for element 3 as well -- that very important footnote to these tables, that it does not need to be an exact match. It comes into play in element 2 somewhat, but for element 3 there are quite a few factors in the description pieces for each score. So it doesn't all have to align to warrant that particular score.

Jon mentioned for element 1 and this follows through for elements 2 and 3. We have found it beneficial when we've been conducting vulnerability assessments with industry to include a written rationale for each score. So again, this is not

required, but we have found it very helpful. And when I talk about what we're doing with these scores in making a determination if a point is vulnerable or not, this piece can really make a difference depending on how these scores shake out.

Another thing that we've highlighted in the guidance and we found through our experience with conducting vulnerability assessments is that element 2 is the easiest element to evaluate. So we actually recommend beginning with element 2. It's fairly easy to rule-in or rule-out if something is accessible or not. And I'll mention once we talk about it again what to do with all of these scores, how this comes into play.

Element 3, ability of an attacker to contaminate the product. Same -- we've laid this out in the same way in the guidance document, as the other elements, at a very high level what this is, provide a scoring table. For this particular element, I think on first read, on first look at the scoring table, it could seem a little onerous, it could seem burdensome in the amount of information we're asking you to read and evaluate.

But with that footnote, with that asterisk in mind about flexibility and not everything needs to happen to merit the score -- I think the element 3 table can be kind of flipped on its head if you look at it through the terms of flexibility. There are a lot of different factors that you can consider when you're assigning a score for element 3. You don't have to consider everything that's in the table. You can consider a subset of factors. We've actually brought in a number of those factors into this particular table from the stakeholder interaction that we've had over the past number of years.

So again, as with element 2, with element 3 an explicit inclusion in these factors in the tables for inherent characteristics and inside attackers. A few other things that we talk about -- this is not a complete list, but a few other of the factors in the

table are level of observation at the point: is this something that has a lot of eyes on it all the time or is this something in an isolated part of the facility?

A slightly different way to look at that is: are there a lot of workers in the area? Jon had mentioned as part of an inherent characteristic example that there are some points, steps or procedures that simply require three or four or more workers for that step to function properly. Or is this a step where there are no workers or maybe there's one worker associated in that particular area or assigned to that particular area?

Jon did a really nice job talking about the sufficient volume of contaminant added. That's where he walked through the worksheet, and there were some red boxes there. Again, this is one factor for your element 3 consideration. You do not have to consider this factor. It does involve a little bit of more math that Jon walked through. We have found that a lot of folks -- when we were conducting our vulnerability assessments with industry, this was an important factor to consider in element 3.

So I'll echo a few -- I'm doing great at this -- I'll echo a few things that Jon did say about this particular aspect of element 3. Again, there are some critical inputs from element 1 if you choose to use either a representative contaminant or a contaminant specific approach. Again, if you choose to use volume of food at risk or of course if you choose the key activity types, these critical inputs are not there. So you can't get to the point of considering this particular factor.

So this bottom worksheet should look familiar. Jon presented it. This is in the section of the guidance for element 1 about the representative contaminant approach. Columns A through H are all geared towards estimating public health impact.

The two columns highlighted in red -- again, FDA provides that value in column I, that's that representative contaminant piece that Jon described.

And then you pull in some of your calculations to get to the point of column J. That will give you the amount of representative contaminant needed per batch.

Again, this is one factor. So if the column J value is translated into something that can fit in a vial, so the amount of contaminant needed to cause wide scale public health harm can fit in a vial, you can put it in your pocket, that would very much influence your score at least from our experience for element 3. So again, 10 is the most concerning score. You would be higher, 8 or 10 maybe on your score.

However, if your calculations end up with column J -- really ended up being something that will only fit in a backpack or will fit in something like a 55-gallon drum, that will very much affect your scoring of element 3 as well. So if you're seeing Jon move a 55-gallon drum through the center of a processing facility, people are going to notice that something's going on there that's off. And so the scoring for element 3 there will be lower, will be a less concerning score. Again, don't need to consider this particular factor, but we found it helpful in our vulnerability assessments.

Jon also mentioned this. These are additional things that facilities can consider when scoring element 3. But these can only be considered even more specifically if you use a contaminant specific approach in element 1. And that's because you're doing a lot of research about specific contaminants. You'll understand their concentration and/or dilution throughout the points, steps or procedures. You'll understand if some processes will remove them or if they'll neutralize them.

But again, as Jon mentioned, there are a number of contaminants of concern for intentional adulteration. A lot of exotic contaminants I believe is how we phrase to that in the guidance. And something that happens with a number of these contaminants is an important amount of data gaps.

And so if there are chemicals that we don't

normally see in foods, there are a lot of data gaps related to what's their concentration or dilution, how will they react in a food processing environment. Again, very much something to think through before going down the contaminant specific route.

This is a snippet of the scoring table for element 3. I noted there's a lot of information in table 3. So this is the description. Seven or eight bullets here-ish of what to consider for a score of 10. The first bullet here does talk about an inside attacker and a level of observation. So again, 10 is the most concerning in all of these tables. So this example of the process step is in an isolated area, folks can't see it very well, and the inside attacker has unlimited time to contaminate the product.

A couple of bullets down, inherent characteristics would lead to uniform mixing of a contaminant. We've talked about that being a concern already. So the most concerning score, a score of 10.

Jon mentioned workers in the area. Second bullet from the bottom for this particular description. There are no or a few workers in the area. Again, the score of the most concern.

Similar to elements 2 and elements 3, you look at the description in the scoring tables and then you look at what's happening around the process step that you're evaluating. If those descriptions match -- if they relatively match, you assign that particular score. Please do note that footnote under the scoring tables for element 2 and 3 about the flexibility here. And an echo to how it's beneficial to include a written rationale for your scores, but again not required.

Okay. So that's a lot of work that facilities have done. They've looked at each point, step or procedure in their process. They've scored each of those for element 1, each of those for element 2, and each of those for element 3. So now you're starting to get a lot of data together. You're starting to put data in a usable form so you can

determine if you've got significant vulnerabilities, and then to do something about that.

I noted in the earlier slide about the background for the IA Rule, that basically what the rule does is it establishes requirements to prevent or significantly minimize acts intended to cause wide scale public health harm. We've heard a lot of industry interest in what FDA thinks about wide scale public health harm: Are there particular thresholds? Or how does industry determine what wide scale public health harm is?

So what I'll start with what it's not. In the context of this rule, wide scale public health harm is not a simple threshold of morbidity and/or mortality. That's an important input into what wide scale public health harm is, but it's not the only input.

So Jon and Julia talked about those three fundamental elements: public health impact and accessibility and ability of an attacker to contaminate the product. So in the context of this rule to achieve wide scale public health harm, there has to be some kind of combination of all of those three at an elevated presence.

We go through some examples in the guidance. This is section 2G-1. So it's not specifically called "Section: Wide Scale Public Health Harm," but it is 2G-1, where we talk about what we mean here, and we have some examples. And so we really hit on the point where it's element 1 and element 2 and element 3 that's elevated in order to achieve wide scale public health harm.

We have an example in the guidance that talks about element 1, the public health impact element being the most concerning score of 10, there's over 10,000 estimated illnesses or deaths. However, that particular processing step has an accessibility score of 1. So basically, what that means is that you cannot access that point, step or procedure. And because you cannot access that, in the context of the

rule, this does not rise to the level of wide scale public health harm.

We think industry will like this particular thinking related to scores of 1 because we're doing -- we hope we're doing some of the work of this evaluation for you. So a score of 1 in any of those tables in element 1, 2 and 3 scoring tables is the score of least concern, is the way to think about that. So for public health impact, it's an impact of zero. For accessibility, it's basically meaning you cannot access the food at that particular point. And for ability of an attacker to contaminate the product, basically a score of 1 means the attacker cannot contaminate the product.

So if industry is -- if stakeholders are working through their vulnerability assessment and they follow our recommendation of starting with the easiest element to evaluate, the accessibility piece, and you start to see some scores of accessibility of 1, you are done with that particular point, step or procedure in the vulnerability assessment. Because it's a 1, you will not achieve wide scale public health harm. So there's -- you could potentially think this as a bit of a shortcut in your vulnerability assessment.

So that's some background into what we think wide scale public health harm is. So once you've done that, what the guidance then goes into is a description of summing all of the element scores. So you add your scores for each step from element 1, element 2 and element 3.

The maximum score you can have is a 30. So there's a 10 for each element, most concerning value for each element. The minimum scores you can have depending on this one situation that I just talked about, you could end up having a 1 or a 3.

So again, 30 to a 1 or a 3. We ask you to rank those scores. You don't have to rank those scores, but we have found in our experience that it's very helpful just to see those scores in descending

order.

I pulled a part of the guidance and edited this slightly just so it kind of fits on one screen. But you'll see on the left is the process step; the middle columns are the scores for elements 1, 2, and 3; and then the sum on the far right. The bulk liquid receiving, and the breading processing steps have the sum score of 26. And then the processing steps follow them with sum scores that are less than that. Just it helps folks, in our experience, visualize how those sum scores are laid out.

Once that happens, then in the guidance we put forth a proposed scoring determination metric. So let's start on the left side of the screen, the green part of the discussion here. If the sum scores are less than 14 -- we have done a little bit of a shortcut again for industry; industry can kind of default to -- these sum scores indicate that the point, step or procedure is not a vulnerable step.

Well, why is that? Remember what's happening beneath the sum scores? You're adding element 1 and 2 and 3 together. So a sum score that's below of 14, really what that reflects is that you have a low public health impact, you have a low accessible score, and you have a low ability of an attacker to contaminate the product. You're looking at inputs into that sum score of ranges of 3 and 5.

Let's go to the right side -- the red side, the sum scores for above 25. Here we're shortcutting again. Here you've got points, steps or procedures that are -- that do have significant vulnerabilities. Why is that? Basically, these are the highest element scores contributing to the sum scores. These are scores of all 10s or 8s and 10s. So highest public health impact, most degree of accessibility, and the highest ability of an attacker to contaminate the product.

Then we have this middle range, 14 to 25. There's a lot of flexibility for industry here. We've started to hear maybe a little uncertainty as well

within this scoring range. But here is where when we've been talking about "it's very beneficial for your rationales for why you're assigning the scores you're assigning for each element," this really comes into play here.

So there's a mixture of scoring for your elements in the sum scores here. You may have a 10 for element 2. You may have a 5 for element 1. You may have any other value for element 3.

It's really important how those sum scores come together and how you make the determination here in the score set of 14 to 25. We do think that on the lower end of the score, folks will most likely come out for steps being not vulnerable. On the higher end, they'll probably come out with steps being vulnerable steps. But again, you have the flexibility here to make that determination based on why you've scored the way you've scored.

Now, we talked about the explanation piece, as well, again, heard some concerns already for what we've put out on the level of detail for the explanation. These can be fairly short. These can be one sentences -- one sentence explanations. Or these -- if you choose, they can have more detail, so multiple sentences.

Again, please do look at appendix 4, the footnotes in appendix 4 and how we've laid some of that out. If there are explanations that apply to multiple -- the same explanation applies to multiple processing steps, a footnote or an asterisk or something like that is also something that you could consider.

A little bit of an eye chart. So this is pulled from guidance as well. This just highlights some of what we've talked about. This is a vulnerability example worksheet using the three fundamental elements approach. On the left side is the process step column. The first row being a bulk dry ingredient receiving.

If you'll see kind of in the middle where

there's some white space, elements 1 and elements 2 not a lot of information there. That's because in this example element 3 is scored as a 1. So you don't have to go and score element 1 and 2. We do have a little bit of rationale there in element 3 and we have a short, just one sentence explanation towards the far right on why this is not an actionable process step.

That's a bit different from the bottom row for a bulk liquid receiving example step. You'll see in these middle columns that we do have more information. We do have information related to the rationale for why we've scored those steps the way we've scored them.

And then the example towards the right is more detailed. Again, showing you ways that you could document your vulnerability assessment, but you do not have to include this level of detail.

So that all was the three fundamental elements approach. It's an in-depth approach. It's a tailored approach. There's a lot of factors that potentially go into it. Industry is -- some folks in industry have been waiting quite a while for us to finish that and publish that. So please do dive into that and provide comments to us. We're quite interested in your thinking here.

The final vulnerability assessment option or approach that we've outlined in the guidance is the hybrid approach. And Julia and I think Jon has mentioned this. The good news here today is that you basically know how to conduct a hybrid approach from what Julia has told you about the key activity types and hopefully from what Jon and I have discussed on the fundamental elements approach. It's a simple combination of those two methods.

Why we're putting forward a combination of those two methods? Is because there's strengths and there's weaknesses to both. The hybrid approach really does draw upon the strengths of both. Again, the key activity type, less resource intensive, somewhat off the shelf, not totally. And then the

three elements is a deeper dive, it allows you to consider more detailed characteristics of your facilities, of your points, steps or procedures.

So the key activity type aspect of the hybrid approach is exactly what Julia described. This is exactly the diagram that she used in her slides. Basically, you have your process flow diagram. You have FDA's description of the four key activity types. Where they overlap, you have a significant vulnerability.

However, in the hybrid approach, there is a subset of those overlapping spots that don't fully align with the key activity type. There's an inherent characteristic that makes them not fully align, or there's something -- a specific detail that makes them not fully aligned.

