MEETING OF THE

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY INSPECTION SERVICE

FOREIGN MATERIAL CONTAMINATION,

VALIDATION, AND PREREQUISITE PROGRAM

September 24, 2002
FIRST SESSION
8:00 A.M.

September 25, 2002
SECOND SESSION
8:00 A.M.

Doubletree Hotel, Omaha, Nebraska

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I N D E X

September 24, 2002

September 24, 2002 (Continued):

September 25, 2002

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REPORTER'S CERTIFICATE:

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County of Lancaster)

I, CAROLYN S. FREEMAN, reporter, certify that I reported the proceedings in this matter and that the transcript is a true, accurate and complete extension of the recording made of those proceedings.

IN TESTIMONY WHEREOF, I have hereunto set my hand at Lincoln, Nebraska, this _____ day of October, 2002.

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Reporter

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PROCEEDINGS: (Morning Session, September 24, 2002)

MR. DREYFUSS: Good morning, ladies and gentlemen. My name is Moshe Dreyfuss. I'm a food technologist with the Meat and Poultry Advisory Committee Staff from Washington. I'd like to welcome you all here this morning. We will go over the agenda shortly, but I'd like to introduce first DuWayne Metz, who is the deputy director of the Technical Service Center here in Omaha, who will present some opening remarks.

MR. METZ: Good morning, everyone, and welcome to Omaha. On behalf of Dr. Paul Thompson, the director, and the rest of the staff at the Technical Service Center, we'd like to welcome you all to Omaha and to our third technical conference since we've been located here in the past five years.

We look forward to these opportunities to deal with you one-on-one in person. It's much better dealing with a face than a voice on a telephone. So I would encourage, while you all are here, if you want to make any contacts, we do have several Tech Center folks sitting in the audience in the back and I would ask for them to stand. So if there's any questions or issues you'd like to talk to them about, some of them will be on the agenda. Others are here basically just to visit with you, to provide information, to discuss any issues that you prefer in the hallway or, if you so choose, make an appointment for later on.

Some of you all have made appointments to deal with some of our folks, and if you're not familiar with the Tech Center, it's located -- it's actually -- it's close by. We're on the corner of 13th and Farnam, which is the big glass building if you just walk out front. There's two ways of going. There's many ways. But the two fastest ways, you can either go up to -- south to Farnam Street and over to 13th, or go down on Dodge, which is out front, 'til you hit 13th and then go south. It's approximately four to five blocks, so it's not a bad walk from here. So those of you that have made appointments or plan on making them, hopefully we won't get any rain or inclement weather and everything should be fine.

Some of you may or may not be aware of, but the

Technical Center Service is going through a reorganization that we will be implementing in the near future. From our perspective, that will not change any activity that we deal with the industry. One of our main responsibilities will still be to provide technical information to the field and to the industry, industry organizations, states, federal governments, counties, and that function will not change. So if you hear rumors about a reorganization, they are true. Basically, we just basically -- Some of the functions have been reassigned to different divisions in headquarters. But the function that deals with the industry in providing technical expertise has not changed. So as soon as we get this finalized and we get more information, we will be sending some type of document out to everyone and we'll go from there.

So having said that, I'd like to turn this over to Charlie Gioglio, from the Office of OPPDE, and he will take us through the remainder of the session. Thank you, Charlie.

MR. GIOGLIO: Thank you, DuWayne. And good morning and thank you all for coming out. I'm going to be very, very brief now so we don't fall behind. And Moshe is going to work us through -- walk us through the -- sort of the detailed agenda and what we have.

I just wanted to make a couple of quick remarks.

Thank you to DuWayne's staff and the folks here at the Tech Center in working with us in the Office of Policy in putting this agenda together. And also I think special thanks to Lloyd Hontz and other folks from NFPA and others that work with us in putting together what I think is a very good, full agenda here and getting for us, I think, quality speakers and to deal with a topic that, obviously, from the turnout here, has got a lot of interest and maybe has been sort of problematic in different aspects over the years.

I guess what I was going to say really was since we have implemented HACCP, overall the focus has been on pathogens and biological contamination and so forth, and that's for obvious reasons and all the right reasons and everything. And we have, I guess, both as an agency and an industry, haven't focused directly on the issues regarding physical contamination, which is really what we want to address here, the issue of physical contamination and how that needs to be dealt with in the context of a HACCP plan and a plant and within the larger context of the HACCP regulations.

I won't go into much detail, but we have folks on the agenda that are going to be discussing it from a pure health and safety aspect, of what really are the physical dangers that may be presented to, you know, to human health by physical contamination. We'll get into some detail of that, and then we'll begin -- and then we'll have further discussion into the policy and how we expect these things to be fitted into the HACCP plans.

With that, so we don't fall behind, I'd like to turn it over to Moshe Dreyfuss from my staff in policy who can just walk us quickly through the agenda, and I'm going to rely on Moshe to keep us on track throughout the morning today and this afternoon and tomorrow, because, like I said, we do have a fairly packed agenda. Thank you.

MR. DREYFUSS: Thank you very much. We will have a series of speakers this morning, beginning with Dr. Morales and Kimberly Elenberg, and we will begin one of the first panel discussions on the evaluation of potential hazards. Each of the speakers will present some material, and then we will open it up for questions.

After the break, again, we'll have another speaker, Bob Richardson. Following lunch we'll discuss validation and the current thinking and draft directive on foreign material contamination. And then at two o'clock we'll begin the second panel discussion, discussing controlling foreign material contamination through HACCP.

Tomorrow we will continue with the third panel discussion on controlling foreign material through the prerequisite programs and SSOPs. There will be plenty of time at the end of each speaker for questions. We've set up a couple of microphones. We ask, if you do have a question, please approach the microphone, announce who you are and with what agency or organization you are, so we could have it on record. Plus, it will also help so everybody can hear what the questions are.

Tomorrow -- Let me just say today we are meeting in this room. Tomorrow we will be meeting in the ballroom. So please don't leave anything over at the end of the meeting tonight. Take everything with you, and we will reassemble tomorrow wherever the ballroom is. I'll find it myself.

In terms of what Charlie just said, that if I announce the wrong hour, I'm still on East Coast time, so just please bear with me.

Our first speaker is Dr. Roberta Morales, who is going to discuss the state of affairs on foreign material contamination. Dr. Morales is a senior research scientist and assistant director in the Food and Nutrition Policy and Consumer Behavior Program at the Research Triangle Institute Center for Regulatory Economics and Policy Research. She's a veterinarian with a Ph.D. in epidemiology and economics and has had 18 years of experience in food safety, animal health, epidemiology, risk assessment and economics of food safety issues. She's currently a member of the National Advisory Committee of the Microbiological Criteria for Foods and has served on the U.S. delegation for Codex Alimentarius Commission's committee on food hygiene. She is also an adjunct assistant professor in epidemiology and public health group at North Carolina State University's College of Veterinary Medicine. She has authored several book chapters on food safety and has published extensively.

She will be discussing one of the aspects of the USDA agency's contract with Research Triangle Institute on the overall evaluation of HACCP and its effectiveness. So

I'm pleased to present Dr. Morales.

(Slide show presentation.)

DR. MORALES: Good morning, and thank you for the opportunity to be here this morning. I apologize for this title slide, but what I'd like to describe this morning is one of a series of studies that we've been doing at RTI that was commissioned by FSIS. It's a multi-year study that we started in 1999, and really the purpose -- overall purpose was to do -- conduct an evaluation of the HACCP rule and emphasize those activities in this regard.

Physical hazard studies was one of several studies that we were doing in that -- several hazard studies we were doing. We're also looking at and finishing up reports on chemical and biological hazards. But really this is one of many studies where we're looking at what are the changes that have occurred since PR/HACCP implementation. And we're looking at those changes in food-borne illnesses, consumer confidence, animal production practices and industry productivity, just to mention a few. But it is a fairly extensive study, and so this is really only one small part of that multi-year study.

We worked very collaboratively with various FSIS program offices, as well as other agencies, to try to get this -- these studies accomplished. For this particular hazard -- physical hazard study, this is by no means an inclusive list, but these are the -- some of the folks that were very instrumental in helping us to get this work accomplished.

Now, the objectives of this study really were to identify whether and how identification and control of physical hazards in establishments that are under federal inspection has changed since PR/HACCP implementation. The methods that we used for this study were twofold.

The first one is the one that I'm going to describe more extensively this morning, and in that study we did a study of circuit supervisors, and we asked them about practices of the establishments in their circuits before and after PC/HACCP implementation and what were these practices that were used for detecting physical hazards. And, primarily, we were concentrating on metal, bone, plastic and glass.

The second part, which I'm really not going to spend a lot of time on is we also did an analysis of the FSIS consumer complaint data related to extraneous material in meat and poultry. But the following speaker is going to discuss that in more detail so I'm just going to give you a very quick overview of what our results were on that.

So in terms of the survey, what we did is we randomly selected 34 Circuit Supervisors, two from each FSIS district. And those circuit supervisors, we asked them how many establishments were in their circuit, what were the sizes of the establishments, do those establishments slaughter only, process only, or did they slaughter and process meat and poultry. And the circuit supervisors represented 1,024 establishments in all those circuits, the 34 surveyed circuits. We conducted a telephone interview and essentially asked them what methods do establishments use to detect physical hazards, do establishments address physical hazards in their HACCP plans, do they do so by specifying CCPs and what are the critical limits, and is industry in general assuming more responsibility for identifying and controlling physical hazards.

For the study on consumer complaints, we looked at consumer complaint data related to physical hazards, extraneous materials in meat and poultry. And we used the FSIS consumer complaints database, or the CSIS database.

The data that we had -- that we used for this analysis was from 1997 to 2001. We excluded complaints -- consumer complaints that were related to spoilage, chemical hazards, allergens, microbial hazards, and we also excluded complaints that were related to extraneous materials in imported products. So we had a total of 817 complaints from 1997 to 2001 that were related to extraneous materials in meat and poultry.

This slide just describes the characteristics of the 1,024 establishments that were in our survey, and basically what you'll see is we have a representation of large, small and very small plants, and we also have a representation of a mix of plants that do slaughter only, slaughter and process, and only do processing.

Of the circuit supervisors that were in our survey, they had an average of 10 years of service in that circuit, or in the agency. And the average number of establishments in circuits for the circuit supervisors was 30 establishments. But there was quite a wide range of from three to 72 establishments in any one circuit.

Overall, if you look at all of the establishments that were represented in the surveyed circuits, these are the methods that we asked about primarily and we asked whether or not these were used before and after PR/HACCP implementation. So what you will see is overall visual inspection and grinder checks are the most frequently used. And grinder checks really is when they dismantle the grinders to look for metal fatigue and it's also a way to find out whether or not they've got -- they're going to be introducing some kind of a metal contamination in the product.

We also noted that audits of suppliers increased by 17 percentage points after PR/HACCP implementation. And that's a much larger increase than we saw in any of the other methods, comparing it with before and after PR/HACCP implementation. This increase in the use of supplier audits was across all plant sizes. So large, small and very small plants increased their use of audit of suppliers as one of their methods for detecting physical hazards. And audits of suppliers, there was a range of what was described as what establishments used, and it ranged from doing site visits to requesting routine documentation that was based on HACCP plan or on monitoring, to letters of guarantee from packers, or meat and poultry suppliers, and also letters of guarantee from non-meat and poultry or other ingredients -- suppliers of other ingredients.

I apologize, but these slides -- I think we -- somewhere in the e-mail transmission they got messed up. Let me just go through some of these results here with you.

Visual inspection is the most commonly-employed.

If you look across these different plant sizes, what you've got here is large, small and very small establishments. Visual inspection was the most commonly employed across all plant sizes before and after PR/HACCP implementation. If you look at post-HACCP, after HACCP implementation in large plants, a very close second and third of these methods was metal detectors at 61 percent of surveyed establishments, and supplier audits at 56 percent.

If you look at small and very small plants, grinder checks are a clear close second, with 56 percent of small plants saying that they use that and 52 percent of very small plants using grinder checks. Also, supplier audits were 36 percent and 26 percent, respectively, in small and very small plants.

Metal detectors is a close fourth in small plants at 34 percent, and this is after PR/HACCP implementation. And then the rest are pretty far down in terms of frequency of use.

If you look at the results before -- what they reported as before HACCP use of detection methods, the overall picture is pretty much similar, where you have visual inspection again the most commonly employed across all plant sizes. But before PR/HACCP implementation, in large plants metal detection was a very close second at 57 percent. And grinder checks and audits of suppliers was tied at third at 45 percent for both of those.

When you look at small and very small plants, grinder checks were second, the second most frequently used detection method at 46 and 44 percent for small and very small plants. Metal detection was a third most frequently used before -- detection method before PR/HACCP implementation for small plants at 29 percent. But before HACCP implementation, defect pickers was, I believe, the third for -- third most frequently used for very small plants, and that was at 14 percent. But you'll notice that that's a really much lower frequency of use of detection methods for the very small plants.

We also asked establishments whether -- We asked circuit supervisors whether establishments addressed physical hazards in their hazard analysis and HACCP plans. And 79 percent of the circuit supervisors reported that all plants in their established -- in their circuits addressed physical hazards in their hazard analysis, and the rest said that some to most establishments in their circuit addressed physical hazards in their hazard analysis.

All but one of the circuit supervisors reported that establishments specifically addressed metal in their hazard analysis. Seventy-three percent of the circuit supervisors said that one or more plants in their circuits specified a CCP for metal, but the critical limits varied across establishments.

With regard to bone, glass and plastic, almost two-thirds of the circuit supervisors reported that bone, glass and plastic are specifically addressed in establishments hazard analyses. But the rest of them only addressed them generally as foreign material. However, only one circuit supervisor described a CCP for bone over the critical limit of eight-tenths of an inch. One circuit supervisor reported that some plants in their circuit had a zero tolerance for glass, and another one -- another circuit supervisor reported a critical limit of 1/32nd of an inch for plastic. So there were fewer CCPs and critical limits reported for bone, glass and plastic, for metal.

We also asked about noncompliance records that were documented in their circuits. And over two-thirds of the circuit supervisors said that inspectors in their circuits have documented NRs for physical hazards in some establishments. The circuit supervisors reported a total of 39 NRs that were documented across the 34 surveyed circuits. Most reported only one NR in the circuit, and many did not -- reported that there were no NRs that were documented in their circuits.

But the ones that did report that there were documented NRs, said that only one was reported and very few actually said anywhere from two to four were reported.

Nobody reported more than four NRs in any one circuit. And the most frequent procedure in trend codes were 01C01, 02 and 03. The trend codes -- The trend indicators were all monitoring primarily.

And then very briefly, to describe the analysis of the consumer complaint data, the top line is all -- total consumer complaints from 1997 to 2001. And the red line underneath it are the extraneous material complaints related to meat and poultry. So if you look at the comparison of this, the trends seem to mirror each other, but consumer complaints about extraneous materials in meat and poultry declined 28 percent from 1997 to 2001. But if you adjust the number of consumer complaints related to meat and poultry by the domestic -- total domestic production, then the decline is somewhere in the vicinity of 34 percent over that same time period in extraneous materials related to meat and poultry.

So just to summarize the key findings from the study, overall, circuit supervisors reported that meat and poultry establishments are using more methods for identifying and controlling physical hazards since PR/HACCP implementation. Most establishments rely primarily on visual inspection for identifying and controlling physical hazards. But since the implementation of PR/HACCP, a lot more -- many more establishments are relying on audits of suppliers, and that was a 17 percent increase since PR/HACCP implementation.

Large establishments tend to use detection methods more frequently than small or very small plants. And if you look at the large plants, many will use visual inspection, metal detection, supplier audits and grinder checks. Those are the four most frequently used detection methods, and they're all pretty high up there in percent of establishments that use those -- percent of large establishments that use those. Small and very small plants tend to rely on visual inspection and grinder checks as their primary methods of physical -- detection of physical hazards. And most establishments address physical hazards in their hazard analysis. However, metal is the only physical hazard for which a CCP is frequently identified.

And then, finally, on the consumer complaints data, the extraneous material complaints declined 28 percent from 1997 to 2001. And if you adjust that by total production, domestic production, then that decline over that same time period is 34 percent.

And if there are any questions, I'd be happy to go over those.

MS. RAEDE: Thank you, Roberta. I'm Jeanne Raede. I'm representing Chef America here. That was a very good presentation. It's maybe not so much a question, but I wanted to point out at least what I thought was very interesting in your data. The increase in the vendor audits, I just wanted to point out that as I look at that from an industry standpoint and from a company that's very strong, in those vendor audits I would like to point out that it would seem also that a lot of the decline in the foreign material, perhaps a lot of the use of metal detection, grinder checks might be a result of industry going out and auditing those vendors as well. So I just wanted to --

DR. MORALES: I think that's a good point. It was interesting that the circuit supervisors felt that that was a critical part of the detection methods that were being used, and many of them did comment specifically on use of supplier audits. That's it for questions. Thank you.

MR. DREYFUSS: Thank you very much, Dr. Morales.

(Applause.)

Our next speaker will be discussing the FSIS consumer complaint system. Lieutenant Kimberly Elenberg is our speaker. She is presently at the USDA as a public health nursing manager of the Consumer Complaint Monitoring System. She came to USDA from the National Institute of Health where she was a clinical research nurse. And she is a graduate of the University of Maryland School of Nursing and currently pursuing master's degree in informatics. Just to let you know, she was researching donor engraphment following non-myoablative chemotherapy regimes after allergenic bone marrow transplants in children. I don't think that has anything to do with food, but in case it does, I'm sure she'll explain it. She will -- I understand she is currently a member of the Commission Corps in the U.S. Public Health Service and will soon be entitled to lieutenant commander. I'd like to introduce Kimberly Elenberg.

(Slide show presentation.)

MS. ELENBERG: Can everybody hear me pretty well in the back of the room? Yeah? Good, okay, great. Well, thank you very much for inviting me to participate and to be here. I've learned a lot since I've come to USDA and about the food process. I guess more relevant to that is growing up on a farm. I grew up in Hershey on a farm and apprenticed as a chef at the Hotel Hershey, and so I've gone from the farm to the table and certainly enjoy eating all the foods that you prepare.

The USDA has always played a role in protecting our food and making sure that the product that comes out is wholesome for consumers to eat. It really started in 1906 officially with the Federal Meat Inspection Act. In 1957 we went on through poultry and continued to develop all the way up through egg products until 1996, when I think we really hit a significant level of procedure that really helped with improving the quality of our food, and that was the 1996 Hazard Analysis and Critical Control Point.

This is just to get us in the mood now for the talk. Every time we have a process or procedure, it's always important, once you've implemented it, to go back and look and review to see how effective that procedure has been. In 1999, the OIG came back and reviewed the HACCP activities, and this came under the Food Safety Initiative of the last administration. One of the things that they reviewed was the handling of consumer complaints. As much as we have our eyes in the plant, our production of food is very large. As you know, it's one of the largest aspects of our economy in the United States.

Our best eyes and ears are the consumers. What are they seeing and how are they responding to it? Because they're the people who are going to be consuming the products, so we want to protect their health, and they're also the persons that are going to be supporting our industry. It's their money that's keeping us going. So we want to listen to them, and we want to see what it is that's occurring and use their input as our eyes and ears kind of out in the field, just like a nurse is the eyes and ears for the doctor.

The consumer complaints the FSIS gets in -- and

FSIS, I'm sure as everybody here knows, stands for Food Safety Inspection Service -- uses these consumer complaints to help identify unsafe meat, poultry and egg products in commerce that may have to be removed from commerce. We don't just look at things that need to be removed. What we do is we look at these complaints and most of the time what we do with the complaints is once we've reached a certain threshold, more than one complaint of the same product from the same production lot, is we take a look back at the HACCP procedures in the plant. That's most frequently what happens. We call up. We work through the ADME's, and I'm going go through this shortly, in the different districts, and we go back to the plant and we do an 02 review of the HACCP procedures, or an 04 review of the HACCP procedures, and we think, you know, where -- how can we help industry. You know, because that's what it's about, is working together. How can we help industry to locate where there might be a problem within their procedures, so we can prevent this health hazard.

Recently we had a case where there was a huge knife that was sealed in a package of meat. And we went back. Apparently it had fallen in during the process line. Someone had used a knife to cut open the boxes and it had fallen in before this product was vacuum sealed. Now, the product did go through the metal detector and the metal detector, when it was checked through the HACCP regs, was working properly. But what we found was that the weight of the box for that particular product wasn't moving through at the time that it needed to for the metal detector to work appropriately. And so, indeed, we helped this plant to fix and adjust the timing of the conveyor belt with the process through the metal detector.

The purpose -- Roberta was talking about data from 1997 to 2001 on a consumer complaint monitoring system that was called CSIS, I believe, at the time. That has evolved into what is now CCMS. And what CCMS is, is a passive surveillance system designed to document and track all consumer complaints that are reported to the Food Safety and Inspection Service.

Now, let me explain to you what a passive surveillance system means, because that will help you really put the numbers in perspective. A passive surveillance system is a system that receives consumer complaints. We don't go out and seek complaints. We don't seek information from the public. It is received. So it's voluntarily given. So it is not -- It's representative only of what consumers have called in and given to us, only of the information they have provided to us voluntarily. So the incidents that we're going to talk about when we look at these rates of foreign material are only representative of that population that has called in to a hotline or to a state health department and have provided us with complaints. Many, many more times there occurs foreign materials or other problems with food products and consumers don't call in. We don't really know the incidents or what percentage of complaints are reported, but what we did find was, of the complaints that were reported, the numbers I'm going to demonstrate and show to you today related very closely to the literature and to the research.

So we think that even though our numbers are small, that they're probably a fairly accurate representation of the incidents of injury related to foreign material and the incidence of foreign material in food. It's just I want you to understand that it is a passive surveillance system.

We define consumer complaint as any complaint that is reported to FSIS that is initiated by a consumer, on behalf of a consumer, like by a state health department, that is related to an FSIS-inspected product. Now, these complaints, I need you to understand, are alleged by the consumer. It is not possible to verify all of the complaints that we get in. And oftentimes some of the complaints that we get in are retracted. We had a consumer who called up concerned about a tooth in their soup. Well, we had reports of several bone particles in soups and other reports of teeth in this particular product. And so -- But we hadn't had it verified as of yet. So I sent a compliance officer out to verify it because I really wanted to see if there was a problem somewhere.

In fact, there was a tooth with a filling in this person's soup. Twenty-four hours later the gentleman recalled -- called the hotline again and explained that he didn't realize his wife had lost her tooth while preparing his soup.

So what I'm trying to do is really establish that these complaints are alleged by the consumer. We do verify many of them, but it is not possible to verify all of them. Sometimes product is totally consumed. Sometimes consumers throw it out. There's just various reasons why we can't verify all of the complaints.

The intake areas for our consumer complaints are through the USDA Meat and Poultry Hotline, the Compliance and Investigation Division, district offices, Office of Public Health and Science. We get e-mails, Labeling and Food Protection, state and local health departments and other federal agencies. Right now we haven't really done a huge PR blitz on our consumer complaint monitoring system. We've been running a model for the past couple years in the database to learn from this model. And it has been extremely effective in using our resources as best as possible and in responding and tracking to these consumer complaints and working with the HACCP plans. But it needs to be re-architected so it can support an intake larger than what we currently have. And at that point, we will, you know, go ahead and let it be known on a more wide scale that this system exists for consumers to call in to.

Some of the examples of complaints that are associated with the consumption of meat, poultry or egg products are things that allege an illness, an injury, foreign object or material, an allergic reaction, underprocessing of ready-to-eat product, misbranding, economic adulteration or inferior quality.

Now, sometimes many of these complaints have more than one component. Oftentimes, the foreign object or foreign material in food has the component of illness related to it. And it's not necessarily a microbial illness, and that's not what we're focusing on today. It's more of a, I guess, mental anguish on the part of the consumer. "I saw this in my product and five minutes later I was throwing up," you know. People are very sensitive about the food that they eat and consume.

Examples that we do not enter as consumer complaints are the school lunch program complaints. We have specific ways to handle these that are separate -- and district complaints that are not initiated by a consumer --

so in other words, the competition calls in -- retail prepared product, and product tampering or bioterrorism, and those go directly to the OIG. Sometimes -- One of the concerns that we have is that something that might be product tampering or bioterrorism, particularly bioterrorism, may not be identified as that originally, and so, therefore, may be entered as a foreign material or illness at first. So right now we're coming up with ways to elicit and tease out information that would confirm that it is product tampering or bioterrorism.

Screening the consumer complaints. One of the things we do is we determine if the consumer complaint meets the criteria for inclusion. If so, we search our database for similar cases and determine if further investigation is warranted. If we decide that -- If there's a foreign material that we decide is possible, perhaps it's a very, very small piece of plastic, it doesn't seem to pose a physical health hazard, only one complaint, there's no other complaints against this, or it's really not clear, there's no clear link established to that foreign object in the food product -- A lot of times we have consumers perhaps who are looking for financial rewards, and we really, really can't identify how that foreign object gets in there. We keep track of that because it's important to know that it exists, and it helps us if there's another complaint of a similar nature, to identify that there's a problem.

One of the things that we do to make sure that everybody is aware of the complaint is letters are sent out to the complainant district and to the establishment district so that they're aware of it, and we also send a letter to the plant, making them aware of the complaint, and then a disposition, a letter of disposition to the consumer.

Investigated cases are warranted for one complaint of underprocessing of a ready-to-eat product, one lab-confirmed illness or injury -- we've had many injuries related to foreign materials -- one allergen complaint, two or more foreign material complaints, two or more of quality or economic adulteration and misbranding.

The procedure we have for investigating cases is the ADME of the district is notified, and they send out a compliance officer to initiate an investigation. They verify and collect samples, if necessary. Oftentimes we send these samples to the lab. We do an organoleptic exam, which is a visual exam. A lot of times we have the ability to digest the food product to identify any further foreign materials. The ADME of the district is notified as needed, and they contact and involve the inspector in charge of the plant. And all information continues to be documented and flows through CCMS, giving us a database to work with so that when we do presentations like this, we can look back at the data we have and use it to help eventually guide policy.

Sometimes presence of foreign material or illness can lead to a potential recall, and that is handled by our Recall Management Division.

We follow this up with a letter to the consumer. The consumer is also able to FOIA this letter, so they are able to gain some information on the case. And the letter to the district management of the establishment district also occurs. What they do with this oftentimes is a review of the HACCP procedures, the SSOPs and make any changes or re-education of the plant staff as necessary.

At times, an establishment will have numerous complaints that are not about the same product or not about the same problem or the same product. Maybe different products that have different types of foreign material, plastic, metal, wood, whatever. So we wouldn't necessarily initiate an investigation on this unless it fell under one of the criteria as stated previously. But we do ask the ADME to follow up with the IIC in the plant to evaluate the plant processing activities.

What has CCMS found? Okay. First of all, from 2001 until present, our number of complaints are 1,309. The foreign material complaints make up 331 of those complaints, which is 25 percent of all of our complaints. Those relating to injury represent 6 percent, and those relating to illness represent 7 percent. In the literature, and that's going to be delved into a little bit further by Dr. Goldman, who is one of the next presenters, it really -- they also confirm that it's about a 6 percent relationship of injury to foreign material.

This is my breakdown of foreign materials. Metal is the largest single identified foreign material in our products, followed by plastic and glass. Chemicals was only 3 percent. We can see "other" makes up a huge grouping, so now we're looking at "other" to see if that can be broken down a little bit further. And what falls under "other" primarily is wood, slivers of wood and fingernails.

We also have a lot of complaints that come in, and these are not included for this presentation, on insects, larvae, worms, things like that.

The incidents of glass, "n" is 32, representing 10 percent of the foreign material complaints. This has allegedly resulted in four injuries. So 12 percent of those 10 percent of the complaints resulted in injury, and two of them resulted in illness. Metal represents 30 percent of our foreign material complaints, and 5 percent of them allegedly resulting in injury. The largest injury related to metal are lacerations to the tissues of the mouth, the gums, and throat. And it also led to multiple broken teeth, a lot of denture work that needs to be followed up because of this.

Plastic represents 15 percent of our foreign material complaints. Four percent of them allegedly resulted in illness. One of the cases that we've had recently has resulted in requiring surgical intervention. Ten percent has allegedly resulted in injury or choking, and you can guess primarily these are children that are choking. A lot of this has to do with plastic in emulsified products. I think a lot of times products are reworked, like hot dogs, and this is a big area of identification for plastic in products. Some of that plastic is soft plastic, kind of like the casing, like a thick casing that can't be chewed, and a lot of times it's small, hard plastic. Of special concern, obviously, is for young children because of the size of their esophagus.

And chemicals so far that we've had have not resulted in injury or illness. Complaints identified chemicals usually through smell, taste and sight. What these have primarily have been, have been cleaning fluids that have gotten into the product, you know, resulted from not getting the equipment cleaned properly in the plant, and in one case we had mercury in some soup. It was confirmed in our lab that it was mercury. But really we could not identify the source of this.

And then as I said earlier, "other" is 44 percent of our consumer complaints, and those are wood, fingernails and stones, primarily. Four percent have allegedly resulted in injury. Wood has led to lacerations, and stones have led to dental problems. And 12 percent have resulted in illness. Now, most of those illnesses are not lab-confirmed. As I said, they seem to be more anguish on the consumer's part, the idea of having a foreign material present in their food has led some consumers to violent action, or the threat of.

Some of the papers that we reviewed are by Hamilton, Polter and Hyman, and as I said, our findings really are consistent with their findings, that 5 percent of foreign materials in food result in minor to serious injury.

I have one case summary, like a case study a little bit. We had received at one point two complaints about an Italian sausage with extraneous material. And, in fact, what this extraneous material was, it looked to be like a piece of mirror or something. It was shiny on one side, plastic on the other, and the measurements you can see were pretty long and very thin. And these are the types of foreign objects that seem to cause the most injury, long, thin slivers. Both of these complaints that came in were from identically-coded product from the same store. The alleged consumption of this was from a mother who gave her child some, and this child ended up having blood in their stools. The mom did not relate this to the sausage until as she was leaving to take the child to the doctor, she fed the rest of the food to the dog. The dog consumed the product and ended up with having glass embedded in the roof of its mouth.

The IIC in this case was notified. The other -- The second complaint came in from a woman who, when she was preparing the sausage, found the slivers in her cooking pan, so she did not receive injury from it.

The IIC was notified and the HACCP plan was reviewed in this plant. A Health Hazard Evaluation Board met with numerous representatives of human health, and it resulted in a Class 1 recall with a press release. So it's obvious and clear that the presence of foreign materials in food can present both a public hazard, a public health hazard and a Class 1 recall is definitely felt economically by industry.

Now, these are the recalls that we have that are related to foreign material, and this is from 1982 to present, and that is 122 recalls. The majority of them are related to metal; secondarily, plastic; other, and then glass, which is pretty representative of the complaints that we're receiving in CCMS.

In conclusion, CCMS is one of FSIS's tools used to help assure a safe food supply. Obviously, as we go through the day and we discuss HACCP procedures, there are many, many tools the FSIS has to ensure wholesome, safe food. Consumer complaints are very effective in providing an early warning to possible hazards. We really have come to really appreciate the complaints that we receive from consumers for their value. And the number of reports as a percentage of true incidents, I just want to clarify again, is possibly low because this is a passive surveillance system and it's not widely, widely known, I don't think, to the public yet.

But over the course of time we will make this a tool that consumers can be more aware of.

Data from CCMS, from our Consumer Complaint Monitoring System, suggests minor to severe injuries have resulted from foreign material in 6 percent of the cases. And that's it. Does anybody have any questions for me?

(No response.)

Well, thank you very, very much, and have a good day.

(Applause.)

MR. DREYFUSS: We will now begin our first of the three panels. We will have -- We have two speakers arranged to discuss -- sorry. We have two speakers to arrange (sic) the evaluation of potential hazards, Dr. David Goldman, who will speak first, and Dr. Kerri Harris. It's listed that Ron Eckel will moderate. Unfortunately, he's not here with us today.

Dr. David Goldman is currently deputy director of the Human Health Services Division in the Office of Public Health and Science at FSIS. He is a family practice in preventive medicine public health physician and a member of the commissioned corps of the U.S. Public Health Service. He has been with FSIS since February of 2002. He has spent the last 10 years with the U.S. Army Medical Corps, both in family practice and preventive medicine, and he has been with the Virginia Department of Health, District Health Director, and briefly is the deputy state epidemiologist. Dr. Goldman will talk about the physical hazards of foreign materials. Dr. Goldman?

DR. GOLDMAN: Thank you and I'm very happy to be here today to present to you a discussion about the physical hazards of foreign materials. You're going to get a little anatomy lesson, and I'm going to talk first generally about physical hazards, what the potential is, and then talk a little bit about some reviews that have been done by other federal agencies in their attempts to study the risk of physical hazards. And we'll proceed through that and you'll see what I mean.

(Slide show presentation.)

As I mentioned, I want to start out generally talking about the physical hazards of ingested foreign bodies. Then review some of the literature that's available to us that talks about the epidemiology and the clinical aspects of foreign body ingestion, and then as I mentioned, discuss some of the other federal agencies' efforts to attempt to minimize the risk to human health.

I should first say that there is no literature really available for foreign materials in foods. What exists and has existed over time in the medical literature is what are known as case reports. That is, there's a newly recognized hazard. A physician sees a patient who has a particular unusual presentation and writes that report up and submits it to a journal, and that exists as a case report. But there have not been any long-term studies or studies which have attempted to put together case reports into what we would call a case series or an actual study for analysis. So the literature about foreign materials in foods resulting in illness or injury is quite scant. The literature that exists about ingested foreign bodies really has to do mostly with children, first of all, and ingestion of non-food foreign bodies. So just bear that in mind as we walk through the walk.

As you can imagine, there are various parts of the human body that are at risk from foreign materials. Primarily, the top two, what is known in the literature as the arrow digestive tract. As you all well know and probably have experienced personally, when you swallow foods, you're often or occasionally, at least, at risk of some of that food material getting down into your trachea or windpipe and causing you to cough and gag. So you've had that experience. And I'll show you in just a minute with a couple of slides how that's possible.

Obviously, the mouth and the teeth are at risk for any foreign materials in foods because that's where the point of entry is. And then I'll talk briefly about how the hands or extremities may be at risk.

The hazards to the digestive tract. As you know, when you take in food, the esophagus is the connection between the mouth and throat and the stomach. This is primarily where most of the injuries related to foreign materials have been documented, either laceration or perforation. Laceration is simply a cut in the mucosa of the esophagus. A perforation implies an actual through and through laceration. That is, it's a laceration that extends through the complete wall of the esophagus.

A fistula -- I'll demonstrate with a picture in a minute -- occurs when there is a hole or a communication established between the esophagus and either the trachea or the aorta, which can be even more serious. So there's a passageway that forms there. Obviously, as the food, material proceeds through the digestive tract, other parts of the digestive tract are at risk for either laceration or perforation.

Believe it or not, with all the technology on the internet, it was very difficult to find any good pictures of the digestive tract, so I've got a couple. I didn't have any idea how well these would project, but I'll try to point out a couple of key features, and I've got two slides that are a bit different.

This is a cross-section, obviously, of the mouth and throat. And what I want to point out is that this is the esophagus here. In the front of the esophagus is your trachea or windpipe. The trachea is supported by cartilage, and that's why it's an actual space. The esophagus is supported by muscular tissue, which is soft tissue, and that's why it's what we call a potential space. Obviously, when you swallow, the esophagus opens and allows the food stuff to move downstream.

This slide representation demonstrates a little better the next point. This is your tongue, which, of course, is a big muscle. In the process of swallowing, what happens is that the epiglottis, right here, when you swallow, closes. It proceeds kind of downstream and abuts against this piece of tissue here, which is part of the larynx and closes off your windpipe. This is what prevents you from food, mostly, from getting into your windpipe, because this epiglottis works every time you swallow, with rare exception. Of course, there are people who have difficulties with swallowing who have neurologic conditions which prevent that from happening. But generally speaking, the epiglottis works every time and closes off the trachea to prevent food or liquids from getting into the windpipe.

I mentioned earlier -- and I'll talk more about children. Obviously, children who put any number of foreign bodies into their mouths, especially when they're young, don't necessarily intend to swallow them. So their epiglottis is not necessarily in action when they have a foreign body in their mouth. So what can happen to them is that they're running around with something in their mouth. They get excited. They scare each other when they're playing with other kids. And that's when the -- Because the epiglottis is not in action, that's when some of those foreign materials can actually get into the larynx and down into the bronchial tree. And we'll have a picture of that in a bit as well.

I'm going to talk first about hazards to the respiratory tract. Choking is an occlusion of the airway. Back to that earlier slide, it's some occlusion or closing off of the trachea or some portion of the respiratory tract which would cause choking, obviously, gasping for breath. And, obviously, as I mentioned earlier, children under three are at greatest risks.

Common hazards or commonly reported hazards are foreign objects or food, but not foreign objects in food. Typically, the foreign objects are coins, or toys, or pieces of toys. The way in which food becomes a choking hazard is that if a child swallows some -- a piece of food that is too big for his throat, it can actually become lodged in the upper esophagus, back to that earlier picture, and compress forward. I mentioned that the esophagus essentially is soft tissue. It's muscular tissue, but it can compress forward against the trachea and thereby cause the choking or asphyxiation.

Aspiration is a term that's a big different. It implies that foreign matter has been inhaled into the respiratory tract at some point, whether it's just into the trachea or down into the bronchial tree. And there are several pathologic conditions that can result from this. You can actually get partial lung collapse. I'll show you in the next slide how that might happen. Obviously, if it's organic material, if you've got a foreign body in your respiratory tract, the body's natural tendency is to try to defend itself and it will send white blood cells and other macrophages and cells to try to attack the foreign body. And if it's organic material, then there can be a process set up where infection will occur. In rare occasions you can actually get destruction of lung tissue from a piece of foreign material that's retained.

I had a personal experience. My daughter was about 21 months old and was -- became sick. And it was believed that she had aspirated some foreign material. And children can get quite sick. She was quite ill for a period of time. And although they attempted to look down into her bronchial tree, they never did find a foreign material and she recovered fine. But, of course, you may all have your own experiences with children. It is quite common that they put things in their mouths, and occasionally that material may get into the respiratory tract and cause injury or illness.

Here's a picture again. This actually projects a little bit better than I thought it might. What happens is if, for some reason, foreign material of any sort is inhaled, that is, is aspirated down into this -- into your trachea or beyond, when it causes problems is when it becomes lodged. You know, obviously, the diameter exceeds the diameter of the portion of the bronchial tree in which it's contained. So that especially if it gets down here, for example, and occludes this particular airway, then all this lung tissue beyond that will not receive air exchange as it normally is accustomed to doing with your normal breathing. What would result is, first of all, probably partial collapse of this portion of the lung here. And then as I said, in some instances, especially with organic material, you might get an infection that would set up in pneumonia, which is apparently what happened to my daughter.

Eventually, if it's organic material, it may be ingested by the macrophages and the other defender cells in the lung tissue so that it will eventually resolve itself. But in some cases, especially in inorganic material, it can cause local lung destruction and may require surgical intervention.

Hazards to the mouth and teeth have been frequently reported. I'll mention some specific statistics in a little bit. As you can imagine, if you have a sharp or pointed object that's embedded in your food that you're eating, lacerations to the mouth and tongue would be quite possible. There have been some reports of chipped teeth or broken fillings, damage to dentures and similar types of injuries.

There have been a few reports in which lacerations on the hands have occurred from sharp or pointed foreign materials that are contained in food that occur when the food preparer is handling the food products. Again, that probably makes sense that it would occur in those instances as well.

There are also, in addition to injuries, a variety of illness complaints that have been documented. Kimberly mentioned this a little bit earlier. Many of these are unexplained. That is, there are not any lab tests to confirm these. Again, much of the data is from a patient's report and can't be confirmed. But these are some examples of the complaints that have been reported in the medical literature: Nausea and vomiting, diarrhea, headache, fever, chest pain. A variety of systemic complaints have been attributed to ingestion of foreign materials.