So for this particular subset of steps, you may choose to look a little more deeper and include a little bit more specificity in your vulnerability assessment. And that's where you bring in the three elements approach and you overlay that on top, on this subset of steps.

So again, the same diagram. The mixing step does in this particular example completely align with the key activity types. That decision has been made. That's a vulnerable point. However, the grinding step, there's an inherent characteristic about this particular step. This grinder is not accessible. So if you would overlay the three elements approach, basically this particular step would be scored a 1 for element 2. And then your determination is made for you that this is not a vulnerable point. Again, you would need to write an explanation on why you made that determination. And we have examples of that in appendix 4 in the guidance.

So with that, I think we've thrown a lot of information out this morning already. It does look like we're a bit ahead of schedule. But I will turn it back over to Kari for a few remarks for a break.

MS. BARRETT: All right. Well, why don't we

give a collective round of applause for our presenters. Thank you. They covered a lot of ground.

And we are going to take a break here in just a minute. We are going to break a little bit early. We still have half an hour. So we'll -- well, maybe we'll do 35 minutes. So we'll come back at 11:00.

That said, we do -- when we come back from a break, we're going to cover a few more chapters, and then we're going to have some time for Q&A.

Just based on this morning's presentation, there was a lot of content. I hope you're taking some notes of where you have questions because you have a great resource here today. And I hope we have a lively Q&A. But please do -- you know, hold on to those questions. We'll come back, we'll give you some more information, and then we'll dive into that. So again, let's come back to this room at 11:00 o'clock. Thank you.

MS. BARRETT: Folks, if we can take seats, we are going to get started in just a minute. All right. It's 11:00 a.m., so we're going to get started again with our program and we're going to keep moving through some of the chapters of the Draft Guidance, we're going to work through chapters 3, 4 and 8 in this next segment. We have the same speakers that we had earlier, so again they're listed there, but Ryan Newkirk is going to be speaking along with Captain Jon Woody, Julia Gunther, and also Colin Barthel, who is another policy analyst on the Food Defense Emergency Coordination staff in our office of analytics and outreach here in our Center for Food Safety and Applied Nutrition at FDA. So like before I'm just going to hand this over to them and we'll move through those chapters. So Colin?

MR. BARTHEL: Good morning. I'm bringing my water up here because I in the process of getting ready to come here this morning forgot to take my allergy medicine and I've got a little bit of a tickle in the back of my throat, so. And all of that's going on the transcript for the permanent record.

(Laughter)

MR. BARTHEL: Right. So we've talked about this morning kind of the general provisions of the rule. Ryan and Jon and Julia talked about kind of the preliminary steps that you would want to engage in as you're building out your food defense plan. Jon gave a really good introduction as to what the purpose of the vulnerability assessment is. It's a step along the way to future decision-making. It informs where you need to put your protections, it will inform and prioritize your resources and so it gets you to this next chapter which is identifying and implementing mitigation strategies. We'll get into the regulatory definitions in just a minute, but mitigation strategies really are those things you put in place to reduce the significant vulnerabilities that you identified in the vulnerability assessment. So they are a response to your identification of a significant vulnerability in that food processing environment.

Now, the chapter on mitigation strategy starts out with an overview of the requirement. And I'm not going to just read this verbatim to you. They are on chapter 3, Section A and that's page 67 of the published guidance if you want to kind of follow along and look at them, but the requirement is that for each actionable process step that you've identified in the vulnerability assessment, you need to put in place those protective measures and those mitigation strategies are those protective measures. Now it's important to recognize that mitigation strategies are risk-based and they're reasonably appropriate, that's what I want to highlight. We want to pull people back from the expectation that they need to put into place, you know, laser fencing and extraordinarily expensive sensors and all kinds of things like this. That would be expensive and would be very hard to implement.

We're looking at common sense approaches, reasonably appropriate mechanisms that would reduce significant vulnerability around process steps. Now, we know that food defense is relatively new for some

people and as the future progresses scientific understanding might advance and such that we might identify mitigation strategies in the future that are more appropriate or more protective or more effective et cetera and so the system will grow in the future. But what's important is that the mitigation strategies that you would identify in the current term should match up with the current understanding of food defense and the principles surrounding this discipline.

Now, mitigation strategies have a few characteristics that we talk about in the guidance. They are customized to the process step to which they are applied. This is a big thing about the flexibility of this requirement. Mitigation strategies need to be customized and tailored to a particular facility's vulnerability and that particular process step's vulnerability. So they're tailored into how the facility does business, what are the practices surrounding that process step, what does that process step do, how does it operate. Mitigation strategies need to be cognizant of those existing practices and to be built into the system that the facility is operating.

These are important lessons that we learned when FDA was conducting vulnerability assessments that when we would interact with industry and identify potential mitigation strategies, one facility might say, well, that doesn't work in my facility because of A, B and C. Another facility might say, yeah, that works perfectly because we do things differently than facility that you just talked to. So this is where decision-making comes into play, this is where your expertise as food industry professionals comes into play because there's nobody that's better equipped to identify appropriate mitigation strategies than the facility that's going to be implementing them and we freely and fully understand that and have built that into what the guidance lays out.

Now, we do not expect absolute reduction of

vulnerability. This is an important term, "Significantly minimized," which is a regulatory term within the rule, means to reduce that significant vulnerability to an acceptable level. Sure, you can include elimination of that significant vulnerability, but that is not our wholesale expectation. You're moving from an area that was significantly vulnerable, now you've put into place protections, now it's not significantly vulnerable, but naturally there might still be vulnerabilities there. They're just not rising to that level of significantly vulnerable. What we're doing with this rule and what the mitigation strategies achieve are to buy down risk, so we're moving from significantly vulnerable into the range where it's no longer at a significant level.

So we do not expect eradication of all vulnerability within a facility. We understand that that is very likely an impossibility especially within food production operations, especially within operations where people need to move around and work. It's practically impossible to virtually eliminate all vulnerabilities in that environment. But what we're doing is we're making a potential active and intentional adulteration more difficult or more likely to be interdicted or discovered through the use of these protective measures called mitigation strategies.

So what are mitigation strategies supposed to do? And this is where we're kind of moving from the concept of what a mitigation strategy is and what we define it as, but how do you think through identifying a mitigation strategy and putting it into place? Now you'll see here on this slide that mitigation strategies, and we talk about this at great length in the guidance, tend to align themselves to element 2 or element 3 of the vulnerability assessment. They either are designed to reduce the level of access around an actionable process step or they're designed to make it more difficult for an attacker to successfully contaminate the process step at that

area.

So they're making it less likely that a successful contamination would occur. What you don't see on this slide is much of anything associated with addressing or reducing the score for element 1. We recognize fully that production of food intends and is designed around efficiencies of scale, batch processing, processing food in large volumes because the food industry is highly efficient, and it delivers a lot of food to a large population in a very short timeframe. It just doesn't make sense to have a facility reduce the volume of food they're processing. That is not our intention and it just wouldn't make business sense for a facility. And so what mitigation strategies do is they're targeted towards your assessment of what element and element 2 and element 3 were driving the vulnerabilities at those processing steps.

So a food defense plan is kind of a narrative from start to finish. You're gathering information, you're conducting an assessment, that assessment informs the protections that you put in place, so the person that's conducting the vulnerability assessment -- this is one of the reasons that we include the recommendation for writing down that rationale for each of those element scores is because that rationale can be very informative when you are identifying mitigation strategies. If you've characterized a process step as highly open and accessible, that might be one of the areas you want to look at first when you're considering mitigation strategies.

And so we kind of categorize mitigation strategies within the guidance into two general types of mitigation strategies. This categorization may be helpful to some people, this may not be intuitive and so we'd be interested in your comments on how we've kind of delineated the different types of mitigation strategies, but this is how we kind of lay them out in the guidance.

You have mitigation strategies that would be

associated with managing the behavior of personnel, authorizing specific individuals to be around a particularly vulnerable actionable process step and then restricting other people from that area through personnel management practices. So that's what we call a personnel-based mitigation strategy. You also might have an operational practice that you're doing that you can alter or amend such that the process step is less vulnerable. So you might have areas in your facility where you have ingredients in open staging for an extended period of time. You could look at that process step and say, you know what, we really don't need to stage 4 hours in advance. What we could do is simply change our staging protocols so that we're staging in a much more confined timeframe surrounding that actionable process step, and thus the timeframe that those ingredients are open and accessible would be significantly reduced. That's an example of changing an operational practice as a mitigation strategy.

Now, generally what we've seen is we've been discussing these with industry members and stakeholders is a lot of the time personnel-based and operations-based mitigation strategies generally don't require a capital level investment of installing new technologies or buying particular equipment or sensors or that kind of a thing. So you could achieve protection simply by altering your personnel practices or by modifying an operational procedure. That's an important thing to think about when you're going through and identifying potential mitigation strategies and weighing that against the cost that you want to include in your food defense program.

Now, the opposite to that are what we call technology-assisted mitigation strategies. Now, a technology here we use as a loose term, we're not necessarily talking about, you know, hi-tech bells and whistles, we're talking about things that go from as simple as a lock on an access hatch, lock being a technology technically. Somebody had to invent it one

time a long time ago, so a lock is a technology that is implementing an access restriction. We talk about other technologies that you can use to facilitate mitigation strategies and I'll have a slide here about remote observation via closed caption television systems or CCTV. That would be a technology-assisted mitigation strategy that would elevate observation around a processing step.

So that's what we're talking about when we categorize these mitigation strategies into personnel or operations-based or technology-assisted. That's how we've kind of defined them and broken them out. But again, if you don't think that differentiation is particular helpful to you, we would be welcome to see your comments on that.

Now, we have a couple of terms in the guidance that I want to talk at length with you this morning, so we're going to park on these concepts for a little bit on this slide and the next few slides. We have a term in the guidance called "Facility-wide security measures." We had a lot of engagement with stakeholders and industry members as we were going through rule finalization and also developing the Draft Guidance about the practices that facilities are already conducting and how those practices that are already being performed, whether they're from a security perspective or from some other perspective like quality control, worker safety, biosecurity concerns about contamination coming in from outside sources on an unintentional basis, but there are practices and we've recognized them and we want facilities to value their existing practices and look at them as a starting point either as a foundation upon which a mitigation strategy is built or in some cases an existing practice in its current form can be used as a mitigation strategy, so no additional strategies might need to be developed.

But if that facility is using an existing practice as a mitigation strategy, they would essentially just recognize that fact, put that in

their food defense plan as the mitigation strategy that's achieving protection and then they would follow along with the other requirements of that which would be they would identify monitoring procedures to make sure that that process is consistently implemented, corrective actions, verification et cetera. So it's important that we want people to understand that they should look at what they're doing first because this is where the cost to compliance can be minimized to the extent possible and where cost savings can be realized is if facilities look at what they're doing now, can I slightly alter what I'm doing now, is what I'm doing now already achieving a protection and start from that point.

If in fact, you go through the analysis and you find, yeah, what I'm doing now really doesn't, you know, achieve what I needed to achieve, then you can move forward with identifying whether additional mitigation strategies are needed or whether you can change something you're already doing to modify that so that it is protective and we'll talk about that in a little bit.

But coming back to this specific term facility-wide security measures, these are those general non-targeted procedures, practices that are put in place at a facility to protect point steps -- the facility as a whole, personnel, et cetera. So think of security procedures around access control and perimeter fencing and external security, that kind of a thing. And so these are put in place to protect the facility as a whole, but they're not put in place in a directed fashion at specific point steps or procedures. So what does that mean? It means that facility-wide security measures can be put in place as best practices and implementation around a facility without a vulnerability assessment.

You don't need a vulnerability assessment to put protections around the entire facility. What the vulnerability assessment does like Jon and Ryan were talking about is that it provides the specificity

within the facility of where significant vulnerabilities are present. Facility-wide security measures apply generally to the facility as a whole. Now, we do have, and I'll talk about in a little bit an example where a facility-wide practice can be used as a mitigation strategy and then you can identify that. Now, I have an example for that in just a minute.

Now, another term that is in the guidance is "Existing measures." We kind of differentiate existing measures from security-wide -- pardon me, facility-wide security measures in that facilities frequently have existing practices that are directed at an actionable process step, but are put in place not from a food defense perspective, but are put in place from quality, that are put in place for workers' safety et cetera. So these are practices that a facility is already doing that may not have anything to do with facility-wide security and that they're doing at a particular process step. So things like this would be certainly things that are not inherent characteristics.

So we talked about what inherent characteristics are. These are things that need to be present for the process step to physically operate. And what an existing measure is, is a practice that a facility has put in place that's not inherent necessarily, but put in place for another purpose, whether that's quality control, worker safety, business processes, et cetera. So these measures should really be evaluated to determine whether these existing measures that are already being put in place at that mitigation or at that actionable process step could serve as mitigation strategies and I have a couple of examples here that we can think about.

One that comes up frequently in food processing and in our interactions with industry is that of a process step where a worker is a senior employee or is an employee that has established elevated level of trust and so the facility is saying,

well, this process step, yes, it does have vulnerabilities and they're significantly vulnerable, but we have this person that's been working there for 15, 20 years and I trust him implicitly to be able to protect that process step because they're there all the time. So the thinking would be that, yes, this process step might be significantly vulnerable because there's a high degree of mixing, there's a lot of food present, it's open and accessible, but if you have a senior employee or someone who's been established elevated levels of trustworthiness stationed there, you can, if it's appropriate, rely on that particular person to act as the mitigation strategy.

And so you would look at that person as being the protection. So you would say, okay, John has been working at this process step, he's undergone additional vetting or he's established elevated trustworthiness by working at the facility for a long period of time, we're going to make sure that he controls that area and he excludes anyone else. So we're specifically authorizing John to be in that area and he's empowered to be in that area and to protect it. That would be the mitigation strategy. You would document that in the food defense plan and then periodically you would monitor that it's only John in that facility or in that area and that he is in fact excluding other people from that part of the facility. So that's an example where you can use existing staff as a protective measure around an actionable process step.

Another existing measure that could be leveraged is where you have worker safety protocols that are put in place that provide a peer monitoring function. Here we talk about if you have a buddy system, and I've seen this many times in facilities where there are hazardous working areas, you require two or more employees to go into that area so that if someone gets injured there's somebody that can, one, witness the injury and then go get help. So that is a practice that let's say this area was identified as an

actionable process step, the facility could say, yes, it has high degrees of accessibility, it's got, you know, large amount of food et cetera, it's got all of those conditions under the three elements or it's a key activity type, so it's an actionable process step.

But we mandate that it's always a dual worker area from a worker safety standpoint. So what that would be is that, yes, we now have a specific environment where there is elevated observation that's intentionally put into the system from a worker safety standpoint and you would document that as a mitigation strategy and make sure then under your monitoring procedures you would potentially say, okay, every so off and I'm going to make sure that it is in fact only a dual worker environment that there's nobody there by themselves. If they are by themselves, then I'm going to have to put a corrective action in place et cetera. So that's another example where you could use an existing worker safety practice potentially as a mitigation strategy.

You may also look and see if additional mitigation strategies need to be put in place. So for example, does this room now need to be locked or secured such that only those two people or only two people at a time or more could go into it. But if there's not two people, then it's locked and secured, something of that nature. So we'll talk about layering mitigation strategies in just a minute, but these are examples of where existing practices could be put in place and incorporated into your food defense program.

Now, we go into a lot of detail and a lot of examples in the guidance about, you know, what mitigation strategies are. And so we break out these examples to cover mitigation strategies that might be relevant, more relevant to element 2 and mitigation strategies that might be more relevant to element 3 to help people understand how to reduce those elements to an acceptable level. So if you've got a process step that scored as an actionable process step because it's

got a high degree of accessibility to it, you might want to look at these examples within the guidance that are around reducing the level of accessibility to the product and start there as a conceptual starting point I'd like to say. And then you can go in and say, okay, well, this one might work, let me look at my process step and see if I can put this in, yes or no. And you can just go down the list and see what works for you.

So the top sub-bullet here is the one that's most, you know, easy to think about. To reduce the accessibility to the product, you would just restrict the area to only those authorized people. And so this is easier in some cases than it is in others, so you might have a process step that is kind of set aside from a high traffic area where it would be easy to physically restrict that area and prevent people who are not authorized from going in there. So you might have a secondary ingredient premixing room that you would be able to lock, and you would only empower the people that are authorized to do that function with the keys. So that might be an example of where you could restrict the area to only authorized personnel with the help of a door and a lock.

Another way is if you have an open floor, a production floor and you need to make sure that your otherwise unsecured mixer is protected by restricting that area to only unauthorized personnel, you would essentially zone that mixer as a restricted access area and the people working in that mixer you would authorize to be there and you would empower them to exclude people from that area. So that's a personnel-based mitigation strategy around a restricted area.

Other uses of mitigation strategies to restrict accessibility to the product might be using tamper-evident tape or seals on ingredient storage containers such that if access was attempted, it would be readily evident, or it would be impossible to access the product in that way. Installing locking mechanisms, I talked about this, locking mechanisms on

hatches, access ports, lids, other access points to equipment where food is being either stored or processed. And then we talk about this way to block access pathways to equipment. So we've been in discussion with a lot of stakeholders. A stakeholder came to us and said, "You know, Colin, we've got a number of storage tanks that are -- they're kind of grouped together, but the only way that you could get up on top to get to those hatches is through a ladder access and then you get on top of a gangway and you'd be able to get to each one of those tanks." And they said, "And it really -- just the design of the tank is not amenable to installing a lock on each hatch. It just -- we don't think that that's going to work."

And so the discussion kind of settled around okay, well, there's only one access point to get up to the hatch area. Would it be appropriate for you then to block that access point and install a ladder cage there? And you would then lock that ladder cage and make sure that the keys are controlled in the security office or something else. Yeah, that might work. We'll think about that. So mitigation strategies don't need to be specifically directed only to the hatch or the specific access point on equipment if you can block access pathways through other means. And so this is all part of the flexibility of this provision of the rule is that you as the facility are the person who knows the design of your facility, the layout of equipment, how they can be accessed, where and by whom, and so it really is beholden on the facility to think through what mitigation strategies are appropriate.

And so that's where the largest degree of flexibility of this rule comes into play. We do not specify any individual mitigation strategy is required. Yes, we do provide examples as an illustration of what could be a successful mitigation strategy in different scenarios, but we do not require or stipulate or specify any individual mitigation strategy within this rule.

Now, talking about blocking access, here are examples that are within the guidance on reducing that element 3 consideration, reducing the ability of an attacker to successfully contaminate that product. Now, a lot of these strategies deal with some level of increased observation that would enable the facility to discover, interdict and disrupt a potential attack. So if you've got a highly vulnerable area, you might look at ways of increasing observation in that area. You might look at making sure that that area is free of visible obstructions, that nothing's being stored in that area, that it's -- that lines of sight are clear, and so that increased observation might make it implausible now for a potential attacker to enter into the area, conduct the introduction of the contaminant, and leave without being discovered. So that's what increased observation achieves is it makes the attacker's actions more obvious and more likely to be detected.

We can require workers at actionable process steps to take precautions that would make it more difficult to actually carry a contaminant into that area. So in this case, it's a requirement for workers at an actionable process step where a particular type of uniform or particular type of protective equipment that prevents them from concealing any items and the monitoring procedure for this might be that before they enter the area, they just check in with a supervisor, the supervisor says, yes, you're in the right -- you're in the right apparel and then periodically that supervisor might look and say, okay, those three guys, yes, they're wearing the correct -- the correct uniform for that area. So that's a way that would make it more difficult for a potential attacker, a potential inside attacker to bring a contaminant into that area because you've made it more difficult for that person to carry it.

Now, we also talk about installing access indicators, alarms, signal lights, those types of things that might notify workers in an area that

aren't -- necessarily have dedicated observation to a process step that something out of the ordinary has occurred. So consider that you've got a mixer that raw food is in it, it's supposed to be mixing, it's supposed to be closed, it may not be pressurized or have any other inherent characteristics that would mean that it would be difficult for somebody to access it, but let's say that lid just as a matter of practicality, you need to open that lid several times a day as you're putting food in or out or what have you, so it doesn't make a whole lot of sense to lock it. But what you could do is install an access indicator, a contact switch or something to where if the lid is opened when it shouldn't be and when people aren't working in that area to observe it, it notifies a control room or it notifies management or security staff or something that something has occurred that's out of the ordinary. And then it makes that process step more difficult to intentionally contaminate because now you've provided a notification mechanism to facility management that something suspicious has occurred and that you would need to respond to.

So those are some examples of how, you know, mitigation strategies can be directed towards accessibility or vulnerability, likelihood of successful contamination. Certainly mitigation strategies can transcend both of those groupings and frequently they do, but it just kind of help you understand that if you've got a process step that became actionable because it's got a high level of access, you might want to look at some of those mitigation strategies first because they might inform your protection of that process step by kind of looking at mitigation strategies that align with each one of those elements individually.

Now, we've received a lot of comments and a lot of feedback regarding cameras. We got comments from the proposed rule regarding cameras, we got feedback after we finalized the rule regarding cameras. FDA, how do you want us to use cameras? I

can't put somebody in front of a camera screen all day. Also do you expect us to hold tape? How many years of tape would you want us to hold? All of those kinds of questions. So we wanted to get into this example in particular in this meeting to help inform people's understanding about how we would expect the cameras to be used.

Now, in reality in their base function, a closed-circuit TV system establishes a mechanism for remote observation of a process step. We are not looking at using a CCTV system as a retroactive investigatory tool. The entire rule is preventive in its design. And so we want to make sure that an actionable process step, that if you're using a CCTV system to observe it, it would need to be observed through the course of its operation, not after the fact, not after if you think something happened go back and check the tape. So what does this look like? And so -- well, that should make some people feel good because that means that we don't even care if you keep tape.

We're looking at the quality or the elevated level of the observation of the process step on a daily basis during its operation et cetera. So this would be essentially the CCTV system would enable remote observation from an area that's not immediately adjacent to or alongside that actionable process step. So you could have a control room where you have workers that are overseeing production equipment through, you know, feedback from the equipment, they're reviewing time control and temperature numbers et cetera. They're in there observing other equipment functioning, so you could essentially pipe in that CCTV feed to them and say "Look, we need to establish an increased level of observation over this actionable process step. We think the best way to do that is to have the feed come in here where you guys are working and you guys just periodically look at that screen to make sure that nobody is coming into the area, that nobody is opening that equipment et cetera. You don't

have to do it all the time so, Bill, you don't need to sit there your entire shift staring at that computer or at that screen."

But what it does is just like if you were removing visual obstructions from an area and you were relying on workers in that area to observe the actionable process step, what the CCTV system enables you to do is essentially perform that function from a remote location using the TV system. So it's not something where we're expecting people to hold tape, it's not something where we're expecting people to have a dedicated staff person to 100 percent oversee that processing step. It is a way to incorporate an observation behavior into the duties of other people who are already observing something else. This may not need to be a control room for equipment, you could pipe this into a security office. You might have your visitor intake and sign off area say, okay, we're now empowering you also to look at this actionable process step because we know that you know how to watch security cameras anyway.

So this is what we're talking about when using cameras. We're not talking about holding tape, we're not talking about using it as a retroactive tool. We're using it as an active tool to increase observation. And so Dr. Newkirk, when he gets into monitoring procedures, he will carry this discussion forward as to how you would design a monitoring procedure around using a CCTV system.

Now, in the guidance we talk about using multiple mitigation strategies and layering mitigation strategies on top of each other. We have recognized and our vulnerability assessment certainly have highlighted that there can be more than one driver of the significant vulnerability around an actionable process step. So you may conclude that, yes, this mitigation strategy deals with reducing access a little bit, but it doesn't go far enough, I need to do something that also elevates the level of observation, let's say. So now you've got two mitigation

strategies working together holistically to bring down the level of significant vulnerability at that actionable process step to that acceptable level. Now, sometimes incorporating two relatively inexpensive strategies might be cheaper and easily -- more easily to implement than doing something more complex that's a single strategy that might require capital investment and all of these kinds of other cost drivers.

So if you can identify mitigation strategies that are relatively inexpensive and easy to implement, but they don't quite do everything to reduce that significant vulnerability, you don't necessarily need to dismiss them and say, well, we've got to start over, we've got to look for something more robust. You might simply say, okay, this gets us 60 percent of the way there. Do we need to change something else, or do we need to put something else that's reasonably simple into place that would then get us that additional 40 percent? So it's not one-for-one. You can layer strategies on top of each other to achieve a comprehensive protection.

Now, similar to the vulnerability assessment requirement, we do have a requirement within the rule that facilities explain their identification of mitigation strategies and that explanation should include what the mitigation strategy does. What is it doing that is protective--and we'll get into this in future guidance upon how you can leverage these explanations in other aspects of the rule including verification and reanalysis and those kinds of things. So those are for future guidance chapters, but the explanation within the guidance that's open and available right now includes the, you know, what is the mitigation strategy achieving.

In the vulnerability assessment you've already concluded that this process step is significantly vulnerable, thus it's been elevated to an actionable process step. How does this mitigation strategy achieve that reduction of significant

vulnerability--and so this can be quite straightforward and quite simple. And we're not looking for, you know, tons of information. Nobody is going to be getting a Pulitzer or another award for their food defense plan. We want to make sure that the information contained within the food defense plan, it's straightforward, it's logical, and it flows kind of through the system. So it doesn't need to be verbose or in copious amounts of detail.

We do go into a number of examples within the guidance on what these explanations might look like. Dr. Newkirk started out the day by saying some of our examples include a lot of detail and we've heard from people that, you know, this is a lot of information, FDA. Do I really need to write this much? And the answer is no. If the explanation satisfies that logical, you know, justification for why that mitigation strategy exists, you don't need to go into copious detail. When we were writing the guidance, we found that it was more beneficial as an informational tool to put some details into those examples, but that is not the standard necessarily that we're looking for in terms of the absolute level of detail that needs to be in those explanations. So they can be very simple.