I want to now get a little bit more specific about some of the reports that do exist in the literature. About 80 percent of foreign body ingestions do occur in the pediatric age group. In some reports that's specified as under age three, as I mentioned earlier. In other reports it's not as specific. It's been variably reported, but generally between -- It's thought that between 80 and 90 percent of foreign bodies will eventually pass through the digestive tract spontaneously, without any need for any intervention whatsoever, and this occurs over a several day period of time. It is also estimated through the variety of reports and case series that have been studied, that anywhere from 1 to 5 percent of foreign bodies that are ingested will result in some injury.

Although sharp objects account for a small proportion of foreign body ingestions, as you might imagine and it makes sense, they account for a disproportionate number of the injuries. A hospital in Pittsburgh did a case series of all foreign bodies over a certain period of time, and of those that required some surgical intervention, so that is these were the more serious cases, and they did a consecutive series of reports over a period of time, 37 percent of the foreign bodies were removed from the airway and 63 percent were from the upper digestive tract, primarily the esophagus. So you can see over a period of time with serious foreign body ingestions, roughly it's a one-third, two-thirds ratio of airway to digestive tract foreign bodies.

The FDA, our sister regulatory agency, published a report several years ago in which they reviewed their consumer complaints. They have a consumer complaint system somewhat similar to ours, and they reviewed, in this particular report, all the complaints from 1989. So it's a little bit older data, but in that year they had nearly 11,000 total consumer complaints related to their food products. And of that number, about 25 percent alleged foreign material as the reason for the complaint. Of the total number of complaints, 123, or slightly over 1 percent, were complaints that alleged injury or illness. The most frequently reported injury was mouth or throat laceration. The second most frequently reported condition was gastrointestinal distress, not an injury. And the third most was dental damage.

In that same review, glass was the foreign material that was the most frequently reported as the cause of injury. Actually, in their review, their second most common cause was what they term slime or scum. And, obviously, those resulted not in injuries but in illness complaints. And the third most commonly reported foreign material was metal.

Now, I want to move now to -- I said the last portion would talk about some of the various federal agencies' efforts to characterize foreign materials in their efforts to help minimize risk to consumers. Most of the characterization and study that have been done by the regulatory agencies have to do with the size of the object. Although the shape of the object and the consistency of the object, I'll mention toward the end, have been -- should be considered as well.

FSIS actually convened what was, at that time, called a Public Health Hazard Analysis Board when there was a proposed rule about bone particles back in 1995. This was essentially the forerunner to the Health Hazard Evaluation Board, which is the current format for our considerations of health hazards in food materials. And it was a body that was convened by FSIS and included representatives from the private medical community, as well as representatives from the FDA, who obviously have a lot of experience as well with consumer complaints and food hazards. And one of the things they concluded related to size was that bone particles less than one centimeter did not probably present a safety hazard. Those particles between one and two centimeters did not -- were considered a low risk. And those greater than two centimeters were probably a safety risk or safety hazard, rather.

Interestingly, I read through this several times. They didn't specify which dimension the centimeter referred to, whether it was in length or diameter, but that was the result.

At the same time, they said that the presence of any other foreign material. So they didn't consider things other than bone, but that the presence of any other foreign material might pose a potential hazard, and each of these instances should be considered on a case-by-case basis, regardless of the size.

Many of you are familiar with the Consumer Product Safety Commission. Fairly recently they declared that object -- spherical objects, that is, round objects of a certain size, should be declared hazards to children. Again, the children specified under age three might be at risk for choking, or ingestion, or aspiration of an object that's less than one-and-three-quarter inches. In addition, the Consumer Product Safety Commission uses a device they call a small parts test fixture, which is essentially a cylinder that's, I think, one-and-a-quarter inches by two-and-a-quarter inches. And any small part or piece of a consumer product that fits into that cylinder or is deformable and would fit in that cylinder is judged to be a choking hazard for children.

The FDA, in a separate report, reviewed all of its

Health Hazard Evaluation Board conclusions over a long period of time, 25 years. And when it came to considerations of size, they judged that particles that were one to six millimeters might pose what they termed a limited acute hazard in 56 percent of the cases. Any object, though, that's greater than six millimeters, which is essentially about a quarter of an inch, was considered to present a possible hazard in greater than 97 percent of the cases.

The FDA and the Office of Regulatory Affairs of FDA issued a Compliance Policy Guide several years ago in which they characterized or used the characteristic of size as a guide for their field staff to use in considering potential actions against producers for foreign material contamination. And they came up with these criteria. Any food product that had hard or sharp objects of a certain size, again, about a quarter of an inch to an inch in size, and ready to eat, and they defined that essentially as a product that would not require additional preparation or much additional preparation, which would have -- which if it were possible, would allow the consumer an attempt to recognize this hazard -- So if there was not any further preparation and it was of a certain size, then that would be criteria for direct reference seizure.

Criteria that they established for recommending legal action to the Center for Food Safety are these listed below: Objects of the same size, but those objects in foods that do require some additional preparation, chopping, or cutting, or some manipulation of the food so that the consumer might have an opportunity to recognize those hazards, or objects less than seven millimeters, again, less than about a quarter of an inch and intended for special risk group. They define special risk group as surgical patients, the elderly and infants. They didn't otherwise define those any more specifically. And then, as might be obvious, any foreign object in foods that was greater than 25 millimeters would be a reason to recommend legal action.

I mentioned most of the study and concern has been about the size of objects, but there is also concern about the shape of an object. Obviously, spherical or cylindrical objects and when it comes to foods, you know, pieces of hot dog, or grapes, or raisins, those sorts of things, present the greater risk for choking. But not surprisingly, slender and sharp or pointed objects present the greater risk for laceration or perforation.

There has been some study about the consistency of objects. This is mostly having to do with ingestion of non-food objects in children. Rigid objects, coins or toys, hard plastic toys have caused the most choking deaths in older children, whereas what are called conforming objects, those that are deformable, like balloons, or pieces of plastic, conceivably, that have that same characteristic are more a cause of choking deaths in children who are under age three.

To conclude here, foreign material contamination does occur in foods. Both the FDA reviews and our own reviews have demonstrated at least that through the consumer complaints we do get complaints of foreign material contamination, and we do get complaints of injury or illness that have occurred as a result of foreign materials in foods. And size seems to be the characteristic that is of most concern when it comes to judging the potential for foreign material to cause a hazard.

Interestingly, those particles in food that are small are more likely to escape detection, but the research and data in the medical literature would indicate those are less likely to cause injury, fortunately.

If anyone would like to contact me or get further information, please feel free to do so. And that's the end of my presentation. I think we'll wait until the end for questions. Thank you.

MR. DREYFUSS: Thank you, Dr. Goldman. We'll have questions for Dr. Goldman and Dr. Harris after Dr. Harris's presentation. And just a note of information, we were concerned about the volume of paperwork or papers in terms of handing out some of these presentations. We will be making them available on the web shortly after this conference. So if you have any -- would like copies of the presentations, they should be available, hopefully within the next couple of weeks.

Our next presenter is Dr. Kerri Harris. She's currently the Executive Director of the International HACCP Alliance and has been very involved in standardizing HACCP training programs, assisted with the development of the train-the-trainer course and accreditation program for HACCP training providers. She is also a member of the faculty of the Meat Science Department at Texas A&M where she gained all three of her degrees. She is responsible for team teaching HACCP course for graduate and undergraduate students and coordinating various HACCP and food safety training -- industry training programs. She is the recipient of the Vice Chancellor's Award in Excellence for Industry, Agency Association Partnerships in December of 2000 and the American Meat Science Association's Achievement Award in 2001. Dr. Harris?

DR. HARRIS: Thank you. This morning I've been asked to kind of take the information that we've heard and start the transition into how it applies to what you came for and how you use that information to make decisions about your operations. So part of what I will do is go back and emphasize some of the information that we've already discussed and then talk about how you start using that to make assessments about whether something is a food safety hazard or not.

First, I thought we ought to look at definitions. We've heard through the previous presentations extraneous material, foreign objects, foreign material, physical hazards, food safety hazards and a lot of terms. Just so that everybody is on the same page through the rest of the discussion and the presentations for the next day-and-a-half, we as speakers kind of talked about, we're going to talk and put things in a HACCP perspective from a food safety risk. We're going to talk about foreign material and how they may fit in other prerequisite programs, not food safety issues.

The agency and the draft directive that you received has defined foreign material as non-animal objects, metal, plastic, rubber, glass, et cetera. Not including, if you will note, is bone or those that are from animal -- from selves.

From an industry, when we just talk about foreign objects, we basically mean anything that shouldn't belong in the product. And when you ask somebody to go through and list those, there's usually a long list. I mean, it never fails. You get paper, cardboard, band-aids, plastic, rubber gloves, cotton gloves, string, hair, dirt, mud. I mean, you know, the list goes on and on and on, that people talk about foreign objects, foreign materials that can be found in food.

Taking that a step further and saying, well, what's, then, a physical food safety hazard, if we look at the agency's definition of a food safety hazard for physical, it's a physical property that may cause a food to be unsafe for human consumption, if you take that out of the pathogen reduction HACCP reg. From an industry, using the National Advisory Committee definition, it's a physical agent that is reasonably likely to cause illness or injury in the absence of its control, which is where, when we start moving forward, when we get into the use of these in HACCP today and the use in prerequisites I think is where a lot of our confusion and concern about how to use the definition from the National Advisory Committee on a hazard, which is a very precise, consistent with the principles of HACCP, and gives us some guidance on how we can identify those properties and look at all factors, not just one particular point or one particular factor within our operation, but look at the total operation, the total steps, the total processes that you have in control in preventing, then, the risk or illness.

Today, and if I look across the room, I think there is a lot of confusion over how do we evaluate what's a potential hazard and how do we determine if it's a significant food safety hazard. And if not, how do we deal with it? If we weren't in this state of confusion, I don't think we'd have a standing room only that we have here today. We probably wouldn't be having a technical conference and bringing in extra chairs. Because if we all understood this issue, there wouldn't be any point in being here. And hopefully we can resolve part of the issues and resolve part of the confusion so that when we leave here we don't have to come back in a couple of months and still be discussing the same issues of what -- how to deal with physical hazards in our food safety programs.

If we go into the hazard evaluation, which is the key part of what we need to do, we have to be able to differentiate between a foreign object and a physical food safety hazard. We all agree we don't want foreign objects, extraneous materials in our food. We also agree that there is an adulteration issue about having foreign objects in food. But not all of those foreign objects make the food unsafe. Now, in some of the previous discussions that we heard this morning when we talk about customer -- consumer complaints, one of the slides there said we can use consumer complaints to identify whether the food is unsafe and if, you know, it may cause injury or illness to the individual, the consumer. The rest of that presentation talked about when those came in, you had to be able to distinguish and use the information to make a determination if it was a foreign contamination or if it was something that could make the food unsafe that required additional, you know, support and information and investigation.

How do we make that determination? When do we decide that it is truly a food safety hazard and not just a foreign contamination? You heard some of the previous speakers' references. I went through part of the literature that's available and pulled out some of the information. If you don't have copies of these references, feel free to let me know and I'll try to get them to you. Probably the one as an industry that we wrote -- that we reference most often, because it's a scientific peer-reviewed publication, is the Olsen document, which goes through and talks about the criteria for extraneous material as far as a health hazard. It references some of the same numbers that we heard in the previous presentation on size, shape, particle differentiation, when it is a health hazard and when it is not. So that's one reference.

I think we have the wrong slide set. For the -- Because part of the slides that you just saw are in the next presentation. This, I think, goes back to our e-mail, so we're not going to confuse the issue. There are some other references, and when we post the slides on the internet, we'll make sure that we get the correct one up there for you -- that talk about whether lead is a hazard. There's a case study, and we all are very concerned about lead shot. I thought it would be brought up in the previous presentation, but since it wasn't, I guess I'll be the one to bring the topic up. In fact, I'll be real honest. We were very concerned about what may be in the presentation about lead shot from the previous speaker. So since there wasn't anything, let's throw it on the table.

There have been a lot of discussion on, you know, lead toxicity and lead shot, and how do we deal with it, and is it detectable, and what do we determine, you know, as far as safety issues. There are some documents and some research articles and information out there that talk about lead, intact lead shot versus non-intact, exposure and amount of lead that you would have to consume and whether it's, you know, a child. There was one of the references that was actually in the slide set that goes through and is a case report, as you referenced, for a child who was five-and-a-half years old and consumed multiple lead pellets, metal pellets out of an ankle weight. When they took the child in, I mean, you know, they said there were just multiple, that you could see them, you know, on the x-ray. Definitely, a toxicity issue there and a drastic increase, you know, in elevation levels, and they went through the chelation and the whole treatment.

Most often the information talks about having low risk of having an illness when you just have, you know, one -- if you consume, you know, one lead pellet, one lead shot, you're not going to have very much impact. The number of having high numbers is different. And so when we're talking about incidental contamination in food versus sitting there and consuming, you know, the metallic beads out of an ankle weight, those are two different issues. There are other references. The FDA information that we heard that talks about particle size, consumer complaints. There are references that go through and have looked at all foreign object complaints related to food and whether those, you know, are defined as risk or not risk. And so we need to pull out and look at those.

From an evaluation standpoint, as individuals in our operations, the first thing that we have to know and understand is our process and the instances that we are finding foreign contamination, foreign, extraneous materials, whatever your preference for terminology is, so that we can then evaluate those and look at the particle size, look at the incidental -- the incidence levels to make the determination on whether those things are food safety hazards and whether they're reasonably likely to occur in our process.

From that standpoint, then we can proceed forward and start making the issue of where we're going to put those. And I'm going to skip over these, because the last slide here is applicable to where we're going to go for the rest of the presentations today and tomorrow. We're going to start trying to identify the foreign contaminants, the food safety hazards, and mechanisms that we as an industry and an agency can deal with, addressing them in prerequisite programs, or in our HACCP systems so that then everybody is on an understanding when we're talking about terms and referencing those. So we're kind of setting the stage and moving from all the information that we heard of what we know about our food from the consumer complaints, from, you know, the risk studies that have gone on, from the information that the agencies collected into what we as an industry know about the types of food and products that we're producing.

So with that, I think we'll open it up for our panel questions and move forward.

MR. DREYFUSS: Thank you, Dr. Harris. Are there questions? Dr. Goldman, I guess let me throw the question open from Dr. Harris. Can you address lead, in terms of lead shot from your standpoint?

DR. GOLDMAN: The tack that our agency would take for lead essentially would not be different from the methodology we would use to characterize and evaluate the potential hazard of any foreign material. We have a procedure in place. I mentioned earlier the Health Hazard Evaluation Board. We have had Health Hazard Evaluation Boards convene in the past on the question of lead, not commonly, but I think maybe twice it's come up. And so we would have to consider the potential exposure, that is the dose, the amount ingested, if that's known, the special vulnerabilities of the exposed population, which is also a very important factor and I mentioned earlier in the FDA review they characterize this special risk group. Typically, it's the elderly, the very young and those who are maybe immuno-compromised or who have underlying medical problems. And then we would put the factors that are known to us together in the course of a scientific review of the particular scenario presented to us and make a determination.

So I can't give you a general guidance about lead that is any different than the hazards that we would review of any other nature.

MR. DREYFUSS: The -- What's the more common source of lead in relationship to food?

DR. GOLDMAN: Certainly in our products, the issues that have arisen have to do with lead shot that's found in meat products, mostly beef products.

MR. DREYFUSS: Is there a high leeching of lead from the shot in terms of through the tissue and body?

DR. GOLDMAN: It seems like a straightforward question, but it's actually quite complicated because there are a variety of factors that enter into this equation that would determine the answer, which is how much lead might be leeched out of a product and, therefore, might be absorbed by the body. Just generally, some of the factors are size, irregularity of the surface of the piece, and, of course, you know, its transit time through the digestive tract. I mentioned earlier that foreign bodies tend to pass through spontaneously over a period of days. So, you know, the transit time varies from individual to individual. And, therefore, the amount that potentially could be absorbed by an individual will vary according to their own digestive tract. So those are some of the general factors that would enter into this evaluation.

MR. DREYFUSS: I see. Yes, sir, have a question.

MR. SEWARD: Skip Seward with American Meat Institute. I think I heard in an earlier presentation that about 6 percent of the foreign object complaints that come into FSIS had caused injury and about 4 percent had caused illness. And I wanted to know whether we could have some idea of, have those been confirmed and also, can you characterize what those were? In other words, I think it would be helpful to know more about what those actually were in terms of objects or foreign material, and to what extent your characterization of those parallels what was in the Olsen paper or other characterizations of linking those to be hazardous.

MR. DREYFUSS: I asked Lieutenant Elenberg to join the panel.

MS. ELENBERG: It correlates very -- Can you hear me?

MR. SEWARD: Yeah. I don't know if your mike is working, but I can hear you.

MS. ELENBERG: It correlates very closely with the literature. Olsen is specifically who you stated, and it's within 1 percent correlation. I was busy walking up here so I have to review in my head exactly -- You asked more than one question.

MR. SEWARD: Well, I guess my question was, have those been characterized, logged somewhere, pictures taken --

MS. ELENBERG: Yes.

MR. SEWARD: -- posted, and if so, can you give some description of what those objects were?

MS. ELENBERG: Most of the objects were related to metal, stone or glass. Stone and metal related primarily in dental type of injuries. Glass, relating mostly in lacerations, and plastic relating in choking or problems within the intestinal tract, surgical interventions. Yes, we do, as of recently, have posting abilities to take photos and post them into our system. We do keep photographs of them. Did I answer all his questions?

DR. HARRIS: (Nodding head.)

MS. ELENBERG: I think I answered your questions. Most of the objects that have caused a problem as far as plastic goes, plastic would be hard, rigid. Plastic causes problems with lacerations. The soft plastic seems to cause more problem with choking. The metal and glass and wood objects that cause problems are primarily long, thin slivers.

MR. SEWARD: Have you been able to characterize the root cause behind those? In other words, is it from a tote, the hard plastic from a tote, or is it from a plastic shovel, or is the metal from, you know, a grinder plate, you know? I'm just curious how much you work to -- with the companies or with, you know, people to try to determine what the root cause of those are.

MS. ELENBERG: Yeah. Unfortunately, a large majority of the times, even with a HACCP review, we aren't able to identify the source. We are not, unfortunately, often able to identify the source. Metal grinder plates do play a role in metal foreign objects, for certain. Wood objects, we're just not successful in finding these. Objects that come in, you know, there are foreign objects that we are not talking about today, that we're not focusing on, things like hair. Obviously, we know the source of that. Fingernails, we know the source of that. When it's a foreign object that relates to scum or such, you know, unidentifiable objects like that, a lot of times we'll send that to the plant. A lot of times it ends up being seasonings that aren't, you know, thoroughly mixed, things like that, and they appear to be green and yucky.

But, no, we haven't had a huge success in being able to go back with a review of the HACCP plan and identify the source of these foreign materials. At least that's been my experience.

MR. SEWARD: One more question on this same area.

On the illness side, I think you -- I think in one of the slides there was a discussion about illness, and I'm sort of curious as to what illness results from -- what illnesses have resulted from foreign material contaminations specifically, you know?

MS. ELENBERG: The possibility exists of having a microbial infection, secondarily, result from foreign materials. But that is not our focus today. Our focus today is on the primary complaint. And when we get a primary complaint on foreign material, any illness acutely associated with that seems to be, or appears to be nausea, vomiting, mental anguish, emotional distress on the part of the consumer.

MR. SEWARD: Okay, thank you.

MS. ELENBERG: Thank you.

MR. DREYFUSS: Out of curiosity, in terms of metal discovered as part of a complaint, how much of that is related to the dental work in terms of something being bitten and a tooth breaking off or an actual filling? Has that been investigated?

MS. ELENBERG: When I receive a consumer complaint and I have the description of the metal, I have not yet identified metal that came from dental work, but it's certainly a possibility, but it has not been identified.

MR. DREYFUSS: Okay.

MS. MORALES: Roberta Morales, RTI International. I did not mention this earlier in my presentation, but I did want to follow up on the comments about lead shot. We did ask -- There were several circuit supervisors who did mention that there were establishments in their circuits that expressed concern about lead shot. And, in fact, one of them specifically described one establishment that had an incentive payment for employees when they discovered lead shot in their products. So apparently there is some industry concern about that.

MR. DREYFUSS: Are there any other questions? Go ahead.

DR. HARRIS: Can I make a comment? Going back to, I think, part of what Skip was bringing up on what the hazards actually are, as many of you know, when you have claims or you have consumer complaints coming back to you on foreign material, very often when you get that foreign material, or you get a picture of it, or if you end up in a court case somewhere in trying to settle the claim, we also have to make a note here today that some of those are determined to have never been possible to have been in your product to begin with. And so I want to be very careful that when we're talking about consumer complaints and issues, that part of those, as I think were mentioned, they are there for monetary gain. And, I mean, we all know the stories of taking in the grinder plates or, you know, showing how the emulsification process works and how some of those things that are claimed to be hazards from food could have never been in the food without it being placed there outside of the manufacturing system. And so I don't want us to overlook that particular instance as we move forward.

MS. ELENBERG: In addition to that, I wanted to add that when we look at actions that we are going to take as far as our compliance officers and district managers, further, you know, actions toward the establishment, towards the processing process, we keep that very much in consideration. What really is the possibility of this foreign object to go in?

The other thing I wanted to say was that I believe when you come up as an industry with your HACCP procedures, it's with the consideration of what could possibly be introduced into this food product and how could we prevent that from happening. So just as it is very difficult for us to identify a lot of times the sources of the object, and we've already stated the source may be the consumer themself trying to gain monetary benefits, we just, as you have -- I think it's a difficulty both for us and for industry to identify these possible sources. If we could identify them, then certainly we would issue HACCP procedures that would try and prevent them. I think that has to be -- You know, that's a joint effort we all have to look into.

MR. HANS: I am Lloyd Hans with the National Food Processors Association. While we were on the subject of lead shot, I just wanted to ask a question which I think will come up later on in the program as well. But maybe while we have some experts in the area of lead it would be good to raise the question. But can we conclude that the finding of a single lead shot in a batch of product would not automatically lead to condemnation of that lot of product, that, if necessary, there are mechanisms by which the product could be reconditioned, such as x-raying, and that that would be acceptable?

MR. DREYFUSS: Dr. Harris?

DR. HARRIS: I wondered who would be the lucky one to get to answer that. I will tell you that from the approach of finding the contamination and then trying to deal with the rest of the product produced, that my initial response to you is that the company, then, would be responsible for going through and showing how they evaluated the product, and, yes, there should be other mechanisms. A single finding, in my opinion, would not deem that lot, that production of product, as adulterated product or, you know, require condemnation. The plant would have to be responsible for showing how they evaluated the product and to support their determination on the safety of the product from that point forward.

DR. GOLDMAN: I would just add that from our agency point of view, such an occurrence may not come to the Human Health Sciences Division, necessarily. It may be dealt with by, you know, the office of field operations, or the recall management division. There are different entry points into our agency in terms of the questions about adulteration and not all of which result in some consideration by the Human Health Sciences Division or our

Health Hazard Evaluation Board that I mentioned, as to whether a health risk exists or is posed by this situation.

MS. ELENBERG: And also from an agency point of view, we agree with Dr. Harris. Any complaint that is a single complaint, we always go back to that plant, to that establishment, and it is on the responsibility of that establishment to demonstrate to us the possibility of how that entered, what they've done to prevent it and consideration is given that way on an individual case-by-case basis.

MR. DREYFUSS: If there's no further questions, why don't we take a break and reconvene about 10 minutes -- I'm sorry.

MR. TAPSELL: My name is Phil Tapsell from Bone Scan in the U.K. One or two observations and a question for maybe the panel. One of the observations is about glass. I think they set these microphones up for the short lady. I don't know how the process works in the U.S., but certainly in the U.K. they take a lot of time and effort to track the source of the glass contamination. The mass majority are domestic. They don't come from the plant. That's an observation. It's not --

My question, it seems that the definition is a little bit confusing of the foreign material. Foreign material can be defined as extrinsic or intrinsic. So it doesn't necessarily mean it's metal, glass. But, of course, they are, but also bone. Size doesn't matter because it's what the consumer thinks is a foreign body. Now, a consumer can feel a piece of sand, tiny piece of human hair. But whether that's -- That's definitely a foreign body, and that should be a separate distinction as to whether or not it's hazardous.

And the question is, you mentioned some points about bone, some definitions about sharp, pointy objects which is like bone. But you didn't say whether or not bone is defined as a foreign body. And if it is, is it hazardous? I'm working for a company called Bone Scan. That's probably why I'm asking the question.

DR. GOLDMAN: I think the draft directive before you specifically excludes bone and other organic matter that might be introduced by the food animal in this case. I did mention that our agency had reviewed the issue of bone particle size, as to whether that -- as to whether the size might play into the potential risk to human health, and I presented that earlier. But I think for the purposes of this discussion and conference, we're not talking any more about bone.

MR. TAPSELL: That's an interesting answer because I'm not sure that I've heard of a complaint for, say, metal or glass in something like a chicken sandwich or a chicken nugget.

MS. ELENBERG: We have.

MR. TAPSELL: Are the majority of the complaints for metal or glass, or are they for bone, because bone is -- from a European perspective, is considered a foreign object. It's also considered a hazard, especially to young children in further processed product.

MS. ELENBERG: We do consider it a hazard. It was just specifically that this draft is not addressing it today. Today it's addressing the foreign materials as defined earlier, excluding bone and other animal products. But other animal products definitely have the possibility of posing a human health hazard, and certainly bone does, too. The majority of our complaints are other than bone; however, we do receive complaints about bone and other animal products.

MR. TAPSELL: Thank you.

DR. HARRIS: Before we leave the topic of bone, I do want to make a comment here. We have to remember some products are intended to have bones. I mean, you know, not all product is sold on a bone-free basis. And so I think when we're talking about bones as foreign contaminants, foreign particles, that's when we get into those products that we have an expectation of being bone-free. And most of you sitting in this room will know that you may have had claims where you've had dental claims or whatever because there was a bone fragment within the product.

Particular products very often, when we go back to and we have choking issues or whatever, and then we start looking and they say, "Well, it was because it was a bone," in a lot of those cases the choking from the child is on the food they're consuming and there was no foreign material in the product to begin with. It was the fact they just didn't chew the food, which caused the choking instance. So it was the food, not a foreign object. And I think a lot of times we get confused because we start talking about the risk of having a particle such as bone in a product that shouldn't be there and, you know, they say, "Well, children can choke." Well, going back a lot of times to the production process for those, the particle size of the bone would probably not be sufficient in some of those to have allowed choking to occur to begin with.

And so I think the reason we excluded bone for this topic for the conference was because we were talking about bone as being part of the animal, knowing that it's dealt with separately and moving forward with the other contaminants. But we do agree and recognize that bone for products that are supposed to be bone-free can be considered a foreign body or contaminant and would have to be dealt with, not necessarily a food safety hazard, though.

MR. RICHARDSON: Bob Richardson with General
Mills. I just had a question, if you could help me figure
out a little more on the dental aspect. Is there a
relationship between the dental claims and bone, for
example, within your database? And my second question, I
think it was also asked, and that has to do with whether or
not there's an analytical procedure FSIS uses that would
actually analyze any metal that was found by a consumer
and/or the issue of household glass.

MS. ELENBERG: Okay, yes and yes. Some of the
dental injuries are related to bone. The majority of the
dental injuries we receive in our consumer complaint
monitoring system are related to stone or metal. That's the
majority of ours, are related to that. I don't have the
statistical numbers in front of me right now to present to
you, but that's, you know -- I had those earlier, and

they'll be posted on the web. And if you need any further clarification, you can also contact me through David's e-mail, Dr. Goldman's e-mail, which he posted.

The second question was the procedure for how we identify the glass or metal. I'm not particularly clear on that. That's an expertise of my field officers and what they have developed. As far as identifying whether it's a public health safety, we use measurements from the literature. We use our Health Hazard Analysis Board. And from that we have representatives of different areas of human health science and epidemiology and so forth.

DR. GOLDMAN: And we do have in the agency three field service labs who often assist us in identification of materials, in addition to their usual work in microbes. And so, for example, the -- one of our labs has helped us frequently with identification of metals, and they use procedures in their lab to, as Kimberly mentioned earlier, digest the food material so that the metal remains. And then they help us with the identification of that metal. Occasionally we have had to go outside of our agency's lab capabilities, either to the Agricultural Research Service or even a time or two to the FDA labs for assistance with evaluation of products or contaminants.

MR. DREYFUSS: All right, thank you very much. Appreciate your participation.

MR. POCIUS: I won't be long, I hope. I can't help it. We've spoken too much about bones and I've got some observations, if not questions. There is a certain allowance of bone, bone particle, bone residue, particularly in ground products. We have a reg that allows that. But I've got to tell you, if a complaint comes through FSIS and it's delivered through compliance, the response is going to be expected to be made in terms of zero tolerance, period. And that's how the agency is going to address industry. How will you prevent this from ever happening again? Particularly if there's an injury involved. If a consumer is eating a preformed hamburger and they chip their tooth and it comes through compliance, we will have to do a reassessment, even though there is a tolerance set for this, which may be a good segue as we move forward to what is a CCP. When we set these things, and we talk about these things, and we have various size and shape confirmations that we consider, a CCP is a zero tolerance. We either make it or we don't. We'll either pass and you have safe food, or you fail and you have a recall. It's fairly black and white when you come to a CCP.

I don't think -- Speaking for myself, I'd like to discuss this part of it a little bit further as we go along, even though the intention was not there for today. Keep it in mind, please, that bones are, as the gentleman U.K. said,

those are primarily complaints for us, moreso than anything
else that came up on the screen.

MS. ELENBERG: Thank you. Your point is well
taken.

MR. DREYFUSS: Thank you. Going once? Going
twice? Thank you. We'll take a break now. We're reconvene
at half past the hour, so you have a nice, long break.

(Off the record from 10:10 a.m. to 10:40 a.m.)

MR. DREYFUSS: Ladies and gentlemen, we're ready to begin the second half of our morning session. We have essentially one speaker for the rest of the morning. I was asked, as a matter of just logistics, for those of you who do come up and ask questions, the court stenographer would like you either to spell your name or to come up to her later so that she can get the correct spelling and association. She's sitting up here at the front table. Not to dissuade you from asking questions, but to let you know that we are transcribing this entire meeting and at some point that also will be posted on the web, or at least hopefully it will.

Our next speaker is going to talk about foreign material detection and control. This is Mr. Bob Richardson. He is the senior principle quality engineer with food safety operations at General Mills. He's had over 30 years experience in quality control, has worked in food safety systems and quality auditing in areas of regulatory compliance and quality systems. He's currently focused on food safety aspects of allergens, foreign material control and engineering standards and specifications. He also told me he is not a doctor, but he does know a few. So, Mr. Richardson.

(Slide show presentation.)

MR. RICHARDSON: Thank you. I'm fortunate enough that I have a brother who is a doctor, so any little ache and pain comes in quite handy, although I've never really asked him about the impact of foreign material, which should spur some heated debate the next time we get together at Thanksgiving.

It's a pleasure to be here today. It's a topic that's near and dear to my heart. I want to also preface my comments by saying that I come from a slightly different perspective. A lot of my experience has been around other consumer products, in bakery goods, dry mix business, cereals, yogurt, other kinds of things that don't necessarily include the many and myriad things that we're learning about foreign material and the regulated environment dealing with meat and poultry.

However, we do have lots of potential issues that we have to get into that deal with foreign material. I have spent 30 years working at General Mills, working with the plants and facilities out in the trenches, and basically, as you know, and as everybody else probably knows, that in the trenches every now and then something gets dirty and something has to happen. So foreign material is a way of life. It happens all the time out in the plant. It's not a question of whether or not something will occur one time. It's when it does occur, what's the potential risk. There is some risk associated with any kind of endeavor that we get into, so the real question is how to evaluate that risk, what is its potential impact and then how do you go about solving and resolving that issue.

So we've been doing it for a long time, and one of the things that hasn't quite come up, although I think we touched on it a little bit earlier, and that's the impact of consumer complaints and whether or not that represents something that relates to your overall quality system. Certainly in the world of business and the food industry these days, there's an awful lot of things that happen in the name of the consumer that have nothing to do with risk in terms of a public health impact, but it's the perception of risk.

For example, we've had, in the past, meat products that had a piece of cardboard in it that was also in some sort of a sauce that contained tomato-type ingredients. The cardboard soaked up some part of that red color, and to the frayed edges of this piece of cardboard, make it look like it was fur. We got nationwide publicity for the fact that a consumer found this particular product in California, as luck would have it, went to the local media, and with a TV camera in tow on the deck on their house, showing this pouch of this sauce material that had obvious, obvious packaged rodent, partially eviscerated inside. So try as we might, we can't get the sample. We can only see pictures of the sample. There's lawyers involved on both sides, and you know how that can get.

Finally, when they finally did release it, we had it analyzed and it ended up being a piece of cardboard, correlated-type material that had tomato sauce on it that made it look like blood. This is a consumer type issue. I don't know how it would be reflected in the database. Well, I don't know how it would be reflected on the compliance people. It would show up at the plant. But, anyway, it took a long time to resolve that.

And I think when it comes to foreign material detection and control, it's -- as we're going to talk about the next couple days and the comments that Kerri had, that this is really a complex thing where we don't know what's going on. We're not sure the definitions. We're not all of one mind when it comes to evaluating risk and that's natural, and it's going to happen. We've done HACCP training for lots of people in our company, and the one thing that always comes up is foreign material. You can get into debates that last for days on foreign material and what is the risk. And I think it's because there's so much judgment involved and we're dealing with issues and situation that happen on a very infrequent basis.

There's no chain of events. There's no continuing cascade of findings on a metal detector, on an x-ray device, or a magnet or a scalper. We're dealing with individual events that have to be looked at in a totality that's outside of our commonly-accepted thought process about whether or not we can release a batch of product.

So it takes a lot of debate, a lot of discussion. I'm glad it's going to happen over the next couple days and tomorrow afternoon we'll be of one mind? Is that right?

(Laughter.)

I wouldn't miss this for the world. Anyway, let's talk about foreign material detection and control. Like I say, I come to this thing with a little bit of a different perspective, although I have a lot of experience and we certainly have been working this thing for a long time, just because we've got the same issues that everybody else has. We've got to operate in regulatory compliance and we've got to have satisfied customers. That's what pays the freight, and they're the ones that we're trying to protect.

Along with all of the other regulations that you have, you've got your HACCP regulations, Federal Meat Inspection Act, Poultry Products Inspection Act, et cetera. You know, the Food, Drug and Cosmetic Act is pretty straightforward. If it consists in whole or in part of a filthy, decomposed substance or is otherwise unfit for food, certainly that would include foreign material, or it's been prepared, packed or held whereby it may become contaminated or rendered injurious to health.

The GMPs, which deal with an awful lot of that unrelated industry that's out there, well, so-called unregulated, the FDA covers it. A lot of state people cover it, et cetera. It certainly doesn't fall under the USDA purview, a lot of it doesn't. I'm talking about spices, batters, breadings, other types of ingredients that you get in. And I was glad to see that the impact that ingredients inspection or supplier inspection apparently has had on, you know, helping to reduce the overall incident rate of foreign material. That's certainly something that we've been working on for a long time.

But the regular old GMPs, 21 CFR, you know, talk about the design, construction and use of equipment and utensils, precludes adulteration of food with lubricants, field metal fragments, contaminated water and other contaminants. And it specifically in there talks about metal fragments. So it used to be something that we did just because it was a good idea. Basically, the regs require something in there around metal.

The same deal when you talk about manufacturing operations in 21 CFR. Effective measures shall be taken to protect against the inclusion of metal or other extraneous materials. And that can be accomplished by using sieves, traps, magnets, electronic metal detectors or other suitable effective means. So they don't tell you how to do it. The idea here, of course, just like the rest of us, is we've got to have an overall effective program and it's a performance standard that basically says we're going to get to where we need to be.

It also says that when you talk about effective measures, that there's more to it than just the physical equipment. And I'm sure that over the next couple days when we talk about prerequisite programs, that we're talking about having a process in placing, having instructions, operating methodology, et cetera, and trained employees. All those other kinds of things will come up. What I'm going to be talking about primarily here really has to do with the equipment that can help us achieve these goals.

So we know that controls are necessary. It's required to control forms of adulteration, keeps us in regulatory compliance. Specifically included as HACCP in terms of physical hazards and again, you know, whether it's a prerequisite program or a CCP, and we can debate that over the next couple days.

Overall, though, we need a system in place that's going to allow some sort of a judgment of system integrity. And it seems to me that an awful lot of the evaluation of the complaint pictures, a lot of evaluation of the kinds of things that are found really gets back to how is it managed locally. How can we judge whether or not the system has got, you know, the integrity that we want it to have? And certainly we want to prevent customer complaints. For one thing, it loses business.

Surveys have shown in the past that a consumer that has a poor experience with a product tells 17 to 20 people. My wife raises that average. Seventeen to 20 people will hear about a bad experience with somebody. And if a person has a good experience with a product, they might tell three to five. When was the last time somebody walked up to you and said, "You know what? I had one of your hot dogs the other day and it was average"? "Thanks. It wasn't too salty, wasn't too hard, you know, fit the bun perfectly. Thanks." But they might tell you whether or not they found something in there, and that's just the way it is these days. So consumer complaints have a big impact. And, obviously, we want people to be satisfied because surveys have also shown that it takes five times the promotional spending to get one of those customers back. So it's a lot easier to keep a customer satisfied.

Generally, these programs that we talk about would cover four basic areas. One is certainly incoming ingredients and raw materials, particularly for the non-regulated type industries where they don't have somebody looking over their shoulder, a, quote, approved, unquote, plan for manufacturer.

Secondly, we're going to have equipment in place to protect some of our equipment and system. We've got some fragile pieces of equipment out there. Certainly, if there's foreign material present on inbound materials or raw materials and ingredients, we don't want to break it into smaller pieces, make it harder to find. On the other hand, maybe we want to grind it up so people -- you know, it doesn't -- gets below that size limit. You know, that's a strategy I jotted down.

(Laughter.)

After equipment which may fail or cause foreign materials, we all know that we've got a piece of equipment, that it can fail and does fail, and it's certainly related to fatigue. It's related to maintenance. It's related to the overall equipment design. And sometimes it's just not very reliable and needs changed, and certainly at the end of systems. For example, packing and load-out points, something that's close to the end of the consumer that would actually tell us that everything we were doing ahead of that point in the system was effective and worked, a true CCP. After all, it isn't a health hazard until it leaves the plant. Anything else that happens internally is up to us. So it isn't a health hazard unless it's gone.

When we think about ingredients and raw materials, certainly, you know, catching it early is the best preventative approach and something that we really have to look at, you know, scalping ingredients, running them over magnets, you know, running even, you know, muscle meat through some sort of a device in order to try to find pieces of metal is certainly something that could help us overall. Liquid ingredients through strainers, et cetera. I mean, let's find it first. Keep it out of there. Don't have to find it at the end when you've got to make a huge decision.

It's really important to tie what you find in the ingredient, raw material side, to a supplier performance measure. And the idea that somehow there is more involvement with suppliers and other people that are providing us material and giving them that kind of feedback is really important to us. It needs to be one of the important things that our procurement people evaluate when they think about who is a good vendor and who isn't. And that is this idea of extending your quality parameters and requirements back to your sources. Really an important way to measure supplier performance. And if they don't have the systems in place, they can't manage their programs and procedures, it's really difficult to tell somebody down in procurement to go find another supplier, but sometimes it has to be done. There's a total cost factor here that we're looking at, the price of nonconformance.

There are other regulations. You know, the GMP, Food, Drug, Cosmetic Act, Meat Inspection Act, Poultry Inspection Act, HACCP regulations, all those kinds of things certainly fit in. And then the great idea here is the downtime and associated costs with situations where you actually find foreign material that has an impact on your operation, having a measurement system in place and quantifies what that time is actually worth.

We did an analysis a long time ago and, you know, one of these old quality diagrams shows a triangle -- or a pyramid. At the top is the number one. In the middle is the number 10, and at the bottom is the number 100. And it basically symbolizes something that almost holds up if you do the analysis, and that has to do with finding things early in your system can cost you a dollar. Finding things later, but in your finish form or in your warehouse can cost you $10, and by the time that thing, if it hasn't been discovered, hasn't been prevented or hasn't been effectively dealt with, gets out in the marketplace, is going to cost you approximately $100 to get back.

And we've done some analysis in the past that show that the numbers aren't exactly correct, but the idea certainly is in terms of the expense of recalls, market withdrawals, et cetera.

So we're going to use things for equipment protection. We're going to protect sensitive equipment that also is expensive. Extruders, other types of devices can be very expensive. For example, you may not know this, and maybe you don't care, but the actual dough heads that we use to extrude cereal cost right around $30,000 a piece. That's why cereal costs five bucks a box. Most of you were wondering. We have two of those heads, yeah. We have lots of those things laying around. And the deal is that you've got to protect those things. They can be damaged by foreign materials, so, obviously, we're going to protect that. We've got other cutters, grinders, extruders. We're going to lose blades. We're going to lose downtime. We're going to generate foreign material. And certainly those things need protection as well.

There are places that generate metal potentially. You know, cutter blades and other mechanical wear points that we might have within our systems. We've certainly got the impact of our humans that habitually come -- you know, occupy our facilities. The operators, the people that are in there, the maintenance activity, contractors, construction debris, any and all circumstances that you can possibly think of that could possibly end up generating foreign material that somehow gets into our systems and gets incorporated in the products. So we need not only the programs and procedures to prevent that, but also, if possible, ways of detecting when that actually has occurred.

We also have very long and complex systems, and it's really important to have various production points along the way that help us break those systems into measurable parts. You know, there's nothing as confusing as having only one way to find metal, for example, a metal detector on the end of a system that might be 300 feet long and come up with a metal finding when you've got lots of different operational steps in between. So breaking the system into parts allows a much better evaluation of what's physically happening and an evaluation of potential risk, all with the idea of getting back toward the potential source and making some sort of corrective action where it actually started to occur.

Finally, at the end of the system we're going to verify our overall program was effective on the basis of the parameters and the specifications that we've got and what we have to work with at the end of that system. It's going to basically provide some sort of proof of compliance, you know, that has regulatory implications. We've had those kinds of situations where we've had consumer complaints. The FDA and the FBI have showed up, for pins, for example, and essentially run their -- this pin through the metal detectors, as it were, to find out whether or not it could be detected. And, you know, we've been able to prove that we had a system that was in place. We've shown the records, et cetera, that helped defend us.

I say protection against consumer or customer issues only from the standpoint that in some cases, and it did come up earlier, we have had situations where customers have foisted these pins upon their children. So having a system that basically, you know, is reliable, you can find those kinds of things helps protect you from other issues.

So let's talk about some of these devices. A lot of these, Moshe and I were talking, are a lot of fun to play with. I grew up in Austin, Minnesota, home of Hormel. I think they process a few pieces of animal every now and then. Interesting, when you go abroad and still go to the U.K. and can find Spam sandwiches, which I think are one of the real treats of all time, at least compared to normal U.K. fare. I just say that. I'm an anglophile. I mean, I love the beer.

(Laughter.)

But, anyway, we used to play with cow magnets. You know, cows would get a magnet and it was like -- I thought it was like a vitamin or something. I used to stick them down their throat. And then collect barbed wire and every other darn thing in there, and my dad worked at Hormel for many years, so he used to bring these things home. Apparently they'd just find them laying on the floor or someplace. He never did tell me how he got them. I couldn't imagine I reached down there and poked them out, but maybe. But, anyway, we used to play with these things and certainly it's a known technology, been around for a long, long time and was a standard for a long time.

There's screen, scalping and sifting that we might be able to do, not necessarily on meat. Certainly strainers fit into that category. There's other things that we can do, though, for dry ingredients. You know, beans, vegetables, pasta, all kinds of other things can basically get screened and scalped potentially to be able to find out whether or not there's foreign material there.

Metal detectors have been around. They've been mentioned. Some people actually have them as CCPs. You know, I find out it's one of those technologies that the surveys show has been around for a long time and people have tried to use. And then the latest thing that's kind of kicking around out there is these x-ray devices. Not the old x-rays that maybe some of you remember.

I remember going to Buster Brown Shoes when I was young. I should have been a doctor, but I never was. But, anyway, you'd go to Buster Brown Shoes, and you'd put on the Buster Brown shoes, stick your foot in a fluoroscope and wiggle your toes. It was the darndest thing I ever saw. Who ever did that? Somebody else in here. Yeah, see. Wasn't that fun? It was the first time we ever found out that we weren't solid inside like a Gumby or a baked potato. It's like, "Hey, there's stuff in there."

(Laughter.)

But, anyway, there are some new developments that are happening in x-ray devices around the software and the technology that offers a lot of advantages over some of these other things, but they do have some limitations and we'll talk about those.

The issue with magnets is that most of our operators believe that we're actually trying to find a horseshoe. We're trying to find something that's a lot smaller than that and it's pretty easy to get them convinced that, you know, that thing is there to remove nuts and bolts and washers and other kinds of magnetic stuff, pieces of wire and twist ties and what have you, pallet nails. But that isn't what we're looking for. We're looking for something that's a lot finer than that because that represents more of a potential threat, as one of the earlier speakers said. You know, smaller size, but potentially more injurious, depending on what's there.

Our motto is nobody ever eats a bolt. Some people might have tried and maybe it's hard on the teeth, but nobody is going to eat a nut or a bolt. And I'll tell you, we've got an advantage in the cereal business, right? You pour it out. It goes clink. You say, "What's that?"

(Laughter.)

It isn't like a meat loaf that your mother-in-law made where you think she's trying to kill you.

May require several passes to retain paramagnetic materials. You know, unfortunately, there's so much aluminum, stainless steel and other kinds of things, other substances that are out there these days that are not magnetic, that magnets, in a lot of ways, are losing a lot of their attraction, shall we say, just because of the fact that there aren't that many targets out there. Sugar, you know, that's pretty loaded up a lot of times with regular old soft iron screw conveyors and other kinds of handling systems. There may be lots of other types of chemical ingredients that you get that might have some magnetic materials in it. A lot of times magnets really are limited just because of the sources, the facilities and the use of other types of stainless steel, et cetera.

But, in any case, even if we do have something that is highly magnetic, if it's been oxidized or it's reduced in size, it's generally something different. It might take multiple passes over several magnets in order to physically remove that, depending on what the substrate is that it's actually entrained with. So maybe it takes more than one magnet. We find out just because you may have to, you know, have an ingredient stream where you're actually passing it over magnets multiple times. You always wonder why you find the same thing on two or three magnets, and a lot of it just has to do with the nature of the material itself.

And certainly in some places we're going to protect equipment, explosive atmospheres and all that kind of thing if you do any form of grinding. Most people don't. But if you do, it's obvious that -- what the issue could be there from sparking.

The attraction is proportionate to size on magnets, so basically small materials are not attracted to the magnetic surface very well. Large stuff will definitely go there. And, in fact, I know a gentleman who put a -- We had a really large magnet. It was like the hugest magnet visible from space above a cereal packing system one time, and it was called a brute magnet. This is before the word brute was really used extensively in marketing. And it was a brute magnet and it was really big. It was so big it actually ran on a track, you know, like a Big Bertha cannon. And we had a pneumatic system that moved it back and forth, and it would actually, you know, track things. It was so strong that we had to actually later put a stainless steel sheet, a hinged sheet over it in order to be able to clean the magnet.

But a gentleman was doing a plant tour, who also happened to be wearing a tie and was from the office -- it wasn't me -- who went in there and said, "Is that magnet strong?" And they said, "Oh, yeah. That magnet is strong." "Is it really strong?" "Oh, it's really strong." And he picked up a wrench and walked over there, and when his hand got about three feet from this magnet, it suddenly lurched to the face of the magnet where he was hanging, nearly suspended, and it took about a half-hour, and they had to go find a very large aluminum crowbar to actually get his hand out from under the wrench.

Now, if he would have held up a small steel BB, for example, it wouldn't have quite had the dramatic effect. Strength is proportionate to size, so small pieces are not going to be attracted as well as large pieces. Strength varies by the inverse square, the distance from the surface, one over D-squared, for the physicists in here. And that basically means that if you double the distance from the magnet, you're going to reduce the strength by a factor of four. If you triple the distance from the magnet, you will reduce it by a factor of nine. I mean, all those kinds of things. So it basically means that you have to have intimate contact or the magnet itself has to actually be in contact with whatever it is you're trying to run over there. If it's a batter or breading, you know, type material, or spices or you've got some sort of a corn material because you make some sort of meat-filled tortilla thing, or tamales, or whatever, I mean, you've got corn over that thing, you really have to have the magnet in contact with the material itself.

The field can't be insulated out, like I say, so that gives you some advantages sometimes to be able to actually mount a magnet on the bottom of a stainless steel chute or some other place and actually some sort of a good effect. And they can be demagnetized by abuse, but it takes a lot of abuse. It takes some real extremes of heat, generally, you know, in the excessive temperatures that we would normally operate in, 1,100, 1,200 degrees, stuff like that. Hotter than the hottest day at a retort operation. So generally it takes an awful lot of heat. There could be opposing fields from some sort of a way that these things are actually used in series or in combination. That could start a demagnetizing process. So there could be other things that would actually affect their situation, their ability to be able to perform as magnets.

Magnets are actually sized by their strength, and the problem is that I'm learning from an engineering perspective, once a magnet gets installed, nobody knows what was actually specified to put in there. The records totally disappear. Five years later you come out and you say, "Hey, what kind of strength is that magnet up there?" And nobody knows. So you need some documentation someplace because you can actually get magnet strength testing kits, and I highly recommend it to you if you're using a lot of magnets. There's a magnet strength testing kit. I think you can get them from Eriez, MPI. There might be some others that have them out there. It basically specifies some ways of testing full strength and holding strength, and that's important to be able to know, because you need to know where you're strong and where you're weak.

We had a policy at one time that said that you had to test magnets every year to see whether or not there was a change in their magnetic property. And magnets generally have a half-life of, say, right around 5,000 years. So we're thinking that we're not going to see that much, you know, I mean, in terms of change. But when it does occur, I'm sure we'll react appropriately.

But the key thing is you need to know how strong they are or aren't because they're sized by their ability to be able to perform. If you get a rarer type magnet, for example, that might cost you three times as much as a ceramic magnet. And so you need to know that so that you don't get somebody in procurement saying, "I'm going to out and buy a bunch of magnets," and then you get the weakest magnets that somebody has because they're the cheapest. You need to be able to specify what it is that you want to actually have happen.

They come in a blistering array of various sizes, shapes and configurations, but they essentially feature plates, which can be used in chutes or spouts. They can be suspended above things. They have barrier or taper steps which basically help protect anything that's collected on the magnet from being washed off the face of the magnet, which is really important if you've got smaller, particulate pieces there that are going to get collected, so that the cascade of product across the magnet face doesn't actually knock it lose with kinetic energy and, therefore, make the magnet ineffective.

There's other types of magnets. Hump magnets, for example, is basically just plates that are used in series for free-flying materials. They can collect -- They can catch hard-to-collect pieces only because you've got them in series, so you've got more than one magnet in place. They can be used in gravity or pneumatic spouting with the right kind of housings.

There's bar magnets that are designed for fine contaminants and shell product streams. The product has to be free-flowing for those things to actually work. And then there's these great magnets that you're probably all familiar with, which are the small tubes. They're fine for, you know, smaller type contaminants. And what actually happens is, in a free-flow situation, you know, assuming that you've got product that's fine enough to flow through there, is that anything that's collected and held by the great magnet itself is actually washed to the underside of the bar away from the stream and is protected from being knocked off. But the product has to be free-flowing, not a choke feed type situation, and you really want to product to actually come into contact with the bars. Generally, these things have got very strong holding power, not necessarily separation power in terms of being able to reach out into a product stream and collect material, but once it's on there, it's very difficult to remove.

There's also other magnetic types that are basically wet-type installations that can be put into liquid systems, hoops of round bars that are vertically installed in a pipe fitting and basically, you know, these things are set up so that you can pump a viscous liquid through there, whether it's a syrup, or a sauce, or some sort of a slurried material, you know, through this system. You can actually have a set of bars in there, and they work pretty well, depending on the viscosity and the speed with which you're actually pumping that material through.

We used to do a lot of products that had -- used a lot of fruit purees, very thick type materials at one time, and we actually had to set three of these liquid traps in series on some pumping systems in order to get the degree of separation that we needed. So that viscosity can really affect the results. And they're available in a lot of sanitary versions. They're stainless steel housings, et cetera. I mean, they're basically -- You know, you'd have to take them out, but you can pull the great magnets out for COP cleaning and then basically pump through on the rest of it.

And a lot of times there's baffles. You can also get liquid plate traps that are available. They've got a fitted baffle that directs the product stream right down onto the magnetic surface itself. Don't see too many of those types of installations. Primarily it's just the other round liquid traps.

But, again, knowing what you have to collect or what you're trying to collect is really important in terms of the types of contaminant that's there. You have to size these things to the capacity of the site, so you actually know or have an idea what the velocity is of the material that's moving through there. For example, if you put it on a loading system because you handle flour, you make other kinds of things, or you've got starch or something else that you're handling pneumatically, that pneumatics might be moving that product, you know, several hundred to 1,000 feet per second, or per minute, I should say, not per second, per minute.

But it means that whatever is flying through there is moving extremely fast and your ability to find small pieces is going to be very limited. Again, sizing that thing to the capacity of the site and then looking at your flow characteristics to make sure that you've actually got the product flowing across the face of the magnet is really important.

Fabrication and construction are really important as well, and that has a lot to do with your own maintenance people or the engineering support that came in behind it, making sure that it's installed properly, not upside down, where you actually can get -- maximize your product flow, and the, obviously, select the proper strength, and to make sure that you're going to be successful.

And any magnet installation, access to that magnet is absolutely critical in order to try to collect some information on what that magnet might be able to tell you about the product stream, ingredient stream, et cetera. You've got to be able to get up to the magnet. Sometimes they're mounted way high. It takes a ladder. You can't get at it. Sometimes they're mounted real low, you know, and you have the tall person check the low one and then you have the shortest person in the plant check the one that's up close to the ceiling. But you want those things at floor platform level, if at all possible, so they can be checked. And the best thing to do is to have some sort of an insulation where you can actually check it during normal operational conditions, not at the end of some sort of a process, because you may have to get at it at some point in time, just to do an evaluation.

Heavily contaminated magnets lose their separation ability, so their pulling and holding power is going to be decreased, and that could include things like just normal old enrichment buildup, or, you know, some other type of metal that you actually would collect on there.

The expectation should be that there is a complete cleaning and removal of any magnetic materials when the magnets are actually checked by the operators. It doesn't do any good to leave things on there or to be incomplete in that cleaning, because if you have to come back and do an evaluation because you have magnetic contaminants, you've got to know that magnets were actually cleaned at a certain specific time to help you put together a proper chain of events.

Again, there's some performance implications, particularly if you're adding ingredients from more than one supplier across a magnet and you want to properly evaluate that supplier, and then timing for the decision-making process and understanding product flow and how the accumulations actually are.

So determining the frequency of the checks, where they're located, described by documentation, collect and evaluate any findings, any findings, not just the nuts and bolts that your employees think you're looking for, but everything else as well, and then documentation of evaluations and follow-up action. Save that stuff over time to determine what's going on.

In terms of scalping and sifting, sifts and screens can detect and remove materials of differing size. They can be used to detect oversized or undersized material, depending on what you want to do. If you've got pasta, for example, and you want to scalp that for something that's smaller than pasta, you can run it over any number of sieves that would give you a, quote, fines, collection, that could tell you something about what's in there. Or if you've got flour, you can run that through a very fine sieve, 30 mesh or less, and basically generate an overs that you can also evaluate that could tell you whether or not there's something hazardous there or something that isn't hazardous and is treated as food in some parts of the world, and that would be, of course, insects.

The capabilities of scalping and sifting is actually dependent on differences in particle size. And for that reason alone, we're very limited in using scalping and sifting as a means of trying to find potentially hazardous foreign material. If we're dealing with something like beans or lentils, or we've got other kinds of ingredients that have got some size, shape and configuration to them and they're approximately the same size, those pieces would be expected to actually tail off, along with the good food product that we're actually looking at.

So particle size differentials are really important. They're effective on both dry and liquid systems in terms of having some sort of strainers on a liquid system, certainly. It takes a lot of prior planning in order to figure out that relationship between what sort of particle size are you looking for, in terms of your hazard evaluation, and what are you actually trying to detect and where could you put it, and what is the throughput expected to be through that system. So it takes a lot of planning.

Takes a lot of engineering. We've got to match it to the system, the specific point in the system. What is the purpose that was intended for? What sort of screen size and type are we going to actually try to use? Are we going to use a drilled plate? Are we going to use wires? Are we going to use magnetic wires? Are we going to use nylon? Are we going to use silk? There's a lot of decisions that have to be made around screen size and type with what's actually installed. I'm sure regulations would help determine what that is in terms of its cleanability, et cetera, but there's a lot of decisions that would have to be made.

And throughputs really have to be taken into account in terms of the open area of the screen and the available footprint that we have for this particular piece of equipment. Particle size is actually defined where that separation capabilities are and bulk density is the key. So they can have a role.

There's a lot of different types of screens around. There's flow-through types where we can pump liquids through screen traps, round hole slots, wires, wedge wire. There's lots of different kinds of systems that we can use on the flow-through type liquid systems. There's also these vibratory type of devices that are out there, where we basically have got the screen placed in the product conveyed bed, and then the depth of the bed, the flow rate and particle size all affect what we're going to get in that tailings off of those systems. I call this a sweco. That's kind of a trade name. It's basically just a circular vibration that has a reduced footprint, you know, type of a sifting system. There is a vigorous screening movement. It can increase the separation rate. It may physically damage whatever it is you're running through there in terms of size reduction, so whether or not you choose to use this particular type of device would depend on what was going through it.

Certainly we're all familiar with the old flour milling systems where we've got some sort of a gyratory type of box sifter where we're basically moving fine particles across screen surfaces. And by having multiple layers of screens within this box, we can increase the total cloth surface area and allow for these very fine particles to gently fall through.

There's other types of sifters that are around that we've been looking at, that I would say you need to look at with a lot of consideration, and that's some of these turbo sifters that are out there these days. They have a high speed rotary device within some sort of a round, horizontal screen assembly. And sometimes those things are moving around, you know, six to 1,000 RPM and that inbound auger there can actually generate foreign material if something gets into it. So you may or may not be able to find it. Might actually reduce its size. There are some paddles that basically move product around inside the screen surface. And a lot of places -- I know there's a number of other auditing companies around that don't consider those things as effective product protection devices just because of that potential to actually break up foreign material. So there's different sizes, different types around. It takes a lot of engineering to get it to actually fit.

But in any of these systems we have to make sure that we can maintain the integrity of the screen and whatever it is that we capture and those tailings observations. I've been to a lot of places where the tailings are basically open, and because they end up getting thrown away, because they're marked inedible, sometimes they become repositories for various maintenance activity. Pieces of wire, other kinds of stuff, debris gets thrown in there, and basically it's that tailings that tells you what's physically happening in the system, and they have to be treated with a great deal of respect and be -- the containers need to be dedicated and properly identified so that you don't confuse yourself with what actually can end up in there.

We've got to be able to collect whatever it is that the screens and/or sieves are actually trying to tell us. And that has to do with an organized method of being able to collect the tailings for evaluation. And it's important to realize that some of the screens and sifters may not actually empty at the same time. A lot of these big box or gyratory screens, for example, really won't empty. So if you end up with a tailings finding, a lot of times the first thing you have to do is physically get inside the system very carefully and actually look at the sieves to try to find out if there's still something laying on the wire or something that's still hung up within the sifter or scalper itself.

And periodically, of course, the screens have to be checked for overall integrity. They represent just as much of a potential threat as the stuff that's moving through it potentially. And so if you end up with torn wires, then you've got wires, you know, contributing into your system.

Again, frequency of the tailings checks and the screen checks as well, making sure that those things are documented. Documenting the findings for overall evaluation. Again, you're looking at, you know, time is a river. And, you know, it's never the same twice, and you're looking at what's physically coursing through the system and trying to figure out what's going on.

Document the maintenance of the screens and the sifting devices to make sure that you know that the sieves were intact at certain specific periods and points in time and that there aren't any issues with those things, and then certainly documentation of evaluations and other necessary steps.

Metal detectors, which everybody has one, apparently, according to the surveys, or most people do or have heard of them anyway, and we all probably went through one to get here. They use an electronic field to detect metallic objects, and their detection capability is basically set up around ferrous materials, which are the easiest to detect. Stainless steel is the hardest, and then the nonferrous materials, so that is copper, lead, aluminum and all those kinds of things fall somewhere in between. So generally there's been a tremendous improvement in the capability of metal detection in the last 10 years, as far as my experience goes. And a lot of it has to do with the manufacturer of the metal detection head. The technology involved in embedding the wires, specific distances from each other, to be able to detect the minute differences in electronic field between the sending and receiving coils has improved tremendously. And the software around cell checking devices, their ability to be able to detect and do their own diagnostics has improved tremendously.

What hasn't improved tremendously is the ability of us to, as humans, connect the metal detector device to a reject mechanism, because that involves a maintenance person working with air pressure and other simple mechanical principles.

So metal detection has improved tremendously. Rejection capability is still dependent on knowledgeable, active, trained maintenance people. Really important.

Most of these systems these days are three coil systems. You've got a center coil that's a transmitter and two coils on either side act as receivers. The coils are an identical distance from the transmitter, and they have the same strength of signal. A metallic particle moving through the aperture changes that signal strength. It's detected by the internal electronics. It's amplified and processed electronically to produce a, quote, detection.

Now, there's lots of factors that influence whether or not that thing is going to be very sensitive. Environmental conditions, product moisture. High moisture material itself reacts differently to the signals and may create situations where there's, quote, false positives. Same thing with salinity and other pH factors that influence the conductivity of the material itself. The temperature of the material in terms of whether or not the moisture in there is locked up or if it's a free-flow. The operating speed of the system. You know, the line speed moving through there at some sort of a consistent rate. The throughput rate. The variation in product sizes that we might have between -- if we're using muscle meats, for example, the different sizes that are created, different kind of an effect within the aperture itself.

The type of metal that we're looking for, whether it's ferrous, or nonferrous or stainless steel has an influence. The shape of the metal itself has an influence on our sensitivity. How it's oriented within the aperture is extremely important. What the aperture dimensions are, and typically the smallest dimension determines and is going to be the greater determiner of your capability. So if we've got a box that's seven inches by seven inches, it's going to have a seven-inch capability. If it's seven inches wide but it's three inches tall, it's going to have much better sensitivity because that three inches is going to allow us to have a much better definition of signal strength.

And then the position of the metal in the aperture, whether it's in the dead center or whether it's actually close to the one of the sidewalls where it's close to the sending or receiving coils. Typically, the dead center of the metal detector aperture is its weakest point.

We used detector spheres, and I'm sure everybody else does. It basically gives us a common language. We can describe what a metal detector is supposed to be doing at that point in time. It's a standard method for checking for sensitivity. There's a constant shape within the aperture opening and it easily helps us describe and clarify as our communication. We tell somebody we want a certain kind of a test sphere, two millimeter, three-sixteenths, stainless steel test sphere. We can get them anywhere. We can call the New England Miniature Ball Company and have a thousand sent to us, and we can make up our own test spheres. And we can describe that to somebody. We can talk to a vendor and say, "Do you have a metal detector?" "Yes, we do." "What is its sensitivity?" We've got a common language. So it's important that the spheres be used.

Two parts of a successful operation. One, we need to know whether or not we're achieving a proper sensitivity, and that really has to do with the adjustments on the equipment itself. And then, of equal importance, is some sort of rejection or reaction or other operational confirmation in the case that we get a, quote, detect, unquote. Now, we want to collect the rejects for evaluation. Obviously, that's a big part of it as to find out what triggered it. Maybe it was a false kickout. Maybe there was vibration. Maybe somebody used a radio close to the device. Maybe there was some other unknown electrical charge from a grounding failure that we had. Maybe it actually is metal within the device itself -- within the product, I should say.

And we want to use fail-safe installation. You know, some people say that a metal detector is a critical point, and I've heard this from various other people, not necessarily in FSIS-regulated industry. And I say, "Really, is it a critical control point?" And they say, "Yes, it is. We wouldn't operate without it." "No kidding." So I go over and I unplug the metal detector and the line keeps running. I missed it. It's not fail-safe. You're going to find it later whenever the check is potentially, but we're running, and it's unplugged. Nobody knew.

So there's other ways of making sure that we actually get the rejects, and, again, the issue that we have is not necessarily the detectors. Those things have improved. It's actually confirming the action and the proper action of the reject device itself.

Now, metal detectors are great. Don't get me wrong. We've used them for a long time. Everybody else apparently has, too. You know, they're pretty common in the industry and I think there isn't a supplier out there that would be caught without one. It's just part of what's going on out there. There's lot of people that are asking for it. Everybody has the same suppliers. You know, it's just out there.

But orientation effects on long contaminants could really be a problem, particularly when we think about size. They may not be 100 percent effective, even when they're operating. Even when they're operating on a known, consistent specification they may not be actually effective. So just because we're operating at two-and-a-half millimeters, or three millimeters, or four millimeters, we don't necessarily get the assurance that all of the stuff going through there is metal-free. It's not like a cook stop.

There can be drift on sensitivity or the reject device can change its capability. Simple -- Somebody doesn't like how many false kick-outs they have, so they turn down the air pressure on the reject device. The electric eye that's supposed to trigger the reject device because of timing gets dirty and doesn't see very well and can't reject in the proper amount of time. The operators may not know what our actual standards or check procedures are. They don't know how important it is. If any of you have done, you know, supplier audits, you've all seen somebody check a metal detector with a set of car keys, which is great if you lose your keys. And, in fact, we actually had a situation one time.

If I might digress, we had a situation one time where we had somebody that called up our consumer complaint line and said, "I won the car. I won the car." And after we calmed them down a little bit, "You what?" "I won the car." They actually had received a package of a product, a Chrysler key fob with a brand new Chrysler key on it. And, of course, we offered coupons. I think we might have lost that customer. I'm not sure. We tried to be nice.

(Laughter.)

But as luck would have it, we actually got the keys back. We had the production date. We actually went back to the plant that made it. It was a contracted deal, and we found out that, yes, indeed there was somebody there that day who had bought a new Chrysler and he had to get a ride home because he didn't know where his keys were or he would have told somebody. He thought he left them in the locker room or something. Apparently they fell out of his pocket.

But, anyway, a product defect may actually limit sensitivity. And, again, when we talk about product effect, we're talking about moisture, salinity. We're talking about pH and all that kind of stuff. In the meat industry, that's extremely important because it's going to change the way we have to operate the detector. And when we make those changes to that detector, we're going to basically test with the ferrous test balls. We're going to lose our sensitivity on stainless steel, and our plants are made out of what? Stainless steel. Doggonit. Wouldn't you know it? Just our luck.

Now, if we basically determine that we've got some sort of a ball size, and this is just a normal -- this is under normal operating conditions where we're operating a high frequency detector and we've got certain kinds of spherical sensitivities. And this is going to be on the web site, too. This is from some data that was provided by

Safeline Metal Detection. And basically what they show is that if we've got a regular steel paper clip that's 37,000ths of an inch, you know, .95 millimeters in diameter, but if we're operating at two-and-a-half millimeters, we can still get a piece of that paper clip through there with the proper orientation that's 44/100ths of an inch long.

And if we're basically over here and we're talking about a piece of stainless steel that's 1.6 millimeters in diameter. We can actually get at two-and-a-half millimeter sensitivity a piece, if it's properly oriented, in the dead center of that aperture. We can get a piece of metal through there long and thin that's two-and-a-half inches long, even when we're operating properly. So a metal detector in this case ends up being an indicator device, potentially. Same at two millimeters. I mean, you can basically see it. We've got tinned wire that's .91

millimeters or a copper wire that's at 1.37 millimeters, and there's various pieces there that theoretically can get through, even when we're operating at these relatively fine sensitivities. That's just dry products. So we can get higher frequency operation there. That gives us much better stainless steel detection, and stainless steel is the hardest thing to find.

What products require lower frequency operation geared to ferrous detection? And because of moisture, solidity and shape, they may show huge product defect. This is from Safeline also, and this is basically ferrous test ball sensitivities. Length of 2.3 millimeter stainless steel wire in worst orientation that can actually get through the aperture, again, with low frequency operation, and a length of 2.3 millimeter stainless steel wire in the best orientation. Best in terms of being able to detect it. And what it basically shows us is that, you know, when we're at three-and-a-half millimeter ferrous test ball sensitivity in a low operation, that, at best, you know, we can -- in a best orientation, you know, there's something that might be 37 millimeters getting through. And on the worst orientation, you know, I mean, we're basically looking at about twice the distance, 74 millimeters.

There's some of these -- These last two boxes basically show in the worst case orientation at four millimeters. Our best orientation, we can pick up something 65 millimeters, but theoretically we could run an infinitely long wire in our worst case scenario through the metal detector. I would suggest that that means that the metal detector, in this case, is an indicator. And if we translate what that actually is, from ferrous test ball sensitivity in that kind of a situation and the things that have irregular shape, then you can actually get this kind of thing where you can get a stainless steel 316, you know, piece of wire and all of these at 316, but basically if we're operating at four millimeters, you can actually get this piece through it.

If you take that piece and you actually translate it down here to the centimeter scale, you will see that that shaving is relatively long when it comes to centimeters, not millimeters. It's centimeters. And that's the kind of stuff that our maintenance people pride themselves in generating every day, and contractors, and anybody else, and two pieces of metal that are stuck together, and something that's close to something else, and something that's turning, and something that -- where an auger, we lose a bearing, and a screw conveyor, and an auger chews a trough up some place. Sometimes it has that shape.

Unfortunately, we don't generate enough spheres. That's what I've come to determine. We don't have enough spheres. So when somebody is out welding, I'm glad. No, I'm not.

So any kind of metal detector detection program or confirming the operation of the checks, we want to make sure it's done properly. In the middle of the aperture is the weakest point to tell us whether or not we're going to get some sensitivity. We want to confirm that the documentation of the checks and findings is done on some predetermined frequency so we can understand what's physically going on through our system so we can assure something is going on. And certainly we want to make sure that actions are taken and investigations happen with any kind of kick-out materials that we have. Again, there's lots of things that can kick out stuff off a metal detector. Sometimes it's actually metal in the material. Sometimes it's other environmental factors.

Let's talk x-rays a little bit. We're starting to really learn a little -- a lot more about x-rays because they have a tremendous capability to be able to find other quality defects. You can program these things to actually do counts. So if you're doing a TV dinner, for example, it will actually kick out missing component packages. Say you didn't get some sort of a cornbread muffin in one of the little slots in that thing, the x-ray device will kick that package out, even though it's sealed up. It looks right through the aluminum and can count things by its programming. It can look in specific zones inside the image that's generated to be able to actually find things and count them, so missing components.

There's a lot of people that are working right now on whether or not these things, for lots of different applications, can actually do net weights because of the software. It will actually look at a package and it will calculate how much absorption actually happened within that package. It will be able to calculate what the weight is.

There's ways of using x-ray devices that tell whether or not you've got appropriate proportioning. And for us, that's a big deal. Say you've got too many raisins in your Total with raisins, it's all raisins, say you didn't get any, you know, we want you to get just the right amount. So we can actually set up a metal -- or an x-ray device to be able to scan all these packages, and it will actually do a calculation in there, roughly, to get you in some sort of a raisin range.

We're looking at the same deal, although we don't think we'll be able to do it for marbits, the thing you really want, you know, those little things in Lucky Charms, different shapes and stuff. You know, we always get complaints from people who don't have any, but we never get a complaint when they have too many. I wonder why that is.

But, anyway, it operates on a totally different principle. It operates on differential absorption, and that absorption is related in product density and thickness, and just about everything is density and thickness. So being able to figure out what your targets are and how you can actually use the software to separate those specific targets from a substrate really determines what your detection and identification capability is within an x-ray device.

Basically, what it is is it's not an atomic pile anymore. They've changed that. So what it is now is it's basically a fan beam that's projected out of a tube. And this fan beam basically comes down onto a diode array that's set across the line of travel of your product, and it can be in packaging. It can even be in aluminum. We've used it for aluminum. We use a lot of aluminum metal, metal metalized film in order to create a moisture barrier for cereals and other kinds of products, of course, but it will look right through aluminum. Projects onto a diode array, and that converts the energy into visible photons, and the photodiodes that pass through energy. There's an absorption picture that's created, and that is then electronically compared to a standard that's programmed in the machine. And then there's some sort of a reject or some other kind of signal that can be triggered, you know, from that.

There's different kinds of units that are out there. There's linear transfer of systems, or there's even some enclosed liquid systems that are out there. They have the capability to detect some sizes of contaminants. For example, metals, glass, maybe bone, maybe some other things. And it really takes a good software program that's associated with these devices to be able to interpret that image, and that's really a critical component in what you're able to actually do. It isn't necessarily the tube or the diode array. It's the software and the ability of that software to be able to interpret what those pixels are actually registering in terms of a grayscale reading.

The sensitivity is determined by the number of the photodiodes in that array, and sometimes fewer diodes work better. It all depends on the product. It all depends on the specific application. Resolution is affected by product speed through the detector, and so is that image, you know, in terms of if you've got intermittent speeds, you're going to get different images that actually come through that because the picture that's going to be generated is related to the software, not necessarily to the line speed. So you need something that's relatively uniform speed moving through. And whatever that speed is, again, is going to be determined by the application specifically.

The absorption is affected by the density differential between what we think is a, quote, contaminant in this case, not the highly desirable things, like raisins, or marbits or anything like that, but let's just think about contaminants -- the difference in -- the differential between a contaminant and whatever that substrate is and how that substrate lays plays a key role in it.

For example, if we've got shredded meat and it's in some sort of a tub, how those strands actually lay across each other creates shadowing, because in some places it's thick and other places it's not so thick. And when they x-rays -- When that passes through that x-ray array, basically it's going to determine that there's going to be different rates of absorption through all of those different layers, depending on how they lay. And how that actually works in terms of what you normally see can affect the ability of that device to be able to differentiate a contaminant that's laying under layers of folded over meats, or shredded meat strands. So that has a big effect, but it's the software that really makes the difference.

Now, the advantages of these x-ray devices so far that we can tell, let alone all the other things they claim are on quality factors that deal with doing counts, missing components and all that stuff, net weights, is that they can see through aluminum materials. So you can run aluminum cans through there. You can run aluminum trays. You can run metalized foil and all those kinds of things and it will look right through it, something that you physically can't do without a serious amount of jiggering on a metal detector and then lose a lot of sensitivity at the same time. It really doesn't have any sort of a freeze-thaw type of an effect there because it all has to do with absorbants and essentially that water and the moisture content has an overall effect, but it doesn't matter whether it's frozen or thawed. And then salty, wet or variable fat content type materials, there's very little difference, no real effect in terms of what the x-ray will be able to do from the product.

So when we get into that issue of reduced metal detector sensitivity, for example, because of, you know, high moisture content, salinity and all those kinds of things where we have to go to a low frequency operation that reduces our sensitivity on the stainless side, these things don't have to go through that.

Now, it does require a larger footprint than a metal detector, generally. It's generally not for drop-through applications. Again, we want to regulate its speed of product, or package or whatever going through these applications. They're very application dependent, that have to do with understanding the density and the variation in density of the products that are actually going to be running through and what you're looking for in terms of a potential foreign material. It takes a lot of testing. We have to know what our expected contaminants are.

Line speeds operate slower than metal detectors, but they're improving. They're up to 400 feet per minute versus metal detection in some of our big cereal systems running at approximately 700 feet per minute, reliably. So they are getting the speeds up, and there's going to be continued improvements, you know, in that software for differentiation. But the contaminant shape and orientation also affects its capability. We're still using spheres.

We're still using spheres, and that's because we want to present to the x-ray the same shape. We want something that's round. We're measuring a depth of absorbance differential that the machine can differentiate, base as its background. So we're still using spheres.

Now, the issue is with x-rays, is that essentially its ability to differentiate things deals with density, and that's related to the value of water. And say we say water is one. Just say water is one. If you look at the metallic type contaminants that we might possibly be looking at, you're looking at different, very different densities. Aluminum is not very dense, you know, 2.7. Bismuth, the stuff that you actually drink when they take an x-ray, that's easy. I mean, doctors aren't even challenging themselves when they have you drink Bismuth. They should have you drink something out of an aluminum can. But, anyway, that's pretty dense, 9.8. You know, brass, 8.5; bronze, 8.8; copper, 8.9; lead -- did somebody say shot -- 11.3; stainless steel, 7.9; mild steel, 7.8; titanium -- no wonder they use it for golf clubs -- 4.5.

So, basically, what you have here is this differential where on a metal scale standpoint, looking at things like, you know, smaller size spheres in meat, we can improve. Or we could run maybe a four-and-a-half millimeter test ball on some of the test pieces that we've actually run through with some of our standard products. With x-ray devices now we can get down to below two millimeters. We can run 1.8 on an x-ray device, again, looking for a sphere.

The issue is, if we actually try to, and in some cases they have been, somewhat oversold for various other things. The heaviest thing we've got is bone, right? I mean, that's why you call somebody bone-headed, I guess. It's thick. It's the densest part of the human, but it's only 1.8 compared to water. It's basically pretty lightweight stuff when it comes to x-ray sensitivity. And poultry bone, I'm sure, is a lot less. They were intended to fly.

Concrete, 2.4; epoxy resin, 1.1; crown glass, 2.6; some flint glass, 4.2; nylon, 1.1. Now, say we grind up a barrel. Say we grind up a tray. Say we grind up a scoop. What have we got? Polyethylene, polypropylene. Say we lose a gasket. It's a rubberized type material. We're talking about stuff that floats. It's not going to be very detectable if it's incorporated into product with an x-ray device.

So, basically, when we think about other types of foreign material, hard plastics and other kinds of things, and, you know, x-ray is -- "Hey, we'll just run it through some x-ray devices, you know. We should be able to get it," that's kind of a broad, sweeping statement that may not hold any water, depending on the substrate, depending on, you know, what you're actually looking at. So, again, the form of the material going through these x-ray devices and what we're actually looking for is extremely critical in order to understand what it can do. And we have to realize that as amazing as it is, and as amazing as medical science can use x-ray technology, it's not line speed technology that's used in a food plant yet. It's the technology that basically says, you know, there's some stuff out here that we can't tell. We can't find it. We can't get wood, for example, through an x-ray device.

Now, like I say, we have improved. We've actually -- We've been doing some work on bone, and right now we can't find a 2.5 millimeter cube in some of the stuff we've been looking at. It just doesn't have the density differential versus our substrates. And maybe there's some stuff that's out there that would work very well. You might make some sort of a potted meat that's foamy and fluffy, airy, so to speak, has very little density. I mean, you might be able to, you know, get an x-ray device to work through, you know, something like that. It doesn't sound very appetizing, but I'm sure you could do it.

Anyway, the location of that object within the product makes a big difference when it comes to x-ray capability. If it's laying on top of a substrate, it's going to be a lot easier to find than if it's actually entrained into the material itself. If it's buried within the product, it's going to be much more difficult to find.

Objects smaller than the test sphere have an effect. So if it's on edge, it needs to be as deep. Since we're looking at something through a vertical type of an orientation and we tested it, say, with a two millimeter sphere, we need something to be at least two millimeters in height to be able to be detected and to have the register more than two millimeters of absorbance from the x-ray device in order to differentiate it against its background.