For example, your explanation for a lock on an access control or on an access point like a hatch could simply be install a lock, the lock reduces accessibility and keys are maintained in the security office and are only provided upon proper justification. Four sentences, you could be done with that essentially. So we're just looking at commonsense logical approaches to what the explanation is. And here's an example from the guidance, from one of our appendices about this is your identification of the mitigation strategy in that middle table, so what is the mitigation strategy that you have put in place? First, you have to identify the mitigation strategy in your food defense plan and then you have to explain how that mitigation strategy is protective. So they go hand-in-hand. And again, this might be just more

content than you technically need in your food defense plan, but we are using it to help illustrate what, you know, kind of the information that you might consider when you're developing out your identification of mitigation strategies and the associated explanations.

And so with that I believe I am done, and I will invite Dr. Newkirk to come up and move us into the monitoring chapter. I didn't break down, cough, how about that?

DR. NEWKIRK: Well, thanks Colin. So apparently Colin doesn't care about the quality of the food defense plans he writes, but I definitely am shooting for a Pulitzer on the plans that I write.

(Laughter)

DR. NEWKIRK: So there's a little difference there, Jon, when it comes to our reviews. Please do take that into consideration. So Colin did note and gave a lot of really important details on mitigation strategies and we've engaged with stakeholders quite a bit on mitigation strategies, what are the appropriate strategies, how to choose the strategies, so please do look at those examples in the Draft Guidance, we're interested in your thoughts. We've also engaged with industry on food defense monitoring, maybe not as much as the VA and mitigation strategies requirements, but it is a theme that we've heard. There is some uncertainty for food defense monitoring and then there's also some concerns related to cost for potential food defense monitoring procedures.

Just like with all the other guidance chapters that we've covered today, we start with an overview of the requirements. So food defense monitoring is part of a combination of requirements called "Mitigation strategies management components." For folks familiar with PC rules, this is analogous to preventive controls management components. For the Intentional Adulteration rule, management components are made of food defense monitoring, food defense corrective actions, and food defense verification. In a nutshell what this is, is that industry is required

-- stakeholders are required to conduct a planned sequence of observations or measurements to ensure that the mitigation strategies are operating as they intend and this is a direct tie to what Colin noted about the explanation for the mitigation strategies and how they are working. So that's how you're thinking the mitigation strategies will be operating, direct tie here to that.

What you'll need to do in your food defense plan is establish and implement the procedures to do just that also indicating the frequency that you're going to monitor the strategies. So again, I know that food defense management components and preventive controls management components, we've heard from some stakeholders they've got a great handle of course on food safety or preventive controls management components, some questions related to management components for food defense.

So we do have a little bit of guidance real estate here where we highlight the differences, but folks coming from a food safety background know very well monitoring for food safety includes documenting maybe minimum and maximum parameters, lot of monitoring procedures include continuous monitoring. We don't expect that level of resource intensity for food defense monitoring. We do expect that it will occur less frequency in most cases and we also expect that in most cases it will be some kind of an observation of the mitigation strategy.

We go into subsections in this chapter related to what and how to monitor. A lot flexibility here, you can pull from quite a few different procedures and resources that you have in your facility. Again, the key point is this last bullet. As long as those procedures allow you to assess if the strategy is working or is operating as you intended to do, again directly tied to the explanation in the mitigation strategies on how you think it will work.

One of the uncertainties as well as cost concerns we've heard with monitoring, because again

this is mostly an observation piece, so there's a human resource component here. Anytime there's a person-time situation, there can be these amounts of costs related to that. So we do talk about how we see food defense monitoring is being less frequently occurring than food safety monitoring. And one thing that we did want to highlight here for the Intentional Adulteration rule is thinking through the monitoring frequency of being conducted on a periodic basis, but at irregular intervals. So say the monitoring procedure should be conducted four times a week, but the irregular interval piece, that means it's not conducted Monday at 2:00, Tuesday at 2:00, Wednesday at 2:00 et cetera. You just need to be able to work in that four times a week to monitor your strategy. A few different reasons for this; it'd be more difficult for the attacker to kind of expect or estimate when the strategy would be monitored and then again if you are doing it at an irregular interval, less frequent interval, that does have implications for reducing cost.

A little bit more on what and how to monitor, these are just a few examples in the guidance of what we've included. Of course you're welcome to develop new procedures if you wish, but you do not have to. You can assign an employee observation responsibilities to see whether or not that mitigation strategy is operating as intended. You do not have to use that; you could use electronic monitoring systems and/or you could build that monitoring responsibility into an employee's existing responsibilities. And we do have a few examples in the guidance on how we see that that could potentially work. We have got some initial feedback that there are concerns that we're redirecting employees away from their food processing, food safety, worker safety activities. That is not the intent there. The intent really is for the employees to be able to conduct relatively limited monitoring while they are in fact proceeding with their food processing requirements or

responsibilities.

So just as Colin did walking through some of the examples for mitigation strategies in that chapter, I'll do the same thing with a couple of slides for monitoring. So I'll start with the mitigation strategy because really what monitoring procedures need to do is take into account the nature of the mitigation strategy and then write the procedure around that. So I'll highlight what we mean here.

The mitigation strategy, one of the mitigation strategies examples in the guidance is to secure access hatch on an ingredient storage tank with a lock. The monitoring procedure for this particular example is that we would assign an employee to observe whether that lock is in place and locked at the beginning or end of the tank's 48-hour cleaning cycle. So we include this here today and, in the guidance, because this is an example of where the monitoring frequency depends on the nature of the mitigation strategy, right? So that lock should be locked and in place through the entirety of the 48 hours. It should only be unlocked when you're cleaning it. So you can design the frequency of your strategy to be directed when that lock was unlocked and then relocked, so at the end of the cleaning cycle.

Another example in guidance. The mitigation strategy here is tamper-evident seals are placed on conveyances or shipments. The monitoring procedure would be for an employee to be assigned to check the seals for integrity or any example of -- or any indication, excuse me, of tampering and then match the seal information on the conveyance with paperwork information that you had received before a receipt of the conveyance. This -- we highlight this here and, in the guidance, because it is an example of where monitoring could be conducted concurrently with implementation of the mitigation strategy.

So the same person can be looking at that seal, checking to see if the documentation lines up on

that same piece of paper that you're looking at the documentation, that person could sign off that -- the mitigation strategy is operating as intended. Some cost savings implications there. We also highlight this particular example because again, designed around the nature of this particular mitigation strategy, the frequency absolutely depends on the receipt schedule of the conveyance. So of course, you're going to monitor this mitigation strategy when you receive the ingredients. Monitoring won't occur at any other time for this particular example.

Colin noted cameras. We have heard a lot about cameras, we've talked a lot about cameras. Stakeholders, this is a theme we've heard quite a bit about. So again, the mitigation strategy here is increased observation of the significant vulnerability. So kind of you can think about that as -- that's a hard stop, that's what the mitigation strategy is, increased observation. In this particular example, you are using a camera to facilitate that increased observation. Again, Colin described the situation or the example, well, that it's piped into a room where an employee is assigned to periodically observe that feed. So that's the strategy, monitoring that.

Sometimes we have a little bit of a phrase or a terminology issue here about camera monitors and monitoring and food defense monitoring and sometimes wires get crossed when we're talking through this. So think about the monitoring procedure as once per shift the manager observes whether the employee that is assigned to the mitigation strategy is observing the feeds and is doing so as they're assigned to do so. To document the monitoring procedure, the manager records a "yes" if that manager observes the employee looking at the screen or "no" if the employee is not looking at the screen.

So again, there are a lot of nuances and terminology crossovers when we're talking about cameras as mitigation strategies and monitoring those

cameras for mitigation strategies. Please do dig into this slide as well as Colin's slide on the example for cameras and there's a number of spots within the guidance where we talk about cameras. We pulled a lot of that detail here as well as Colin's slide, but just if you can do a search function in the guidance document, you'll find everywhere where we talk about cameras.

A little bit about monitoring records. For folks familiar with food safety monitoring records, a lot of this is very familiar, the same basically. What I'd like to highlight are exception records. A lot of flexibility potential here for stakeholders as well as potential cost savings. So exception records demonstrate a deviation, documenting monitoring with a record when the strategy -- the mitigation strategy is not functioning as intended. And that's compared to an affirmative record that documents the mitigation strategy is functioning. There are some cases where exception records won't fit and we talk about that in the guidance, but we'll give a few examples of what we mean here.

So on first pass about how exception records may be able to be used in your facilities, at least in my mind it's easier for me to think about an automated system. So in this example an automated monitoring system, an alarming type system indicates that a gate around a vulnerable point is not secured. So it's automatically monitoring that a lock is indeed locked. After a given time if that gate is ajar, what the system does is it alerts -- automatically alerts and generates an exception record that documents something's wrong here with the mitigation strategy. This gate's open, it's been open for too long of a time and I'll document that automatically with an exception record.

We also have examples in the guidance where exception records are not automated systems, they're more personnel-based. So in one example we talk about responsibilities of personnel working in an area

around a vulnerable point and their responsibilities are modified that they all include some monitoring of the area for the mitigation strategy that prohibits personal items. So here the exception record application would be that a record is generated when an unauthorized personal item is discovered in the area by these employees. So really what they are doing in this example is they are working through or they're continuing their food processing responsibilities, and if they notice that there's a personal item within the area around them, that's when they document the exception record reporting.

They can do this by contacting a manager or something like that. There’re more details in this particular section of the guidance that we do want stakeholder feedback on, we do think this is a way that adds flexibility for the monitoring requirements and potentially a number -- or a decent amount of cost savings.

Just like we've done with the previous chapters, so what we're showing here and what Colin showed and some of the VA slides showed, these are those food defense templates that I mentioned in Appendix 1, they are filled out with examples. So this is a food defense monitoring template with the example, the left hand is a vulnerable point starting with a mitigation strategy written out, the monitoring procedure being a technician signs and dates a log prior to liquid food being added to the tank after the monthly cleaning cycle.

We highlight this particular example here, but more so -- more details in the guidance because this example leverages this facility's food safety activity. So how we lay this out in the guidance is that for something like a preventive control monitoring procedure to ensure that this tank is clean for food safety reasons. If this facility also identified this tank as a vulnerable point, mitigation strategy is to inspect to ensure no contamination happened. These things can be leveraged. So again,

cost savings here between food safety and food defense.

So with that I am going to turn it over to Jon to talk about the education, training, or experience requirements in the rule and that's a brand new chapter from the second installment of the guidance and that is chapter 8 I believe. So, Jon.

CAPT WOODY: Okay. Thank you, Ryan. I really wasn't trying to make a dramatic entrance there. I just needed to stretch my legs for a minute, so. Okay. We're going to transition now and talk about training, education and experience. One of the things I think I would -- I have noted over the past number of years in -- since the rule has published, in talking about training, education, experience, there seems to be a lot of misconceptions around it and some assumptions are made that are not in keeping with the requirements of the rule. So one of my goals in the next couple of slides is to try to help delineate some of that.

I understand there may be industry best practices around who they believe needs to be trained, but what I'm trying to distinguish is what does the rule require and then how is training one option to fulfill that. So I'm going to try to lay that out in a little bit of detail here as we move forward.

So the 121.4, if you're keeping track, is the qualified individual section of the IA rule. It specifically states you must be qualified to do certain activities, subpart C, and I'll explain what that is in a moment. It is a defined term "Qualified individual." To paraphrase is that you must have training, education, experience or a combination thereof to perform the activity that you're doing. Those sections under subpart C include conducting a vulnerability assessment, identifying and implementing mitigation strategies, conducting food defense monitoring, conducting corrective action activities, verification, and reanalysis. Got to be qualified to do those things.

Okay. There's another callout for individuals working at actionable process steps and their supervisors. They must also be qualified to perform their activities, and this is the one and only instance in the rule where you must take training. Individuals working at actionable process steps and their supervisors must -- must take food defense awareness training, period. Hard stop as Ryan would say. Okay. You may elect to train more people in your facility on food defense awareness, you may think it's a good practice, we want to build a food defense culture and so we're going to train all our staff on food defense awareness. That is your option. That is not the requirement of the regulation. Okay? So I want to make that clear first, as clear as I can.

We have been working over the past 3 years with the Food Safety Preventive Controls Alliance, which I'm sure many of you are familiar with based on the work on the Preventive Controls Rule with FSPCA on FSVP rules. So 3 years ago when the final rule issued, we began very specifically working with FSPCA. We helped -- we funded the establishment of an Intentional Adulteration Subcommittee under FSPCA that has been helping us build out training courses to meet the qualified individual section so there is a training option available for industry and I'll get into what some of those training courses are here in a moment.

So one of the things I would say as an aside as we start to move into these training courses is there's been a lot of opportunity I would say for me personally interacting with FSPCA to learn what's worked with some of the other training programs, what they've had to modify along the way, and some things that they've said, well, you know, if we had to do it over, we'd do it differently. And so there's been a lot of good lessons learned through that interaction with FSPCA and the many people that have been involved in that alliance.

So what I want to do is first outline the

training courses that are available through FSPCA that we've worked in collaboration with them to develop. The first is this food defense awareness training that I just mentioned, remember this is the only place where training is required and FSPCA last June I believe it was, 2018, issued about a 20-minute online food defense awareness training course free of charge.

We looked yesterday, there's been about 50,000 -- the course has been accessed about 50,000 times since its launch. The course is free, I think I mentioned that. So this represents one way that industry can meet this food defense awareness training requirement. It is not the only way. A company could develop their own food defense awareness training, they could avail themselves of another provider's training. So there's not a hard stipulation here that you have to use this course, it's simply one way to fulfill that training requirement.

The second course you see listed here is the overview of the IA rule. This is in no way, shape, or form connected to any requirement of the regulation. We just thought in working with FSPCA that this is just good baseline information to have out there in the community. So again, this is an online training course free of charge, basically provides an overview of what the regulation is, okay, so we can point people there and say if you need that overview, here that information is available to you. Okay, this is where we start to get into the good stuff. There are -- in addition to being qualified, there are specific callouts for activities where you have to be, as the guidance puts it, a "Food defense qualified individual," so you've got to be qualified first and you've got to be a food defense qualified individual.

Those four areas are conducting vulnerability assessments, identifying and implementing mitigation strategies, performing reanalysis activities and preparing the food defense plan. Those four activities, you must be a food defense qualified individual to perform those responsibilities. How do

you get there? Well, what we say is you have to have the education, training, or experience, or a combination thereof necessary to properly perform that activity. That's essentially the qualified individual definition. And -- and you have to complete training for the specific function that is at least equivalent to that received under a standardized curriculum, I'll show you what the standardized curriculum is in a moment; or -- that's why I bolded the "or," or be otherwise qualified through job experience.

I'm going to pause here a moment because I hear it almost every week that all that mandatory training we have to take for the IA regulation and we understand -- I've been working with alliances for 20-plus years, I understand the value they provide, particularly around new regulations. Everybody wants that shiny new certificate that says, look, I'm qualified. But that is not what the reg says, okay? Did I make that point?

So what we have been working on with FSPCA is the standardized curriculum that if a company says, you know what, we need people to be qualified to do this and we're choosing training, they have a place that they can go and the curriculum is standardized and it's recognized by FDA. So they're not essentially at the mercy of the marketplace to take any course that comes along, that's the value I think that the structure offers.

So let me quickly detail the courses. I'll note which ones are out and available and which ones are still under development. So in -- let me get my dates right, in November of last year FSPCA launched an online training course on conducting vulnerability assessments using the key activity type method, remember that straightforward simplistic method for conducting a vulnerability assessment. This isn't the three elements, this isn't the hybrid approach, it's just that match that Julia showed you. This is an online training course and this is getting back to some of the lessons we've learned in working with

FSPCA in rolling out other training programs to package all this up into a multi-day course, what FSPCA heard back from industry often was that's a lot of time for our folks to be out of the office.

So we took a good hard look at, number one, the structure of the regulation. It's not a single qualified individual requirement, it's broken out based on the activity and we said what courses could be delivered online. So would that make them much more available to a much broader audience without having to travel and train up lead instructors and all that kind of stuff. Okay. So this is an online training course that's been available since November.

Then I'll skip over the next one for a second. Then there's the identification and explanation of mitigation strategies. This is also an online course. This was released in I believe January of this year, so that course is also available. The next one coming down the pike is a face-to-face course. This is a one-day face-to-face course on conducting vulnerability assessment, so it goes into the details of how to conduct a vulnerability assessment using inherent characteristics, considering an insider, evaluating those three fundamental elements that we talked at length about today, that's what that course is centered around. That course is launching in May next month. There will be a lead instructor cadre. Built-up FSPCA is finalizing an application process on their website, so people can go on and become lead instructors to teach that course.

One of the other lessons learned with working with FSPCA is they have moved through the years in developing out these training courses much, much more focusing on quality lead instructors over quantity lead instructors. We want the cream of the crop lead instructors for this vulnerability assessment course and so the criteria, which are available in the FSPCA website now, point in that direction, okay? We fully expect that we will have lead instructors from the bevy of stakeholders, industry trade associations,

academicians, state and federal government, on and on and on, consultants et cetera. We fully expect that we'll have lead instructors from all of those stakeholder groups, but we have set -- we have aimed to set a higher bar, so we have the quality lead instructors we believe are necessary to teach this particular course. Remember, this is a course on conducting a vulnerability assessment in accordance with the IA rule requirements. It's not even a course in the entirety of the IA rule. So we need real good lead instructors for that.

And finally at the bottom of the slide the "Food defense plan preparation and reanalysis course," this will also be an online course and will help to be a training option for those last two pieces of a food defense qualified individual developing the food defense plan and conducting reanalysis activities. So this is the current breakdown of courses. So just to kind of put an exclamation point on this, four areas where you have to be a food defense qualified individual, preparation of the food defense plan, conducting the vulnerability assessment, identify and explaining mitigation strategies, performance of the reanalysis, I grabbed this sentence directly from the guidance because I thought it was so good and it was cleared, you have flexibility, you have flexibility to determine how many and which people will be food defense qualified individuals at your facility. If that's none, if that's 10, if that's a thousand, you're making that decision. Yes, there's a requirement, but there's options in terms of the way you go about doing that, okay?

And with that I'll turn it over to Julie and she'll talk about food defense plan builder software.

MS. GUENTHER: Hi folks, I know why you really came today, you really just wanted to see the unveiling of the Food Defense Plan Builder version 2.0, that's right? Food Defense Plan Builder version 1.0 is currently the version on FDA's website. It was developed and released back in 2013. It was developed

under the voluntary framework of food defense. The genesis of it was actually a number of international workshops that the group of us went out to do on kind of a voluntary framework of food defense doing workshops and teaching those internationally how do you develop a food defense plan.

And so that was, when we went out there, we used an Excel version of food defense plan generator if you will, and actually it was translated in multiple languages, we took it on the road and people actually really, really liked it. And so based on that positive feedback, we came back to our management here at FDA and sought out funding to develop a software tool, and so version 1 is a user-friendly desktop software application and the goal of that tool was to help the food industry develop a food defense plan.

Since its release in 2013, it's been downloaded, I checked couple weeks ago, over 56,000 times and so that was kind of a surprise to us when we hit 10,000 way back when now to see it going up to 56,000. So that was back in 2013 and since then obviously a lot has happened. The proposed rule, the final rule, and now that revised Draft Guidance has been issued. And I will say that when we go out and speak to food industry, the number 1 question we get is when is version 2 coming? When is it coming? So we've heard you loud and clear, we've been working on it and if I can get this thing to advance you can see it.

UNIDENTIFIED SPEAKER: Building the drama.

MS. GUENTHER: There you go. There we are. Well, so we have updated the Food Defense Plan Builder and now have version 2.0. We've updated the content to align with the guidance that is currently out and to align with the IA rule requirements. Now a few caveats here is that the use of this tool is 100 percent voluntary. Again, it's completely voluntary. You are not required to use the tool. And the use of the tool does not connote or guarantee compliance. So

I like to use a TurboTax analogy since Tax Day just ended.

You know, you can use TurboTax and answer all the questions wrong or inaccurately and still submit a 1040 to the IRS. That doesn't mean the IRS isn't going to come and audit you and find all these errors. So similar to that, this is helping you put the information together and organize the information into a food defense plan. Another kind of caveat is we've only developed the tool and we have only developed the version 1 even in format that's usable on a personal computer. So PCs only, not Mac-compatible. Unfortunately we just don't have the resources to do a second development of that tool in a Mac version. And more -- most importantly the tool is not meant to be used as a standalone. We do not intend for someone to be able to download the tool and just plug-and-play, we expect that the user will have read the guidance, perhaps gone through training if they choose, but have some sort of education or experience or training on the IA rule and food defense requirements prior to using this tool.

So it wasn't built to have all that guidance information in there. That will all remain in guidance. It's really just the functionality that you'll have in the tool. A couple of weeks ago we conducted usability study on version 2.0 and those guinea pigs helped us test out some of the bugs, so they got to see it, used the tool a little bit, at least the beta version and that was really, really helpful. We had two groups of industry participants and some of you are here in the room and online and again I thank you for your time, that was a very good feedback session because, you know, we can sit around in a room and build the tool and design the tool, but it's really the industry that's going to be using and so having that feedback is crucial to having a tool that's going to be successful and helpful to you.

Some of the new things that we've added in version 2 are the sections for monitoring, corrective

actions and verification, as well as a signature. Obviously, these are the requirements of the rule that were not around when we did version 1. And I'm going to be going through some screenshots of the tool. Another disclaimer, these are not the final versions that you'll see in the actual tool. As I said, we just had the usability study a couple of weeks ago. We are making some changes and tweaks based on their feedback, so this is just a glimpse into what that tool is going to look like.

More or less it's going to look similar with some minor changes in look and feel, usability enhancements. Lastly, I know this question is coming, when can we get the tool? It is coming soon, I promise, I promise. We are working on it. As you can imagine, developing a software tool, any software tool is a lot of work and requires a lot of time, resources and most importantly we want to be able to test the tool so that what we release is quality, that it's not filled with bugs and you're not -- it's not going to crash a computer. So we have to do what we need to do for the content, and then we've handed over to our friendly folks in the IT department, and they go through their list of exhaustive tests that they have to run through, and then it has to go through legal. So as you can imagine, there are lot of steps, but we are working on it, we've heard you all that you want this tool ASAP and so we're working on it.

But as I'll show you in the output of the tool, you already have all the resources you need in guidance and you will have the training in order to develop a food defense plan. What this basically does is just helps you organize the information and the output of the Food Defense Plan Builder version 2 is just the worksheet, completed worksheets that are in Appendix 1. So while we know it's really helpful because who doesn't want to do their taxes using a TurboTax? Who wants to read through, you know, the 1040 and fill out the boxes themselves? We get it, but I want to emphasize that you have the resources

that you need to develop a food defense plan. This will just be kind of helping you along in making that a little easier. So with that I know it's kind of hard to see. It's at least blurry for me. I don't know if it's better up there, but here are the screenshots from the Food Defense Plan Builder version 2.

The first one is facility information and, on this screen, you'll be able to include just basic information about your facility, about the parent company. What we've added is on the bottom there you'll see the food defense team. You can include the names of the food defense team members that helped you put together the food defense plan. And what you don't see right there is a feature or functionality to be able to add training records or any other associated records related to that individual if they have, you know, education or experience that you want to document, you can upload that, and it will save those records with the food defense plan that you save.

Product description, as I mentioned, this is something that we recommend that you do, not a requirement in the IA rule, but this is similar to worksheet 1-B in the appendix where you can write the information about the product that you are assessing and the products that this food defense plan applies to. The vulnerability assessment tab is kind of the most meaty of the Food Defense Plan Builder. We have two options for the vulnerability assessment tab here. You'll see the two radio buttons, one for key activity types and one for three elements, so I'll go through the key activity types section first.

This is where the user can enter a process step, a process step description and then within the tool determine whether or not it fits with one or more of the key activity types. So they can select that it is a bulk liquid receiving and loading key activity type. The descriptions of the key activity types are on the right-hand side there and those are expandable

to read the full description. So it's all there for you in one easy place when you're going through plan builder.

On the bottom of that dropdown, you'll see an empty box here. That's where you would write an explanation and we've actually built into the tool kind of a add sample content button. So let's say you have a number of process steps that are not actionable process steps because they are not key activity types, you could just select on the dropdown not key activity types and then click that button that says add sample content and it will automatically populate that with this process step is not a actionable process step because it does not fit within one of the key activity types. So it really kind of speeds that process along, especially if you have a number of process steps that are not key activity types.

Similarly if it is one of the key activity types, the sample content will default to whatever key activity type you select. So if you selected mixing and similar activities, then it will say in the explanation box this process step is an actionable process step because it maps with the key activity type mixing and similar activities. So that's kind of what we built in there for key activity types.

For the three elements, it's a little more complex. Now, remember all that math that Jon talked about and that Ryan was afraid of. This does the math for you, so you'll see here the three dropdowns for elements 1, 2 and 3 here and depending on which element you click on, that scoring table changes, so you actually have those scoring tables right there for you. If I click on element 1, there's a calculator button there in blue, you'll get the element 1 calculator. This was, remember, that worksheet that Jon showed you the different columns A, B, C, D, F, G et cetera, these are the same fields.

So you would put in your batch size, amount of product et cetera and it will calculate out for you whether you want to use the volume of food at risk or

whether you want to use the represented contaminants. So you can toggle back and forth using those radio buttons to determine which method or which approach you want to use for element 1. So based on the numbers that you put in, it will calculate the number of deaths and it will automatically map to the scoring table and give you a score for the public health impact score.

That will automatically populate in the tool, but you can still change it if for whatever reason you want to score it higher than what the tool scores it, you can certainly do that, and obviously for each of the scores we would expect either a rationale or an explanation for that. So that's the part where the tool does the math for you and hopefully that will help a lot. It does have under the right-hand side there you'll see the units, so you can select gallons, fluid ounces et cetera. If the batch size is in gallons, but your servings are in ounces, it will do that conversion for you. So you don't have to, you know, ask Google -- how many fluid ounces are in a gallon. It will do that for you.