So if we've got a wire and it just happens to be standing upright and the x-ray looks at it longitudinally and it gets more than two millimeters of wire, then we've got a good chance to find it. But if that wire isn't two millimeters in diameter and it's laying horizontally, then it's going to be a difficult capture because it doesn't absorb enough material in one spot on the pixel array to be able to detect it, unless we've got a software program that we can also put into the software that is looking for adjacent pieces. Then we might have a chance, because you can actually program these things to look for long, thin type things. But we still may not get the absorption that we need to differentiate that material from its background if it doesn't meet spherical dimension. So flat pieces need to have a necessary depth. And, that again, we can specify by looking and using spheres.

The software is really important. And like I say, there's a lot of people working on the software. And as luck would have it, this thing has really been spurred along by -- I wouldn't say luck, bad luck, I guess, but kind of a side benefit is this whole idea around bioterrorism safety, there's a tremendous amount of x-ray technology and capability that's being used right now at airports and other kinds of things that you walk through when you go about your normal course of business. And that technology, that ability to be able to differentiate objects in your carry-on stuff that drives all of these people crazy because you've got wires, and radios, and connecting stuff, and phone accessories, and a DVD player and all that kind of stuff, the technology that's going to help us figure that out, we can also then use in terms of software that will help us on the food side.

Manipulation of the grayscale values is really the important factor, and then that software allows pre-program shapes. We can be looking for things that are round and long and other kinds of things.

So, in conclusion, let me just say that sources within facilities are many and varied. We've got ingredients. We've got systems. We've got people. We've got lots of different things that can contribute potential foreign material. We've got to do something in order to assure compliance. Prevention of issues is certainly the key. There's many factors that determine the selection of these various types of equipment that are out there right now, but the most important thing is collecting this information over time and using it to evaluate the product safety, system and capability of our existing systems. Because when we talk about foreign material, we're talking about something that doesn't happen all at once. We're talking about interpreting the drip-drip-drips that show us where there's a hole in the dike.

Detection equipment is required. You've really got to do a lot of prior planning to make it work better, and that includes testing devices with our substrates, with our potential foreign materials, and doing that prior to an installation. All parts have to work, including the important and really important factor of employee training. Operation and documentation has to be expected. Findings require evaluation and follow-up, and records really are important.

So over the next couple days we're going to be talking about all of that. We're going to be using these pieces of equipment to tell us more information about it, and hopefully that will come into play when we get into these case studies and other kinds of discussion. Otherwise, thank you very much. Any questions?

(No response.)

I know I ended 10 minutes early, and Moshe said I could talk until noon, but I know you guys are all into food safety and want to go wash your hands.

(Laughter.)

Thanks.

(Applause.)

MR. DREYFUSS: Thank you very much. We'll take a break for lunch now. And I was asked that we extend lunch a little because of the dining room downstairs only has so much capability to handle so many people. So we'll meet back here at 1:15. That will give you about an hour-and-a-half.

(Off the record from 11:55 a.m. to 1:20 p.m.)

PROCEEDINGS: (Afternoon Session, September 24, 2002)

MR. DREYFUSS: Welcome back. Hope you had a nice lunch. I was just walking through the streets down here and I noticed the building over on 16th and Harney. The outside of the building said OPPD, and the first thing I thought of was the reorganization our agency is going through, and then somebody told me it's the power company out here, so I don't have to worry too much just yet.

Our first speaker of the afternoon is Charlie Gioglio, who is going to speak about the HACCP validation from the FSIS perspective. Charlie is the current director of the Meat and Poultry Advisory Committee Staff for whom I worked for for the last year-and-a-half. He's been a great boss and I'm sure you'll enjoy his speech.

MR. GIOGLIO: You know what? He doesn't realize that performance ratings have already gone in and, you know, they've already been reviewed, you know, by the execs and everything, so it may be too late, Moshe. I'm sorry about that. My own boss pointed out that I have a mistake on the slide already because we are, as Moshe just pointed out, OPPD and no longer OPPDE. So we'll go from there. I think I got the rest of the presentation correct.

Some of you, I know, have already seen this presentation in different venues and all that, and I think to try to, you know, get us back on schedule as best we can, I'm going to go through fairly quickly. But there are some points I want to make about validation in general that would sort of set the stage for later discussion that we're going to have this afternoon and certainly the next speaker coming that's going to walk us through our policy. So we'll just go.

This is a rehash, I think, for most of us, but we're all aware that according to 9 CFR 417.2(b), the HACCP rule, or that part of the HACCP rule, "Every establishment shall develop and implement and a written HACCP plan covering each product produced whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur." Then a food safety hazard is further defined as a food safety hazard that is reasonably likely to occur. It is one for which a prudent establishment would establish controls because it has historically occurred or because there is a reasonable possibility that it will occur in the particular type of product being processed in the absence of those controls.

I think I mentioned earlier, probably, for the most part, we focused quite a bit on pathogens and bacterial, microbiological hazards, but certainly the agency has an expectation and you all should have an expectation to look for potential physical contaminants in your processes and products that you produce that may be hazards that reasonably -- that are reasonably likely to occur. That requires you to do a hazard analysis, and that hazard analysis has to have the documentation that supports the decisions made. And that's really what I'm trying to say here in this slide, that you need to take into account those hazards that may occur. Decide whether or not they are likely to occur. If they are likely to occur, they should be addressed in the HACCP plan. But you need to, you know, having the supporting documentation to justify or to support the decisions that you have made, even in cases where you have identified a potential hazard but then decide that, in fact, it's not reasonably likely to occur for whatever reasons.

Talking about, then, validation, validation of the adequacy of the HACCP plan, 417 of the regulations require every establishment shall validate the HACCP plan's adequacy in controlling those hazards that are reasonably likely to occur, those that were identified through the hazard analysis. What do we mean by that? It's the process of demonstrating that the HACCP plan -- and I have a phrase up there, "If operated as designed, can adequately control the identified hazards to produce a safe product."

The question comes up, what really do I mean here when I say "if operated as designed"? And what I'm really trying to get to is there have been times and we've had some experience with folks installing equipment, so forth, in their operations that the type of equipment is designed to control a particular hazard. But when they get it in the plant setting, it's not actually able to operate the way it's been designed. In other words, they cannot routinely meet the particular parameters that they should be meeting to control the hazard they are looking to control. We may get into some more of that discussion later on, I think maybe when we get into the panel discussions, and try to apply some of the information we heard this morning to real life type situations, you know, typical situations that we face in a plant setting.

Verification, then, and just to differentiate the two terms here, are activities designed to determine that the system is operating as it was designed and as it has been validated to operate. And that's both a plant activity. I mean, certainly you should have verification steps, verification procedures built into your HACCP plans, and, obviously, it is also the agency's responsibility to verify that the establishments are, in fact, operating their HACCP plans as designed. I'll stop -- Well, let me just go on. I'll stop at one of the next slides and make the next point.

The elements of validation are really two. You need the scientific or technical justification. This is sort of the paper or the documents on which the controls in the system are based. And then the rule also talks about the initial practical demonstration or sort of start-up date. And I forgot the exact words that are used in the regulation, but we talk about the initial practical demonstration, proving that the system will perform as expected. And this is sort of going back to the point I made a few moments ago, that when you actually install either a piece of equipment or a certain set of controls in the plant setting, that early on you've run "X" number of lots of product, so forth, to demonstrate that you can routinely meet the parameters that have been set up. And that's true whether or not we're looking to control for a pathogen or we're looking to control, in this case, for foreign material contamination or some other, you know, chemical contaminant or other hazard that may have been identified in the hazard analysis.

The supporting documentation can consist of, and this, again, going back to the paperwork, either peer-reviewed, you know, from a scientific journal, peer-reviewed article, a documented challenge study that maybe you've contracted to have done, you know, of the product that you're producing in your establishment, the data underlying published guidelines. And those may be agency guidelines, may be guidelines, in some cases possibly published by another federal agency or even trade associations and so forth. But we're looking to have, you know, an understanding that it's not necessarily just a reference to a particular study or particular acronym, it's the data underlying those guidelines that are important, or your own in-house generated data.

The documentation needs to be specific to the particular hazard that, in fact, it's designed to control or that -- you know, and to the particular level of either reduction or control that you are aiming to achieve, and all associated factors, conditions, you know, having to do with the processing steps that need to be in place for you to achieve the particular level of reduction or control need to be considered and monitored, again, related to the specific hazard or pathogen and identified, the control parameters.

The practical demonstration, then -- and this is what we talked about. And I think there was a lot of confusion early on about what we were really looking for here. This really is the early testing in the plan through observations, measurements and test results, that are designed to demonstrate that you can routinely meet the parameters of the plan. The critical limits are set based on that, and you need to be able to demonstrate that you can routinely meet that in the plant setting. It's -- Again, it's very important. I think this point was made earlier also that records should be kept, obviously, of that early testing. And that all then becomes part of the supporting documentation of your -- for your plan.

I mentioned before that the agency is going to verify, I mean, not only the ongoing operation of the plan, but we are beginning also now, with our CSOs, our consumer safety officers, to go back and begin verifying that this scientific documentation, the supporting documentation that establishes the validation of the HACCP plans and the critical limits that were decided on and so forth are, in fact, in place at the establishments. Too often we'll find that there's simply just a reference to a particular study or a particular guideline, that maybe the agency had put out and the actual study or the actual information is not there on file.

Again, I guess I'll make the point again just to differentiate. Looking at your validation information, for the most part, we consider consumer safety officer work, and the daily routine verification that, in fact, you are following your HACCP plan as it's been designed and validated is inspection work, or in-plant inspector work. The CSOs will attempt to ascertain the status of the reference material and so forth.

Some of the criteria, then, is the research widely accepted by the relevant professionals. We don't have a list or a checklist that they're going to go by, but if there is a question raised, they may raise the question and then seek guidance through the Office of Policy, Office of Public Health and Science and so forth about a particular article or particular research. You should seek to have the best science available to support your decision-making. And some stuff may be dated, but it may be the best that, in fact, is around. The supporting documentation, again, it could be plant-specific or broad-based. I said this earlier, I guess, but, you know, we need actually -- You should have on file a copy of the article or the study, not just a reference to it.

Just a couple of examples to go through. If you've established that the product -- the product you were producing were beef carcasses and you decided that salmonella was a hazard reasonably likely to occur in your operation when you performed your hazard analysis. You may set up a critical control point for steam pasteurization, and then you need to set up a specific set of critical limits. In this case, in this example, let's say you set up six-and-a-half seconds exposure at 180 degrees. We go on up. The supporting documentation, then, should be from published articles stating the time and temperature of the process and the level of pathogen reduction that is expected. And the recorded documentation, or that early practical demonstration, that data that we'd be looking for are records confirming that the steam pasteurization process can be applied per the specifications in the article, or the study, or the documentation that you're relying on routinely in the plant setting.

Need to take into account, you know, if a study had been done in a laboratory setting, so forth, when you installed a particular piece of equipment in your plant, can you reach the 180 degrees for six-and-a-half seconds all the time. Is your line set up that way? Are there other factors, the climate or whatever have you, that may affect that? And take all of those into account as you're designing your system. And that early testing period is really -- should be designed to determine that.

So I tried to come up with an example of a critical control point that would be specific for metal detection, and this may or may not be good, and I'm not particularly advocating this, that we expect to see this particular CCP in everybody's HACCP plans starting next week. But if the product were ground beef and the hazard were foreign material, specifically metal, one way you may go about it is to establish the CCP and the CL as a functioning metal detector calibrated at two millimeters.

I think -- I sort of throw this out here because I'm hoping really to generate some discussion later on and especially with our panels about how should we -- you know, what is the best way for us to go about establishing these critical control points, if you do, in fact, find that metal contamination or other foreign material contamination are, in fact, hazardous, reasonably likely to occur.

I'd sort of really urge everybody or basically really I want to state that the reason we are here, those of us in policy, are to listen to, you know, the discussions and generate as much open, frank discussion in sort of a non-emergency situation as we can here, so that we can best, then, go back and formulate policy and guidelines and so forth that are going to be able to work for everybody's benefit in the plant setting. I mean, what we're really all about is to be protecting the consumer and making sure that no product that may become a health hazard is actually marketed.

The type of documentations that may be, you know, an example of what would support a CCP like that would be a document of risk assessments, journal articles, regulatory compliance guides. I think Dr. Goldman mentioned and some of the other presenters mentioned some of the FDA documents that have been published in this area that actually set certain sizes, and the hard and sharps paper that's been published by FDA. Those are the types of documentation that you may be able to rely upon to establish and support these critical limits.

And, again, the recorded documentation, I think Bob Richardson gave us a great presentation on this, all the different factors that you need to look at in the plant setting and to assure -- to convince yourselves and us that, in fact, you are finding the type of contamination that you want to be finding. That's the wrong way to say that, but that, in fact, the equipment is able -- is capable of routinely detecting the type of hazard that you may be finding.

Just sort of go on. Reassessment. The rule also talks about reassessment of your HACCP plans in 417.4, that "Every establishment shall reassess the adequacy of the HACCP plan and hazard analysis yearly and when changes are made." If there are things that come up in your establishment, if you're finding some level of contamination that you didn't expect to find, that may be an unforeseen hazard, but that should, we think, trigger for you to go back and reassess, was your hazard analysis adequate. Was this something when you had gone through that decision-making that may have been left out? Why really, then, are you finding this level of contamination in the product? And those types of events should then trigger, I think, a reassessment of your HACCP plan.

That's not to say that in each case that means automatically you have to establish a critical control point or a set of critical limits and so forth, but you should be going back when you find these incidents happen. Go back and assess whether or not you do need to -- was there something that you missed. And the reassessment also includes reviewing the validation documents upon which your critical limits were based or upon which the critical control points were established.

That's the end of the slides. I think I'm going to close right there because I really would like Lee to continue. Lee is going to go through our draft document that talks about foreign material contamination and how we would expect, then, that specifically -- to sort of lay out various ways that companies may be addressing it in their HACCP plans. And I'm going to turn it over, then, to Lee Puricelli from the Office of Policy. I think you all have -- you should all have copies of the directive that we gave out with the agenda.

MR. PURICELLI: I'm Lee Puricelli from the Regulations Development and Directive Staff, and I think everybody has, as Charlie said, a copy of the directive, so we'll just go through it fairly quickly so we can open things up to discussion. Again, this is just a draft and it's just our current thinking to kind of get the ball rolling here. Let's go through it.

First we talk about our general philosophy on foreign particles in the beginning part and what this directive does cover and doesn't. It doesn't cover bone. That was discussed earlier. This is all metal and items like that, plastics, glass. Also, the directive -- The way it was set up, I think it could possibly look like these are either/or decision-makings. They're not. None of these things preclude one of the other decisions. So you can have a prerequisite program, HACCP, not addressing something in HACCP. It depends on the particular foreign material. Or for a certain foreign material you may have part of it in HACCP and part of it in a prerequisite program. So I just kind of wanted to say that. I didn't want anyone to get the impression it was either/or on these decisions.

That being said, let's start with how the directive set out some of the decisions. The first -- This is the first scenario that we laid out in the directive on page 2, and we're saying that you are determining in the hazard analysis that the establishment concludes that foreign material contamination is a food safety hazard reasonably likely to occur. And actually Charlie gave -- His example that he had out almost laid all this out, what you would do. You would have to, in accordance with the regs, establish a CCP, and you'd have the supporting documentation. I think we give an example here of what would be the critical limit, you know, everything functioning to a certain standard, your monitoring. You're to be checking to make sure, if it's a metal detector, it's kicking out some kind of seeded product or a seeded package. And your verification would be that it's calibrated, that it's calibrated to the standards that it's supposed to be, considering all the factors in your documentation and that were discussed probably earlier today. You'd have to have your corrective and preventive actions as well. Then we set out what the inspectors -- basically, the questions inspectors should ask when -- to themselves when looking at the records or how an establishment has made its decision.

I think it's important to note, and the one thing we want to get across is, if you're using something like a metal detector, or a magnet or whatever, if it's catching what you set it to catch, then everything is operating.

That doesn't mean if it's finding metal, it doesn't mean you have a problem. That means it's working correctly. So, you know, we're talking about inspection people don't react if -- as long as it's working right. If it stops working, if it doesn't kick out a seeded sample or they're seeing something go through, then you have to take your corrective actions because something wasn't set up correctly.

Also, an overall comment I would like to make, too, is everything that we set out in this directive stems off the hazard analysis. I would like to point back to what Charlie was saying, that that's what you have to do initially. You consider the hazards, and then you pick those that are reasonably likely to occur. So that's why we are having you look at foreign material in your hazard analysis and make your decisions on where you're going to put it, even if you're not even going to put it in your HACCP plan. But in something like a prerequisite program you've got to do that and justify it in your hazard analysis.

And that brings up the second scenario where -- Well, actually let me quickly -- not to confuse anybody. What we have as a second scenario is you say it's not -- it's a hazard if it were to occur, but you're saying it's not reasonably likely to occur. If it does, then it's an unforeseen hazard. I just wanted to put that example in here. It's kind of an attachment to the first one. That's why we didn't flow chart that out there. They all kind of go together.

Now, if you have -- If you determine that you have a foreign particle or material contamination that would be a food safety hazard but you have some controls to prevent it in a prerequisite program, again, your documentation would have to be in your hazard analysis and the same thing. You know, we would have our inspectors check to make sure you continue to have support justification in the records from your program in your hazard analysis to show that it is still supporting that decision, that it's not going to occur because of the programs. So the decision has to continue to be supported by documentation and by the records you're generating.

And, again, that's what the inspectors are going to be looking at. They're not going to be looking at the program in operation, like looking at monitoring records and writing NRs for things like that. They're looking for the decision being supported. And there's a lot of verbiage here. We can discuss it, you know, but if it's assessed by -- if this is set up this way, we're going to have a CSO come in and look at it and do their food safety assessment, and that's all set out in the directive.

Our next scenario goes back again to when I say in your hazard analysis, you're going to determine that it's not a food safety hazard, but it's something that's occurring. It's something that you know is happening in your establishment, so, you know, if you have a program for it, we want recognition of that program. And if it starts occurring or something changes, then you're going to have to reassess and see if it's now become a hazard. And this flow chart doesn't say it, but this could also be done in your SOP, in your SSOP, either place. But it's just some recognition that you have an ongoing occurrence, but you have historical data to say it's not a food safety hazard, but you're handling it somewhere and we want you to keep supporting that decision.

And the last scenario is really a catchall for something, either you didn't consider it or you don't have any foreign particle, foreign material problems in your establishment, or it's a known incident, something happens, something falls into something. These are the decision-making steps you'd have to take at that time. You first have to -- Is it a hazard? Did whatever occur -- hazardous. If it is, then you handle it as an unforeseen hazard because you hadn't addressed it and you follow the regs accordingly. If it's not, if it's non-hazardous material but it still has to be removed because you can't have foreign material, then, since you haven't addressed it anywhere, the action would be taken under the sanitation SSOPs corrective action. That's not to say you have to adjust your SSOPs in any way. It's direct product contamination. Those regulations cover those situations, so we would react and the instructors would react in accordance with those regulations. But, again, we're not saying because it's happened you have to change your SSOPs. I think that's an important point.

That's kind of a quick -- quickly went through it and now if there are any questions, we'll take them and we can discuss however you want to go through the directive, from the beginning, middle. It's up to you.

(No response.)

Okay, good. Well, we'll get it for signature today and we'll -- No questions? There has to be questions.

MR. SEWARD: This question may not be specific to what you just went through, I couldn't really read the slides, I apologize, but I did get the directive, so thank you.

MR. PURICELLI: Okay, yeah, sorry about that.

MR. SEWARD: That's all right. I think in responding to some of the things that Charlie presented I have a couple of questions here. And I'll just start with the first one and get through as many as I can, allowing other people to ask. But you, in your slides, Charlie, you indicated that reference to an accepted paper in support of a CCP would be inadequate if the establishment didn't actually have the document there. And, you know, I guess my question is, in this particular case, when I hear that, if it's an FSIS or a government-established document, and I think you referenced an example of that in your comment there, you know, to me it gets into a situation where it's almost, you know, form over substance there, to a certain extent, because I'm looking for the rationale behind why an establishment is going to be penalized in some way when there's a well-established, scientific rationale for validating the critical control point, but they're going to be penalized simply because they don't have the paper. They have the reference to the paper. It's well established. It's being implemented. They're monitoring it and verifying it, but somehow they're being, from what I heard you say, that, "Hey, that's not acceptable because you don't actually have the paper in your file." Is that what you're really communicating, that that's unacceptable just because they don't have a well-established -- it's everybody is doing it across the board and they're making reference to the document, but I heard you say that's not good enough. You have to have the paper in your file.

MR. GIOGLIO: Yeah. Let me just say I did say that, and I would stand by that in that we would expect an understanding of what is being implemented in that plant.

In other words, if there is a set of guidelines, let's say, that we've put out -- you know, Appendix A, Appendix B is a great example of this -- that folks actually do have copies of those documents and someone in the plant has actually read those documents and, in fact, there is an understanding of what, you know, they are intending to implement there, rather than just sort of listing Appendix A and Appendix B. What I think we find is that that becomes just sort of a, you know, a set of buzzwords that people point to. And that's what we're saying.

I mean, it's not -- I don't want to say that we're going to, you know, take some drastic enforcement action or something like that, and I don't want to give that impression if somebody doesn't have the document. But if that, in fact, is the document or is the justification for the particular critical limits that you're intending to follow, then there should be an individual, at a minimum, some individual in the plant that understands that and knows and has gone through that document and so forth and has worked through and made those decisions, rather than simply -- what I think I'm trying -- we may be trying to avoid there, Skip, is the one size fits all, that people just simply may, you know, take the easy way and point to, "Yeah, Appendix A" and not really know what it says in Appendix A. And I will grant you that maybe in 90 percent of the cases they were actually meeting the parameters of Appendix A or, you know, Appendix B, whatever it is. So that's the point that I'm trying to make.

MR. SEWARD: I think it's more important that there -- just what you said, that there's understanding and so forth and that's --

MR. GIOGLIO: Obviously, it's more -- yeah --

MR. SEWARD: -- the execution part, and it seems to me that ought to be the thrust of what the agency is after, not whether you --

MR. GIOGLIO: I think both things are, in fact, important. I would grant you that the execution part is, in fact, more important than the paper part, and I don't see, you know, a sort of Draconian enforcement action happening, you know, until somebody gets the piece of paper, but, in fact, we think it is necessary.

MR. SEWARD: To have that, okay. Does somebody have another question, or can I ask another one? Go ahead.

UNIDENTIFIED VOICE: I have a question on page 2 where it talks about the policy, Part A, and then it talks down on the bottom there, on Part C, about the also extraneous materials such as debris found during finished product standard testing. Can you expound on that a little bit and how that relates to 1? I mean, we talk about boneless meat reinspection, having certain criteria for cardboard and wood and things like that. Has that gone away, or is it still in effect?

MR. PURICELLI: That's still in effect, and that's what we're saying, that's not going away. We're not -- Those inspections still apply, so you wouldn't -- we wouldn't -- and those are the consumer protection activities so they don't fall under this directive, this directive. We're talking about food safety issues. Does that help?

MS. HANIGAN: I have a question on reassessment of the HACCP program or the SSOP. If you find a one-inch piece of cardboard in product, which is clearly not a food safety hazard, and you go ahead and you take corrective actions under your SOP program for direct product contamination, does that also require a formal reassessment of the SOP for direct product contamination?

MR. PURICELLI: No, no, no. There would be no -- Actually, there would be no reassessment of the SSOP. If you had it, I mean, you would just take your actions -- the regulatory requirements for the corrective actions, but you don't have to reassess the SSOP. That was the point I didn't make very well, I guess, but that was what I was trying to make.

MS. HANIGAN: So you can have direct -- You can fail to prevent direct product contamination -- a plant can fail to prevent direct product contamination and not have to reassess the SOP? Is that what you said?

MR. PURICELLI: Well, yeah, because we don't have -- There aren't regulatory requirements for reassessing SOP's. I mean, you have to look at -- I mean, you have to follow the corrective actions, and I think there's steps in there, in the SOP's. I don't have the regs in front of me. But you have to fulfill 416 -- 16 or whatever it is -- 15, yeah. That's what you have to do.

MR. SEWARD: In Charlie's slide he listed a list of bases for validation, and a scientific article, and in the next to the last one there was the word "or" there, so that conveys to me that, you know, you don't have to have all of those. You can have one of those, or two, or -- but -- and that type of thing. It wasn't like you have to have all of these. I think what I hear a lot from people who may be confronted with this situation where they provide one of those items and they may be asked a ques- -- or be told, "That's not good enough. You know, I don't accept that as being enough information," and I guess I would encourage that when it comes to validation, that the field force and the people who are out there doing this, whether it's a CSO or someone else, that if they're going to make the statement that your validation data is not enough, that they also, then, should be required or put in the position where they, then, communicate, "And here's what I need. Here's what I will accept. Here is the information that I am looking for specifically."

Because otherwise many times we find ourselves in a situation where we're playing this guessing game. "I'll give you something else." "Well, that's not good enough. I need more." "Well, what do you need?" "Well, I'll know it when I see it." I mean, I'm oversimplifying it a little bit, but I think that it's a responsibility that when you work through this validation process, whether it's foreign material or whatever, that if the agency is going to make a judgment that that's not adequate, they should have to say, "Here is specifically what I need." So then the people at the field at the establishments can provide that. So that would be a recommendation that I think would be helpful for everyone in getting the job done.

MR. GIOGLIO: Let me just say, Skip, I hear the point that you're making, and I don't think that we want any type of review, you know, done by a CSO or anybody else to become, you know, a situation where we put an establishment in, you know, a complete, unwinable situation or unapproachable standard. However, I say that I also think we have an expectation that we would expect the plant, or the establishment, to do the work that's involved in their hazard analysis and so forth and not rely on the inspector or the consumer safety officer or the circuit supervisor or anybody else to actually, in fact, do the hazard analysis. You know, and I don't mean to dig up old history or whatever, but draft the, you know, HACCP plan for anybody like that.

So, I mean, I think your point is -- I understand what you're saying, but I wouldn't say that we can give you exactly what we're looking for or give you the documents. But, you know, basically the criteria, yes, of the type of --

MR. SEWARD: Yeah, and I think that what we're saying, is it's a two-way street, not just keep me guessing type of thing. And I think that the CSOs, part of what I've heard is their job is to -- is an educational component and is training in a helpful --

MR. GIOGLIO: Uh-huh, right.

MR. SEWARD: -- scenario, so I think that's a big part of their job, is to try to, then -- "Yeah, you try as an establishment, but then if you don't quite make it, I'm going to be there for you to help provide greater guidance to take you down that road."

MR. GIOGLIO: It's specifically part of the CSOs job as far as training, especially small establishments and so forth, to help them through that process. But I would go further to answer you to say that the agency right now is, in fact, investing a lot, and it's been directed to us from on high to, in fact, have the best possible training for our CSOs. And that's an ongoing process and one that, you know, we expect to continue as, you know, we bring more CSOs on board and so forth.

I mean, I would say also that, you know, these types of forums like this are places where we really all need to, you know, have these kind of exchanges and, you know, get the information out so that we all come to, I think, a better understanding of, you know, the things that we're facing.

MR. SEWARD: Yeah, it's good.

MR. GREGORY: Mike Gregory from ConAgra. We backed into this. You started out with validation. Then you went to verification, which, I think I basically understand where you're going. But we missed one big part of the step that is a fundamental part of when you put your HACCP plan together, and that's monitoring. Now, you know, if we've validated that our HACCP plan has a metal detector program in it, and we've verified through the seeding of the samples that the 2.5 millimeter ball is going to work and all that kind of stuff, then is the fact that it's kicking off or not kicking off monitoring? Or where does monitoring come into this thing? Because, quite frankly, we're going to get into a lot of issues, both from our design of our HACCP plan and from a regulatory compliance issue with inspectors and CSOs about what monitoring is. And I'm really confused about what you guys' vision on monitoring is.

MR. PURICELLI: I think on monitoring we actually envision some established frequency where you would -- that's where we give the example of running a seeded packet through. The way we see verification is more to ensure that it's still calibrated. Where if it's supposed to be calibrated or supposed to do certain things, you verify the certain frequency, that it does that. Then you monitor to make sure, I mean, that it meets all those criteria. Then you monitor to make sure that it's working, like it's kicking off, or it's grabbing or whatever. That's how we --

MR. GREGORY: I don't want to draw too fine a line, but I think you're -- to us, at least in my way of thinking, this calibration that you're speaking of and the running of the seeded sample is all one and the same. In other words, the running of a 2.5 millimeter or 3.5 or whatever you happen to be using for your standard is the calibration issue that we use. Now, short of bringing in somebody from the manufacturing company that actually built the thing and really understands how they can calibrate it, I'm not sure that verification activity in what we would do in the plant every day, in your terms of -- And I'm not trying to split the hair too much, finely, guys, but what

you're looking at for calibration and verification I think
we would all throw all that into verification. I'm still
not getting the monitoring activity going on.

MR. PURICELLI: Well, I think our panel can
discuss that, you know, more, too, and see where we go
there.

MR. REINHARD: My name is Bob Reinhard with Bar-S
Foods. And my question is about Part No. 9, Part A, where
it talks about -- and you can answer this with a simple yes

or no. This is straightforward.

MR. PURICELLI: I love those.

MR. REINHARD: It's stating there that you can determine a hazard is not likely to occur based on prerequisite programs. Is that the new regulatory model that FSIS is willing to live by?

MR. PURICELLI: I think in the conte- -- that's kind of what we're discussing, to see how it works, how the prerequisite programs all work into -- Again, it's all part of the documentation in the hazard analysis. I can't just do it yes or no.

MR. REINHARD: Yes, is what you're saying?

MR. PURICELLI: Yes, we're considering it. We're heading that way, yeah.

MR. GIOGLIO: I think -- not to be -- not to sound like I'm joking, but these are the kinds of questions that we hope to have a full discussion on, you know, both later this afternoon or this afternoon and tomorrow morning specifically on prerequisite programs. I mean, I would say that's the kind of thing that we want to work -- sort of work through and all of us have a better understanding.

MR. REINHARD: I commend you for that.

MR. GIOGLIO: Well, thank you. In our office, we take that as a, you know -- The office takes that as a compliment.

MS. CRAWFORD: Cathy Crawford, Advance Food Company. Today we learned in the presentation that many pieces of metal are not detectable. We also learned that many instances of foreign material contamination are not assignable to a cause because they can't figure out where it came from. What does FSIS expect from a company when we're talking about hazards that are not detectable, we can't assign a cause and we can't prevent them?

MR. PURICELLI: Well, I mean, if you can't find them, then, you know, then you can't do anything about them. I mean, I think, again that being said, I think that being true, it's all -- you know, the documentation, what you've considered, what justification you have for considering the ones you have and the ones you haven't, I think it's important and we're going to look at it, but if you can't detect it, then no one knows about it.

MR. DOPP: Mark Dopp, AMI. I want to go back to what Skip was talking about a little bit. And since you are the guys who write these directives and notices, let me make a suggestion. I don't think Skip was asking when a compliance officer, or a CSO, or an inspector raises questions. He wasn't asking for the inspector or whomever to say, "Here's what you have to do," or to ask that person to write the document. But it's not unreasonable in this document or in any other document that you folks prepare, that the people who are doing this be able to articulate what it is they find missing. There's a difference between us looking to you to finish the job versus saying, "It's not good enough. It ought to be -- It's not good enough and here is what you're missing to get to where I want you to be or what you need to do to meet the standard." That's not unreasonable.

And my view is if you look through the document here that you've put out, when you talked about inspector responsibilities, I would suggest that you incorporate that concept throughout this directive, frankly, and every other directive that you write. Just a thought.

MR. GREGORY: Mike Gregory. I want to go back to her question a minute, because we didn't follow through in what I would think would be the last step. >From the first speakers we heard from today was basically the feedback loop, for lack of a better term, from the complaint system. In other words, the consumer has found the piece of wire. That is the fact that we're faced against. Now, you couple that with the succeeding presentations that show, okay, we have a real hard time making sure that we can detect that metal, and I think that's where she's -- without putting words in her mouth, she can, you know, correct my position, but we're faced with a loop here where all of a sudden now, from a consumer's perspective, whether you look at that from a regulatory person following up or just the fact that the consumer had a piece of wire, you're now faced with how do you address the hazard with a metal detector, or an x-ray machine, or whatever else we want to use that can't detect the metal and do the hazard analysis that says it will never happen again. Because that's -- you're getting into a Catch-22 situation. Is that more what you're saying? Somebody did find the problem and you say it's undetectable. That's true. But it was detected by the consumer when they bit into the product.

MR. GIOGLIO: Let me just jump in one second, Mike. I understand what you're saying, and I'm not joking when I say I really do think this may be, you know, more fully discussed a little bit later on and some of our panelists may have a different perspective than I do on this issue. But, I mean, the first thing, let's say, as was pointed out this morning, there may be a consumer complaint and that's how you learn about the piece of wire, or the stone, or the -- you know, whatever the thing is. I think the first question that -- you're going to have to walk through a series of decisions or ask yourself some questions. One, is it, in fact, a hazard reasonably likely to occur? First of all, is it a food safety hazard? That's the first question. And you may answer that yes or no, depending on the type of material that you found, size, sharpness and all that.

Two, I guess, is it -- Then you have to walk through and think about, is it reasonably likely to occur? Well, you know, you may come to the conclusion that it is an isolated incident, that it's not expected to happen on an ongoing basis. There was no historical, you know, finding of that particular, you know, hazard. Even though it may have been found in more than one unit of product, it may have been, then, an isolated incident and you might be able to go back and hopefully look at your system and maybe point to an assignable cause and maybe not. But I don't think we're saying -- I don't want to give the impression, at least from my personal perspective, that we're saying every time you find something that we expect you to go back and reestablish -- you know, and establish a CCP. But you do need to do some thinking and ask yourself some questions.

And the answers to those questions would drive, then, your action about whether or not you need to establish controls or not.

MR. PURICELLI: It could be different than the technique. There could be other controls you could take to prevent --

MR. GIOGLIO: Sure, I would think so, that's right. And, I mean, that's something that I don't know that we talk about enough from an agency point of view or an industry point of view, maybe we need to do more of, think about preventing the hazards and what controls, you know, can be put in place. I mean, you and I actually, years ago, had worked through a problem, you know, it must be 10 years or so ago, where there was sort of an ongoing problem and, you know, you put some controls in place before HACCP, before we termed things in the way we term them now. But, you know, those seemed to work in that instance. So, you know, without giving you all the direct answers, that's what I think we need to address.

MR. PURICELLI: And that's why we say you can do many of these things at one time in scenarios.

MR. DREYFUSS: Thank you, Charlie. Thank you, Lee. We're going to now turn from the agency's discussion to the -- a three-panel discussion on the perspectives of controlling foreign material contaminants through HACCP.

We've arranged for three speakers to discuss this subject. We're going to start with Dr. Kerri Harris, who spoke earlier today, who will present exactly -- perspectives on controlling foreign material contaminants.

(Slide show presentation.)

DR. HARRIS: We did check this morning to make sure that we had the right slides for the presentation this afternoon, so hopefully everything is still there after that, that we all have them.

We're going to talk about controlling foreign materials, specifically food safety hazards in a HACCP program. First let's go back and look at the definitions. And Charlie walked through part of these. You, hopefully, all know these. Physical food safety hazards are identified as reasonably likely to occur for a particular product and our process should be controlled in a HACCP system. And I don't think that any of us that you will hear presenting information today are going to give you anything different in response to that.

If it is a physical food safety hazard that is reasonably likely to occur, it should be controlled in a HACCP program. Now, how you get from that statement to using and making those determinations, we've got to look further, don't we. Because we have to go back to that definition of reasonably likely to occur if you're going to use agency terminology for reasonably likely to occur. And this is taken directly out of the pathogen reduction final rule. That whole statement about, you know, if it hasn't historically occurred or if because there's a reasonable possibility in the type of product or process that it will occur, and absence of those controls.

And I think when we get right down to it, those six words at the end is what has caused most of the confusion and the concern over when something is supposed to be a CCP and when it can be controlled in a prerequisite program, because then we get into a loop sometimes, don't we. And you can say it's not reasonably likely to occur because I'm controlling it by my prerequisite programs or my prerequisites programs control it from being reasonably likely to occur. Well, then that always gets turned back on you, doesn't it, and they say if your prerequisite program is controlling the hazard, and absence of that prerequisite program, would you have a food safety hazard that is reasonably likely to occur. And if you answer yes, then your conclusion is supposed to be then it should be a CCP, correct? And so we start talking, then, in circles. But let's walk from there.

If we take this example, using the definition of reasonably likely to occur, and we say, okay, we're receiving raw materials -- On the first step, for those of you at the back of the room, the very first processing step is receiving raw materials. The second one is that standard column that we say list potential food safety hazards. And this is where, when you look at your HACCP plan, you'll usually find out there's a long laundry list of things people list, and it's every physical thing they can think of. That cardboard, plastic, metal, glass, anything that if, you know, the stars and moon lined up correctly, might possibly be in the product, and they will list those.

And then they'll say, is it reasonably likely to occur. Using that definition of reasonably likely to occur, you may say yes, for example, for metal because the plant has previously found metal in raw material. So we have a documented history that we have found metal.

The next step, then, becomes, well, what are you going to do to control it. Well, we're going to use a subsequent step as a metal detector later in the process, as a CCP. So is the point of receiving a critical control point? No. We'll go to grinding, and I always just love this when we're out doing HACCP courses because then we say, okay, we have a grinder. Is there a potential? Yes, it's a piece of equipment and we could have metal coming from that equipment. Is it reasonably likely to occur? Well, based on the definition of it could possibly happen, or maybe it even historically has happened, that you had blades, you know, break or you had a bearing go out, or for whatever reason, you had metal. So, yes, the grinding may cause metal in the process.

Control measure. Well, metal detector later in the step as a CCP. Is this step for grinding reasonably likely to occur? Now, the reason why I always like the bottom one the most, what is HACCP supposed to be? A process control system, right? A process control system for food safety. If the metal that is being generated by your grinder is part of your routine process for producing the product, you'll never have the processing controlled by putting a metal detector in, will you? You need to go back and find a new grinder supplier, a better preventative maintenance program or something to prevent the metal from being there. A random incidence or occurrence of a problem shouldn't mean that you have a reasonably likely to occur hazard. But we get into that loop again, don't we, because you've had it occur in the past, so you have a documented history. We have to decide first if that documented history really documented food safety hazards, or did it document foreign material.

If we take a different approach and you look at the National Advisory Committee on what a hazard analysis should be, going through and doing that list of hazards, that brainstorming list, and then looking at those that are of significance that they are reasonably likely to cause injury or illness if not effectively controlled. And they provide very specific guidelines on how to evaluate the potential hazard, given the severity and the likelihood of occurrence. That risk and severity issue, that prior to the regulation, and even post-regulation, we've continued to stress food safety hazards should be based on risk and severity, the impact to the consumer and the likelihood of it occurring in your process or your product.

If you keep that in mind and you conduct the same hazard analysis, and you state, receiving of raw materials, and you do your laundry list again, metal, wood, glass, plastic, paper, cardboard, whatever you want to put on there, because we've seen them all. And then you say, is it a significant food safety hazard, and, for example, for metal again you could say no. Plant has previously found foreign material contaminants in raw materials, but these were not identified as food safety hazards. And you could go back and base that on the type of contamination that you found and they're not likely to occur in the product, in the incoming raw materials, you may occasionally find foreign contaminants but they may not be food safety hazards, and they're not something that should be occurring all the time in a normal process.

Now, I do know there are some of you out there

that know that some of your suppliers you do get a little
bit of everything, don't you? I mean, when you start asking
people what they get in their raw materials, it's amazing
what people will tell you they found. I mean, you know, we
have everything from the 50-pound, you know, drain cover
that you're going, it didn't accidently get there, to, you
know, the packaged glove on top of the products with all of
the fingers folded except for one, and it wasn't this one,
you know.

(Laughter.)

There's a list, a long list, isn't there, of things that people will find in product. But just because you have historically found something or you have ever found it doesn't mean that it has to be controlled in a HACCP program. So in this case, you may not need a control. It may not be a true food safety hazard that is reasonably likely to occur.