Element 2 is pretty straightforward. There's no calculator there. It's an assessment that you have to determine, but we have included the dropdown of the scores and then the scoring table there for you. Element 3 also has a calculator. If you've used representative contaminant method or approach for assessing element 1, then you can use the calculator in element 3, just like Ryan showed you how we had that worksheet that has the element 1 calculations and some of those numbers carried over to the element 3 calculations that used representative contaminants, this tool does the same thing. As you can see, the 40 milligrams for the FDA-provided value is there and so it does that math for you. However, unlike element 1, where the calculator actually scores it for you, because there is no numerical score that aligns with some number, it still requires some element of assessment and analysis on your part.

So once you get the number on the bottom here, amount of representative contaminant needed per batch, you still have to do that analysis of can an inside attacker feasibly carry that amount to contaminate the food at this point. So we've done half the work for you here if you're using the representative contaminant approach.

So that's the vulnerability assessment. Once you've gone through the vulnerability assessment and selected those that are actionable process steps, those process steps automatically get moved into your mitigation strategy section, and so the mitigation strategies section of the Food Defense Plan Builder has a link to our online food defense mitigation strategies database. As Ryan noted early on this morning, we are updating that mitigation strategies database content and so the updated content will be coming out in one of the appendices in the third installment of guidance that we'll be issuing later this year.

So right now what it does is it does a connect to our online database. Instead of building a database within the tool, knowing that the tool, you know, will be downloaded, but the database may change, we just offered up a link. So you have to be connected to the Internet and provide -- it will give you an option to connect to the food defense mitigation strategies database and from there based on your process steps, you can do a search of the mitigation strategies.

So this here is pulling data directly from our database and as you can see these are the different process steps that are currently on our database and depending on the -- and the process step that you selected you'll get the list of strategies that are currently on our database. And so you can check the ones that you want to bring into the tool, and obviously these are all suggestions, and then even if you've brought them in from our database, we recommend that you read through them and change them

to make sure that they are written in a way that makes sense for your process steps at your facility. So those are all editable and then we have the fields down there for the explanation for the mitigation strategies as Colin mentioned.

We've added the monitoring procedures section here. This tool then shows each of the mitigation strategies that you've identified in that previous screen. So for each of those mitigation strategies, you have to have monitoring procedures. So this is where you would go through and write out those monitoring procedures, the frequency and then also you can list the names of the records that will document the implementation of the monitoring. So similar to that is corrective actions. Again, it brings in the mitigation strategies and on the bottom are the fields where you would identify and correct the problem where you would list how you might reduce the likelihood of the problem reoccurring and then the corrective action records. Then the verification procedures, same thing, you would, you know, write out your procedures and the associated records for those procedures.

We have left the functionality for you to add a supporting document. We know that some folks like to keep all their food defense plan and documents together and so this is where you can upload for example your flow diagram that you used or a facility map or your emergency contacts or maybe a recall plan that you have from food safety. Those are some of the documents that you could upload into the tool. And what it does is it saves a copy of those documents in the same folder where you saved this food defense plans, so it's all in one place.

And can also include a URL so you have an internal SharePoint page where you store all your HR records for food defense team members because it has their training records. You can include a URL to that SharePoint folder so that it's all in one place. You can go to that -- to the tool and easily find where you keep all your food defense records or food defense

plan information and associated documentation. So what all this does is it gathers all the information that you've inputted into the Food Defense Plan Builder and organizes it for you in the food defense plan section.

As you can see here, this is a screenshot of just the vulnerability assessment page and this output is exactly the same as the output or the worksheets that we have in appendix 1, so really it is just helping you organize that information, putting in a user-friendly way so you can type it so that it spits it out into these worksheets. You can print, you can export the food defense plan into Word, Excel or PDF and you can also choose to just select one section or all the section if you have somebody, you know, coming to do an audit that you can just select certain parts of the food defense plan for them to do the audit on.

Then lastly is the signature section and this is new. As I mentioned earlier, the owner/operator, agent in-charge, is required to sign the food defense plan upon initial completion and reanalysis, so we've included functionality for them to do an electronic signature or they can print out the document, sign it in ink and upload it back into the tool and so that the signed versions are in the tool itself. We also have on the right-hand side there, there if you were to sign -- every time if you sign the food defense plan, it will save an instance of that. So it will save it, you can write notes about what changes you made since the last signature. So it's kind of a version control if you will.

The tool also allows you to export a copy of it, so for my facility A and I did my food defense plan, or if I did my vulnerability assessment and you know, Ryan is at facility B, he makes exactly the same thing or very similar foods, I can share my food defense plan with him by exporting a copy and sending it to him. As long as he has the Food Defense Plan Builder software downloaded on his computer, he can open that plan.

So that is kind of the overview in a nutshell of what's to come in Food Defense Plan Builder version 2. Again, we are making some additional changes and enhancements based on user feedback and we hope to have that out pretty soon.

MS. BARRETT: What a great tool. I -- just curious, can we just see maybe a show of hands of people who have used it or are familiar with the plan builder? Okay, a good number. Great. Looking forward to the next version. It truly is a remarkable tool, so congratulations to the team of where you are on that. We're going to ask the team to come up and sit at the table. We are going to move into a question-and-answers segment of our agenda.

So again we've shared a lot of content this morning and really look forward to your questions. We have one microphone here in the room, so if you are interested in asking a question, we do ask that you come to the microphone. I know this room is not a great room to maneuver in, but if you could please come to the microphone that would be -- we really need that for the transcript. We are also taking questions from the webcast audience and my understanding is we have Caitlin in the back who is monitoring, looking for those questions and has the ability -- thank you for thumbs up -- to read those out loud.

When you do ask a question, if you want to direct it to a specific team member, you know, please do. And again, you know, we want to keep the questions to the Draft Guidance. That's what we're here and prepared to discuss today and have the expertise. So again, the -- really the floor is open. If you have a question, please come on down to the microphone and I will periodically check with Caitlin to see if we have any questions from the webcast audience.

Elizabeth, if we could have you come up, thanks. And when you do ask a question, if you could just say your name and affiliation please.

MS. FAWELL: Elizabeth Fawell with Hogan

Lovells. My questions are for Julia. For the Food Defense Plan Builder, and you may have said this, and I apologize if I just missed it, if you previously used 1.0, will your process steps that you entered in port into 2.0?

MS. GUENTHER: Yes, that's a good question. Sorry, I did not touch on that, but, yes, we are working on backwards-compatibility. So you won't be losing all of the information from version 1.0. However, we are eliminating a few of the sections from version 1, so what used to be called "broad mitigation strategies," the action plan that goes with that and the emergency contact section, those will no longer be in version 2 and so what we're working on is for those that'll be imported as a PDF document to your supporting documents.

But if you've conducted a vulnerability assessment using version 1.0, those should carry over to version 2.0 with some tweaks obviously because in version 1 we only had the two elements and so now we have the three. So we're working on kind of the mapping of that, how we brought in from between version 1 and version 2.

MS. FAWELL: Okay, thank you. And I have a second question related.

MS. GUENTHER: Yes, please.

MS. FAWELL: Which is how are you all thinking about companies using the Food Defense Plan Builder tool if they want to use the hybrid approach?

MS. GUENTHER: Yes, and actually I should have touched on this again. Within that vulnerability assessment section, I don't know if Kari can bring it up if you go back a few slides. Keep going. Right there, that's good.

MS. BARRETT: Okay. Thank you.

MS. GUENTHER: So you'll see the vulnerability assessment section, there is the two radio buttons for key activity types and three elements. For each process step you can choose the method that you want to use. So for step 1, if I'm

using key activity types, I can use the key activity type radio button and do that analysis. For the second step, I've done the key activity types, so I decided, oh, it didn't really align with the key activity type, I want to use the three elements. You would toggle over to the other radio button for three elements. So that's how we would use a hybrid approach. Because the hybrid approach isn't exactly a third approach, it's just using both approaches for the one vulnerability assessment.

MS. BARRETT: Okay, now can we have another question. Again, if you'll say your name and affiliation?

MS. BURCHAM: Hello, my name is Sara Burcham. I'm with Lidl US. I think anyone can address this, but I'm curious about the impact on importers.

DR. NEWKIRK: Sure. So I can start, and folks can jump in if they want to, but the coverage -- this speaks to the coverage of the rule, so this is both domestic and import or international facilities that are required to register with the FDA. So if those groups or those facilities outside of the U.S. are required to register with FDA, they are covered by the rule. Now, some of those exemptions may apply, but kind of the universe's coverage registration.

MS. BURCHAM: Okay, I see. And then as a follow-up question to that, would be the responsibility of the importers to make sure that they have two defense plans?

DR. NEWKIRK: So we do get a lot of questions about this too and if I can read into your question just a little bit, and tell me if I'm reading incorrectly, so do the FSVP rule and the Intentional Adulteration rule touch like the PC rules do in FSVP, the short answer to that is, no, they do not touch. So there's not a connection between FSVP and IA like the other rules. What happens for international facilities that are covered by the rule, they do need to have a food defense plan and I don't know if you want to talk about some questions a little bit.

MR. BARTHEL: Yeah, I'll just add to Dr. Newkirk's comments, this rule is facility-based in nature, so we don't have requirements for brokers or importers or other people that are performing business activities associated with the food industry at large that are not operating a registered facility. And so we will implement this rule similar to the PC provisions of that regulation whereby covered facilities that are offering food for import into the United States will be covered by this rule and we will have a similar type of implementation strategy for them to where we would do risk analysis and determine whether we would need to take any kind of inspectional activity periodically in the foreign arena.

MS. BURCHAM: Okay.

MS. BARRETT: Great. Thank you. And I just saw the transcriber look at me, so I'm going to remind our team to when you do respond if you'll just say your name for the record. And for her benefit it was Julia Gunther speaking first and Ryan Newkirk and then Colin Barthel, okay? All right. Yes, another question?

MS. HOFFMAN: Great. Hello, Jill Hoffman with McCormick & Company. This is actually something Colin spoke on, but anyone can answer it. So Colin, when you were going through the mitigation strategies and talking through the senior and trusted employee way of meeting as a mitigation strategy, you suggested an elevated level of vetting. Do you think you could give just some insight into what might be acceptable as an elevated level of vetting?

MR. BARTHEL: Sure. That's an excellent question and it's one that we got fairly frequently, and we went into a decent amount of detail within the guidance chapter on what vetting is, what that might look like, certain aspects of kind of what behaviors an employer would make when they're vetting their employees. So the easiest one to kind of conceptualize would be something about reference checks or background checks as part of a pre-

employment screening process. That's one way to do that to establish this is somebody that I would want to hire.

Now, we also go into a discussion in the guidance on if you have particularly vulnerable points and you really need to make sure that the people authorized to work there have an elevated level of trustworthiness. They can do that through demonstrated responsible behavior at your facility over a period of time or you might want to overlay a level of vetting to make sure that those people don't have any kind of susceptibility to poor behavior or bad judgment. Similarly, you could have a kind of a basic pre-employment screening process for everybody, but for those people that are working at an actual process step, you might want to go a bit beyond what your normal practices would be in that regard, or establish more stringent standards for people in those areas.

So that's one way that you could go about doing that. We do caution in the guidance and we continue to caution since the guidance came out and since the rule came out that we wouldn't necessarily recommend that a facility rely solely on the results from a background check in order to establish that level of trustworthiness, that that can be a data input into that decision and simply because, you know, depending on the provider you are using for that background check or the timeliness of information as it gets put into the system, there might be aspects that you would want to look at aside from solely the background check to make that decision, but that's part of the facility's judgment in their identifying those individuals.

MS. HOFFMAN: Okay, great. So it sounds like there is flexibility in defining what that vetting process is?

MR. BARTHEL: Absolutely.

MS. HOFFMAN: Great. Thank you so much.

MS. BARRETT: Okay. Yes. Thank you for your

question. I am going to go to Caitlin. Caitlin, do we have any questions from our webcast audience?

MS. HICKEY: Yes. The first question is, in contract manufacturing situations, who would be responsible for the food defense plan?

MS. BARRETT: And again, if you can state your name for those who are responding to this?

MS. HICKEY: That question was from Helen Liou.

MR. BARTHEL: Yeah, I'll take a shot at this and then -- this is Colin.

MS. BARRETT: Thank you.

MR. BARTHEL: I can take a shot at this and then other people can join in. So the rule is directed towards individual facilities and the owner/operator or agent in-charge of that facility is the term that we use and it's the same term across other rules. And so whether a facility is engaged in a contract relationship with another company to manufacture a food product on their behalf, the person responsible for actually signing off on that food defense plan would be the owner/operator or the agent in-charge of the facility performing the manufacturing. Anything else?

MS. BARRETT: Caitlin, is there another question?

MS. HICKEY: Yes. This is from Margaret Eckert. And the question is how are foreign manufacturers being informed of these requirements, especially having to do with language barriers?

DR. NEWKIRK: I didn't catch that. Hey Caitlin -- this is Ryan. Caitlin, can you repeat that? I didn't quite catch that.

MS. HICKEY: How are foreign manufacturers being informed of these requirements, specifically having to do with language barriers?

DR. NEWKIRK: So there are a number of education and outreach -- this is Ryan again, sorry. There are a number of education and outreach activities that we've been doing since before we

published the proposed rule. Julia mentioned some of the early Food Defense Plan Builder activities where it was actually paper-based and then Excel-based. So we have been around the world. I don't know if we have current account of countries we've been in, but we also have talked to WTO. We've talked to international associations. Jon, you may need to help me, but a few years ago we talked to -- within South America association -- there has been a number of activities where we've been purposely targeting education and outreach for the international audience. We know that there is a lot of interest. We know that there are folks that really want to comply and need to know the requirements of the rule.

In addition to our education and outreach activities, we are, when and where possible, translating as much as we can, not only the rule, but hopefully also the guidance when we get around to it. For the trainings through the alliance for the other rules, there have been international activities and I wouldn't see why we would be any different for the Intentional Adulteration rule courses either. So lots of geared towards them and Jon, do have extra -- yeah.

CAPT. WOODY: Point. This is Jon. Just one point I would add on this. We -- FDA as I'm sure many of you know also has foreign posts and we have for many years worked with staff at the foreign posts on food defense-related activities. In addition to that, there's an International Affairs Staff here in CFSAN. There's also an Office of International Programs. We interface with them very closely. We have long established relationships with them. So we've leveraged those partnerships at the post level, within the center, at the Agency level to help us disseminate information and there's been individuals at the posts who have been going out and giving presentations on the IA rule now for a number of years. Just wanted to add that. Thank you.

MS. BARRETT: Okay. Thank you. Yes, and we have a question in the room.

MR. BAUER: Hi, Bob Bauer, Association of Food Industries. I have a couple of questions regarding the kind of interaction with the other rules. So I just wanted to confirm before I think I heard that the -- an FSBP inspection wouldn't be the importer is not going to be asked for records related to IA rule. But then also for a manufacturer whether based here or there, is it different types of inspections or is it going to be incorporated into a PC inspection type of thing? Are you -- I know there's a lot of flexibility, are you envisioning separate type of records for each rule? In some cases, it's obvious there'll be some IA -- there's going to be some overlap, just trying to see what you're envisioning.

MR. BARTHEL: Sure. We -- the Agency kind of has broken out the FSMA implementation into what we just kind of internally refer to as Phase 1 and Phase 2. Phase 1 is rule writing, guidance development, training development. And Phase 2 is the development of our implementation strategies to include inspectional frameworks and approaches, compliance processes, those kinds of things. So for the Intentional Adulteration rule, Dr. Mayne, when she provided her opening remarks, mentioned that we will be starting this rule's implementation by what we call "Food defense plan quick checks." These quick checks will be a standard component of a routine food safety surveillance inspection for another regulatory program. So if you're covered by the PC rule and you're also covered by the IA rule, you would go through your PC inspection as you normally do now and when we begin inspectional activity for this rule, as she mentioned in March of 2020, that food defense plan quick check would be a component of that inspection.

Similarly, we have coverage that extends beyond the PC rule for its food safety plan provision. So we include facilities that are regulated by the Juice HACCP Program, the Seafood HACCP Program, dietary supplements, low-acid canned food programs.

Those programmatic inspections will also include the food defense plan quick check. And so in the future, once we begin to really understand where we are with these quick checks, the Agency certainly then could begin a program of comprehensive food defense plan inspections on facilities that we would want to go to for one reason or another through a prioritization process. But for now the plan is to couple those food defense plan quick checks with an existing and scheduled regulatory inspection.

MS. BARRETT: Okay. Thank you for your question. Are there questions in the room? Okay. And again, thank you Colin for…

MR. BARTHEL: Oh, yes.

MS. COOK: Good afternoon. I haven't looked at my watch, but it feels like afternoon.

MS. BARRETT: It is. It is.

MS. COOK: Okay. First question. The address of this document is the one that's been on the screen on the (cross-talk)…

MS. BARRETT: For the food defense plan Builder?

MS. COOK: Right

MS. BARRETT: That -- I think this next version hasn't come out yet. Julia, did you want to speak to that?

MS. GUENTHER: Correct, yeah, so the current Food Defense Plan Builder version 1 is what's on our FDA website.

MS. COOK: okay.

MS. GUENTHER: Version 2 is still under development, so that's not up yet.

MS. COOK: Oh, okay. By the way, I'm Nancy Cook. I'm representing Sunshine Mills.

MS. BARRETT: Thank you.

MS. COOK: One question that I have here is for the Agency proper and you may or may not be able to answer that. A lot of food grade product is imported in the United States for use in pet feed. A lot -- a lot of that, that's how the melamine and

related products situation happened. Are all our suppliers going to be required to deal with those same rules -- these same rules?

DR. NEWKIRK: This is Ryan. So when Julia covered -- when Julia had the exemption slides up there, one activity that's exempt is manufacturing, processing, packing or holding of animal food. So no requirements for those activities in the context of the IA rule.

MS. COOK: Very good. Thank you.

MS. BARRETT: Okay. Thank you for your question. Okay, I'm going to take another question from the room and then I'll go back to Caitlin and see we have from the webcast.

MR. HAND: Hello everyone. Max Hand, Lidl US. My question is about exemptions. This could be I think probably for everybody, but would a distribution facility that only handles finished products and say fruit and vegetables in cases, would that be exempt from the rules here?

DR. NEWKIRK: This is Ryan, and Julia may want to chime in here too, we get a number of questions about the exemptions as you can imagine. So for facilities that only distribute foods, there's a number of preamble comments and responses that we've worked through that indicate for specifics, so if you're only distributing food, if you're doing no manufacturing, there are a number of cases where we can see that that facility is exempt. And then you specifically are asking about RACs, is that correct?

MR. HAND: Correct.

DR. NEWKIRK: Yes. So another exemption that we have is activities under the FSMA Produce Rule. Any activities under the farm definition of that rule are also exempt from the IA requirement. So if you're -- if the distribution center that you're talking about also only deals with RACs, we can see examples where you would be entirely exempt, but I would recommend that you go back to the preamble of the final rule because there are a number of these

specific questions where we work through more details than that. So you may have a little bit more of a stronger answer from that preamble.

MR. HAND: Okay. May I ask a follow-up? So hypothetically if a facility only handled just finished packaged goods and you know, say, you know, 25-pound cases of tomatoes and bananas, would that be a facility covered under the rule?

DR. NEWKIRK: So how you explained it, no. But again, there could be more example or details there that would bring you into coverage for the rule.

MR. HAND: Okay. Thank you.

DR. NEWKIRK: Sure.

MS. BARRETT: Okay. Thank you for your question. Caitlin, I'm going to come back to you and see if we have any webcast questions.

MS. HICKEY: Yes. This question is from Earl Arnold. It's a question for Jon I believe. Can you elaborate on how equivalent training as it applies to food defense qualified individuals would be considered?

CAPT. WOODY: Sure. This is Jon. So I guess the answer is best given in the context of the larger FSMA rules. There is a process underway to establish that equivalency as it relates to the other rules, PC in particular. And I would imagine that the IA rule would closely follow suit with that. I believe the guidance -- if I'm correct guidance working its way through this system. So probably the quickest answer is more information to come on that. There is some guidance that will provide more clarity on what we mean by equivalence there as it relates to training. That's about the best I can offer unless others have comments on at the moment. Thank you.

MS. BARRETT: Okay. Thank you. And Caitlin, I will come back to, we do have someone in the room who has a question.

MR. TANNER: Yeah. Hi, this is Ron Tanner from the Specialty Food Association. I've got a question from one of our members. So if an inspector

disagrees with the vulnerability assessment and mitigation strategy of a facility, is there any recourse beyond that?

MR. BARTHEL: So…

DR. NEWKIRK: This is Colin.

MR. BARTHEL: Oh yeah, this is Colin. Thank you, Ryan, for the reminder. This rule does have, as you saw, a number of judgment areas where a facility would need to make a decision based upon their best knowledge. And so when we are engaging with facilities, we're looking not for -- we're not looking to discredit or dispute something, it's more does the rationale and the logic makes sense through that process. And so if there is an issue, we would come together and discuss that with that facility and with that specific scenario in mind and work through what we need to work through. But we're not coming out of this rule with the perspective of sharp delineations on what would be appropriate and what would not.

It's so facility-specific that it's hard to really get into that type of discussion as medium, but it would be a discussion with the facility in how to move forward.

MR. TANNER: Okay. Great. Thank you.

MS. BARRETT: Thank you, Ron, for your question. Caitlin, I'm going to come back to you. Do you have any further webcast questions?

MS. HICKEY: Yes. This is from Judy Gucius. Is there a requirement for the food defense qualified individual to review and sign monitoring and corrective action records within a certain timeframe or can it be the signature of another individual to be sufficient?

DR. NEWKIRK: So -- this is Ryan. I'll start and then if Jon wants to jump in about the FDQIs in particular. So there's no requirement for initialing the monitoring records that relates to -- specifically to a food defense qualified individual. Jon did mention that for folks that are doing anything under the IA rule, you need to be qualified to do so. But

the more complicated, the more complex requirements that Jon mentioned including conducting the vulnerability assessment, reanalysis, et cetera, there's no tie there for a food defense qualified individual to initial or sign off on those monitoring records. Happy to take a follow-up if that didn't totally answer their question.

MS. BARRETT: Okay. Thank you. And we'll go again to the room for a question.

MS. SERVICE: Hi. My name is Paige Service. I'm with The Hershey Company. I have a question for Colin. So you mentioned cameras. You get a lot of questions about that. How can we view them as a deterrent? So does that count for something that just having a camera there looking at a vulnerable step would deter someone from doing something there?

MR. BARTHEL: It's a good point and it's one that we've heard and it's really not within the level of how we would analyze through the three elements what the deterrent factor would be. It's similar to like a sign or something like that. So there's either access or there's not. And so -- or there's either the likelihood for somebody to successfully contaminate or there's not. The deterrent factor gets to would that person know that they're being observed. And so it would go through the process of would a person that's likely to enter this area with the intent to contaminate the food in that area, would the observation occur such that that person would be detected?

Now, that might be the deterrent factor that would prevent somebody from going in there in the first place. But really it's the observation that's protecting the step rather than the fact that there's a camera in the corner that might make somebody think twice. It's the fact that the act -- the malicious act would be detected and prevented in that regard.

MS. BARRETT: Okay. Thank you for your question. Are there questions in the room? Okay. Caitlin, I'm going to go back to further questions

from the webcast.

MS. HICKEY: Yes. This question is from Karen Whaley-Krumins from Sterigenics. She writes, "I have a question related to contract sterilizers. Our processes do not include any open products and we are struggling with how to apply the IA rule to our facilities. We do not have any of the key activity types and the three elements would be difficult for us to assess. We also do not fall into any of the exemption categories. Do we just need to do the vulnerability assessment and rationalize that there are no areas to mitigate? Thank you."

MR. BARTHEL: So I'll start, and I'll try to verify that we understood the comment correctly is that this was a…

MS. BARRETT: This is Colin.

MR. BARTHEL: Oh.

MS. BARRETT: Thank you.

MR. BARTHEL: So anytime in the transcript when nobody introduces themselves --

MS. BARRETT: Right.

MR. BARTHEL: -- it would be safe to assume it was me talking.

MS. BARRETT: Okay. We got a thumbs up on that.

MR. BARTHEL: So in the comment responses to the final rule, we certainly recognize that there will be scenarios where a facility that's technically covered by the rule may not have any significant vulnerabilities. And so in the case that I believe that we heard Caitlin say, this facility has read through the key activity types, they've concluded they don't have any process steps that align with those key activity types, what do they have to do. And so if they're still covered by the rule, as in they're still a registered facility and they don't qualify for one of the identified exemptions, they would have to go through that process of concluding that they don't have any significant vulnerabilities. Earlier in the day, Jon mentioned that the vulnerability assessment

is a pathway to get through future decision-making and he said that the identification of the significant vulnerability is the point of the vulnerability assessment.

And where you have significant vulnerabilities, then you have secondary actions, mitigation strategies, monitoring procedures et cetera. So if through an appropriate vulnerability assessment, a facility concludes that they do not have any significant vulnerabilities, they would not have any actionable process steps and thus wouldn't have any mitigation strategies to implement. They still, however, would have a food defense plan that would document that vulnerability assessment and justify and explain those conclusions. So they're not exempted from the requirements, they've just concluded that they don't have any significant vulnerabilities in their food defense -- or in their vulnerability assessment and that would be the confines of their food defense plan. Or anybody else wants to join in? Okay.

MS. BARRETT: Okay. So I'm going to step out of procedure for one moment because I've looked at Betsy Booren standing at the top who is our one person offering public comment today. And I understand that it's somewhat brief. So what I'd like to offer Betsy, if you're amenable, Betsy is with Grocery Manufacturers Association, is I'd like to go ahead and offer her the time now to make that public comment with the thought that it might also spur further thoughts for questions.

After the public comment we'll go back to the questions and again if there's anyone else in the room who wants to just offer a statement, you would be welcome to do that as well. But I think in fairness to having you wait, let's go ahead and go through that if you'd like.

MS. BOOREN: Well, thank you. I was quite happy to wait, but I appreciate it.

MS. BARRETT: Okay.

MS. BOOREN: Good afternoon. I'm Betsy Booren, Senior Vice President of Science and Technology. As Kari indicated, I work for the Grocery Manufacturers Association. GMA represents the world's leading consumer packaged goods companies. The CPG industry plays a unique role as the single largest U.S. manufacturer employment sector delivering products that provides the wellbeing of people's lives every day. GMA advocates for rational, informed, uniform regulatory frameworks that are based on risk-based science, promotes choice, builds customer trust across the sectors we represent from household products to food and beverage.