Let's go to the grinder. Grinding. We say metal. Is it significant? No. The plant has a preventive maintenance program in place to check equipment. Plus, the possibility of having metal fragments of sufficient size and shape that would cause injury to a consumer following grinding is extremely low. Now, that's a pretty good rationale of how, if your grinder is in proper operation and you have the documentation and the data to support those decisions, then you should be able to defend why that is not a food safety hazard and why, then, it is not reasonably likely to occur in your process. Are we stating that preventive measures for that equipment are controlling the food safety hazard? No. But we're saying all of those prerequisites that we all teach and that you teach and that you know are supposed to be there prior to implementing HACCP, we're saying they're there and they work.

When we teach HACCP courses, we always tell them, when you get ready to design your HACCP plan, you should have the perfect facility, the perfect employees and the perfect prerequisite programs. And then you build HACCP on top of that and all of the pieces, then, start fitting together to help you be able to identify those things that are truly food safety hazards and that are reasonably likely to occur.

I had one company who had fought really hard on the metal detector and they initially had a metal detector in as a CCP. Well, after having it in for a year, they decided they wanted to take it out. And so they called and they said, "Could you help us support being able to take out our metal detector? We don't think it should be a CCP." And I said, "Well, can you tell me why you think you ought to take it out?" And they said, "Well, because we haven't had any customer complaints in the last year for metal."

And I said, "Okay. Well, was that running with your metal detector or did you have it turned off?" "Well, no, we had it turned on. It was a CCP." I said, "Okay, do you have any data on what the metal detector kicked out during that year? Do you know what it found in your process?" And they did. They went through and they pulled their metal detector records and they actually had a detailed record of all the kickouts, the type of metal that was found, the size, the shape and in some cases pictures of it, and the incidence level.

I said, "That's the data that you need to use to support that metal is not reasonably likely to occur in your process, not your lack of customer complaints," because they were demonstrating process control. The data that they collected through their metal detector had demonstrated everything was effective, it was working. It wasn't controlling metal from getting to the customer. They could have turned it off and they would have probably still had no or very few metal complaints or foreign object complaints. But you have to have the data to make that decision.

And that, and when I read the directive, and I think from an agency standpoint, is the point that the agency is trying to make. They are not stating, in my opinion, and not to speak for the agency, and those of you that are sitting here representing the agency, my understanding is that the agency is not telling you that we can use prerequisite programs to control reasonably likely to occur food safety hazards. But the agency is stating that they understand that you have prerequisite programs in place that may be providing data and information that you can use to support why something is not a food safety hazard as being reasonably likely to occur.

And so if we keep that in mind and we try to figure out how to make it all fit on the forms, well, then it becomes a lot easier. The standpoint of how to deal with it on a day-to-day basis, dealing from your inspector that's there or from a CSO who is coming in, or from anyone else who is coming in and doing the review, very often depends on how well you have documented and supported your decisions. Because then if they can go through your thought process to determine what's there and determine if you have adequately assessed and made those decisions, they ought to be able to decide whether what you have done is appropriate, adequate or not. So two different scenarios there on doing the hazard analysis.

We also have to remember that the hazard analysis must be specific for the product or process. Every one of you in here has very specific processes, and you know the limitations of your operations. You know the history of what you have found and haven't found. You know information about your suppliers and all the information we talked about, you know, in audits and those types of things. So you have got to make the determination of if you're finding food safety hazards versus if you're finding foreign contaminants and how you're going to control those, they should identify all the potential hazards for everything from ingredients, packaging, and then the raw meat and poultry materials.

You should always conduct your prerequisite program -- I mean, your hazard analysis after you have your prerequisite programs in place. Very often when we work with companies that are struggling with their HACCP program and having problems with it, if you go back and start looking at the prerequisite programs that should have been there first, they were weak to start with. And if you will strengthen those prerequisite programs, very often it will take care of the issues that you are struggling with and trying to force into a HACCP system.

Some of you in here have heard me tell this story before. We have a small processing center at the Rosenthal (phonetic) Lab at A&M. We happen to have a HACCP team for which I'm on the team, Davey Griffin, who is in the room, is on the team, Jeff Sable (phonetic) is on the team, Gary Acuff (phonetic) is on the team, large team of a lot of people who we all think we know something about HACCP. Too many of us probably and too many who think we know something.

They called together our first team meeting, and our team leader is Jeff Sable, and he said, "We're going to do HACCP for slaughter plan today. We're going to start with beef slaughter, and we're going to do the flow chart, and we're going to do the hazard analysis, and we're going to do all of this early" because we didn't have to implement until the last implementation date, "so that we can be a teaching facility and be able to help others."

We were like, "Okay, let's go." And Gary Acuff is sitting in our room with us and he kind of crosses his arms and scoots his chair back from the table and he said, "Where are our prerequisite programs?" We all kind of started looking around at each other going, well, you know, "Who brought the prerequisite programs to the table?" We didn't have any prerequisite programs. The things, the way they had been done forever is the way they were still being done. And he made us, that day, stop and focus on prerequisite programs and put those in place before we ever started developing a flow chart and a hazard analysis. And out of all of the things that occurred in our HACCP team meetings, that was probably the best thing that ever happened, because otherwise we would have tried to force all of those problems into a HACCP program. And now then, they were where they belonged in the other particular programs. So make sure that you do that first, that you go back and look at your prerequisite programs, that they are in place to begin with.

They should also identify true food safety hazards and identify the critical control points for controlling that identified hazard. Now, we talk about a lot of different things being critical to our operation and we try to put a lot of things into the category of critical control points. But when you get down to the bottom line, there aren't very many critical control points for most of our operations, are there? There are a lot of things that are important for us to be able to produce the wholesome and safe food that we produce, but that are truly critical for food safety purposes, there's only a handful of them. We need to make sure that those that we have are adequately controlling the true food safety hazards that we identified for our individual processes, not that our neighbor identified for theirs.

Each establishment must identify the point or processes where they can best control the identified hazards. They have to vary from plant to plant. Even when we get to the setting the critical limits -- will vary, specifically when we're dealing with foreign objects. I've never heard such arguments among different companies on how you're going to set critical limits, whether it's the functioning metal detector, which is what Mike keeps bringing up in his questions and how do you define a functioning metal detector, versus if it's a specific limit or level of detection. Every plant is going to have to know what their equipment is and what they're doing. How are you setting those? How are you verifying that the metal detector is operating? What procedures are you using? When is it monitoring and when is it verification? And how do you separate those two activities?

Everything that we do, every control point, critical control point that we pick should be based on science and validated for the adequacy in controlling the hazard. If you do that, I think it also helps to make sure that we're truly picking CCPs. Because if you can go through and scientifically show why something is or is not a hazard, or how that control, that activity that you have chosen, how scientifically it will prevent it from being there, then you've done a pretty good job, based on if you did the first part of it right in identifying the risk and severity of the issue you identified as a potential hazard.

In summary, I think we all know and accept that HACCP is our best tool, and it is just a tool, a place for us to control food safety hazards, that every HACCP plan can be different and yet still be effective, and that we, I think both from an industry and from an agency standpoint, the thing that we often miss is that we have to be flexible and allow the operations to design their programs, and I mean the optimal HACCP program as well as the use of prerequisite programs, to control the overall wholesomeness and safety of the product, allowing HACCP to focus on food safety.

And I think we're going to hold questions 'til the end? Is that correct?

MR. DREYFUSS: Yes. Thank you, Kerri. Our next speaker is -- on your agenda is Dale Rice. Unfortunately, Dale was not able to attend, but Jeanne Raede is here representing Chef America. She is currently a food safety regulation consultant. Until recently, she was the food safety regulation manager for Chef America, manufacturer of Hot Pocket brand sandwiches. She has over 12 years of food safety and quality experience, and she has worked for many of the industries, companies and consulting firms and now runs her own consulting firm. She is going to speak on the impact of multi-component products.

(Slide show presentation.)

MS. RAEDE: Good afternoon, everybody. I want to bring us back to the actual title of what these presentations are to be about, "Perspectives on Controlling Foreign Material Contamination through HACCP," because, again, this is just our perspective. For those of you that haven't heard of Chef America, hopefully you've heard of the product Hot Pockets. So that will help kind of bring in focus where we're going with this. It also states Nestle up there. Chef America was just recently purchased by Nestle, so we actually don't know if we still are Chef America or not, but for the point of this presentation, that's who we'll refer ourselves to.

We have two primary goals for this presentation. One is to let the agency or help the agency understand that there is a very different perspective on controlling foreign material contamination when you're talking about multi-component products. It really has a different impact on how you need to address that. We want to ask that effective regulatory compliance encompasses all the ramifications of food production.

I started my career in the meat industry I'm very familiar with the meat industry and I love the meat industry. And as of the last five years, I've been in the frozen food industry, and I've realized that not all foreign material contamination comes from meat. And that's why we bring this perspective on multi-component products. And it will hopefully help address some of those questions brought up earlier on why is there such a big group of other out there, and that's where we want to go with this.

Again, some basic examples of the multi-component products. Obviously -- well, not obviously, but these are some of the examples. Pot pies, rice bowls, frozen pizzas, those are all examples of multi-component. And so I'll continuously want to bring you back to that when you make policy, please don't be narrow with the idea that we only use metal detectors, or bone collectors, or what needs to be used. There is so much more out there that does need to be looked at that oftentimes our agency inspectors have no idea about when you bring up certain means of foreign material control and detection.

So each of these components relies on a different strategy of managing foreign material contamination. Certainly the way you handle meat is very different from how you would handle contamination in dry ingredients. Just another pitch to say why we want you to be open to multi-component products, the frozen food industry is over $10 billion in sales annually. Those little frozen hand-held items are a big part of that. Roughly, that's about 20 million meal occasions daily, that those frozen, multi-component items touch consumers on a daily basis. So it's a very large category. And with this directive, we feel that if you do encompass all of these areas, you'll have a pretty good program that will be encompassing everything.

A lot of this was brought up earlier, especially with Bob's presentation, which was very informative, about all these different items and different ways that you might have -- either A, you might control foreign material, or, B, you might have prerequisite programs in place at these type of locations that provide you the data that tells you you don't need it as a CCP. So all these items are somewhat different with what we have here.

Fluids, easy to evaluate. Dry material, sometimes in fine matter that can be easy to evaluate for foreign material. Coarse, dry matter is different, provides different levels.

I wanted to point out, it was mentioned earlier and I think it was in a comment or question that was brought up, I'm not sure which, about the zero tolerance when something else comes into our plants. And I'd like to take a moment to make this point, too. Chef America purchases, you know, tomato paste and broccoli and items that already have pre-described contaminants in them, if that's what we want to call them. And certainly to make a point here when we talk about handling foreign material contamination, we don't want to be subject to being told that, yes, that's great, but once it hits your door, it's zero tolerance. And so we somehow need to keep that in mind as we make policy and we address foreign material.

This one -- Certain hazardous foreign material need to be controlled via HACCP plan. Well, that's pretty obvious. I have to share this with you. I have all my notes here and I was all ready to discuss this topic, and Bob brought up, in this presentation, about metal detectors. And as you know, I'm presenting this for Dale Rice, and he's not here and not able to be contacted at the moment, and Bob pointed out that those metal detectors and all those slides about what does get through and what's -- how they're not 100 percent, how can people have those as CCPs? And I thought, oh, my God, I have to cross this out. I can't tell them that Chef America has this as their CCP. But over lunch I managed to come up with the conclusion that, you know, I need to discuss that, and as Kerri mentioned earlier about certain topics of lead, other areas, we need to throw this one out on the table.

I don't think the intent of that comment was to make anybody run back and go, "How embarrassing. I have this as my CCP and these experts are telling us that metal detectors aren't 100 percent. I can't have it as that," or "I'm afraid if I have it as my CCP, what happens if, because it's not 100 percent effective, a piece of metal gets through and the agency jumps down my throat?" And certainly that's a fear I know that people have. And for the agency, please know that. But the goal, as all of us from industry, is to produce a safe product. And if that, at that time, is our only means of ensuring that hazardous metal does not get to the consumer, please leave it in. Please put it in.

Now, a point I want to make with metal detection is that the goal certainly isn't to leave it as a CCP forever. The goal with all these foreign material contamination, CCPs that may be out there, is to prevent the likelihood or the occurrence of finding hazardous metal. That's the goal. So the goal, then, as you go backwards is to reduce or eliminate the need for this to be a CCP, and the data collected from that is what you would use to remove it, as Kerri mentioned earlier, from your CCP program that tells you you're not finding hazardous metal.

I wanted to bring up something else with the metal detectors and as it relates to Chef America and as it relates to lead. That's another one I want to just throw out on the table because we're here and we're speaking very candidly, and it may apply to some of those that have wanted to address it, that don't know how to address it.

Back to Bob's presentation, lead, for the meat industry, is not highly detectable via metal detectors. If I'm wrong, please tell me, but my experience has told me that it is not easily detected. Now, there was a question brought up recently, and it was made to believe that maybe it's associated with metal that can't be detected and how can you find its source, and da-da-da-da. Certainly, I don't buy cooked product and expect there to be lead shot in it. Chef America's products, because they are frozen solid, because of the size of the product, because of the fact that we do use redundant metal detector systems set at opposite angles on each line, it does highly increase our sensitivity to finding items like lead.

The meat industry, I would bring this to you, due to past experience, and I'll go into this further when we talk a little bit touching on prerequisites, though that's for tomorrow's conversation, is that, you know, you can control that. If that's a question out there and you don't want to ask it, you can control it because x-ray is highly effective on your incoming materials. And that's how you prevent it from getting to your customer, to the end point user, whoever it be. So in case that's a question, I want to present that solution to you.

As Kerri mentioned, there's certainly hazardous situations that might occur that don't need to be part of the HACCP program. Here's some examples, as we mentioned, about things earlier, but one I'll share with you that happened prior to HACCP implementation being required, maybe some of you have encountered it, too, and it was brought up with Bob about sifters and dry ingredients.

Flour contamination. We had ourselves a single occurrence of significant magnitude, as not even enough to say the magnitude of this situation that we incurred. And this didn't come from the vendor. This came from our finding, our checking of flour tailings and finding glass and other materials in those tailings at the end of the day, unfortunately. As we explored what occurred, we found that the trucking company somehow was at a railroad site and the hose for the truck fell on the ground, or the flour fell on the ground, and he decided to take the hose and suck up flour off the ground because he didn't want to have his load short.

So in all those years that that's happened, and I'm not trying to put a date that says it has to be many years between occurrences at all, but what I'm saying is sometimes you have incidents of just incredible magnitude that are food safety aspects. And to satisfy the question of, weren't our sifters able to sift out glass, there was chemical material in there, so that takes away that, because we did encompass everything possible. But that doesn't require a CCP. We don't feel that's one that would. So I present that one out to you also.

Again, as we go down this, just to point out, paper in bacon ends and pieces, just to bring you back, foreign material contamination occurs, but you have to go back to is it a food safety hazard, and we want to emphasize that, because a lot of times we're going to encounter our inspectors in the plant that go, "That's a piece of glove.

That's a piece of paper." I know that and I'll address it accordingly, but it doesn't require a CCP, so we want to make that point.

This was all pretty much discussed earlier and so I'm not going to spend too much time in it. It certainly relates to what Kim was saying earlier, so I'll move on to this next one. This was also addressed. This question a gentleman brought up about -- directly to the agency on is it okay to consider that we don't have to have it as a CCP because prerequisite programs exist. And to reiterate what Kim was saying before, I don't believe that's exactly it. What I believe on our perspective that the answer to that is, that the data that you have collected to support that you don't need a CCP that you have a situation where a hazard is not likely to occur, is then a means where you say, "Based on this data that I have collected, this is why I don't need this to be a CCP." Not to fall back onto saying, "I don't need to control it because I have a prerequisite program." That kind of loops is right back to, "That's a CCP, then."

Again, this is just reiterating the comment I just made. The ultimate goal with any CCPs for foreign material, and basically I think for everything, whether we're talking chemical, physical, microbial, is to go back to the main source, is to eliminate it completely. And this isn't new.

We point out that, you know, we're big advocates of having your prerequisite programs documenting that data because -- and that way it allows you also to go back to your source. It's very source-driven. HACCP, of course, is a single point of control. I'm making the comment that together they're both valuable tools.

This is an example. I brought up the comment earlier about vendor programs. This is, again, I believe, part of the reason why you're finding, as was mentioned earlier in the presentations, that you're finding vendor programs have increased. And an example that Chef America has encountered, and this is data from Q199 all the way to the present, Q202, we've had an extensive vendor program in place since that time. And while, yes, we took the numbers of incidents reported off the side, that kind of graph is just what makes you really proud, makes you know that you've gone back and you've worked with your vendors. And I can tell you for the rest of the people out there, it's not just for you. If you're a vendor and you go, "Man, this is what they're forcing me to do or they're not going to buy from me," it makes you better. It opens you up to have that many more people come to you and say, "You make good product." So it's twofold. While it can be a pain, it has a tremendous effect on the goal, which is reducing all that foreign material contamination that may be coming in to you.

Again, in summary, just wanting to point out that as we address this to the agency and the draft directive that's out, when you finalize it, when you talk to your inspectors about it, we need that education, we need that flexibility, as was pointed out earlier. There's many different ways of handling foreign material contamination. It's not all coming from the meat industry. Even so, within that, there's many ways of handling it there as well. But we need to have recognized prerequisite programs in place.

Certainly the vendor one has made its point. But all the other types of systems that Bob talked about, or that industry may present, because industry truly is the expert within their own product, that would be able to present what the best way is of controlling it. So the message is, you know, flexibility. Thank you.

MR. DREYFUSS: Thank you, Jeanne. Our last speaker of this panel is Troie Burch. Troie is the director of quality assurance for Quik-to-Fix Foods, Incorporated, Division of Smithfield Foods. She is responsible for quality assurance, food safety and regulatory affairs for the company, including two meat further processing facilities. She has over 20 years of experience in the food industry. She has also spent numerous years in the medical research field and has published on nutrition, drug interaction, drug receptive bindings. She has served for 10 years on the Board of Directors of Southwest Meat Association and most recently is president and chairman of the board. Troie?

(Slide show presentation.)

MS. BURCH: Good afternoon. I will be speaking to you this afternoon not only from my company's perspective, and our plants are classified in the small plant category, but I will also bring perspective from my fellow companies within the Southwest Meat Association. Some of what you may hear me speak about is a little redundant, especially being the third speaker in a row, and maybe that's a good thing because it shows that we're on the same page. But also I've drifted a little bit into talking about prerequisite programs. One, as Kerri mentioned, you have to have the foundation and the prerequisite programs to make your HACCP plan effective. In speaking with some of my other fellow companies, this is some of the feedback that I had gotten from them.

Again, we'll start out with definitions. Kerri has pretty much covered these. And the final rule, food safety hazard was defined as, in this case here, "physical property that may cause a food to be unsafe for human consumption." And, basically, I think that we've had a lot of discussion about that this particular definition didn't really take into account significance in risk to human health.

The National Advisory Committee's definition, again, "a physical agent that is reasonably likely to cause illness or injury in the absence of its control." And in this publication, there was significance taken into account.

Just a little bit on hazard analysis. I think Kerri and Jeanne did a really good job on that. In any hazard analysis, and I know you've all done this, you have to take into account your product history, which includes ingredients, and your processes. Customer complaints, and Kerri gave a good example there, of how that helps you decide if the hazard is really part of a HACCP plan or not. And then you have to also ask yourself the question, is it a food safety hazard or is it a contaminant?

In the definition of extraneous matter, it's "any object which may become a part of the product being produced, which is not designed to be a part of such product." Usually, and this has been discussed, it's not a significant risk, but it does depend on the size, shape and type.

Adulteration, "the bearing of any deleterious substance which may render the food injurious to health." And as we've talked a little bit about contamination, this should be addressed in your SSOPs rather than in your HACCP plans.

And hazard analysis is part of HACCP. We need to evaluate the information on the hazards to decide which ones are significant and reasonably likely to occur and those that must be addressed in the HACCP plan. If they're not significant and reasonably likely to occur, they shouldn't be part of HACCP but in the prerequisite programs.

One thing to look at, and you've probably seen this scenario in different situations, but you need to look at the risk, the frequency and also severity. So if you have a hazard that has a low risk and a low frequency of occurrence, then that probably is not going to be part of your HACCP plan. If you have, in your hazard analysis, an incident that has low risk but high frequency, that's when you have to look at the individual situation in your plant and what the incident is, and that -- it would depend on if that would be part of your HACCP plan. An incident that has high risk but low frequency, it could be an isolated incident, like the one Jeanne mentioned about the flour. So, again, that would just depend. But when you have an incident which has high risk and high frequency, this should be covered in your HACCP plan.

Now, I'm going a little bit into the prerequisite programs. These are multiple points of evaluation which do form the foundation before HACCP should be even implemented. We talked a lot today about supplier certification, and I think we can all see that the supplier certification process really pushes the responsibility upstream, and we all look at that in a HACCP program and in any process control program. The responsibility or the control needs to be pushed as far upstream as possible. We have incoming inspection programs, sanitation and preventive maintenance, processing steps, employee practices, finished product inspection, employee training.

Some examples I'm giving here, on supplier certification, you may require your supplier of your meats to do a metal detection at, say, 10-and-a-half millimeter ferrous. That's just an example. That's not necessarily a recommendation. On dry ingredients, probably everybody has got letters of guarantee, and you could have requirements for sifters and magnets. In packaging, letters of guarantee.

In the definition of package integrity in the food code, it's defined as "food package shall be in good condition and protect the integrity of the contents so the food is not exposed to adulteration or potential contaminants." And I'm just mentioning that because that's some of the incidents of foreign material that have been found have been due to the package integrity of the incoming materials.

Sanitation and preventive maintenance. Proper assembly of the equipment, no extraneous material and no missing or damaged parts are always important in the prevention of foreign material entering the process. This has been brought up, and I think it's something that, you know, every grinder really looks at. And in order to limit your liability, it's something that probably needs to be done on a fairly frequent basis throughout your processing shift. And that's to have a large object metal detection before pre-grind or a large object visual inspection. The grind plate and knife blade checks are very important in limiting your liability and isolating any contamination. Bone meat checks, looking in your bone meat for any other foreign materials. A knife plate and plate sharpening program will help you identify if the plates and the knives were intact at the start of the day. And then there's metal detection before final grind. Those are all just some suggestions.

We talked and I think it was Bill that talked about sifters and magnets to a great extent. This is sort of a new thing from my experience on using magnets on incoming dry ingredients. But I could probably use a little feedback from some people. One sort of negative thing that we've noticed on magnets on sifting our dry ingredients is that we've pulled the enrichment out. So, you know, we've had to look at some different things to address that.

Employee practices. The use of colored gloves versus plastic gloves. We've talked today about plastic, but just the difference in the color can sometimes prevent the entrance of a foreign material into your process. Employee practices such as proper placement of gloves when they're not in use and a small tool policy.

Finished product. Of course, any operation that has their finished product handled by an individual, somebody that's looking at it, I mean, that's almost your last line of defense, is actually the visual inspection at packing. Then there's different standards that we have all heard today about metal detection.

Again, foreign material that you're likely to see, wood, plastic, cardboard, metal seems to be the one of biggest concern, and then these unidentified foreign objects.

Some likely sources of wood in our particular size plants and probably throughout the industry are pallets. And some ways to prevent entrance of wood into your process are pallet inspection programs, pallet rebuilding programs, the transfer of, say, combos to plastic pallets, the use of slipsheets, and wrapping the combo and the wood pallet together before it's used in the grinding operation.

Plastic. Likely sources of plastic, process and measuring tools. And that's where we mentioned the small tool program is to account for the tools that you use in the day. You know, not to let the employees take them and put them in their lockers so that they can have them for the next day. There needs to be an accounting of what is handed out and then turned back in, to make sure that that scoop isn't missing and somewhere in your process.

Also, plastic entrance can be from packaging of raw materials. Plastic liners in boxes that get frozen into meat. Sometimes we process product that has come in chubs, especially in the school lunch program. And there are specs set up by the agricultural marketing service, but they will find plastic that's frozen into the chub itself, which makes it, you know, hard to prevent that from entering the process. And, of course, we've talked about gloves.

Cardboard. A likely source of cardboard is faulty incoming packaging. The frozen boxed meat, the box itself, if it's not properly designed and properly waxed, it actually sticks to the meat, or pieces of the cardboard are frozen into the meat itself.

Lead shot. We probably haven't really talked about that enough today. Coming from plants that are in the southern part of the United States, this may not be so frequent in plants that are in other parts of the United States, but lead shot is definitely an issue that has to be addressed.

In some of the operations that do injections, they have inspection programs for their injectors to make sure that the needles are intact. Metal also comes -- Incoming raw material from meat hooks and boning knives. We talked today, and especially in grinding operations, metal-to-metal rubbing. The inspection of equipment before start-up to make sure there are not any pieces that are missing. You know, when did that bolt fall out?

Now, the one thing that I''m going to emphasize here at the end, I mean, we've talked so much about metal detection today, but really for the small processor, this -- I mean, to be perfectly frank with you, this is not something that all of small processors have the capabilities or the resources to have in their plants. It's very expensive, and, you know, in addition to that, there's the employee training and the proper calibration, and the set-up and the timing of the belts and the rejection systems. So they have to look for different ways to control that particular hazard.

I believe the gentleman from the United Kingdom talked about bone, and even though it's not specifically mentioned in the directive, from a product liability standpoint, my experience has been that bone is probably the highest incident of product liability claims, mainly for broken teeth or mouth lacerations. So even though it's not inherent -- it is inherent in the process, but it's not really considered a foreign material under what we're defining.

There are ways that we can prevent or reduce this, and that is, one, visual inspection in those raw materials that should not have bone in them. Proper incoming specifications to your suppliers. Grinding specifications. You know, if you are grinding down to, say, one-eighth inch, you should not have any bone particles or cartilage particles that are greater than that in your process. The use of bone elimination equipment and the proper use of bone elimination equipment. I'm sure we could all tell stories on that. And then the use of -- reuse of bone meat, even though it may go through a subsequent process.

Now, in suspected contamination, and hopefully when we get into the panel we'll have some discussion and maybe even some of the audience can give us some input on this, a lot of small processors, like I mentioned, do not have finished product metal detection. But if they do have a suspected contamination from metal, they can often use other resources that have equipment to inspect. There was one story that was told. A processor that found that injection needles were missing, and he went to his local physician and had the ham x-rayed. Just some ideas like that. I mean, we have to keep the small guys in mind. You can use your -- you know, other processors that do have metal detectors. Possibly they would let you use those for reinspection.

We talked about x-ray. And even on x-ray and reinspection with metal, again, I believe the directive mentions lack of visibility or to the lowest detectable level. And we heard some of that. I put .8 millimeters. I think somebody even had mentioned today down to .5 millimeters on x-ray. Jeanne mentioned Chef America requires the double pass on metal detection. Oftentimes if you have a suspected metal contamination, you can have your metal detectors set up at 90 degrees to each other, at the lowest sensitivity, and do the reinspection like that.

Now, with the use of metal detection, again, it's pretty much the same thing, to reinspect the product, use an x-ray or reinspect it at a higher sensitivity and with a double pass.

Plastic from x-ray. Information we heard today, it depends on the density and the material characteristics on what you'll be able to pick up. And x-ray seems to be the method of choice for reinspection on plastic.

As I've tried to present today, some of the challenges that are out there for the small plants, one, they don't have the resources that a lot of the larger plants do for capital expenditures and for, let's say, on-site laboratories or other types of hazards. They have a smaller number of employees and a large number of products.

As Jeanne mentioned, and it's funny how we kind of came to some of these same conclusions here, but in any directive that is put out, we do ask that the agency consider the flexibility for implementation, that we're able to look at non-capital alternatives, the best means available for the company, and opportunities for implementation of the directive based on the strengths of the individual company.

MR. DREYFUSS: Thank you very much. Applause for all three of our speakers.

(Applause.)

I'm looking at the time right now, and we're scheduled for a break. If you have any questions for the speakers, I suggest you hold them until after we get through the scenarios and the panel discussion, by which the microphones will be open for any open discussion. Why don't we reconvene at 3:25 and we'll begin panel discussion then.

(Off the record from 3:15 p.m. to 3:34 p.m.)

MR. DREYFUSS: Welcome back. This will be the second of our three panels. We're going to discuss Control of Foreign Material Contamination through HACCP. We've invited Kerri Harris, Jeanne Raede, Troie Burch, Bob Richardson and Charles Link to be members of the panel to discuss various scenarios. The only one who I didn't introduce is Charles Link, who is the Director of Regulatory Affairs for Cargill Turkey Products, headquartered in Springfield, Arkansas, and has been with Cargill for the last 15 years, and a graduate of the University of North Carolina at Wilmington.

The moderator who will be presenting the various scenarios that are in your handout is Lynvel Johnson, who is the current branch chief of the processing operation staff for FSIS here at the Technical Service Center, and I'm going to turn it over to Lynvel now to run the panel.

MR. JOHNSON: Good afternoon. So this afternoon we're going to have some -- a few scenarios. Try to make them as practical as possible. They're close to real life. We're going to be talking about HACCP. Tomorrow it will be prerequisite programs. So we'll have three scenarios dealing with the control of foreign particles through a HACCP program, and then we'll have some discussion and also questions from the audience.

The first one, and you'll find in your packet, scenario H1. And there is the overhead, and then you'll have a summary of the scenario also. We just summarized it in the overhead just for visual purposes.

So scenario H1 is large beef processor. They control a physical hazard, metal, through a CCP after the final grind. Their critical limit is a functional metal detector, monitored hourly. Metal detected in the product at one point, and this was found one day, approximately 30 minutes after the metal detector was tested to determine if it was functioning properly. Some product which was metal was discharged. Quality assurance was notified, and records show that the last monitoring check was made and everything was functioning. The establishment visually inspected the discharged product and found various sizes of metal fragments. What they found was a grinder blade had broken apart during the operation.

So with that setup, we can go to the panel. And based on the facts provided, how would we proceed or how would the plant proceed? And I guess we could start, maybe Dr. Harris might want to start, how maybe you'd proceed after you find -- after they found their metal and they have a CCP and so forth.

DR. HARRIS: I'll give the easy answer. First you would identify, hold and segregate all product back to your last acceptable good check.

MR. JOHNSON: Okay. So in the opinion of the panel, is the HACCP plan working at this point? Does this affect the hazard analysis at all? Do they need to go back to the hazard analysis, or is the HACCP plan working?

MS. BURCH: I would say that the HACCP plan is working. The CCP was the metal detector in this case.

MR. JOHNSON: Is the metal detector after the final grind? Was the CCP in what they monitor with a functional metal detector for the critical limit?

MR. RICHARDSON: It looks to me like they had a catastrophic failure, so basically they've got 10 kick-outs. You may want to put the stuff on hold back to the last good check. You know, we have a lot of off-line metal detection where you can basically try to reassemble the blade, if possible, just to find out if anything is there, the nature of how the blade broke up, you know, if it was in big pieces, small pieces, if there was secondary damage. You'd want to certainly take a look at the grinder itself and take care of that. You may want to throw away any product, you know, between the grinder and the actual packing system. But then it's a matter of, you know, doing an evaluation and finding out what actually happened. This wasn't a drip-drip-drip where you had chubs, you know, kicking out over the last three days where pieces were falling apart. It sounds like this was a pretty dramatic occurrence. You've got 10 chubs to work with. Like I say, we use off-line metal detection to actually get you down to the real small pieces and see if you can reassemble the blade, that you've got it all accounted for, that your decision on the release of the rest of the material back to the last good check could be made very easily, potentially.

DR. HARRIS: And as far as looking at the action, since it was a CCP, you would not necessarily require reassessment of the HACCP plan or any changes. I know you set the scenario up that they had numerous instances over several years, but if I was sitting in that company's shoes, I would want to look if those were similar instances and did I need to do anything else for the process. But I would probably do that from outside of my corrective actions in response to the CCP.

MR. JOHNSON: There's also some talk on the critical limit and what's verification, what's critical limit. This is something we see a lot out there, and functional metal detector is a critical limit. I guess is that a practical critical limit and what would be verification? Can maybe someone address that, since we had a question out there?

MR. LINK: Since I haven't said anything, I'll try. I think it might be more appropriate to establish a critical limit. You know, we've heard that these metal detectors don't work anyway, but to establish a critical limit based on size of a particular type of material you're looking for. I guess if it's stainless, to maybe go for a particular size of stainless material rather than is the thing on.

MR. RICHARDSON: Yeah, obviously, your decision is going to be based on what you physically can actually achieve there and, you know, what is the blade made up of. How did it actually break up? How fine could you set the metal detector? If you did have the opportunity, there are metal detectors, if you wanted to put it on hold, that you can rent, that you could bring in to do further evaluation with a smaller aperture that might get you much better sensitivity. There might be some other things that you'd want to do. But, obviously, any kind of metal detector that you have set up on any kind of a system is going to only be dependent on what that specification actually is. And, you know, so long as everybody understands that, you know, it does have physical limitations, you know, in terms of what its capability actually is, then if everybody -- including -- I see everybody also gladly walk hand-in-hand down that risk assessment aisle, you could end up with marriage at the altar.

DR. HARRIS: I'll add a comment to the critical limit, whether it should be a detectable level or whether it would be appropriate to have the functioning metal detector. I mean, I think that comes to what the plant has defined as how they're going to set the limit as a functioning metal detector, which most often is based on the parameters on the piece of equipment and the fact that it is functioning as designed, monitoring at the detectable level and the product is passing through there. I mean, I have no problems with the critical limit being set as functioning metal detector monitored hourly.

MR. JOHNSON: And I guess that's what we learned today, was that not only functioning, it's working, but also the kick-out also is --

DR. HARRIS: Which is part of that functioning. I mean, when I'm talking about -- When I think of functioning, I think about the whole component, that it's detecting at the level designed and that it is kicking product out. Otherwise, to me, it's not functioning as intended.

MR. JOHNSON: So you'd be looking beyond just what's on/off, whether it's on or off.

DR. HARRIS: (Nodding head.)

MR. JOHNSON: Any questions on the scenario from --

MR. COBLE: Joel Coble, Tyson Foods. Question. We heard an earlier presentation that when you select a critical limit or define a critical limit, that there should be some scientific basis for that, perhaps. So I'm curious to know what the panel's opinion on what scientific basis you would use for just setting a functioning metal detector as opposed, for example, maybe taking a look at the Olsen article and saying, "Well, you know, I need to have a metal detector that maybe works at a 7.0 millimeter or less level," as an example.

MR. RICHARDSON: I will -- Let me just take a brief little stab. I'm just trying to understand. If we say that the seven millimeters is somehow going to set our specifications, then we'd need to basically understand what that meant in terms of some sort of sphere. And if that's the case, then the question really could be whether or not the metal detector is going to be capable. So it could be that the metal detector isn't capable if we basically define, you know, the worst case scenario, of any wiry piece that would be long and thin going through that metal detector with a certain aperture, then how would we actually set it up.

I think that in a lot of these situations, you know, it's that hazard analysis that -- not the hazard analysis, but the risk analysis was actually determining what got kicked out, what its shape, how did it actually break up, that can help you determine what is the potential overall risk. If you can recover most of the blade, you know, maybe then your risk is pretty slim.

I would also say that this case basically shows that do they set a critical control point metal detector because they had an identified potential source. I mean, I think part of it has to do with this whole idea about some sort of improvement and process improvement, and that is if over the years we know that this thing is prone to this kind of behavior, if we've got some sort of incident tracking, then could we do something earlier on in the system. I mean, the worst case scenario is that we have one critical control point that's at the end of the system and it goes off. Is there something that we can do ahead of this thing that basically is going to help us, you know, make a better, clearer decision later on?

MR. COBLE: Joel Coble again. If I could follow up, what I'm trying to get drilled down to is, is that according to this scenario, we've already determined that we have a food safety hazard. So somewhere along the line we've determined that the object in question that we found that's reasonably likely to occur is a food safety hazard, whether it's because of size, or because it's particularly sharp. I mean, so that's in our hazard analysis. And so what I'm trying to get at is, if we've determined that we have a food safety hazard based on potential for traumatic injury, when we go to set a critical limit, how can we not turn around and set a size definition based on our original analysis of a food safety hazard? How can you just say a functioning metal detector if it does not relate back to either a health hazard evaluation board determination of what may cause a potential injury or because you had a customer that had a potential injury? That's what I'm trying to drill down to.

DR. HARRIS: Okay, and I think -- Let me take a stab at responding here. If you identified the food safety hazard, which in this case they have, at whatever level they have determined, based on their past incident, their thought it would be there, remember in setting the critical control point you have to set that to control the hazard that you identified. So when they put the metal detector in place, they had to have selected a metal detector that would detect at a level sufficient to control the hazard they had identified.

If you know that about your equipment and you've gone through your justification on, you know, what the hazard is and how that point of control, or identifying it, in this case, will meet the detectable level that you have set, whether that's the, you know, whatever size, shape, whatever it is, if you know that -- those parameters of the equipment, then by knowing it is functioning properly, you are, in fact, meeting both. You're detecting at the level that you've determined to be safe by having a properly functioning piece of equipment. If you go out and you pick one that doesn't have that detector and detection level, then I'm going to say you don't have a critical control point to begin with because you're not controlling the hazard at the level you have identified it. So you can't, you know, put in one that will only detect to the 10.5 when you're worried about a different level. And I think that's the point that you're trying to make, that you have to know your equipment to make sure that it can detect at the level you have determined is safety. Is that what you're --

MR. COBLE: Yes.

DR. HARRIS: Thank you.

MS. RAEDE: Joel, I just wanted to comment on what you said, just to further kind of reiterate that before Kerri jumped in. I think what you also mean -- I mean, certainly we're limited to these scenarios and they have their room for improvement as well, but I also think what you mean, along with what Kerri said, is that your HACCP program has to identify that limit. You can't just say, "My CCP is a functioning metal detector." It really should be identifying capable of detecting and rejecting, you know, 1.5, 2.0 ferrous, nonferrous. I think that's where you're going with that, correct?

MR. COBLE: (Nodding head.)

MS. RAEDE: Okay.

MR. JOHNSON: Katie?

MS. HANIGAN: Katie Hanigan with Farmland. I don't mean to muddy the waters, but I do think it's important to note that Farmland had their critical limit set like this and within the last 90 days the agency told us we did not meet the definitions of 417.1 because the critical limit had to be a maximum or a minimum value, and, therefore, we were going to have to state a maximum or a minimum value, if we're talking about metal, obviously, here, that we had to control metal so it wasn't a food safety issue. So we were mandated that we specify whether it was going to be 2.0, 1.5. They said maximum or minimum value. I'm sorry, but that came from the agency to

Farmland.

MR. JOHNSON: Yeah, I mean, I don't -- I mean, we can talk later about your specific plant, but the policy has always been that it has to be measurable and so forth. A functional metal detector, as written here, would be acceptable. It can be measured. To tell a plant they have to come up with a particle size, unless policy has changed in the last week or so, that would not be correct. We would not say you have to come up with a particle size. You can come up with a critical limit that you can measure, and it controls the hazard, it would meet the intent of the reg. So you could have a functional metal detector as long as you're controlling that function of it. It has taken out the hazard.

Lee, did you have --

MR. PURICELLI: That's why we're issuing the directive, one of the reasons, among many. But once the directive goes out, that will be the policy, that it would be the functional metal detector. But you have to have all the provisions. I mean, you just can't say it's working. It has to function to what exactly. The point is, if you set -- I mean, you can set your critical limit as a particle size, that's fine. But if the metal detector is working and catches something bigger than that size, then you have a deviation from a critical limit, and then you have to do your corrective actions. So if you set it at a size --

DR. HARRIS: I don't think we want to go there.

MR. PURICELLI: Right, you don't want to go there. So that's why you want to do it -- That's why you have the critical limits with everything. I woke them up this afternoon.

MR. JOHNSON: Lee Puricelli right over here. He wants to retract that. So properly functioning would be acceptable. Again, if it's measurable, it would be acceptable and that's what we -- that's what policy has always said. If there's specific issues, we can talk later, if you'd like to, or with anybody in the Tech Center.

MR. GIOGLIO: It's not whether or not the machine is turned on. It's a functioning detector.

MR. JOHNSON: On or off, yes, functioning. Exactly, everything that Dr. Harris said about it's functioning. It can detect what you want detected. It can kick it out when needed, all the above. Just not whether the little green or blue light is on or off. It has to be functioning.

MS. CRAWFORD: Cathy Crawford, Advance Foods. Under this scenario, nothing went wrong with their HACCP system. The check previously was fine. The metal detector found metal, like it should. It kicked off the product, like it should, and a subsequent check showed that your metal detector was still functioning properly. So the hazard was, essentially, eliminated. Why, then, would we have to go back to the last acceptable check?

DR. HARRIS: If I was the company, I would want to go back to the last acceptable check to evaluate that product to ensure that there was nothing that had occurred that could be in that, you know, particular set. I mean, from a due diligence standpoint, I would want to do that. From a HACCP standpoint, remember, the way this is set up from your CCP, is this occurred 30 minutes after your last acceptable check. So there's a time period of product in there that you don't know that it was still functioning properly. And so you would want to ensure -- You may want to, you know, verify that the machine is operating as designed and run that last 30 minutes' worth of product through there because you don't know if it was functioning or not.

And, I mean, standard protocol, if you think about what happens in the industry when we have metal detectors, when they kick something out, when we have them set as a CCP, what do most of you do first and foremost? You check to see if the metal detector is functioning, don't you, before you start searching through all that product. You see if the metal detector is functioning.

MS. BURCH: Call maintenance.

DR. HARRIS: You call maintenance. You check to see if that -- because then that will determine whether -- what action you're going to start taking on the product.

MS. RAEDE: If I can add to that, Cathy, your question, you know, I can't help but feel that the company has an ultimate responsibility as well at that point. You know, if we know we have broken blades, we have the responsibility, A, to either piece them all together and find out where they went, or if we determine, you know, contrary -- Joel mentioned that we've established we already have a food safety hazard at this point, maybe it's not something sharp that would cause a hazard so you have metal through there, but, you know, if you know -- once you know you're missing something, you should, just as a good quality practice, want to make sure that you've removed that from the product, if you're able to do that, if you're able to detect it.

MR. TILINSKI: Bill Tilinski with Premium Standard Farms. I have just kind of a follow-up on what she mentioned. This HACCP plan here, your critical limit is a functioning metal detector. There's no deviation from your critical limit. So nothing about this would be documented in the HACCP records whatsoever. If your critical limit was finding metal with the metal detector, then you would document this as a corrective action. But would you document this in your SSOPs? Would you document this under a standard operating procedure for what you found on the metal detector? What kind of documentation would you have to provide to satisfy the agency that you handled this appropriately?

MS. BURCH: Well, not only to satisfy the agency, but by the chance that you may not have detected all the metal and you get a complaint later and you want to go back and check your records to see if you had an incident, it would be documented under what, you know, an SOP or, you know, whatever program -- prerequisite type program that you may have in place.

MR. TILINSKI: If metal did turn up in a subsequent check after this happened, would that be a hazard, unforeseen hazard? Would you need to reassess your HACCP plan to see if it's adequate because you missed that metal?

MS. BURCH: You mean metal on your reinspection or that showed up as a complaint, or either?

MR. TILINSKI: Say you followed your standard operating procedure, you know, tried to piece the blade together or whatever, and you had a different piece of metal show up. You know, seeing how that wasn't covered in your HACCP plan, your HACCP plan didn't address it, I would think that that would be some type of unforeseen hazard.

DR. HARRIS: Another piece of metal?

MR. TILINSKI: Well, a piece of metal related to this incident.

DR. HARRIS: I mean, the hazard analysis, from what limited information we have, just determine metal of any size, shape, et cetera, that they decided to be a food safety hazard -- we don't know what it is because we don't have all the information in the scenario -- didn't have to be the grinder blade. So if you found metal in subsequent product, you've already addressed that as being a potential food safety hazard or identified it in this case as a hazard reasonably likely to occur, so it would not be an unforeseen hazard, according to the scenario that they've described, based on what information we have.

And I think the other point to your question on where you would document it, most companies that I'm familiar with that have metal detectors, keep metal detection logs so that they know if there's, you know, a rapid rate of kick-out, on what's being kicked out, what's, you know, in there, that -- going back to find out what was in the product to begin with type of issue. And those are usually documented on some type -- whatever you call them, but usually metal detection logs. Yes, they probably are outside of your HACCP program. They may or may not be in your SSOP program, but most plants have some information on the documentation of what was found, when it was truly an instance such as this with rapid succession of metal.

MR. TILINSKI: But considering under this program, say you didn't have a log, would this even need to be documented anywhere?

DR. HARRIS: If it was my company, I'd document it.

MR. JOHNSON: If you're asking from an agency perspective and required by regulation, obviously, no. If it's within your HACCP plan, you need to keep the records that's required in your HACCP plan. But as an agency, we also expect you to investigate the situation. Is there more metal out there? Take account for any affected product. We would expect that. In the back.

MR. JONES: Don Jones with ConAgra Foods. A follow-up question relating to the corrective actions that we would take. We've isolated this product. I'll go back and assume that we've held from good check to good check here, or good check to when we found the incident and stopped and did appropriate corrective action with the system. In trying to deal with that product and disposition of that product, some of the assumptions are we'll send it to x-ray or direct it to another metal detector that will detect at a limit that's deemed appropriate to address any food safety issues. Let's say based on some of the numbers we saw earlier today, two millimeters or greater it would detect and kick out.

You would take whatever kick-outs you would find from that process, weigh a knife and a blade and say that's 200 grams, and all of the kick-outs you get, plus what remaining blade and knife that you've got left, and you come up with 190 grams. You've been through your reinspection, deemed it to not be a food safety issue, but you've still got, quote, contamination potential, that you don't know whether it's in there or not. You don't have any information to determine that it's not, but you have gone through your food safety evaluation and reinspection.

We've got into discussions with local level agency folks regarding the contamination issue or their perception of adulteration in this particular case. Is there any guidance from -- and maybe this is more to the agency than to the panel, but any experiences there or any guidance that we could have in regards to, once we meet the food safety threshold, on a lot of these there's also a regulatory type aspect to this that we really haven't talked about.

MR. JOHNSON: Yes. There's a HACCP aspect and then there's also the definition of adulteration and so forth, which the directive does get into. So even if it's outside of your HACCP, it's not a food safety issue. If you've got metal in your product, obviously that's not desirable either, and you would have to account for that. And some of the things that you've explained that you do, you know, re- -- putting it back through your metal detector, trying to account for all the metal that's there, I mean, those are all things that we would look at and how you're accounting for that product, and showing that you got all of the contamination taken care of.

MR. JONES: The follow-up question would be, in that scenario, is there a chance that that product could be released, even though you've been through x-ray and there's a possibility that there's 10 grams of metal, very small in nature, that could possibly -- you don't know for sure, but could be intermixed in. Let's say there's 100,000 pounds of ground beef here. Is that evidence, then, going to lead us to condemn that product? Or is there any possibility of salvaging that?

MR. JOHNSON: I mean, I think in the past we've had precedent where plants have gone through a lot of steps to show, to account for all of that metal and had theories of where they're missing very small amounts, where it could be. And based on those theories and just logic, it's a potential, sure, that you could account for all of it that way. I don't think I answered your question.

MR. JONES: Just to make sure I understand, theoretically what you're saying is if there's a theory that where that 10 grams could be, other than the meat, there would be a chance of saving the meat?

MR. JOHNSON: Sure. I mean, there's been things that came through the Tech Center that way. They said, you know, "We can account for this much, but there's these other places where it could be." And it was logical, and it made sense where -- et cetera, as a possibility.

MR. JONES: Okay.

MS. KOLL: Diane Koll at Pilgrim's Pride. You can't really answer if your HACCP system worked until you go back to that last acceptable check and see if there was metal found in that product, correct, that was bigger?

MR. JOHNSON: If you went back to your --

MS. KOLL: You'd go back to your last acceptable -- 30 minutes ago you did an acceptable check.

MR. JOHNSON: And it was functioning.

MS. KOLL: You can't say whether your system worked or not until you've checked that 30 minutes of product and determined whether there's metal or not metal in that that was not kicked out.

MS. RAEDE: You mean bigger than your critical limit that you've set?

MS. KOLL: Correct, correct, larger than your critical limit, right?

MR. JOHNSON: Yes. I mean, I --

MS. KOLL: So you can't determine if you need to reassess or not reassess until you know the results from what the metal detector did not find 30 minutes earlier.

MR. JOHNSON: Yes, and I think what was part of what the panel was saying, a prudent plan. Go back first and make sure the metal detector is working. Look at that last 30 minutes to see if there's anything in there.

DR. HARRIS: And can I just clarify, because I know we've all used the term corrective action, and I think the point was made earlier, if you did not have a deviation from your critical limit, so if in your check you showed that the metal detector was functioning as designed and at the level that you had set, and it was working from a regulatory standpoint, you would not document 417.3(a). Now, I know throughout the discussion several people have said they would take corrective actions in looking at the following things, but I don't think the intent in those terms was to mean 417.3(a), regulatory corrective actions. So I just wanted to clarify that.

MR. GREGORY: Mike Gregory. Again, I guess I'm going to phrase the question a little bit differently and put Charlie and Lee on the spot. But we're mixing, in this scenario, a lot of, in my estimation, verification versus monitoring, and it's going to be hard to figure out where that line is on this scenario. And, you know, I can build a case -- whether anybody else would buy it or not -- that if you have a 30-minute check, you now have a metal contamination. You come right in behind the metal contamination. You run your seeded samples through and they are -- meet every criteria that you would normally do. You've now supported that the metal detector is properly running, it's monitored correctly, and it's kicked out everything.

And let's change this. And I know this is not fair, but let's change the scenario a little bit, and it's not a ground up blade, but, Terry, it's your infamous buckshot, and you get your two pieces of buckshot coming through. You know, now you verify that your machine monitored it, whatever term you want to put on this thing, and now every time that you find that the machine has done what it's supposed to do, are we going to automatically go back and retain that product and rework it? And I'm not trying to be trite on this, but I think it's some issues of monitoring, verification and what we do on these things, and I think to be so bold to say as I think, you know, I would suggest that there is no pat answer, that you don't always go back and tie that 30 minutes up. I mean, let's be careful that we don't set a scenario down here.

MS. RAEDE: Mike, I would ask you, is one of your critical limits on your metal detector checking for lead?

MR. GREGORY: In some cases, yes.

MS. RAEDE: So you run a seeded lead sample through and that is part of your process?

MR. GREGORY: We don't expect to look for lead, but I've had past lives where, yeah, I mean, we would look for those kinds of things.

MS. RAEDE: Because I guess, just on your basic comment of, you know, if you find lead, well, I would say if you're not originally set up to show that your metal detector is capable of detecting and rejecting lead at whatever given size and you don't have a history of that, now you've got a different material that you need to detect that you haven't previously set precedent for that you're capable of detecting in, as we know that familiar term, of subdivided.

And then as brought up earlier, lead is a very different item, and I -- again, it may not necessarily be addressed that, "Well, did your metal detector work?" "It kicked out metal." I think you really -- you, in general -- You know, we need to go back to the real prudent fact of what we're trying to accomplish here, and that's providing food safety. And if we feel that there is that chance that our metal detector -- we're finding lead, it's subdivided, it's potentially toxic levels, it could harm somebody if it got through, we have a responsibility to at least investigate a little more in depth before we determine that we should continue on as if it's just a common practice. I know that may not always be popular, but --

MR. GREGORY: Let me make the point I'm trying o make, and that is that I think what you just described is there are a lot of scenarios that you play out each time you look at one of these things. And all I'm saying is I don't want to sit here and say that we're going to automatically not go back for 30 minutes or automatically go back, either way. That's not a scenario that I want to lay out that we're going to set a precedent that we're going to just "Oh, well, the machine is working fine so we don't have to go back." That's not the scenario.

The point being is that I think you have to look at some of these things almost on a case-by-case and an application and a kick-out-by-kick-out basis in some cases.

And I know Kerri or somebody mentioned earlier that you take the contaminant, you look at it, and you make an informed and educated decision, not just based on some automatic procedure because some of these things don't automatically -- the rules don't apply themselves every time.

MS. RAEDE: I agree with that.

MR. JOHNSON: Question?

MR. SEWARD: Yeah, Skip Seward, AMI. If I understood some of the presentations earlier today, the critical limit for these metal detection machines is related to the shape of the test object that you put through. Is that correct? Like you have a two-millimeter sphere, diameter sphere or something? When you talk about the limits of the metal detection, it's related to some dimension of an object, right?

MR. RICHARDSON: Right.

MR. SEWARD: So when you set up your -- In this particular case, when you were setting up your HACCP plan, wouldn't you -- and maybe people are -- but you'd want to be very specific, right, about that limit, specifically about what it is dimension-wise and shape-wise that you're setting as your limit, so that in the event that someone comes in, a customer complaint or someone else brings in a piece of metal that's longer -- a long, thin object or something else like you showed today, that really wouldn't be a failure of your HACCP plan if you decided, in fact, to make that a CCP. Is that -- Do I understand that scenario right?

MR. RICHARDSON: Well, if I understand the question correctly, yeah, I think that that would be the case because, you know, what we were trying to demonstrate today and the work that Safeline and others have done is simply to demonstrate that -- a couple of things. One, orientation can have a huge effect. And, two, the good nature of the material going through that metal detector in terms of the product itself and potential foreign materials all combine to give you a capable system.

MR. SEWARD: Right.

MR. RICHARDSON: And it's intrinsically important for everybody to understand what those physical limitations actually are. And I think that a lot of that is dependent on where it's located, what the aperture size is and nature of the products going through there. You might have the same metal detector that's used on two or three different products that go through there, and each of those could have a different capability in terms of how your metal detector could actually be set up, depending on its physical characteristics. But it's really important that everybody who has a metal detector set out, testing it with spheres because it appears to be the easiest way to go through a monitoring process, and specify a degree of sensitivity, along with equipment settings -- is basically to understand what that nature is.

And if you encounter lead shot, for example, the example that we had, would be to understand, can your metal detector actually find that? If you get consumer complaint materials that allegedly comes from your product, you know which line it came off, et cetera, would be to actually test that material through there, basis your existing

specification to find out, is it capable of that, to get a
further understanding of that potential risk factor.
So when we get a kick-out, it basically
demonstrates something happened that maybe we expected to
happen. Now the question is, does that kick-out represent
some continuing threat? Are we on the borderline of some
other, you know, potential risk that we can't detect? And I
think it really gets to that case-by-case evaluation and
understanding what the equipment can do. Whether it's x-
rays, whether it's, you know, metal detectors, I think all
of those things go into that whole idea of the evaluation of
the process.
MR. SEWARD: Well, I think that's very helpful.
So would you recommend, then, for people who are thinking
about using a critical control point for metal detection,
that it seems like you'd want to do a great job of

elaborating around what that critical limit actually will deliver for you in the event that metal is found in your product that passed through there, that would not be detected because of your critical limit. And, therefore, if that was found, it would seem to me that that would not be a failure of your HACCP plan because, obviously, your HACCP plan was not designed to detect that kind of metal. And there's really nothing you can do about it because you're limited by the sensitivity and the dimensions of your product and all the other things that you said. Do I understand that right? Would that not be a failure, then, under those circumstances?

MS. RAEDE: Can I answer that?

MR. RICHARDSON: Please do.

MS. RAEDE: Now, I might be mistaken in my interpretation, Skip, of what you're trying to say, but I think if I came to the agency and said, "Yeah, I have this consumer complaint, but this piece of metal is not spherical 1.5 or 2.0, so you can't say I had a HACCP failure," I guarantee you the agency is going to say, "Okay, that's it. Now you fix it." And I don't think that's what you mean. I hope that's not what you mean because I don't think that's a situation that agency would -- or industry would even want to attempt to go to because it's wrong.

We may test our metal detectors in a spherical manner, but maybe it means, no, maybe we better go test them in a little curly piece of metal, and maybe we better go testing them this way. I don't think I want to do that because that's really burdensome on a plant to sit here and have all these different sizes that we have to set our critical limit around. I think it's fair to say that if I get a consumer complaint for metal, I'm not going to sit here and tell the agency, you know, "Well, it's not perfectly spherical. It's not what I set up my CCP for, so you can't say I had a failure."

I might say, "You know what? It's smaller than the limits that I have set," but I certainly wouldn't go to the point of saying "It's not the exact spherical dimension." Maybe that's not where you were going.

MR. SEWARD: Well, it is exactly where I was going because from a regulatory standpoint, I'm not -- I don't think the establishment is trying to build an excuse for that metal object that was turned in to FSIS and somehow came back to the plant. I think what I'm trying to say is that it's important to have the facts out in your plan because it's not a fault of your plan.

Your plan is written based on the equipment capabilities that you're using to pass product through. So if the capability of that equipment is such that you're using the best equipment you can and it doesn't detect a piece of metal because of its shape, or its size, or whatever, I don't think that your plan should be viewed as somehow having failed because -- I guess that was my point. I was looking for some clarification on that and how detailed a plan should be in order to accommodate that. Because if you were to -- If someone was to come back to you and say "Your plan, obviously, failed because we found metal in your product and you say you have a CCP for this, and, you know, obviously, you didn't catch it. You have to do a reassessment or do some sort of activity," what are you going to do? I mean, you can't -- You know, as far as I can tell, you're limited there.

So I just think it's important to sort of lay it out so that everybody understands. It's not an excuse, but it's a reality check on what the capability is.

MS. RAEDE: Absolutely, and what Bob has said earlier is that metal detectors and x-ray aren't 100 percent, and I think that is very valid to point out and yet a lot of us use those as CCPs. And I guess to present that, then, back to the agency is that, you know, going along with maybe what Skip is suggesting is that we just all be sensitive to that. And if a company is, you know -- has a situation like that, certainly want to be given the opportunity to go back, see if that actually, you know, is from their process. Where was it a situation? Just to be flexible, I think, might be a good way to resolve that.

MR. JOHNSON: And from an agency perspective, if you're getting this new information, of course we'd want you to look at it and see how it does impact upon your original hazard analysis in your HACCP plan. Obviously, it's something new that maybe you didn't consider. Maybe you did consider it and now your equipment is not catching it. But, again, how does that impact upon your hazard analysis and HACCP plan? And we would expect at least you analyze that to meet the requirements of the reg.

MR. COBLE: Joel Coble, Tyson Foods. I wonder if part of this question isn't already answered. When you use a decision tree, one of the decision tree examples, question two of one of the decision trees does say, "Eliminate or reduce to an acceptable level." Dr. Harris, in your opinion, would that cover less than perfect HACCP, CCP -- or HACCP plan CCPs?

DR. HARRIS: I mean, when you're dealing with a piece of equipment such as a metal detector, we're not getting to a level of zero, and we all know that metal detectors, there's a wide variety of things that can impact the detection rate when product goes through metal detectors. I mean, so the industry as well as the agency, and I think goes back to the case-by-case, the flexibility, did you do what you had designed to do in your HACCP is where I hope the agency would be focusing. And did it work as it was intended to work? In other words, had you designed it adequately? You selected a metal detector that you thought would detect at the level that you had identified to be the food safety hazard. It was operating. You were following your procedure, and now, then, you have this that has been, you know, turned back in. That should be evaluated, and I hope, from an agency standpoint, that that would never be taken as a HACCP failure. It's outside of your limits. I mean, we could take this and put it on the standpoint of microbial interventions on a slaughter floor. They are there to reduce microbial contamination. It is an unfair expectation that they will meet a level of zero. The same is true with a metal detector. They are there to detect at that level, but we're not anticipating a zero and we know there are parameters within the operation of that detector.

MR. GALLAGHER: My name is John Gallagher with North Side Foods out of Pittsburgh. And just to beat this horse a little bit more, I don't think anyone in the industry wants to put metal out in the product. I think what industry is looking from the agency for is give us some type of definition of a food safety hazard as far as metal goes. If you're asking for documentation or reference literature and you reference the Olsen study, we can say that metal larger than seven millimeters is only then considered hazardous.

If we're inspecting at, let's say, 1.5 or two millimeters, it sounds like, if that's the capability of our detectors, it sounds like we're establishing a food safety level for metal based on our capability of metal detection.

DR. HARRIS: Which goes to the difference between an operating level and a critical limit.

MR. GALLAGHER: Explain that for me. I don't understand.

DR. HARRIS: You will have operating levels in various parts of your facility in operation, such as the detection level of the metal detector. When you did the scenario of what you determined to be the food safety hazard, you should have clearly identified what you considered to be the food safety hazard. And if that was greater than the seven millimeters and whatever documentation, scientific support you have for that, the Olsen document, and any other documentation that you used to set that, well, then, from that standpoint, through your justification, and this goes back to the standpoint, I think, Skip was trying to make earlier, you should do a very good job of documenting your thought and support and decision on what you have identified as the food safety hazard and how that process is controlling it. It may be detecting at a level lower than what you would have anticipated as being a food safety hazard through your science and support, just because that's the nature of the equipment.

MR. GALLAGHER: Okay, I understand that, but in this instance, then, when they held the product back to the last good check and were to reinspect that product, the recommendation was that they reinspect it back through the same metal detector, if I understood that correctly. Well, if you inspected it once at two millimeters and you'd do it again at two millimeters, you're not going o find anything smaller than two millimeters.

DR. HARRIS: Provided it was functioning during that 30 minutes.

MS. BURCH: It depends on the orientation of the metal, too, on the reinspection.

MR. GALLAGHER: So you don't -- You wouldn't recommend going back to the old .8 metal reinspection that the agency once lived by? That's what I'm asking. I mean, I don't know where to reinspect product back to if we're reinspecting it at one level and --

MR. JOHNSON: The directive you're referring to is one where there is known contamination. We have a lot of product that -- You ground up a blade. You know there's stuff in there. That gave guidance of how to reexamine that product.

MR. GALLAGHER: Isn't there known contamination here?

DR. HARRIS: Which is the scenario that you gave us, known contamination for a blade.

MR. JOHNSON: But that 30 minutes, I guess, you don't know. I mean, you know that it starts kicking out at this point, and anything from that point on, obviously, is suspect, but you're also looking at stuff behind and that may not be contaminated.

MR. GALLAGHER: So not all of that half-hour you would have to be as sensitive as .8, for instance?

MR. JOHNSON: May not if you don't believe that it occurred at this spot and not backwards.

DR. HARRIS: That's correct. And I think part of what we're struggling with here is since this is a fictitious scenario, we don't even have the detection limit. I mean, there's so much information that's missing in here which goes back to that case-by-case, what did you have set up and what were you expecting the system to accomplish. And, you know, when these were made up, I don't know who made them up or what information they had, but I think if you, as a plant, can show that your system was operating and that you have done what it was supposed to have done, according to the parameters that you can scientifically support, that is what the agency should expect out of you.

MR. JOHNSON: And the scenarios were for that purpose, just for discussion, because there could be a million different scenarios out there, and there are. We tried to just come up with a generic one, just for discussion. So there's a lot of information that's missing, obviously.

MS. BURCH: John, are you trying to get some guidance in that if you do have metal rejected or product rejected for metal at a certain limit, and you go back to the last good check, what is the agency's expectation for your reinspection of that product?

MR. GALLAGHER: Right.

MS. BURCH: Is that what you're wanting to get some guidance on?

MR. GALLAGHER: Yeah, because if I do it back through the same metal detector -- Yeah, that is my question. Is it sufficient from the agency's standpoint to just run that back through a metal detector again?

MR. JOHNSON: I think I'd go back again case-by-case is what we're saying. I mean, what happened? What are the parameters? When did it occur? How did it occur? I mean, it would have to be case-by-case.

MR. GALLAGHER: I mean, this happens to us throughout the year. I mean, we have instances where blades break and to Bob's point, we're looking at some process improvement to catch it in the early stages of the stream rather than the later stages. And we'll hold the product and segregate it and try to reinspect it, but we're trying to get, you know, like to a .8 level that's hard to do.

MS. BURCH: And my experience has been on reinspection. If you go down to such a low limit there's so many other interfering factors, that you get so many false positives, that you might as well dump the whole thing.

MR. GALLAGHER: Right.

MS. BURCH: So what is a realistic expectation for the reinspection level without all the false rejections?

MR. GALLAGHER: And that's really what I'm asking, is at what level is there a food safety hazard? Is a piece of metal at one millimeter okay to eat and one at .8 not -- or 1.2 not okay to eat? I know I won't get an answer there, but --

DR. HARRIS: Well, and I think, though, from an agency standpoint, they should look at what you set your critical limit for the safety of the metal, and when you set that, on the detection level and what you had determined in your plant, your scenario, how you defined the food safety hazard. If this is for safety purposes, now, remember, we have a whole different issue over there on adulteration --

MS. BURCH: Of contamination.

DR. HARRIS: -- and contamination, which is a different issue, but for safety purposes, you should have to detect at the level for safety. For product release, to be able to show it not, you know, not being contaminated, adulterated with metal that may not meet a safety definition but is still a contaminant, those are two separate issues, in my mind. I mean, I know they both impact product release. They're the same thing on getting the product released, but they're different if you're defining whether one is a safety versus one is a contaminant.

MR. GALLAGHER: If I said that I could inspect to a certain level but I know there's metal in there, I would hear that it's adulterated product.

DR. HARRIS: Well, and that's adulteration.

MS. BURCH: That's not food safety. I can't arg- -- I mean, I agree with you from standpoint, but that's an agency adulteration issue.

MR. JOHNSON: And the agency would look at it the same way, a HACCP issue and an adulteration issue. You may show that your critical limit is this and that's a safety issue, and you can show through your supporting documentation that this size is a safety issue, but if you know there's metal in there, now we have a contamination issue also.

MS. BURCH: And maybe the question is, what's the agency's guidance on contamination, at what level?

MR. JOHNSON: That will be the next public meeting.

(Laughter.)

MR. GIOGLIO: Let me just -- I'm going to ask Lynvel a question, though, based on this. Would we not, okay, have an expectation that if we're dealing with the adulteration question, if a plant has done everything in their due diligence to try to find where the metal may be and segregate that portion of a lot and so forth, and then use the equipment, calibrated as sensitivity as they could, you know, and have confidence that the equipment will find, you know, metal and calibrate it down to the finest sensitivity that they can, and the old directive, as you pointed out, was point A, because that's what we believed on a routine basis, you know, the equipment was capable of doing, would we not then allow and have we not in the past allowed reexamination of product, and for it to pass that reexamination and then be released so we're not in a situation where -- and I'm truly asking this question, I mean, to sort of bring up the discussion so we're not in a situation where we get in this sort of circular proving the negative argument. I'm going back on my past experience and, you know, some of my old buddies here.

MR. JOHNSON: Yes. I mean, again, and we look at each case, case-by-case and using some, you know, common guidance. And one of them used to be that old directive. But we always looked at each one separately, and that's how we continue to look at them separately. How is the plant -- What is the problem? What did they find, you know? How do they want to screen this if they think there's metal in there, so forth? So it hasn't changed that much from the past, as far as the adulteration issue.

Question in the back and then we'll come to the front.

MR. MARVIN: My name is Andy Marvin. I'm with Swift & Company. I'm the Director of Quality Control for their Pork Division. My question kind of goes off of what Skip was talking about earlier as far as setting the limits on the metal detection. A situation where you have a piece of metal that makes it out into the marketplace. A good example that we fight with all the time are injection needles and stainless steel, little, bitty tiny piece and they go through my metal detector. It is not picked up. Gets out into the marketplace. I may have one a year. I may have five a year. You know, it's a relatively, what we consider a small occurrence, but yet we still get them. We're still out there fighting, trying to take care of them.

My question would be to Charles or to Lee on the validation and verification. Is this something where I'm going to go back and reevaluate each time that happens, or once a year, or how often? And to kind of add to that, the other situation we run into is a customer calls up, says, "I have a small piece of unidentified stainless steel that we found at our grinder plate. And we think it came from you because we had your product in our house, running it at the same time -- or running it." And I say, "Well, that's fine. You know, all of our metal detector checks checked out. Do you have stainless steel in your facility?" So, there again, the question, I've got a situation where I've got, you know, a metal occurrence. How often am I going to go back and reevaluate what I'm doing in-house as far as my metal detector checks and my capability of picking this up?

What we're running through, and I know some of these places here you're talking about small pockets and things like that, I'm running, you know, chucks and butts and picnics and things that have a much larger dimension, and my process capability, I can't go any smaller than .7 millimeter on stainless steel.

MR. JOHNSON: Charlie, are you going -- Do you want me to answer again? I mean, I guess you answered part of that question. You're evaluating the situation. I mean, you know -- You've got the customer complaint. You investigate it. You know it's a needle. It only happens very infrequently throughout the year, so maybe it doesn't impact upon your HACCP plan because it's just such an isolated incident that hardly ever happens. But, again, you are, in a sense, evaluating those things coming in, so you are considering that information and seeing how it really does impact upon your HACCP plan.

MR. MARVIN: But that's not something that any of my ICs are going to buy off on. If it happened three or four, five times a year, they're going to say that it is reasonably likely to occur, and I may look at them and say, "Well, considering the -- you know, I only had it happen once or twice in the first million hogs that I killed this year." So what's reasonably likely for us versus what's reasonably likely for what we're being inspected under sometimes are different.

MR. JOHNSON: All I could say is, I would hope with this directive, this meeting, plus with the Tech Center, I mean, issues like those, those individual issues could be resolved through all those means, the directive, the notice, this meeting, the information that came out of here and the Tech Center.

MS. QUIDAS: Teri Quidas, Allen Family Foods. I'd just like to clarify what the documentation would be under this scenario. And I realize we've kind of beat this to death, but I'm still confused. The metal was found by the metal detector. It says "detected in product," but it wasn't detected in product after the metal detector, according to the scenario. It was detected by the metal detector, which was the CCP. So there was not a HACCP failure, so --

MR. JOHNSON: There's no deviation from a critical limit.

MS. QUIDAS: So there is no HACCP incident report required or documentation as far as that is concerned.

MR. JOHNSON: By regulation for HACCP regulation, there would be no -- other than your normal monitoring, there would not be documentation.

MS. QUIDAS: Correct. All the documentation that we're talking about is really coming in under our SSOPs for adulteration, is that correct? Is that what the panel is saying?

DR. HARRIS: SSOPs or other plant programs or procedures, whatever you have.

MS. QUIDAS: But from a HACCP point of view, this is not an incident. The HACCP plan worked. It did what it should have done.

DR. HARRIS: (Nodding head.)

MS. QUIDAS: Okay, thank you.

MR. JOHNSON: Any other questions? We're still having fun. We can go right on to the next one. That's even better.

The next one is H2. We talked about the -- I'll go ahead and read the whole thing, I guess. I had a request. We covered the red meat. Now we'll cover the poultry. Okay, on establishment B, it's a large processing establishment. Conducted their hazard analysis. It's a poultry cut-up operation, and they determined there was no physical or chemical hazards reasonably likely to occur concerning foreign particle materials at any of the steps in the process. As such, there are no associated CCPs or critical limits in their combined slaughter/cut-up HACCP plan. And this was supported by extensive historical data showing there's no plant history of this occurring.

One day while at the establishment, a quality control technician was performing a scheduled post-chill finish product standards test. Metal and white teflon-like plastic was found on the 10-bird sample. The size of the metal in question ranged up to spiral shavings several inches in length. The QC technician immediately informed their supervisor, who placed all affected product on hold until further action could be determined.

After an investigation, it was determined that the foreign material in question was a result of a bad bearing in the ice augers feeding the chillers. The metal plastic shavings found in the product were from the metal auger grinding through the plastic lining and down to the stainless steel metal in the ice chute, as well as the deteriorating steel bearing itself. So the steel bearing also deteriorated and broke up. This material was then transported into the chiller along with the ice running through the chute. So that's the set-up.

They basically found no hazard likely to occur as foreign particle examination in their hazard analysis. With this incident, I guess the first question is what effects does it have on the original data determined that -- that they used to determine they did not have a hazard likely to occur? If anybody wants to tackle the -- Mr. Link?

MR. LINK: I'll try.

MR. JOHNSON: You're the poultry expert.

MR. LINK: I'm the poultry expert. I guess under this scenario they've been operating three years without any incidents.

MR. JOHNSON: No problem at all.

MR. LINK: So they've got some history that supports their hazard analysis, and then this appears to be another one of those what I'd call a critical failure. I mean, something happens, something broke. Obviously, they need to kind of reassesses and look at their HACCP program because they do have a problem. But I'm not sure that this is going to result in them establishing a CCP for foreign material or their chillers. It may be that their preventative maintenance program wasn't working. Maybe they weren't doing it. Maybe they needed to take another look at that prerequisite program as far as looking at the ice auger, but I don't think an isolated incident of this sort will necessarily result in establishing a CCP for foreign material.

MR. JOHNSON: So you're saying their data is still accurate in saying they don't really have a hazard likely to occur? This is just a fluke thing that happened within their system?

MR. LINK: In my opinion, yes.

MR. JOHNSON: Okay. You're all in agreement?

MS. BURCH: I would agree. But this should be added to the historical data.

MR. JOHNSON: Yes. So this should be part of their files as to, they investigate it, saw what it was and --

MR. LINK: They may find out the bearing breaks every three years.

MR. JOHNSON: Yeah, yeah. Any questions on this one? This was an easy one, I guess. Pretty straightforward? We have one back here.

MR. TILINSKI: One question on this determination of what's reasonable and likely to occur. 417 says if it's historically occurred, it's reasonably likely to occur. And there's a lot of isolated incidents, and it didn't happen enough times, and I don't know how that's being justified against what's in 417.

DR. HARRIS: That's an agency question.

MR. RICHARDSON: That's an agency question.

MR. JOHNSON: Yeah, it -- You want to answer it?

MR. POCIUS: Sure.

MR. JOHNSON: Go ahead.

MR. POCIUS: Joe Pocius with Pilgrim's Pride at the mike. That's an unforeseen hazard. It's covered in the regulation as an unforeseen hazard. All the documentation that you referred to is correct, and it would go into the file as an unforeseen hazard. It's covered within the HACCP rule in and of itself. It's got a special section right there of all the steps that need to be taken, the documentation required. I'm not sure that -- We had a CS that came and tried to pull -- you know, it happened once in five years. "You have a history of this in your plant." We had a very interesting conversation about that. He did not win, and I don't expect that one time in three years on this argument would win either. I really -- You know, I mean the district made that decision.

MR. JOHNSON: And based on what we have here, the agency would probably agree. You have the documentation, as the panel is saying. You investigated that. You brought that back to the data you had and added it to it. You know, one time occurring in three or four years, you know, that's probably not going to be justification to say it's a hazard likely to occur.

DR. HARRIS: And just to make this scenario more complicated, before I would have documented 417.3(b) for unforeseen hazard, I would have first looked at these shavings and plastic pieces to determine if they were food safety hazards. If they're not food safety hazards, then you would not address them under 417.3(b), which is reserved for unforeseen food safety hazards.

MR. TILINSKI: Just to make this a little more -- What if your inspector in your plant told you that this was an unforeseen hazard and you needed to do reassessment because you had this, even though he didn't do any assessment on whether this was a hazard or not? Is this -- This issue has come up for materials found. There's no -- Say it's a wrench, a seven-inch wrench and the guy is saying it's an unforeseen hazard. I mean, do you want for your 30-day letters to answer it or what do you do in a case like that?

MR. JOHNSON: For the sake of the public meeting, those are obviously issues you can always appeal. You can talk to the circuit supervisor. You can talk to the district. You can talk to the Tech Center. I mean, if you truly have that information to show that's not likely to occur, the decision in the field, obviously, is not agreeing with you, you have your appeal options open to you.

MR. POCIUS: I think we established that a seven-inch wrench isn't a hazard. You can't ingest it.

MR. JOHNSON: We have 20 minutes. We can move to the next one, last one. This is a canning facility. It's scenario H3. They produce poultry broth for use in canned soups and gravies in large 300-gallon tanks. Dry broth ingredients are mixed with spices in a large combo holder, lifted mechanically, dumped into the tank, mixed with water, heated, and held at 180 degrees Fahrenheit until used. One day a three-inch by six-inch piece of plastic was found floating on top of the tank after dispersing the broth for canning had begun. The object was removed from the tank. The firm decided to empty the tank and dispose of the remaining broth. That was their decision. Then they cleaned and sanitized the kettle and resumed production.

Plastic piece found to be from the pallet on which the combo -- the last combo holder was sitting. When the ingredients were added to the tank, the combo holder and pallets were lifted together and tilted into the tank. Evidently, the lifter was too close to the tank and the plastic fell and broke off. The broken piece was a clean break and no smaller pieces had been broken off. So, again, this is an issue where they don't have it addressed in their HACCP plan, or they have addressed it in their HACCP plan. They don't have a hazard likely to occur, obviously, for foreign material, and this case -- this situation occurred. So I guess in the HACCP environment, how would you handle this situation? Is it a hazard? Is it a problem? Is it a fluke?

MR. JOHNSON: Well, first I would go back to you're going to look at that three by six piece of plastic to determine if it's a food safety hazard. If it's not, it's a non-HACCP issue.

MS. RAEDE: To take it from there, though, as well, you also -- you know, aside from the size of it, you need to ask yourself if you have any prerequisite programs in place that would prevent this from getting to the consumer. Filters alone, as we talked earlier, probably wouldn't allow this size of material to even get into a can. So, you know, I would take this one and say it doesn't require any action under HACCP. You know, as a plant, you might want to come up with things. Look at the pallets. Make sure somehow you don't get it close enough to break off plastic or -- I'd investigate it that way. But I don't see this as being necessary to be part of the HACCP program.

MR. JOHNSON: So it's more of a prerequisite issue of handling pallets and the dumper.

MS. RAEDE: (Nodding head.)

MR. JOHNSON: Any more questions? Getting close to quitting time, I think, so -- Grady?

MR. OLIVER: I have one. Do you relate to this piece of plastic -- Grady Oliver with Manda Foods, Baton Rouge, Louisiana -- related to the three-by-six inch piece of plastic and it was previously a pallet, part of a pallet. Now, don't we have a sanitation problem here? Or could it have been a sanitation problem? It broke off. How do we know that piece of plastic was clean? Should it be in a product?

DR. HARRIS: They dumped it.

MR. JOHNSON: They dumped it.

DR. HARRIS: The product was dumped.

MR. JOHNSON: They elected to dump and sanitize.

MR. OLIVER: What I'm saying is, though, should that be addressed under sanitation rather than HACCP on your hazards analysis?

MR. JOHNSON: It could in that sense. The way you're presenting it, it could be, yes, if they see it as a sanitation problem, which they, obviously, in this scenario did, and they cleaned it.

MR. PURICELLI: Lee Puricelli. The way we -- That last scenario, that would be that you determined it wasn't a hazard, but it would be a sanitation SOP problem, and I'm sure you wouldn't make any changes, but the inspector would check it under that to make sure you took care of it.

MR. JOHNSON: Is that it? Okay, so I guess we're done for the day. Tomorrow in the ballroom, right, Moshe?

MR. DREYFUSS: Thank you very much. Appreciate the panel. Tomorrow we will be beginning in the ballroom, which is somewhere, I guess, on this floor, or down below, one floor down. My apologies. We'll see you at eight o'clock. Thank you very much for your participation.

(Applause.)

(Whereupon, the meeting was concluded at 4:45 p.m. on September 24, 2002.)

PROCEEDINGS: (Morning Session, September 25, 2002)

MR. DREYFUSS: Good morning, everybody. If we can get seated and begin, now that hopefully we have all of the technical glitches out of the way. That was first on our schedule. I'd like to welcome you back to the second day of our discussions on foreign material contamination.