We thank you for holding this public meeting and allowing for further stakeholder engagement and ensuring that the guidance is understood by those developing the food defense plans. We also welcome the opportunity for additional discussions with the Agency as we do share the common goal of protecting consumers from acts of intentional adulteration. The U.S. food industry has long supported FDA's efforts to address intentional adulteration in our food supply. Since September 11, the various sectors of the food industry have been engaged in voluntary food defense efforts and overall successfully protected the U.S. food supply from these acts.

What we have learned though in the last 18 years is our experience has taught us that there are different options to delivering and implementing food defense programs which we appreciate as you talk about with flexibility for latitude. We are currently working with our members to develop comprehensive and thoughtful comments to the Draft Guidance and we will intent to submit them to the record later this year. As you've all indicated, flexibility or latitude is a key as there's not a one-size-fits-all and we appreciate you developing the guidance in that means to assist industry in that compliance with the rule. Although the -- throughout the revised document there are many useful templates and examples and GMA

welcomes the opportunity if you believe additional ones should be considered to help you work with them to make them practical and feasible for the industry as well as the inspectors that would do ultimately the inspection.

We do recommend that the final guidance along with investigator training should make it clear that there are multiple ways of being compliant to the rule and meeting those requirements. The industry again would work with FDA to ensure inspectors understand how practical food defense systems are utilized within the industry. We believe this will assist in uniform inspections throughout the entirety of FDA-regulated facilities. In addition, to ensure uniform regulatory compliance in the area of food defense, we also encourage FDA to work with their other regulatory partners like the Food Safety and Inspection Service as you share responsibility regulating dual jurisdiction establishments.

These establishments are commonly in a push-pull situation where they have to meet similar but different regulatory requirements. We know that both FDA and FSIS have interagency taskforce working on many of these type of issues in these facilities and we do request that you add this rule and compliance with food defense to those discussions. If it comes out of those discussions that it may be useful to inform and update the guidance on recommendations for dual jurisdiction, we do support that inclusion. At this time, as you've indicated, you've published two of the three-part guidance, but some of the still critical training materials, whether it's FDA as well as other private industry and the tools are not yet available, we want our members to be in the best position to get this right the first time. So we do encourage you to get that information out as soon as possible. We appreciate the update on the tool builder. We appreciate the opportunity FDA to have industry engaged as you were revising that document. I think it makes it more informed, well a better used

tool.

We also recommend that FDA consider engaging with industry as we get through what I'm going to call the shake-down period. As once all the guidances are out, the tools are out, we've gone through the first couple of rounds of inspections, we all know that what is theoretical and what is practical in real world usually comes out at that time. And I think it'd be well worth to talk to and have a dialogue whether formally or informally with industry to see if these guidances, tools and other training materials need to be revised to make sure that we have a long-term successful implementation of the rule. We also want to acknowledge the thoughtful consideration of the agencies throughout the development of this rule and the recent announcement today of industry's concerns.

We do appreciate that inspections will not occur until March of 2020 that will help the entirety of the industry get better prepared. Rest assured that the industry will continue to work to develop and implement food defense plans in compliance with the rule while maintaining in this time period voluntary adopted food defense practices that have successfully worked in protecting the food supply. We thank you for this meeting and we look forward to continued collaboration. Thank you.

MS. BARRETT: Great. Thank you so much for your comment and I appreciate that and again we're still asking for questions and if anyone would like to make a brief statement, you're welcome to do that as well. So do we have further questions in the room? Yes, come on down.

MR. JORGENSEN: The steps…

MS. BARRETT: It is. It is. I know.

MR. JORGENSEN: Good afternoon. My name is Mark Jorgensen with Airgas USA. In light of the FDA and the Food Safety Modernization Act's approach of the risk-based approach to food safety and food defense, in looking at the requirements in Intentional Adulteration, I see that the three elements compose a

lot of the components of HACCP or in the HARPC, you know, where we have severity, detectability, likelihood that we're looking at from a food defense standpoint. In light of that, we also have a cut off with exemptions, but there's also a risk-based component related to food safety and food defense. Do you see any prohibitions where a company or an industry might combine food safety, the food safety plan and the food defense plan component since a lot of the elements, a lot of the mitigating strategies would be the same? Do you expect to see that -- any kind of prohibition in the upcoming inspections?

DR. NEWKIRK: So there are -- this is Ryan. So there are a few different aspects and ways to answer that question. One is through existing activities and records requirements. So records -- the chapter for records is not yet out, but in the final rule we have a provision for existing records. So we do know that folks have been taking lots of protective measures prior to this rule to protect their food from intentional adulteration and some of those measures may have records. So reading through that part of the final rule, the gist is that you can use some of those records to comply with the requirements but look at the details there. So part of the answer there is yes. Another part of the answer there is an example that I highlighted for the monitoring procedures.

There was an example used in the guidance document of inspecting a tank. We highlighted it in the context of intentional adulteration where the mitigation strategy was inspecting the tank to ensure that an intentional adulteration didn't happen with that tank. However, we could see leveraging that with a food safety requirement to check the tank to make sure it's clean. So there are a number of ways that we do see some leveraging. It's not a total one-for-one. The circles on the Venn diagram don't completely overlap, but we can see instances of overlap. Did you want to talk about…

MR. BARTHEL: Yeah. It's an excellent question. It's one we've heard as we move forward from the proposed rule and the final rule. And now that people are kind of grappling with what the vulnerability assessment is actually kind of delving into, we found that people are starting to manage those two plans separately from an information protection standpoint. This is certainly not a requirement of the rule. You can certainly co-locate your food safety plan and food defense plan together if you so choose. What we've found in discussions with stakeholders is that the vulnerability assessment is highlighting a facility's significant vulnerabilities to an attacker, an inside attacker included, as well as the protections the facility is putting in place in order to mitigate that significant vulnerability.

And so facilities wouldn't -- or at least some of the stakeholders that we've talked to don't want those records conflated with their food safety records and would like to manage the food defense plan in a more secured type of approach rather than what they would for their food safety plan. And so that's a decision the facility would make based upon their comfort level with the details that are in their food defense plan and how widely within the facility they would like to manage that. But we have seen industry consistently raise the concern of information protection and that's just one way that industry is -- or some industry members are following to protect the information on -- in their side is by running it as a segregated program especially within kind of the more sensitive parts of the food defense plan.

MR. JORGENSEN: So the mitigating actions to protect against intentional tampering, economic adulteration, that also protect against, you know, the validity scope of intentional adulteration would probably require some blending.

MR. BARTHEL: Yeah, that's an excellent point. You bring up a good point about what a

regulation does is sets the minimum requirements and so in the food safety world facilities frequently go beyond what the base minimum requirement of the regulations state. The same we expect will be the case with this regulation that the IA rule stipulates the basic requirements for intentional contamination with respect to an inside attacker with the intent to cause wide-scale public health harm. There are other concerns that facilities may have with intentional actions by people whether that's product tampering at a much, much smaller level or whether there are economic concerns and they might want to roll those programs into their larger cohesive food defense program, that's certainly an option they could go through if they want to manage it that way. The IA rule simply sets the minimum requirements for the regulatory approach.

MR. JORGENSEN: Okay. Thank you.

MS. BARRETT: Thank you for your question. Caitlin, do we have further questions from the webcast and if we do, can you also indicate how many questions we do have?

MS. HICKEY: Yes. I'm going to read one more question and then there's a set of questions about exemptions that can probably go together.

MS. BARRETT: Okay. Thank you. Go ahead.

MS. HICKEY: First question is from Susan Hough with Masterson Foods. She asks, "How do we manage contracted services that have normal ongoing access to the facility such as pest control technicians, chemical supply, construction companies? Also shipping and transport drivers have access to open manholes of tankers?"

MS. BARRETT: Caitlin, can you repeat the full question if you would? We have a little -- it's a little hard to hear you down here. So if you can speak a little louder too.

MS. HICKEY: "How do we manage contracted services that have normal ongoing access to the facility such as pest control technicians, chemical

supply and construction companies? Also shipping and transport drivers have access to open manholes of tankers."

MR. BARTHEL: So this is a good question and it deals with who you would authorize to be within a significantly vulnerable place. So who you would allow to be around an actionable process step, keeping in mind that the IA rule's mitigation strategies only need to be directed around actionable process steps? So you could have a pest control person or maintenance staff -- contracted maintenance people come in and you wouldn't need to manage them necessarily in other parts of the facility. They could still do their normal stuff, but if you believe that that is a significant driver of the overall vulnerability and actionable process step, you would want to put in place mitigation strategies to deal with that particular issue. That could be something like escorting contracted services at the actionable process step. That could be having dedicated observation of that activity when they're onsite performing those functions.

So that's a way that you can work through that kind of a challenge. It's not necessarily whether they can come into your facility and do their job in other areas. You're directing protections at the actionable process step with those mitigation strategies.

MS. BARRETT: Okay. Caitlin, if you want to go to the second set of questions.

MS. HICKEY: There was one request to see the exemption slide again. So I'm going to try to click back to that, but the first question is from Helen Liou, does this rule apply to dietary supplements?

MS. GUENTHER: This is Julia. The answer is yes, the IA rule does apply to dietary supplements.

MS. HICKEY: And the second question is from Chris Pustizzi. "Would an R&D lab that makes products only for trade shows and customer samples without any product distributed or sold to the public be exempt?"

DR. NEWKIRK: So this is Ryan. We have this exact write-up in the final rule preamble. It's a really good question and it took a little thinking on our part. So basically what that question asked was for an exemption for R&D facilities and we worked through that. It would not be completely exempt. But as Colin mentioned a number of questions ago, we -- in that response we also could foresee where an R&D facility does a vulnerability assessment, determines that they have no vulnerable points, they write the explanations for those determinations and then basically after a signing of that plan they're done.

Now, we announced these triggers, specifically the time triggers, so every 3 years plans need to be reassessed, that still kicks in, but for those 3 years and especially if there's no vulnerable changes -- vulnerability changes there, those R&D facilities are done. But go back to the final rule preamble, search for research facilities and you'll come up with that exact comment response.

MS. BARRETT: Great. Thank you. Caitlin, anything else from the webcast audience? No. Okay. I'm going to come back to the room. Any further questions? Anyone else who would like to offer a public comment or a statement? Okay. I think we may be ready for the wrap-up. Just looking anybody -- everybody good with that? Elizabeth, you have a question? Okay.

MS. FAWELL: Elizabeth Fawell, Hogan Lovells. At what point in the analysis would a company be able to consider the shelf life of their product? And so for example if they have a product that has a long shelf life, could they take into account the ability to potentially conduct a recall or issue a public announcement and therefore prevent wide-scale public health harm should an incident occur?

CAPT. WOODY: So, good question. We actually I think have a good final rule preamble response that touches on this. So this is a really interesting one because you have shelf life, but you also have market

turnover and those things are not necessarily the same. So for example you could have a product with a relatively long shelf life, but actually the market turnover of that is quite short. The example I think of is infant formula. If you look at infant formula, the shelf life of that product is relatively long on the side of the container; however, the market turnover is much, much shorter than that. So the challenge for companies is -- and they may have data that helps them in this regard, but remember something Colin said earlier, this is a prevention-based concept and so relying on the ability to recall a product you're essentially relying on the fact that, well, it's going to be out in commerce, but it won't be consumed based on the shelf life is simply not a good enough indicator because of that market turnover concept.

So that's -- that would be more of a reactionary way of looking at it than the preventative approach of the rule I would say. And we have a good comment response in the final rule preamble that addresses this.

MS. BARRETT: Okay. Thank you. Further questions? Okay. Well, then I would like to invite Captain Jon Woody up to the podium to give some closing comments. Thank you.

CAPT. WOODY: Okay. I will keep this exceedingly short because I don't know about you, but it's past my lunchtime. Let me first of all in all seriousness say thank you. Thank you for those of you who've come out and sat through and listened to all of us talk for many hours. Thanks for those who've stuck with it on the phone. Thank you for your interest, for your collaboration, that's a word I kind of want to key on, the collaboration and the engagement, not just today, not just since the rule is issued, but just faces in the room and I know folks on the phone that have been involved in the food defense space for many, many years even before FSMA came along.

So thank you for your commitment to food

defense. And I want to go back to the opening remarks from Dr. Mayne where she said, we are committed to making implementation as practical and flexible as we possibly can. Balancing that against our desire to protect public health as is the desire of everyone in the room and on the phone. And hopefully you heard the word flexibility a few times today, vulnerability assessments, mitigation strategies, monitoring corrective action, verification not quite so much, but also training. And so hopefully through the day you heard that theme of we want to make this practical. We want to make this flexible and we continue and will continue in that spirit of collaboration as we move forward and as we start to meet these compliance dates when they kick in.

So once again, thank you for your time, thank you for your interest and please don't hesitate to reach out to us if you have other specific questions or items that you'd like to discuss. Safe travels to you all. Thank you.

(Applause)

ADJOURN

MS. BARRETT: That concludes. Thank you.

(Whereupon, the meeting was concluded.)