Our first speaker was given the opportunity to retract everything he said yesterday, but he decided to stay on what he said. So DuWayne has passed along that everything about the Tech Center still exists. So we'll go right into our third panel, our Perspectives on Controlling Food Material Contamination through Prerequisite Programs and SSOPs. We have three very distinguished speakers this morning. I am pleased to announce that not only they came, but they also brought their presentations, and I understand they are all complete.

Our first speaker is Dr. John Marcy. He's a food microbiologist, has over 25 years with the meat and poultry industries. He received his doctorate in food technology from Iowa State, and he has worked for companies such as Stokely-VanCamp, Swift & Company and Jerome Foods and Denny's Restaurants. Over the last eight years Dr. Marcy has been the extension food scientist for poultry processing in products at the University of Arkansas and has held a similar position at Virginia Tech for the preceding five years. Dr. Marcy?

(Slide show presentation.)

DR. MARCY: Thank you, Moshe. I appreciate the opportunity to be here in Omaha. A lot of friends here in the room. This subject came up a lot yesterday. It's hard not to. I wanted to visit with Dennis and Bill Sveum, talk to you about how to manage foreign material with prerequisite programs. I'm going to concentrate on basically one aspect, and that's employees.

A lot of what was talked about yesterday was HACCP, and there will be a little bit more yet today, but if you look at the concept of HACCP in controlling a process, there are things within the production of food that are not part of the process. Not all foreign material comes from the process. If you look at your flow charts, there are things that enter in there separate from it, such as what can be contributed by facilities and employees. For instance, not that this ever happens, but yet we know we can find, you know, insulation, duct tape, you name it, if it's overhead, it can fall. Sooner or later, it can work lose and gravity works against you, and it will get -- it can get in the product.

Contributed by employees. They mean well, but every once in a while something they have in their hand is no longer in their hand. Something they had in their pocket is no longer in their pocket. Something that used to be inside their glove is no longer inside their glove. Something that was in their mouth is no longer inside their mouth. They don't do this on purpose, but it does happen.

So how do we control this? These are things that won't be controlled by HACCP. There is no critical control point that's going to affect the way these people act. But that's not to say it's a problem. It's an opportunity. Employees as prevention. If we look at how to stop those sorts of things, I don't know if you remember Nurse Ellington (sic), Lieutenant, Elenberg, I think her number three foreign material was fingernails, right? It was fairly high on the list. All of you working in plants understand where those fingernails are coming from.

So how do you get employees to prevent it? Proper training. That came up several times yesterday. It can't be said enough. And reminders. As I was putting this together, I remember my first days, my first years as a production supervisor in a processing plant, day in, day out on the plant floor, running an IQF chicken line, cooked chicken, and even though, you know, my background in food science, I lost track of what we were doing. If you work on that shop floor day in, day out, and most of you don't, most of you are in offices handling paper, just remember that these people working on the shop floor may look at this as pounds of product, widgets, you name it, anything but food. And so every once in a while you've got to go back and remind these people they're working with food and someone is going to eat that, not by the case, not by the pound, but by the ounce, every serving. So it's important to remind them, and yourselves, that it's not just widgets they're dealing with.

Management must be fair, firm and consistent, you know, like being a parent, not that I always do it, but I guess I can preach it. Enforcing and rewarding employee adheres to company policies. Setting the tone for those employees, those detections. On the RTI survey, looking for foreign material, you know, visual inspection was their number one report of a means, and that's being done by employees.

Employees should be encouraged to help others.

What employees do is a lot of repetitive actions, and they will do things differently depending on moods. They can help each other do things correctly, and that's the only way that you will prevent those sorts of things.

So what are the motivations for employees to do the right thing? Now, human nature, and we need to take advantage of it, human nature is employees really do care to do the right job, or maybe I should say they're not usually going out of their way to do the job wrongly. So if they're not doing it correctly, it may well be management's fault for not making sure they understand the right way to do it or giving them the corporate culture with which to do it by.

Consumer protection. No one wants to make someone sick or hurt someone. "No one" is a blanket statement, but these people will almost always take product home. You know, the employee stores. You know, what they make they will feed to their families. They are consumers of this product. Job protection. If there is problems with the product, their jobs may be at risk if it's identified back to them.

Of course, they always may lose that Chrysler, too, and brand protection. That's an important part to management. Most product is branded these days. Most companies that are here in this room have a branded identity in the marketplace. So you trust your employees. You depend upon them to keep foreign material out of the product, because the long and the short of it is you don't have a choice. Most of the foreign material that gets in the product you depend on an employee to tell you when it got there because a lot of it is not detectable, plastics, et cetera, the gloves, the knives, you know. You employ (sic) on systems and employees to tell you when they've done something.

I guess this one goes to Dave Bernard in his absence when he wrote the book on HACCP. He made the point that no management plan, whether HACCP or GMP, if you've got an employee that wants to commit sabotage, you're not going to prevent it, just to get that on the record. And we had an incident in one of the plants that I worked at where an employee put a brick in a V-mag. Whole new meaning to grand slam breakfast. And with that, I'll turn it back over to Moshe. I want you to keep in mind that if you're going to deal with employees, you're not going to do it with HACCP. Thank you.

MR. DREYFUSS: Thank you, John. Our next speaker is Dr. Bill Sveum, is the Associate Director of Regulatory Affairs at Kraft Foods of North America, has over 24 years of industrial experience in identifying, developing and implementing practical food safety, quality and regulatory management systems for the manufacture of fresh process meats, low acid and acetified thermal process foods, frozen foods and beverages, and has served on the National Advisory Committee for the Microbiological Criteria of Foods and has received his doctorate from Iowa State University. And he has something written down here about Cyclones and Nebraska, but I'll let him explain that.

(Slide show presentation.)

DR. SVEUM: I couldn't pass up the opportunity. Being in Nebraska, and an Iowa State grad, the fact that

Iowa State is ranked higher than Nebraska and the fact that Nebraska is going to play Ames in Ames. We have the best quarterback, and they always kick our butt, so this might be the first time that Iowa State might beat Nebraska. So we have to make that -- and it's probably, likely to occur. So use some language like that.

(Laughter.)

What I'd like to do this morning is talk to you about the role of prerequisite programs in managing extraneous material and kind of give you an overview of how prerequisites would fit in a HACCP plan. I'm going to take you through a hazard analysis of a comminuted sausage product, where prerequisites would fit in there, and just kind of the overall concept of how PPs, as we're going to refer to them, fit within a HACCP system.

So let's start out with some definitions of prerequisite programs. The first definition comes from NACMCF, and it says that prerequisite programs provide the basic and environmental and operating conditions that are necessary for the production of safe, wholesome food. And as an example, some of the types of prerequisite programs could include GMPs, equipment and process flow design, sanitation, maintenance, receiving the storage and personnel training, as John alluded to. And the key with prerequisites, and it was hit yesterday by Kerri and Troie, is that PPs must be developed, implemented and documented before conducting the hazard analysis and implementing the plan. So you don't do a hazard analysis and say, "I'm going to put a PP in here to avoid having a CCP." That's not the situation. There are the basic foundations for food safety control. They're in place, and then you use them to manage your HACCP plan.

Now, I've seen this in a triangle. I've seen this in a wall. There are eight blocks, eight foundations for food safety management prerequisite programs. I want to take you through some examples here because they came up in the discussions yesterday.

General quality systems, monitoring programs. Do you see the first one? It says "use approved suppliers." And that was discussed yesterday by Kerri because part of that approved supplier process is feeding them information.

And we'll talk about meat receival as a step in this process where we'll actually be providing data back to that vendor so they can improve their process. And that's one of the values of these prerequisites, is you're constantly obtaining data that helps you formalize and document your hazard analysis.

Other ideas such as extraneous detection and removal, recalls, specifications for raw materials, packaging for your finished product, equipment performance and maintenance, all the category such as PMs, equipment calibration, filtering compressed air, personnel training, as John alluded to, pest control, equipment cleaning, the premises itself, the floors, walls and ceiling those outside auditors always want to look at, receiving and storage, raw material management.

And one of the things that's interesting about this is I also have a cheese hat that I wear, not because I'm a Packer fan, but also because what I do within Kraft has a lot to do with the FDA side as well. And we have a pilot study with the NCIMS on HACCP for the milk industry. And they're regulated under what's called the PMO, the Process Milk Ordinance, but they want to move towards HACCP. And what they've done is recognize the importance of prerequisites. So if you participate in this HACCP plan, you have to have a list of eight prerequisites established before you even become a member of that pilot study. So they have recognized the role of prerequisites in establishing a food safety system.

So these are examples of all these different prerequisites, and as you recognize them, you'll see where they might play a role in minimizing a hazard.

Now let's talk a little bit about some of the groups that have recognized prerequisites. Of course, because we have this public meeting, part of the issue is on the recognition of prerequisites by the USDA. The manufacturer of safe food requires the use of a HACCP system built on a foundation of well designed and administered prerequisites, as we discussed. NACMCF, in their original document on HACCP, outlined that it was very important to have this foundation or prerequisite, so in there they're established. The Codex Alimentarius for their food hygiene document came out about a year later, has the same principles, where they look at the recognition of prerequisites and need it be for a foundation. And then the Canadian Food Inspection Agency has the same requirements, and they've actually outlined specifically what those prerequisite programs are. And lo and behold, the U.S. generic model for fully cooked, not shelf stable processed poultry does have reference to prerequisite programs.

So there is recognition by many different groups that prerequisite programs play a role in HACCP management.

Now, one of the issues that came up a few years ago is because of some of the conflict that we had with, let's say -- not "we," but some folks, maybe a confusion by the inspection force on the requirements for CCPs and questions about using prerequisites. Industry actually, then, petitioned FSIS to amend the HACCP regulations, and one of the issues was a definition of a hazard and then also the inclusion of prerequisites. And I pulled this from comments from NFPA, and it really deals with degree of risk assessment, risk presented to consumers by a potential hazard. And I'm going to read this to you, because it kind of plays into this whole concept of prerequisites.

"And NFPA proposed that if a violation of a control limit clearly represents an inappropriate food safety risk that should lead to action against product, then inclusion of the potential hazard within a HACCP program is generally warranted, CCP. However, if nonconformance with a control limit is undesirable, but unlikely to have health implications, and, therefore, unlikely to require action against the product, then inclusion of such a potential hazard in the HACCP plan as a CCP is not appropriate." And so it kind of gets that concept out in front of everyone.

So let's have a few definitions and then we'll get into the details of prerequisites. A critical control limit within 417.1, it says it's a "point, a step or a procedure in a food process at which control can be applied and as a result, a food safety hazard can be prevented, eliminated or reduced to acceptable levels." And then prerequisites, what we're going to be talking about, this foundation for food safety, it represents "the sum of programs and practices, no individual step, but the series of basic control programs and procedures which must be applied to design, produce and distribute safe products in a clean and sanitary environment."

So what are the benefits of these PPs, prerequisites? I believe that by relying on prerequisites and building them into your strategy, it focuses food safety management on process control. And that was alluded to by our speakers yesterday as well. And it really doesn't rely, then, on the limited effectiveness of after-the-fact inspection practices. And if you look at the statistics of trying to inspect a defect out, you know it's not very effective. It may be 10 percent effective. In fact, I think that first case study yesterday where there was a metal detector and the folks put it in process because they had often had metal problems, that was really an inspection process, and they needed to figure out what the root cause was for process control and figure out where the metal was coming from, rather than trying to grade it out with a metal detector.

By using prerequisites, it really directs your resources to effectively manage, then, those scientifically-based CCPs. Because we know the records that are involved, the training, the validation, the verification, the document review with CCPs. And effective implementation of HACCP requires a sound foundation of prerequisites capable of reducing or even eliminating the likelihood that a potential food safety hazard will occur in a process.

So when we talk about food safety systems, what are they really supposed to accomplish? Control all potential food safety hazards, of course. And that's what will work when you have your CCPs and your prerequisites supporting that system. And a food safety hazard that is reasonably likely to occur must be controlled by a CCP. But when we think about prerequisites, some hazards are not food safety hazards reasonably likely to occur because you've got prerequisite programs in place. And the difference, of course, with a CCP and a prerequisite is you have to validate your CCPs and they must be supported by implemented and documented prerequisites. Prerequisites must be audited for effectiveness, though. And then prerequisite programs, the records associated with a HACCP plan, are accessible for review. Because you have said that this part of my HACCP system, those records are available.

Now, we are under TQC, so all those records are well documented in our prerequisites. The IICs know where they are and they can review them. But we've gone to that kind of extent in documenting the prerequisites, and it's really helped some of the operators as well because the details are there.

So because I'm with Kraft, I thought we would talk about how we conduct a hazard analysis, because this has been an issue with us with prerequisites, and it's very similar to what the discussions were yesterday. But as with anyone, we would identify every potential food safety hazard that's associated with ingredient packaging materials or processing steps. So the same thing that was done yesterday.

And then as we would go through and look at the ingredients or the package, we'd look, is there a likelihood of occurrence. And with foreign material and raw meat, you would have to say there's a possibility that there is bone, glass, maybe not glass, but wood, those types of things. But then you would have a potential control mechanism. We would list the prerequisite, and I'll go through what those types of things are. We would do through meat receival, through our supplier audits, those types of things. As we go through, then, what the control mechanism is, we would list prerequisites, then, for some of those things where it's not likely to occur.

Of course, you have to look at the potential frequency occurrence and severity. That would tie in to how you then determine whether there's a hazard or not that's likely to occur. And I think we had a really good discussion yesterday, the physician from USDA talking about size and relative risk, and we have all referred to those. And if you think about your processes, the potential is very small, minimal that something the size that would exceed that seven millimeters would get through a system, particularly in comminuted products, through grinders, things like that.

And a real essential thing with prerequisites is they really generate the information that supports your hazard analysis, because you just can't say, "Well, there's not a likely occurrence that there's going to be metal in raw materials." What you have is all the results of your inspections, how you work with a vendor. And the fact that you find a meat hook once every year doesn't mean it's likely to occur. You have the data to support that. And the fact that you don't have wood in your system because you invert pallets, go to slip sheets, those kinds of things, that's data from your prerequisites and support your hazard analysis.

So we would recommend you use a prerequisite whenever a hazard can be reduced or eliminated through a series of basic control programs. And to try to put these in line, foreign material. GMP's could be equipment checks, can be raw material inspection, can be routine sanitation and metal detection. And all those in series, not one by itself, but in a series is how these work. And then what it allows you to do is really focus your efforts where there's a CCP and a real food safety risk.

Now, the key with a hazard analysis, it's going to be specific for every process. And I'm not saying that extraneous material is not a critical -- not ever a critical control point. It could be a hazard that's reasonably likely to occur, depending on your process. You might not have enough ingredient data to support that, or you might have ingredient data. You might be dealing with a process, cherries that have stone pits, olives that have pits. You know that there's a potential hazard there and you don't have a control mechanism. So you might not have the ingredient history to justify that you can manage with a prerequisite.

Or, for example, you might be packaging with material such as in glass. And I would mention to guess anybody that has a glass operation, you have a critical control point for broken glass, not maybe just because of a break in the filler, but someone might forget and not temper the glass, bring it in from outside and it's too cold. Gets together and it cracks, those kinds of things. So there are going to be definite critical control points for foreign material, depending on your process.

So when we look at a hazard analysis for extraneous material, what's the rationale for classifying extraneous material as a hazard not likely to occur? And that's what I'd like to spend some time on. And that's going to begin with ingredient history. And that's really going to be based on the kind of programs you have in place, beginning with meat receival, beginning with other raw materials. We heard someone from Chef America talk about the mixture of materials that come in. You might be producing an entree of a soup product that has all kinds of different streams, and there could be foreign material options there you have to monitor. But you have that through these records that you're monitoring. You've documented what you've found, and then you can feed back to the supplier rand make improvements.

Process history also indicates introduction of foreign material large enough to cause injury is not likely at each specific step. And we'll go through those steps, the kinds of things, the interventions you do at each step to control the process, to limit your exposure by looking at each batch, what you monitor, and you would then have data from those types of inspections that demonstrate that foreign material is not a hazard likely to occur as well. And then the effectiveness of GMPs and prerequisites and minimizing the likelihood of occurrence. And, again, that gets to those records.

And then scientific references. I didn't list -- we have the same ones, the Olsen article, Hymen, (phonetic) those types of things. And really what those get into is the likelihood of injury, and that is what you get into your hazard analysis. It's not just occurrence, but it's the potential severity, and that's based on size. If you look at the kinds of -- the process that I'm talking about, comminuted sausage with a fine grind, there is not a likelihood that there is a severe potential injury based on the foreign material in that process.

So let's review a hazard analysis. We have to identify all potential hazards that pose a food safety risk. So we're going to say yes, there's a potential for metal, for bone, for plastic, for wood. But we're going to have control mechanisms. And we'll utilize a series of prerequisite programs that reduce or eliminate those risks that those hazards might create. And it's kind of tied together. We would have an integrated approach to food safety management, so these concepts of prerequisites and CCPs, we'd select the CCPs based on science. And that's really what HACCP is all about. Support them with prerequisites, and then really what it does, it allows you to focus your attention on those really critical HACCP activities. And that's really the issue with CCPs and prerequisites.

So I mentioned, let's talk about how we would control and eliminate extraneous material, and this process is a flow diagram for comminuted cooked sausage, frankfurters. And all these various steps have some type of prerequisite program associated with them, that overall work to minimize a potential risk and then end up with not needing a CCP for foreign material in this process. They all have a record with them. And, in fact, what you'll see on here is there is a meat inspection. There's another metal detector and another metal detector. There's actually three metal detectors in sequence in this process, but they're not there to minimize -- to protect a consumer from a hazard likely to occur. They're all part of the process.

The fat -- The last metal detector is a verification of all the controls prior, because we have ingredient history from meat receival and meat inspection that we have a very low probability of foreign material. We have actions at these various steps. We were going to inspect this grinder between every lot of material that goes through. We're going to inspect it for broken blades, some things behind the plate. We're going to run all of our rework through a metal detector. We're going to limit the amount of rework to a small batch so that we can control that.

We're going to have whoever is running batching is going to observe combos of meat as they're dumped to look for materials. We'll look at the bottom of the output of the batch, at the pump rotors after every load so that we see if there's anything that was caught there and we might have damage in a rotor. So you do that with every batch. The corn syrup filter is going to have a sock on it. Your water is going to have socks on it when it goes in. We'll have a metal detector following this that basically is preventing anything getting to the emulsification system, because if you think about all those fine blades, you wouldn't want to cut something up there. So you prevent any damage. You also will then take that emulsifier apart every time from batch. We'll have a rare earth magnet in line after that, and Bob talked yesterday about the power of the rare earth magnets, and particularly the riffle magnets as that stream goes across. It really can pull things out.

Then we'll have a finished product metal detector that verifies all those other controls are in place, and with a metal detector, it's a functioning metal detector, but the definition of functioning is it must kick out five of five tries. And that's a little different than we talked about the light. Really what the requirement is, it's a functioning metal detector set to a certain requirement, and then it must kick out five of five, ferrous and nonferrous. So you have those kinds of requirements.

You'll have visual inspection. We'd actually have operators take a sample of finished product at certain intervals, cut it open, and then clean-up. And this is a real powerful one. Unfortunately, some operations that are run 20 hours, it's 20 hours of product that might be at risk, but you might find, looking at equipment, you might find excessive wear, and this might be an indication that you had a problem as well.

But all these work in sequence. And as I mentioned, it's a series of basic control programs. No one point in this process works by itself to give you an absolute guarantee. But what it does, they work in sequence because you've got a hazard that's not likely to occur and you've got a system of interventions at various points in the process.

The way we would put these prerequisites on a HACCP process flow diagram is beginning with a receival, and then you'll see that the prerequisites would be referenced with a number. Now, we would use prerequisites for temperature control as well, condition of the truck. So some of these at receival aren't just related to condition of materials. They might be related to condition of the incoming trailer. They might be related to the temperature of the meat or the storage temperature that we would put it in for the prerequisites. What we would also do at receival, and people have talked about the likelihood of wood as a hazard, we would then transfer all palletainers (phonetic) of product to captive -- either to slipsheets or captive plastic pallets. So then you would minimize that potential hazard. Any pallets that were pierced, there was damage, forklift, that kind of thing, those would be rejected. So you have all these things even before it comes into your receiving area to be processed that you're going to eliminate potential hazards.

Ingredient storage. This prerequisite relates to temperature, but then large foreign object inspection, and we'll kind of go through what that is, but we've got prerequisites for that, metal detection and grind.

So for our process for meat inspection, and this comes after the meat receival, we'd be running a large -- running the meat over the inspection belt prior to grinding. So there's going to be an operator making a visual inspection, and this is -- I had a guy that used to work for me years ago and he said, "Well, this is where we catch the car bumpers." But really what you're looking for is the odd foreign object. This is a great place that you might see that glove that comes in on occasion. And this is where you generate data now. You support your analysis. You get ingredient history, and then you provide feedback to that vendor, "This is what we found."

All the trimmings are run through a rather large metal detector, a large orifice, if it says it's 10.5 millimeter ferrous, but that's to catch that car bumper. In-line metal detector, check for proper function. And then we would have, within the plant, a policy for the plant manager's standard instructions. And then these are the kinds of documents that come from this. And so we'd have a foreign objects and raw materials report. That's what's going to go back to purchasing. Purchasing is going to use that information to work with a vendor as part of that cycle of improvement to inform if there's foreign material.

There's a metal detector verification, and then that lot is tied into a grinding log. With grinding, and I think we talked about this yesterday, but we would disassemble grinders after each lot, vendor or a species change. We would then look for damaged or extraneous material behind the plate because this is where, maybe, cardboard could get caught or plastic. And we would also inspect at any time, disassembled or during clean-up. Change the knives in the plates daily. Take them back to the shop to sharpen them up. Again, there's a standard instruction. And then we'd have a grinding log, a pre-op sheet, the condition at start-up, and then from those points forward.

Since it's not the company I'm with now I can refer to the fact that for 24 years, I've been around a while, no gray hair yet, but that's my Norwegian genes -- was in a plant overseas, and there was a metal issue, and they did an excellent job of documenting every kick-out.

And they had them all taped to a piece of paper, but they never went in the plant to look where they were from. And I said, "Well, let's go take the grinder apart." And they hadn't been doing this except for clean-up. And there were holes that had been broken spots between them. There was a blade and they just never put two and two together to go back and do the preventative action to find the root cause.

You'd find wire in things. The standard mechanic always had a spool of wire on his tool belt because that's how they would put things together. Hadn't heard of a cotter pin, hadn't heard of those kind of things. So they just didn't do the root cause analysis. That's what this log and pre-op sheets let you do, because you go back and determine what the source is.

Then the finished product metal detector, again what we're doing here is we have a verification step of all these series of basic controls prior to this. In line, it's checked for proper function at start-up, every two hours and at the end of the run. And what we would set it for is to be able to detect 2.5 millimeter stainless. And the discussion yesterday is that's the most common source of -- type of metal that we've come across, so we'd look for that type of sensitivity. Again, there is a plant manager standard instruction, and then if these records were going to be reviewed, they're available and they're called the metal detector check sheet. And then that would be the record that we would use, then, as part of our process.

So to summarize some key takeaways, the approach that we have with HACCP management is we use an integrated approach to food safety management. Of course, it's the foundation of prerequisites. It's verified prerequisites, validated CCPs. We use science to select the CCPs for the hazard analysis, just as was discussed. Use the ingredient history, the data that we gather from the prerequisites to support those conclusions, and really would take a position that failure to recognize prerequisite programs diverts attention and resources from critical HACCP activities. And that prerequisite programs are used whenever a hazard can be reduced or eliminated through basic control programs, GMP's equipment checks, temperature controls, sanitation, metal detection. But they have to be in place, implemented and functioning before you do the hazard analysis and before you implement your HACCP plan. Go Cyclones.

MR. DREYFUSS: Thank you very much, Bill. Our third speaker this morning is Dr. Dennis Burson. He's the extension meat specialist at the University of Nebraska at Lincoln. He received his bachelor's degree there and his master's and doctorate from Kansas State University. He is the extension meat specialist in the Department of Animal Science and conducts cooperative extension programs and food safety in HACCP programs and beef and pork programs, emphasizing quality, consistency and value of meat products. He has also received the Distinguished Industry Award from the American Meat Science Association, the Achievement Award from the Nebraska Association of Meat Processors, and the Distinguished Extension Specialist Award from the University of Nebraska Cooperative Extension. Dennis?

(Slide show presentation.)

DR. BURSON: Good morning. I was set up. I got invited to this conference and then have to follow somebody from Iowa State, and the Nebraska team loses the last time they play. I just -- I sat my whole time over there, Bill, while you were talking trying to figure out what it is that I'm going to say just to get going. You must have been around about the same time I was when I was in school and we had scholarships from Aksarben, and Iowa State and Nebraska both had scholarships. And so I got to travel to Iowa State to a football game with the Aksarben scholarships, and I think the Iowa State people came to Nebraska on alternate years. And I'll never forget the one story that was related during the time that we were over at Iowa State. One of our students got up and said, "Boy, we were out on the streets last night before the game and things were getting pretty tough. The Iowa State people were getting really mean and nasty, and Iowa State was on one side of the street and

Nebraska students were on the other." And the next thing he says, "They were throwing dynamite at us." He says, "And I really got worried when the Nebraska people were picking up the dynamite, lighting it and throwing it back."

(Laughter.)

Let's talk a little bit about physical material, prerequisite programs, and I work mostly with small and very small operations in the State of Nebraska and in the region, actually. And I want to put some perspectives on what I see as examples of these programs that they might put in place to try and assist them through their control of physical or foreign material.

And I was hoping that somebody would cover this, and Bill did a nice job, and you've seen diagrams like this over and over again if you've been to trainings and workshops and discussions about HACCP and the good manufacturing practices, and the SOPs and so on, and you can probably put a lot of different blocks and bricks in that diagram, as Bill did. But this is something that we all believe in, that if you're going to build towards some level of quality or process control in your facility, there are different things that you have to build on in doing that process. And so we always talk about that when we go through our trainings for HACCP. We try to include standard operating procedures and good manufacturing practices as part of the things that a company should be aware of and should be doing.

One of the challenges, though, is that -- Well, before that, the prerequisite programs, as he said, will influence the likelihood that a food safety hazard will occur. And as we talk about HACCP and teach HACCP, we always think of the hazard analysis as considering occurrence and severity of the hazard. And I thought Bill did a nice job in outlining those two things. He used different terminology than I have here, but we still look at it from an occurrence and severity standpoint, and then you can say what are these prerequisite programs doing to help you with occurrence or severity of the potential problems.

So small and very small plants are unique in some of these ways in terms of prerequisite programs and the application of HACCP. First of all, there's a small number of employees. Well, that may have some advantages in that if you have a small number of employees, they can be focused on their observation of equipment or the product that you're working with, and the -- many times also would have a close relationship with the management or the owners of the operation. And so those would be some real positives about a small operation in terms of number of employees.

Of course, there are also some negatives. Some that I don't have listed here in that maybe you don't have the right human resources, or the right people for the job, especially if you're trying to put some things in for statistical process control or prerequisite programs that some of these employees may not have had any exposure to in the past. And so that's one of the challenges that we work with as extension specialists at the universities, is to try and bring some of these companies and these employees that work at these companies up to speed in those areas.

Also, small operations tend to use fewer pieces of equipment used in their production, and so they have a fairly simplified process that they're working with. That also means that they're challenged if you want specialized things. If you were counting on metal detection to be in an operation, you probably won't find it in most of these operations. The operations themselves are close to the consumers. Many of the very small operations that are the owner-operator types, their customers are basically their friends and their neighbors in their town. And so many of these operations will depend, in some way, on prerequisite programs, although many of them are not written down formally within their operation.

So what I wanted to do is go through and give a few examples to kind of back up some of the information that Bill had talked about, and we'll point to three different areas of operation for prerequisite programs that would deal with a physical material.

First of all, there's an example I know of, and I guess that yesterday this was talked about some. I was not able to be here all day yesterday because I had to go back to Lincoln and teach class, but there was a reference to some of this in slaughter, and hopefully I can expand a little bit on some of the thoughts about a slaughter program. Where in this case we're talking about slaughter of cows and bulls and, of course, the concern that's usually raised in that type of operation deals with BBs or buckshots that can occur on the carcass. I can never figure out why cows are picked out as targets or whether it's the angry rancher or whatever it is that causes that. But we know that it does occur.

And so this plant had a multiple-step system for identification and elimination of this problem. One was to have visual observation on the slaughter floor by the employees. And, so, again, small number of employees, you can increase the emphasis to look for something like this. They also had visual identification as they went to the fabrication floor, and then at the very end of the fabrication line, this plant has metal detection of the lean trimmings as another follow-up. And so kind of many steps within the process, the same kind of thing that Bill talked about in terms of controlling this physical contamination.

To expand a little bit more, the detection on the slaughter floor was put in place that the plant actually rewards the employee for discovery of the BBs or the carcasses that have it. And so this emphasizes again the importance of the employee. And then, secondly, they maintain records of the employee findings. And my comment here is that if they are able to identify the carcasses early in this process, why, then that would help them to come back and identify the supplier of that product. Now, in marketing of cows and bulls, the person that sells to the slaughter operation may not be the person that actually owned and produced the cattle or the bull, the cow or the bull. But by bringing back this identification, perhaps you can make some tie with where the original root of the problem is at.

The metal detection in the lean trimmings kind of provides a second check in the system, detection of metal that cannot be seen by the workers. You have to come with the realization that when you're running various checks of meat through the metal detector, the accuracy may not be where you want it to be. One of the challenges in this system, though, is that they are less able to connect to a supplier because usually by the time the meat gets onto the fabrication table, it's difficult to identify it back to the carcass or to the supplier where it came from.

Now, in addition to those things, I've seen this plant do other things that really try to address the industry as a whole. And the beef producing industry has become concerned about quality issues in their products, and over the years there's been some time spent talking about quality assurance. There are programs for training for beef producers on beef quality assurance. And so this plant assisted with some of these programs. They provided speakers. They went and talked with the committees that helped develop some of the materials and the educational items for the quality assurance programs. And so as a result, there are things about the educational programs and quality assurance about physical contamination, especially concerning buckshot for cows and bulls.

Some plants have gone beyond that even and require quality assurance training by producers before they can be a supplier to their plant. I don't know that we can specifically target or give an example for a cow and bull operation, but there are some that require quality assurance training before selling animals to their operation.

And so the conclusion I get out of this is that this plant is not only taking actions internally, but is taking actions outside of their operation to help reduce the occurrence of physical contamination.

Fabrication, another fairly simple example. Well, two examples here. One is a knife inventory control and the other one is an equipment monitoring, which I gather you've talked about a number of times already. This one plant, we were going through the hazard analysis and talked about the possibility of material being left on the table and then ending up in the product. And, in fact, yesterday one of the first speakers talked about finding a knife in a box of meat. And this plant has a knife check-in and check-out for all of their employees. And so at the start of the work day and at the end of the work day, they would know where their knives were and basically an inventory check.

While this is effective in keeping the knives in control, the program probably doesn't provide a lot of room for improvement. Are there ways that they could avoid these potential problems by improving it further? Instead it's more of a police action type of step, and it's probably effective, but where does the improvement come?

Another example is in equipment monitoring. In this case, this plant was working with a needle tenderizer, and the plant had a -- found out it had a history of equipment breakdown. They had found a couple of needles that had been broken over the past year or so. And so the plant established a standard operating procedure for checking the equipment, and I wanted to share what it is that they wrote.

They established a pre-operational standard operating procedure where they said the needle tenderizer and other mechanical tenderizers that they had would be inspected prior to the start of production by their operational manager, and that the inspector would focus on the intactness of the needles or the blades. Once they did that, then that would be recorded on their standard operation procedures log for tenderizing equipment.

They also established something during operations in that they would check it twice daily, in the morning and afternoon, and the terminology reads about the same as the pre-operational, so I won't read the whole thing, but they -- checking in pre-op and then twice during the day. And so they went from no checking on these items to where they were checking three times a day during operation. And maybe that doesn't seem like a lot, but yet for a smaller operation it may be sufficient. And then they would record and gather all this information on their inspection log, and you can create logs however you want to, but this is an example of what they did.

And so what does this type of inspection do? Well, first of all, in the past they knew they had a problem because they had to replace some needles, but they also did not have any kind of a record of what the dependability or the faults of the equipment that they were using had. And so this type of an approach gave them some information and data to be collected. In the future this data, then, could be used to make better decisions about what their monitoring frequency should be, or whether this is something that needs to be focused on, replacing equipment or so on and so forth. And so they've gone from basically keeping no information to now they have some information, and hopefully that will help in decision-making into the future.

Now, the final one that I want to talk about is a very small processor that I worked with here in Nebraska. And, basically, if you talk to small processors, there's very little recordkeeping that goes on in terms of prerequisite programs. That doesn't mean that they don't have some idea of what they should be doing in terms of a prerequisite program. And that's one of the challenges that I see in working with these people. Because a plant operation, in this case, had set up a ham pumping operation and had instructed the employee to pump the hams. And this is a hand-held unit. Most of you are familiar with needle injection systems that are on a belt system. But in a small operation they'll just use a hand-held unit. And so he set the thing up, and he knew that it was in functioning, working condition when he set it up. He told the employee to go in and pump the hams. And after the employee had finished that, the operator, the owner-operator went back and checked it found out that there was a tip of a needle that was missing on this hand-held injector. And this guy is concerned to no end about this. I get a phone call late in the afternoon and we talk about things and all possibilities, what he should do in order to try and discover whether the tip of this needle had been left inside of one of the hams that the employee had pumped that day.

And I don't know how he came about the decision to do this, but we talked about, well, you could slice the hams small enough, thin enough sections that maybe you could find it, and so on, and finally he decided to take the hams to a local medical facility and they x-rayed the 15 or 20 hams that they had pumped that afternoon in order to try and find the needle. Well, they went through the whole process and didn't find a needle in any of the hams that they were looking for. And so they were concerned whether it was picking it up or not, and they actually took a needle off and put it in a ham, and sure enough, you can see it just bright as day in the x-ray. And so he was pretty confident that it was not in the x-ray.

And the only thing he concluded is that it must have fell off onto the floor somehow during the operation, and he couldn't find it in his facility. And so he never really did know where it went to, but he was confident that it was there when he started. He knows that it wasn't there when he left and he did his best to try and find it. I think he also notified his customers when they came and picked up the hams as to what his problem had been.

And so with this very small processor, no records were being kept on the equipment. However, the plant operator was aware of what his responsibilities were, and he also was able to detect the problem when it did occur. And the other thing I would say is that this plant operator was truly concerned about his customers when we went through trying to solve this problem.

So, in summary, I'd like to say that there are a number of things about prerequisite programs for foreign material. Prerequisite programs can work to reduce physical contamination by utilizing many approaches. And so we don't have to think about metal detecture, or we don't have to think about visual inspection as the only ways to look at preventing it. We can apply a number of different measures, and maybe some of that is education of the suppliers of your product.

There are some prerequisite programs that are probably just going to have to be ongoing, the knife inventory thing example is one that there's probably no way they'll get away from that. They'll just keep on doing that kind of an inventory. Increased inspection may provide additional information, and so the plant that was picking up and checking equipment more frequently not only was going to try and help prevent things, but they were also going to get more information to help make decisions in their process. And, finally, very small processors know their equipment and they are concerned about their customers for the most part.

Thank you for the opportunity to be here, and I look forward to the discussion of the scenarios later.

MR. DREYFUSS: Thank you very much, Dennis. We're going to take a break now until 9:30, and we'll reconvene and begin our panel discussion then.

(Off the record from 9:10 a.m. to 9:35 a.m.)

MR. DREYFUSS: Just want to remind you for something we said yesterday, that the presentations that you have seen yesterday and today will be posted on the USDA website within the next couple of weeks, now that we have all the presentations and certainly the ones with errors in it we'll correct. So we will have it available to you shortly.

We ask, for those of you who do have questions, please approach the microphone so we see you ahead of time, and announce your name and your association. These meetings are being transcribed and part of our record, which will also, at some point, be up on our website.

We are now at the point of our last panel discussion, which we will present the panel with several scenarios in foreign material contamination involved with prerequisite programs. Our three speakers are here again, along with Charles Link, who I neglected to say yesterday is a member of the National Advisory Committee on Meat and Poultry Inspection, the organization for which staff I am on. So, again, welcome to all of you and I will turn this over to Lee Puricelli who will act as moderator.

MR. PURICELLI: The scenarios are attached to the handouts, but we'll just go through them, starting with the first one. I'll read through it and then we can discuss it. This is just a little breakup of the scenario, too.

The first one is, it's a small ground beef processing facility that manufactures fresh coarse and fine ground beef products. The establishment conducted its hazard analysis and determined that they had a physical hazard for wood when the combos of product are dumped into the grinder hopper. However, they deal with this through a prerequisite program. And the prerequisite program the establishment has involves shrink-wrapping the combos of product and its associated pallet to prevent any possible wood from entering the grinder when the product is dumped. The employee running the meat dumper is responsible for assuring the combos of product are properly wrapped prior to placing them into the dumper hoist.

One day during production the batch blender operator was about to run out of ground product, and to continue production he decided to not shrink wrap one of the combos. A short while later while the batch blender operator was completing a 5,000 pound batch of ground product, he noticed brown pieces of material mixed in with the batch of coarse ground beef. The blender operator notified the production supervisor and upon further examination, it was determined that the foreign material was pieces of wood. So the supervisor halted production to further investigate the situation. That's the scenario. And would anyone like to start on the panel?

MR. LINK: I'll just make a comment or two about the scenario, I guess. Obviously, you know, thinking about the product, but obviously they had -- the prerequisite program was not adhered to. And I think getting -- trying to identify why, you know, why this new employee didn't do the job and wrap the pallet properly, obviously he was behind, but you've got to wonder if he even understood the reason for doing it, other than, you know, maybe it's "Here's your job. Wrap the pallet, put it on there and go." Maybe if he had understood the reasoning behind it and the seriousness of what would happen if he didn't do it properly, he may not have had the situation. So it may get back to training the employee properly to start with, make sure they understand, I guess, the reasoning behind some of the things they have to do.

DR. BURSON: I guess I'd just add to that in that if you look at employees, if this was a new employee, one of the things that we propose is that you should go through some of the food safety requirements of the job with them before they're even hired. They should be aware of that and maybe many of you do that. But even with that, there's probably the possibility that this could happen with a new employee. And so I think that you've hit on the right thing in that here you have a system that's supposed to work for you, and it failed, primarily because you had somebody who basically forgot to do their job or did not know what their job was in order to conduct it properly.

DR. SVEUM: I'd like to make a point that this is a good example of what a small processor has put in place to manage a potential hazard and, of course, that's wrapping the pallet. But it gives you an example of the different ways to approach prerequisites. And as I mentioned, with larger company like ours with Oscar Mayer, and Tombstone, and DiGiorno, we'd have more resources. We would have the same prerequisite program like this, and to manage wood and decrease the potential, but we would use captive pallets and slipsheets. So there's different approaches, but you're still accomplishing the same thing in a prerequisite. So you wouldn't expect to see all the prerequisites look the same, just how you would tend to manage it and then document it.

MR. PURICELLI: Okay. Any questions on this scenario?

(No response.)

Nothing? I guess not.

Let's do the second one. In the second scenario we have an establishment that has produced over 750,000 salamis in the past two years. In that time the QC director has received only five customer complaints. Of the five complaints, three have dealt with strange blue material found in the salamis. Two of these complaints were received in the last six months. In the investigation, the QC director had 100 recently packaged salamis that were ready for shipment, pulled from storage and examined. More blue material was found visually in two of the 100 salamis. She also noticed that employees in the plant used blue gloves when working with -- in the processing area. On further examination, she noticed that the gloves, at the end of the shift, are frayed and that the supply department regularly replaces its supply of blue gloves every three to four months. The establishment has a prerequisite program to visually examine product for extraneous materials, but sometimes such materials do get through the screening process. That's the scenario.

DR. MARCY: It would appear that the company has the opportunity to be a little bit more generous with replacing blue gloves and also working with the employees to make sure they understand that they can trade in gloves more often.

DR. BURSON: I think they ought to use white gloves so that they wouldn't be able to see it in the product and then they'd get along just fine, right?

(Laughter.)

One of the things we argue about in our facility is if you're dealing with a cooked meat item, do you have employees wearing gloves in the process before cooking? And, obviously, there are some cases where you would like to wear gloves, but if you follow normal hand-washing procedures in the handling of emulsions and so forth in a small operation, is it really necessary to have a glove on?

And so that might be one of the things they want to look at, what is the purpose of these gloves in their operation, and are they really concerned about -- What's the reason for them there in the first place? And, obviously, if they are necessary to have in the operation, why, then, they've got to do something to make sure that they don't fray and get into the product. That's an obvious answer, but many times we'll talk about just the emulsion production side of the operation, which was where this blue glove would have to come from. Is it really necessary, since you're going through a cooking process, for them to wear gloves, unless you have injury or something like that? Then maybe you do need a glove. But in normal work operations, is that necessary?

DR. SVEUM: I guess the thing I would comment on is the first thing is from a prerequisite perspective, they probably missed this concept, as John talked about, of looking at these gloves more frequently, so there wasn't maybe adequate training on employee practices to think about what these frayed gloves would have meant. But I'd be more concerned that this sounds like just a random inspection of 100 recent packages and you have a 2 percent defect rate. And how long have you been running with a defect rate like this? And here you've had information and you saw blue material quite a while back. So there really isn't an effective root cause corrective action program in this facility, in my interpretation of this case study. And to go this long and then now do a random sample and find 2 percent, how much more is in that product? I would be concerned about that.

MR. LINK: To have five complaints in two years is pretty awesome, I think, but it appears that maybe this blue material problem just recently started happening. And, you know, maybe the purchasing guy decided to get a cheaper glove or something. I mean, who really knows? But you've got to wonder, if the gloves are fraying, it doesn't sound like they're probably rubber or plasticized material either, which probably isn't a good idea to be using in the processing plant either. So they need to -- Obviously, they need to look at what's causing it. Did we change gloves? Did something happen to start creating this problem, to get us this defect rate that we're getting this blue material in the product? And apparently their prerequisite program just to visually inspect, obviously, is not catching the blue glove. So it's not -- maybe not as appropriate as it should be.

MR. PURICELLI: Also, what would the panel suggest in terms of what would this establishment look at and how this would affect -- impact their hazard analysis and that program. Would you have an opinion? What would you do?

MR. LINK: Well, I don't think that the blue material -- at least I didn't get the indication here that the blue material was a food safety hazard, more a quality defect that's in the product. But I think, obviously, do we need the gloves to start with? Do we have the right kind of gloves? Is there something we -- maybe a different glove that would work just as well? Obviously, change colors.

DR. SVEUM: Or pay more for a more expensive glove that doesn't fray.

MR. PURICELLI: Okay. Any questions?

MR. QUIDAS: Teri Quidas, Allen Family Foods. In this scenario you have a prerequisite, a program that appears ineffective. In the previous scenario you had a prerequisite, a program that apparently wasn't applied. Is there a difference in how those two situations affect your HACCP program?

MR. PURICELLI: Yeah, I think that's a good question.

DR. BURSON: I'm sitting here, kind of just thinking that the first scenario, you're looking at that and it occurred. But things happen, right? And so that's maybe looked at differently in my mind than in this scenario when it appears to happen over a longer period of time and you should have been able to pick that up probably before they did, according to the way the scenario is written. And so not knowing details, if they had been using -- The real question is how long had they been using this blue gloves? And if it's been for an extended period of time, a year or two, then you have to wonder how long this has been going on or the potential for this has been going on without them really picking it up in their prerequisite program. And so you might have more concern about how they're operating in their process control in this scenario than you did in the first scenario where they simply had one incident where it happened.

DR. SVEUM: The difference that I would look at in these two situations, in the first one, when the pallet wasn't properly wrapped and you had wood in the product, the batch was controlled, it's going to be destroyed, but that was a special cause. That was non-adherence to a policy. It's an occurrence and you can address that because they're going to counsel the employee and explain the process. It was a new employee.

This one here, as previously mentioned, this is more systematic with a glove. There's something that's been going on for a while. It may not create any kind of hazard, but it's a quality issue, and, of course, it's not on the label. So you've got an issue with the product. And this is more over time and something should have been caught through your normal monitoring procedures, whether it's in communications with the employees, whether it's the preventative program, but it just seems to have gone on for a while. And particularly now when we found 2 percent defect rate. Yes, there was a low level of complaints, but has something occurred recently? Have they changed the process of vendors and now there's more potential for gloves fraying?

MR. PURICELLI: I think --

MR. DERFLER: I'm Phil Derfler from FSIS. You've got this blue material that's from a glove that's never been through any sort of color additive approval process by FDA. How do you know it's safe? How do you know it's just simply a contaminant? How do you know it's not a significant food safety issue? And what you're seeing is migration from the glove into all your product. Why shouldn't we do a 750,000 salami recall?

DR. BURSON: That sounds like the industry response to me. But to start with, you know, we don't use gloves in our processing plants that aren't approved.

MR. LINK: Nor do we.

DR. SVEUM: That's a fair question, but there is going to be an approval process, and you're going to buy from an approved vendor, and you're going to understand what that material is that -- You know, you always run the risk that someone is going to buy outside the purchasing plan.

But the idea is that what you bring in is food grade material and this would be approved for use, as Charles said, and there would be letters of guarantee and an analysis that comes with it that it's approved for contact with food.

MR. PURICELLI: Anyone?

MR. POCIUS: Joe Pocius with Pilgrim's Pride. I just want to play devil's advocate here for a minute and question whether the prerequisite program actually failed.

At a 2 percent level over five years you had two incidents. Recently, you've found a 2 percent level, but you found a 2 percent level. Did you really fail? It depends on how you act now, I'll grant you that, and what actions are taken and disposition and whatnot. But did the program actually fail? You found it.

DR. MARCY: I would think the short answer is yes. It had failed in that they only found the 2 percent because they went looking. It wasn't through a normal inspection methodology that she was looking for that root cause. And I think Bill characterized it correctly, you know. A systematic problem, indicative by the frayed gloves. Now, whether or not they should be wearing gloves at all is a whole different issue, but, yeah, I think the -- you know, the company culture was not the best possible at that particular moment in time.

DR. BURSON: Perhaps to help back that up, whether it was a long-term or short-term issue would be to go back and look at the supply department ordering and inventory of the gloves. In our scenario we said the gloves were replaced every three to four months, and so has that practice been going for every three or four months, replacement for a long period of time, or is that just something that happened in the last three or four months, or so. And so you would, as your quality assurance person, be able to go back and look at a few details like that and try to make a decision as to whether it's a long-term or short-term issue.

MS. HANIGAN: Katie Hanigan with Farmland, and I have a question for the agency. I am wondering, in light of the scenario that's up there, how the agency views this as it would apply to the operational SOP program. Would the agency say "You, the company, have failed to prevent direct product contamination"? I'm wondering what the agency's view is on this, now that, if you will, there's adulterated product in the field and they've determined it's not a food safety issue. But what about the operational SOP program when you have a 2 percent incident rate? Can you give us direction on that, please?

MR. PURICELLI: As written in the directive, I guess, the corrective action would be in the SSOPs. And then I think we would expect -- Again, it's a prerequisite program, so the supporting documentation should be done in the hazard analysis, and that's kind of why I asked that. We'd want them to look at the prerequisite program and do all the things that were suggested up here to see whether the program is still -- I think two things. It's the last page of the directive. I mean, you would look to make sure at the conclusion, that the material isn't hazardous. If it is, then it would be treated as an unforeseen hazard and then you'd have to determine whether you'd have to now put it in your HACCP plan or not or whether the prerequisite program is working or can be adjusted. And then if it's not hazardous, then, you know, what are you going to do in terms of looking at the prerequisite program and fixing it?

So you walk through -- What I'm trying to say is you walk through that last part, that last flow chart. You have to make all those decisions.

MS. HANIGAN: Just one more point of clarification, I guess. I'm looking for really a yes or a no answer. At this point, is the agency going to say to the industry, "Your operational SOP program has failed because you now have direct product contamination"? Because when you look at the pathogen reduction rule, the operational SOP program is in place for -- or to prevent direct product contamination. So I'm sure you'd at least draw an NR on this, and I'm sure it would at least be directed towards your operational SOP program. That's my question. Has the SOP program failed to prevent direct product contamination?

MR. PURICELLI: It didn't prevent it, but I wouldn't say it's necessarily failed. I mean it's exactly -- We would write an NR. There would possibly be an NR, and we would want to see what actions you take to address it. Would you have to change your SSOP? No, maybe not. I mean, it really depends on what you decide. But I can tell you we're not -- Automatically we're not going to say you have to. I mean, there's nothing automatic. The agency isn't saying there's anything automatic in how you deal with it. What's automatic, though, is that you deal with it and you consider all the particulars. We want to see that. But, no, it's not like, "Now you have it. SSOP is gone," or "Oh, no, now you have it. You've got to make a CCP." That is not what we're saying. That's not what we're saying with any of this. And then that's where the documentation is so vital for all these programs, so you can justify it and we can see it. So I hope that helped.

MS. HANIGAN: Thank you.

MR. LEON: Hello, Pedro Leon with Advance Food Company. You know, when we listened yesterday to Lieutenant Elenberg, she said that two complaints would trigger an investigation. How would that correlate with the findings at the plant level to have a progressive enforcement action from FSIS?

MR. PURICELLI: I'm really not sure. She's not here today and not -- Yeah, go ahead, Charlie.

MR. GIOGLIO: This is Charlie Gioglio from FSIS. Let me try to address and maybe clarify what Lieutenant Elenberg was talking about yesterday. She was, I think, bringing up if there were two consumer complaints about the same lot of product and so forth that had come into the agency, that she would dispatch or ask to have a compliance officer go to the plant to -- and they would, you know, inform the plant and so forth of the complaints that we found or that were reported to us, and expect the plant, then, to initiate an investigation into what happened. That would not necessarily equate to any enforcement action that would happen to that plant or at that plant, provided the plant followed through, then, and did maybe the same type of actions that were, you know, suggested here by the panel to go through, try to figure out exactly, first of all, whether or not they're dealing with a food safety hazard, that the material that was found that triggered the complaints were a food safety hazard.

Assuming it's not, then sort of go through and look at their prerequisite programs and look to see where the failure may have occurred and to see what changes they need to put in place. So I don't think that we should think about, you know, notification of the plant, that we've gotten "X" number of complaints, and even the dispatching of a CO out to the plant as something that's automatically going to trigger an enforcement action.

MR. PURICELLI: Any more?

(No response.)

We'll do the last scenario and then continue discussing. The last scenario, we have a large red meat slaughter and packing company and deals with many suppliers and regularly produces a large quantity of meat for a local grocery chain. The establishment conducted a hazard analysis of the slaughter operation and found that while physical hazards for metal were unlikely to occur, based on historical data, they knew it did occur infrequently and they could not stop it from coming into the plant. So to be on the safe side they installed a metal detector prior to the packing area for the smaller wholesale and retail cuts.

One day the metal detector indicator sounded on several cuts of skinless meat. The meat was segregated and found to contain buckshot. Examination of the tissue also showed small penetration holes. The QA supervisor was called and production was stopped until all the contaminated meat was found. The source of this meat appeared to be a carcass whose animal ID was left intact. The paperwork for this animal showed that it came from a small independent ranch that sold its stock at auction and that this was the only animal purchased from that lot.

MR. LINK: I've never found buckshot in a turkey, but apparently it's a problem with cattle. You know, at first blush it looks like -- I mean, I know they can't stop it from coming in. They're going to get some cattle in apparently that has some buckshot. Without getting into the lead contamination issue, just from a foreign material perspective, it appears that their program worked as intended. The metal detector went off. They were able to isolate all the product, actually identify the animal back to its source. So it appears that it worked, without getting into the contamination issues. I can't go there. I don't know.

DR. BURSON: I think there are some things here that the plant could do. The last part of the scenario that talks about identification of the supplier, you'd certainly want to contact them and provide notification about it. If it came from a ranch in Nebraska, they may not have any knowledge that it had buckshot in it. You get out in the middle of the Sandhills and the cattle out there, you can't watch them all the time. But it is something that should be a notification back to them and certainly education of the producers and maybe even the hunting population would be a good idea at some point.

But one other thing that confuses me somewhat in trying to work with companies is in this portion where we talk about the physical hazards were unlikely to occur. And then based on historical data, they knew it did occur infrequently. And so in doing your hazard analysis, do you recognize that and then say, no, you're not concerned about it because it's infrequent, or do you leave it off? We've run into those kinds of decisions in putting together HACCP plans, and we've always been taught, from a HACCP standpoint, from science that we'd like to brainstorm and recognize things that could occur during the process. And so here's another cases where that kind of comes out, you know, that it infrequently happens in your facility. So do you recognize it on your plan, or do you not? And my sense is that you recognize it and justify it in that it's an infrequent occurrence, but sometimes that's not how it comes out through companies and working with local inspection.

DR. SVEUM: Just to follow-up on what Dennis said, I think what they've done with this hazard analysis, they've looked at the occurrence and realized that it's not going to be that frequent. So what they have done is put in a preventative measure or prerequisite for the metal detector and it worked. But what's really unique about this is this animal ID source really allows you to segregate this small portion of the product that may have the buckshot and allow you to do a salvage and probably x-ray this and know that it's not throughout your system because you've got animal ID and know the source. You've got it rejected to the side, and it probably doesn't say that your entire lot is at risk. And I think that's what the records here also allow you, and the controls they have, to then minimize your potential exposure. I think it's an example maybe of additional prerequisites such as recordkeeping, things like that, and your conditions with your vendors.

MS. CRAWFORD: Cathy Crawford with Advance Foods. Under this scenario and the proposed directive, doesn't this point pretty clearly that you are going to be essentially forced to have a CCP for metal at this facility?

MR. PURICELLI: I think what it does, this scenario, it says this would be an unforeseen hazard. And so it would be a reassessment under 417.3(b), which they've met some of that already by segregating. So in the scenario they've covered that. And what we would, again, expect them to do is, you know, just to show, is it now reasonably likely to occur, I think, based on, you know, the research? Is it just this supplier, or can they do something about it? And I still -- You know, the quick answer is no, it doesn't mean they automatically would have to have a CCP for it. It depends on what they can show in their records and what their corrective actions are.

MR. LORIMER: I'm Gary Lorimer with Henningsen Foods, and I had two questions. First of all, on metal detectors, would you require a scientific statement that metal under the detection limit is not a health hazard? And, secondly, in the case of the wood in the combos, what if that wood was found in the combo before grinding and that combo was destroyed and not used? Would the rest of the product from that day be contaminated and condemned? Thank you.

MR. PURICELLI: Anyone can take it. I don't think there's a quick answer. I think it depends on the situation. I mean, we -- I don't think we're going to say we would necessarily require a certification that has to be from anything, but, yeah, we'd want to see what the plant does, you know, what can they justify and how much they can detect. I mean, there are two levels to it. There's the food safety, the hazard part of it, and then there's also the removal of anything. So if I say at a hazard it's .8 millimeters -- I'm just guessing at something. Let's say you've determined it's a hazard of .8 millimeters, so we expect you to get that out. But if you can detect lower, we'd like you to get that out, too. But the directive says, you know, any visible or detectable needs to be removed. If you can't do any better, and you can show to us that you can't do any better, then case-by-case. The product would be released, like we said yesterday.

The second part was the wood in the combo. That, again, depends on what the establishment did in terms of showing that they had isolated it or they had evidence that it was only in the amount of product they found. Nothing is automatic. They wouldn't say, "No, it's the whole day's production," or whatever. I mean, you'd get a chance to show us the steps you were taking and the evidence you have to justify your decisions. And I think -- And like we would expect the inspectors to review that, and if they have questions, to tell you what else they need. I mean, that's -- Nothing is automatic.

DR. SVEUM: Just a comment on the wood on the pallet of product. Another way of looking at that is when I talked about the series of controls that we have at Oscar Mayer, at a batching operation when a pallet is dumped like that, the operator is making a visual inspection. So that may be where that piece of wood was found. And since they're doing that with every batch, it would be isolated just to that particular pallet. So that's one way of minimizing your risk, as well as having many intervention points in the process for reinspect. So rather than going all day before you look and realize potentially wood was ground up, you know, taking apart the various pieces of equipment you easily get to different segments between pallet, between lots. Those kinds of things will minimize your exposure and justify why you would limit it to a smaller portion.

MR. PURICELLI: Question?

MS. KOLL: Yeah, Diane Koll at Pilgrim's Pride. What was the prerequisite program here? Was it the metal detect -- Putting in a metal detector was the prerequisite program?

MR. LINK: That's what I understood.

MS. KOLL: Okay. So why would you have to reassess your HACCP program if this happened, because clearly it worked, because you found the metal before it got past your plant?

MR. LINK: I think the answer is, you found the potential food safety hazard through your prerequisite program, so now it's a question of going back and looking at the hazard analysis and determining, "Did I address this properly? Is it going to happen again? Is it going to happen at a frequency that I need to do something different?" So I guess you have to just go back and look at the hazard analysis and see if you've done it properly.

MR. PURICELLI: Right, yeah, thank you.

MR. TILINSKI: Bill Tilinski, Premium Standard Farms. All three of these scenarios, it looked like in the hazard analysis, in the original one you said there were no hazards that were likely to occur in your hazard analysis. And I was just curious on these, what changes would you make to your HACCP plan? Would you do a reassessment for an unforeseen hazard for each of these and document that and have that on record? Or what documentation would you actually do to show that you handled this appropriately?

Because it looks like, you know, Lee is expecting the plant to do a reassessment on each of these and have something available to be looked at by the agency. And I was just curious on what exactly you guys would do as far as documenting each of these things and addressing it specifically with your HACCP plans.

MR. PURICELLI: Let's see. Were all the scenarios the same?

DR. SVEUM: I'll take a shot and then Charles is going to back me up. The easiest one to me is where the employee didn't follow practice. That, again, this was the wrapping of the pallet. That's a special cause. That's a training issue. To me, you had a prerequisite program in place. That's not a reason to review your HACCP plan, it's to review your training procedures and simply to document that you've worked with that employee and explained the correct process.

This scenario three with the metal detector, to me this is a success. The prerequisite program was designed to meet an infrequently occurring hazard. Occasionally, buckshot is going to come through. You realize it's not going to be of consequence every time, so you put in a prerequisite program to control that, and it worked, and you've got it isolated. And, to me, the system is working. So I don't see the need to reassess the hazard analysis on this point because you determined that it's an infrequent occurrence, except in the Sandhills of Nebraska. But you have that kind of control.

And what was the first scenario? The wood. And the second one, unfortunately, from my perspective, it looks like all of a sudden the defect rate is spiked. The point was made earlier that there was a very low level of complaints over two years, five, but now all of a sudden when you went in and did an audit you had a 2 percent defect rate. Something has changed in that process, not necessarily that these gloves would cause any kind of chemical hazard, and it doesn't sound like the size -- I mean, you'd be asking these questions, if size would cause any kind of choke hazard. But you've got something that's not on the label and something has failed within your GMPs or within your purchasing system that you've got some material that you're working with, employee protection material that's not functioning. That's kind of how I would look at it. Now, I realize I'm not with the agency, but --

MR. LINK: I don't even have anything to add, other than, you know, we just talked about that third scenario, and I guess you could debate whether you do actually do a -- go back and look at your hazard analysis and see if you need to do something different or not. I agree. The system worked. The program worked. It found the buckshot. I guess it depends on how often that's really happening. If initially you said once a year it might happen, and if it happens to be more, we don't know that. But -- So you may have to go back and reassess and you may not. I guess it depends on the situation. The short answer is always.

MR. TILINSKI: Just to ask the people from the agency here, if a situation happens where there's a prerequisite program in place and the HACCP plan says there's not a hazard reasonably likely to occur, if a hazard occurs, would the inspector write an NR because that hazard has occurred, and request that a reassessment be done? Is that what they're being asked to do? Because that seems to happen on a frequent basis when there is a prerequisite program in place and your plan says there was not a hazard likely to occur. If any type of hazard occurs, there's an NR written because the HACCP plan did not specifically address that.

MR. PURICELLI: I'm trying to -- I don't -- I would say -- Yeah, I mean, if that occurs, it's an unforeseen hazard and we expect you to do the 417.3(b). I don't know if we'd always necessarily write an NR. I think that would -- I don't think it's -- You know, I'm not saying you would automatically -- yeah, it depends -- I think in the two scenarios, let's do the first one where they made the mistake. In that case, you are more likely to have an NR because they didn't do what they said they were going to do. Then we'd want to see the reassessment addressed. You know, are they going to get it in order? That doesn't mean they automatically have to do a CCP or anything. They just have to retrain the employee or whatever. That could do it.

In the last one, it's true. You know, I'm reading it closer. It worked. So at most, you know, we would expect the establishment to make sure that it now hasn't become a hazard, you know, because it is a prerequisite program. So we do want them to make sure that -- I think the best way to say it, that the prerequisite program still is showing the justifications that this isn't a hazard reasonably likely to occur. But I don't think -- There would probably be no NR in this situation because it worked.

MS. KOLL: Diane Koll at Pilgrim's Pride. If I got an NR for an unforeseen hazard here, wouldn't I successfully be able to appeal that? Because how can it be

unforeseen if I put a metal detector in because I've had
incidents of buckshot coming in the plant?

MR. PURICELLI: Right, yeah, I would say you
wouldn't get an NR, that you would not get an NR for that.

MS. KOLL: And it would not be considered an
unforeseen hazard, correct, because I have a prerequisite
program that deals specifically with --

MR. PURICELLI: Exactly. I would think it
probably -- I still think it may not be -- have to be

treated under the 417.3(b), this last scenario, but, again, you know, I think as the directive does say, you know, in your prerequisite program, although this one is catching, so it's working, but we'd want you to look to make sure it's not a problem. I think that would be part of the corrective action that described it. You know, someone said like call the establishment, or call the supplier, or the farm and let them know you've got something with buckshot. Handle it that way. But I don't -- I would say that probably no, in this scenario it wouldn't be a 417.3(b) type of unforeseen hazard, because you did have the program and it caught it.

MS. KOLL: It would be great if the agency could, like, write their opinions of what would happen in each of these scenarios because we do have so many differences on our own in-house inspectors on how they would interpret whether this was an unforeseen hazard, whether our system worked, whether we had to put in a CCP.

MR. PURICELLI: Okay. Any more questions?

MR. BROWN: Mike Brown, Cloverdale Foods. I'm bringing this one up because the scenario has not been given here. But, briefly, it's a metal detector was on the HACCP program. The morning before it started up, coincidentally, it happened to be checked and was validated that it was working, it was calibrated, et cetera. At start-up it was checked. Thirty minutes later it was checked again. It was working. Thirty minutes later it was checked. It was not working. So the line was stopped, et cetera. The metal detector was checked out. At that point it was found that a board had to be replaced. The board was replaced by the maintenance department and the line was started up again. Thirty minutes later the line was checked again. The metal detector was not working. The line was stopped. At that point the metal detector was checked to see what was wrong, and, again, it was the same board.

The answer to the first one was the board was going to be replaced and that would prevent it from ever happening again. I wrote the same thing for the second one and received an NR because I'm told at that time that the replacement of the board the second time is not going to prevent this from ever happening again. So, therefore, I was also told this could not be a CCP because you cannot prevent this from ever happening again.

MR. PURICELLI: That's kind of case-by-case. I don't know how to answer that one. It doesn't seem -- You'd have to appeal it.

DR. MARCY: Lee, I've got a question. You know, currently if product falls to the floor, a lot of plants have been told if they have a standard operating procedure for dealing with dropped product, that does not constitute an SOP deviation. With this new directive, will that change that, or can you give guidance as to what should be considered, you know, on foreign material -- possible foreign material contamination through prerequisite programs, like a standard operating procedure versus SSOP?

MR. PURICELLI: Yeah, I don't -- This directive really wouldn't address -- we're not talking about foreign -- That situation wouldn't be covered in this directive in terms of foreign materials. It would still continue to be an SSOP type of activity that the plant would deal with or the sanitation performance standards. I would think that -- it worked into their SSOPs, they could have procedures to rectify products falling on the floor, and I would assume that would be acceptable based on the inspectors agreeing to those procedures. But I don't see it really as something in the foreign particle area or material area. It really falls under, I think, that paragraph C on page 2 where we talk about it just doesn't deal with, you know, rail dust or finished product standards.

MR. GIOGLIO: I have a question for the panel just really to maybe generate some discussion here. If an establishment is using the data from its prerequisite programs in its hazard analysis and possibly based on that data has concluded that it does not have a hazard reasonably likely to occur, let's say for foreign material, and that's, you know, this ongoing data that's been -- you know, it's being generated over time. How often should, you know, should you as the establishment, we as inspection, be looking at that data to -- and how do you go about making the determination, based on some of the scenarios here, that incidents did happen and the incidents may or may not have been food safety hazards, but let's say that some were. How, then, do you go about analyzing that information to determine whether or not your hazard analysis is, in fact, still valid and that the decisions that you made, say, a year ago or year-and-a-half ago are still the correct decisions with regard to the way your HACCP plan should be written and operating now?

DR. BURSON: I think one of the things is that there's supposed to be a yearly reassessment, right? And so the plant has the responsibility to check those things out in their reassessment process.

MR. LINK: If we reference in our HACCP program that we're going to -- you know, I guess data that we've collected is supporting the decision we made, we try to review that data on at least a monthly basis and look at, I guess, a summary of what we've seen, what we're finding over time, to see if it's consistent with where we were a year ago when we made that decision, or if we're starting to trend upwards or just what's going on. So we try to take that data, summarize it, review it routinely throughout the year just to make sure that we're still on track.

DR. SVEUM: Yeah, I would just follow up on what Charles said. We would do an internal summary, and the frequency is going to depend on the kind of infrastructure you have. Sometimes it might be a quarterly review, but, you know, often when you have a foreign material issue, you might -- you're going to do an immediate investigation, and that's almost an assessment on site. And it could be for something that is a special cause, that's a one time occurrence, something got behind a grinder plate and you do the assessment. But really the structure is what Charles referred to, and particularly if you have a large organization, you're rolling up this information, particularly to purchasing, because a lot of the things we look at is from the incoming raw materials. And there's an interaction that's going on with that group right there and there's follow-up that's constant, and, of course, the annual validation.

DR. MARCY: And I would make the comment that both prerequisite programs and HACCP, you know, may or may not prevent something from happening. The whole goal is to prevent it from leaving the plant. And any occurrence of foreign material in commerce should trigger a very close scrutiny of how best to make sure it doesn't happen again.

MR. BREHMER: I'm Brent Brehmer with Hormel Foods.

And maybe I missed it, but I just want to know how story number two ended with the blue glove. I just wanted to know what's going to happen with the product, the product that's in the plant. According to Mr. Derfler, if we've decided or been able to prove that it is not a food safety hazard, still it's adulterated, what's going to happen?

MR. PURICELLI: There again, in terms of -- they'd have to look at the prerequisite program, you know, go through the steps to determine -- Okay, they determined it's not a food safety hazard. Then make sure the prerequisite program is still effective. And I guess -- and then take action on -- Let's see, they pulled 100 salamis, and I guess they found it in two. So I guess the other 98 are going to be okay.

DR. SVEUM: Depends on how hard you look.

MR. PURICELLI: Well, yeah. Well, I was giving everyone the benefit of the doubt.

MR. LINK: Then what do you do with the other 8,000 salamis that are sitting in your cooler?

MR. PURICELLI: I thought you were on my side.

MR. LINK: I'm on your side.

MR. PURICELLI: Charlie?

MR. GIOGLIO: I can only give my just an off-the-top-of-my-head answer, not necessarily saying that this, you know -- what's going to be written in the directive or whatever. But I would think that it would then become incumbent on the establishment to come up with a reexamination plan if, one, they've determined that the product is, in fact -- that the material in the product, the foreign material was not presenting a food safety hazard. Let's put -- answer that question that way.

Then I think the next step, and maybe we talked a little bit about this yesterday, is to come up with a reexamination plan to sort or, you know, you want to call it a salvage plan, or a sorting or whatever, to sort that product that, in fact, has the adulterant in it and that which doesn't. And, you know, in this case with, you know, threads of -- blue threads of a glove or whatever, you know, I'm not exactly sure how you would do that, and I don't know if this is, you know, based on a real life situation. But I think there has -- You know, we have to work to try to come up with a reexamination plan to sort through what product is, in fact, adulterated and what's not.

And I think it comes to some point where, you know, there may be, you know, some such low level amount that, you know, the agency would, you know, work with the establishment on making a decision on the disposition of that product. But I think what you need to think about is what the particular material is that you're looking to sort for and then try to come up with the best either equipment or system to sort through to find that contaminant in that product.

I mean, in the case that was brought up, you had consumer complaints and so forth that triggered it. So at least the cons- -- I mean, it is something that the consumer is objecting to, to some degree, even though it may not make them sick. I think, you know, from some of the data that was presented yesterday, consumers can still have violent reactions, even though they're not, you know, maybe clinically ill. They still have, you know -- They still react to something that they don't expect in their food.

MR. POCIUS: Joe Pocius with Pilgrim's Pride. Charlie, let me ask it a different way because I was going to ask the same thing. I don't think we got the rubber glove thing, or cloth glove, whatever it is, resolved yet.

Let me ask first one thing, and this is, again, this is just devil's advocate. I don't necessarily hold this position, but I really love the debate. If we've gone from two in 750,000 now to two in 100, according to the discussion that we've had, our frequency went up. In reassessing, well, the frequency has gone up; therefore, maybe now it belongs in our HACCP plan. If we've had a prerequisite failure and the frequency has increased, do we now have a CCP that we have to put into the HACCP program? That's part one.

But part two, Charlie, with the product, our table back there seems to think we have a Class 2, maybe at least a Class 3 recall. I think that was what you were asking. If it wasn't, that's what I'm asking. Are you going to classify us and come to us and say -- I mean, there's a lot of different ways of handling this product. But the first reaction to most people is you've got a recall on your hands.

MR. GIOGLIO: Let me just say, and I don't mean this to just be a conversation between Joe and I, but I'm not in the recall business so I don't -- I don't know. I mean, I think that's going to be a completely different set of decisions that have to come into play there.

I think the first question, Joe, to answer your point, is you need to decide whether or not there is, in fact, a food safety hazard. In the case I thought we were talking that there was not. If the product is in the marketplace and it's at, you know, 2 percent defect level and consumers are complaining and there may be some unreported complaints and so forth, I think possibly a recall decision has to be made. I'm not saying, you know, one way or the other based on a fictitious case here, but I think that is something that would have to be considered by the establishment and, you know, if the information had come into the agency, they may ask you to consider that. And it may probably be a Class 3.

MR. PURICELLI: Anybody want to touch that first question on the CCP?

MR. GIOGLIO: I thought we had said really, I guess, that the question of the HACCP plan wouldn't really come into play if you've been able to show that, in fact, the hazard -- the material that was found is not a food safety hazard. I mean, that would be the first threshold question, I think, that has to be overcome. That doesn't say, you know, otherwise -- yeah. It wouldn't fall into the HACCP plan. You may need to look at your other prerequisite programs and other controls that you have in place at the establishment.

DR. MARCY: The other concept, Joe, is that just because a prerequisite program wasn't working doesn't mean you can't change that. You're going to eliminate that situation. That doesn't put it in your HACCP plan. I would assume you're not going to choose to put it in your HACCP plan. I can't tell you what you'll be forced to do.

DR. SVEUM: Yeah, I would just add the answer to the first question as we've discussed, it's food grade material. We don't have any pieces here that present any kind of choke hazard, those kinds of things. So we're not talking about the need for a CCP. You know, it could be as simple as just daily evaluation of the glove or a glove change every day, so a prerequisite. Really where it's more of an issue, this is probably a Class 3. There's no food safety hazard here. What we have is something that's not on the label and now you get into that negotiation, and you've got product on hold that has a 2 percent defect rate, and it may have only occurred in the last few days, that these things fray the most towards the end of the fourth month. In fact, I read right here this is the end of the fourth month, so they frayed just yesterday.

(Laughter.)

But, you know, and so you can look at what you have on hold and do an aggressive sampling plan to determine what the defect rate is, but it's not on the label. That's the issue.

DR. BURSON: I think there's some things you need to consider as a company, too. What kind of image do you want to have? The customers are complaining about something and you know it's out there in the marketplace. Are you willing to sit there and say, gee, it's okay to pass this stuff on? Or are you going to take some action to deal with the product in some way, whether that's retaining everything that you have in control or going through a Class 3 recall or whatever. But, you know, I know it costs money to put things in the landfill or wherever you go with it, but what's the reputation of your company worth, too. And so there's some other considerations here.

MR. PURICELLI: Okay, very good. Anything else?

MR. HONTZ: Lloyd Hontz with the National Food Processors Association. I had a couple of comments and questions, not so much related to the scenarios, but more related to the directive and the direction that the agency is headed. In the 1999 HACCP petition that NFPA and AMI and a number of other trade associations submitted to the agency, one of the points we made was that there was, indeed, a need for a dialogue between the agency and the industry on the role that prerequisite programs would play. It seems to me that with the two-day conference that we have here, we are initiating that dialogue and are, indeed, opening the door to more formal agency recognition of the importance and the role that these prerequisite programs play.

One of the comments I wanted to make was in regard to a provision in the directive that if the inspector finds that a company is -- does not have a HACCP/CCP because of the existence of a successful prerequisite program, the procedure, I presume, is to call for a CSO to come visit the plant. I would like to mention that this policy is in effect now and some of our members have had very good experiences with recognition of their programs by a CSO.

I wonder, however, though, as this knowledge of agency policy becomes more widespread, are there going to be enough CSOs to visit all the plants who might be doing this? And I wonder if at some point in time the inspectors in the plant will be able to acknowledge the existence of these programs on their own, without the need for a CSO to visit? And also in regard to the inspection personnel in the plant, we have had concerns that possibly, if you're mentioning in your hazard analysis the existence of a prerequisite program, then we acknowledge that the agency does have access to this information. But we have a concern that inspectors in the plant possibly could spend their day looking at prerequisite programs as opposed to looking at HACCP issues, which, in our view, are much more important. Any comments or discussion about what kind of access the inspection personnel in the plant would have to these prerequisite programs, and also whether possibly a summary of data as opposed to individual daily records might be suitable?

MR. PURICELLI: I would say for -- what we're trying to -- the instructions in the directive and other instructions we give -- what instructors should be looking for with the prerequisite programs would be that the records and the justification remains still that it's not reasonably likely to occur, and then also look at them. If there is an occurrence, to make sure everyone has responded. We are giving no instructions to routinely check prerequisite program records. That's not -- I mean, they are -- It's all part of HACCP. It's 417.5. So if they are checking records or checking a certain activity and there is a prerequisite program involved, then they may, you know, end up looking at those records. But they're not going to do record checks. They're not going to check for, you know, is it monitoring, you know, the prerequisite program and look for monitoring records for that. That's not the purpose. It's not -- The record review requirements are different for HACCP. HACCP, when we have record review requirements, you miss a record, you would get an NR. It's not the same type of thing for prerequisite programs. They support a decision. It's not individual activity that we're looking at. We're making sure that the decision is still supported by the records.

I can't really comment on, you know, the number of

CSOs and the plans for that. That would be more, I think, field operations. Did you have a last part that I missed? Did I get it all?

MR. HONTZ: About being able to look at summaries as opposed to individual records.

MR. PURICELLI: If it's -- That would probably be if it's suitable to the inspectors. If the inspector would get the information that he or she would need, again, that everything is supported, that would probably be fine. It's case-by-case, I think, and the instruction is not to have the inspectors look at every single record related to a prerequisite program.

DR. BURSON: A comment was made about making sure that we have dialogue. And I guess I would echo that. There are some things that are a lot easier to deal with ahead of enforcement action mentality. And so as I look at the audience here, we talk about prerequisite programs for very small processors, those that are in that category, I don't know how many would raise their hand in the audience here and say they're in that group. And so a meeting like this may work for some audiences and may not work for other audiences in terms of dialogue. And so I would encourage the agency to think about how do you dialogue with everybody if you're going to put more emphasis on things like prerequisite programs.

MR. PURICELLI: Any other comments?

(No response.)

I think that pretty much wraps it up. I will say the directive is on-line, and I believe if I counted correctly, probably come off today. It was put on the page, if you're familiar with it, where we ask for the comments in seven days. You can continue to send comments on it. It was a draft. It was really a draft just for review for the meeting. So we'll take the comments and it will continue to be drafted and put through our agency clearance process and the redraft will be re-posted for seven days. So this was just a real preliminary one, and then another draft that would be closer to what we would believe the signature stage, will go out for another seven days. So you can wait or you can send comments in based on this meeting.

(Applause.)

MR. DREYFUSS: Thank you, gentlemen. Thank you, Lee. We have an announcement for members of the AMI Inspection Committee, are to meet at the Technical Service Center located at the Landmark Building, at the corners of 13th and Farnam Street, at two o'clock today. And for those of you who are going, please meet on the second floor conference room, not the third floor where the offices are. Please go to the second floor.

This brings us to the -- just about the end of the meeting, and I understand Phil Derfler would like to present a few comments. Mr. Derfler is the Deputy Administrator for the Office of Policy and Program Development.

MR. DERFLER: I just want to close this out. First of all, with respect to prerequisite programs, probably next week we're going to be publishing a document in the Federal Register. It's a notice on E.Coli 15787. And in that document we have a discussion of prerequisite programs, that given the discussion that we've had today, you may be interested in looking at, even if you don't grind beef.

I wanted to reiterate what Lee said. The draft directive is intended to be a discussion provoker at this meeting. Obviously, it does reflect our thinking, but where we go from here is we'll take the things that we heard here today, the things that we get in comments from you, and we'll take comments even if the document comes off the web, and then re-think the document, and then another version of it will be posted through our program of putting our draft directives and notices on our website for comment.

The questions that you asked Lee that he started squirming about, I would encourage you to put in your comments. You know, some of our directives and notices have Q & A sections at the end where we try and address the questions that we get. And so I would -- I mean, the whole reason why we've started putting our directives and notices up for comment is because we want to make sure that there's no surprises, or we want to minimize the surprises, and we want to make sure that we're not doing things that are unanticipated consequences. So it's your opportunity to point things out to us, and I would encourage you to keep an eye on that aspect of our website and give us comments, you know, whenever you think it appropriate. And I would really urge you to do so.

The last thing I wanted to do was say thank you's on behalf of the agency. I wanted to thank all the speakers and panelists. Obviously, there was a lot of preparation and thought that went into those presentations. They were extremely thought-provoking for us, as well as very informative for us, and I want to thank each of the presenters for what they did.

I'd also like to thank the Technical Service Center, DuWayne Metz, who hosted this meeting, Lynvel Johnson, who was a major contributor to it, Gaye Gerard and Edi Kelly who sat outside and greeted people and had you sign in, and Ron Eckel and his staff who played a really significant role in the planning for this meeting.

I'd also like to thank the National Food Processors Association, first of all, Alice Johnson, who sort of provoked me into having this meeting, and I hope it was all worthwhile, and Lloyd Hontz for the role that he played in helping us prepare for this meeting. I'd like to thank the representatives of the Office of Public Health and Science from the FSIS who talked here this week, Kimberly Elenberg and Dr. David Goldman.

And, finally, I'd like to -- Well, not quite finally. I'd like to thank the people from my office who played a major role in bringing this off, Moshe Dreyfuss, Lee Puricelli and Charlie Gioglio, who led the effort. And, finally, I'd like to thank all of you for coming. Hopefully you've learned something. Hopefully -- But what was key, your participation, your questions, your comments and everything like that really helped make this what I hope is a very, very valuable meeting, and I'd like to thank you very much for attending. With that, have a nice trip home.

(Applause.)

(Whereupon, at 10:50 a.m. on September 25, 2002, the meeting was concluded.)

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