

UNITED STATES DEPARTMENT OF AGRICULTURE

IN RE:

FOOD SAFETY AND INSPECTION SERVICE PUBLIC MEETING -
IMPROVING THE RECALL PROCESS

Hearing held on the 12th day of December
at 8:20 a.m.

Washington Plaza Hotel

10 Thomas Circle

Washington, DC 20005

TRANSCRIPT OF PROCEEDINGS

BEFORE: HONORABLE PHIL DERFLER

MEMBERS OF THE BOARD:

DR. ELSA MURANO

DR. GARRY MCKEE

DR. ARMIA TAWADROUS

DR. KRISTIN HOLT

DR. ANGIE SIEMENS

DR. KENNETH PETERSEN

York Stenographic Services, Inc.
34 North George St., York, PA 17401 - (717) 854-0077

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P R O C E E D I N G S

December 12, 2002

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MR. DERFLER: My name is Phil Derfler. I'm a Deputy Administrator of the Office of Policy, Program and Employee Development. That sounds really weird. And I'd like to welcome you all to the meeting today on how to improve the recall process at FSIS. To start it off, I'd like to introduce the Under Secretary for Food Safety, Dr. Else Murano.

DR. MURANO: Buenos dias. I don't think people are awake yet this morning. Good morning everybody. Thank you for coming. It's a pleasure to be here this morning and to welcome you to this public meeting on recalls. I'd like to, on behalf of Secretary Veneman [ph], USDA and the Food Safety Inspection Service to welcome you all; to tell you that we are glad that you could join us this morning. I want to commend FSIS for bringing together individuals from academia, consumer groups, industry, Congress and within FSIS itself to address this very important issue, that of recalls, which obviously has been in the media spotlight over the last few months. This is our last public meeting, so to speak, for the 2002 calendar year and I want to express to you how important and productive these public meetings have been for USDA. We've had

some very good, open, and frank discussions on a variety of issues, such as epidemiology, pathogen reduction, animal production, food safety, and listeria monocytogenes that are -- some at last month and also food safety education, our meeting that we had in Orlando. So all these meetings have been instrumental in helping us improve the scientific basis for our food safety programs and policies. So I will tell you that these meetings will continue over the next calendar year on various other topics. The role that these public meetings play is not only crucial in terms of helping us improve the scientific basis for our policies, but also to achieve one of the five public health goals that I outlined for the agency last year, and that is to base everything that we do on science. So the more input that we can get from the scientific community and from other stakeholders the better off we are. Well, considering my background in microbiology and food science, my Deputy Under Secretary, Dr. Merle Pierson's background in biochemistry and food science and microbiology and our administrator Dr. Gary McKee's background in microbiology, public health and environmental science, you can see how important -- and

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that we mean it when we say that it is important to us to base our decisions on science. This meeting comes on the heels of some of the largest recalls the agency has experienced since FSIS, or actually its predecessor agency, instituted a voluntary recall procedure after the passage of the 1967 Wholesome Meat Act. I believe that the time certainly is right to examine our recall process and I want to have today's meeting be the venue for this important work. We certainly don't expect to get our job done today just based on this one meeting. But I am looking forward to get practical science-based recommendations from the participants so that we can improve the recall process. With the recommendations that you will provide us by the end of the day, we hope to be able to walk out of here with quite a bit of homework to do, as a matter of fact, so that we can determine what our next move should be to improve recalls. We all want recalls to work in the most efficient and most effective way because we want to protect the public health above all. Speaking of public health, it's my great pleasure to introduce to you our next speaker, who has been in the field of public health for the last 30 years, a little bit longer than me, and

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that is Dr. Gary McKee, our new FSIS Administrator. He brings his expertise and a solid track record in managing public health programs and he is, of course, at the helm of FSIS and we're very glad to have him on board. He's already making a tremendous, positive impact on our operations. So with that I will turn it over to Dr. McKee.

DR. MCKEE: Thank you, Dr. Murano. On behalf of FSIS, I want to welcome all of you here today to this meeting. I'm extremely glad to see so many folks from different sectors of the Food Safety arena. Diverse stakeholder input is extremely important to help improve food safety for everyone. We are here today to explore ways in which we can improve the recall process. Any process, no matter how well-oiled, needs continuous improvement because the environment in which it operates keeps changing. There are many ideas and opinions on how the recall system needs to be improved. However, we are all here with one common purpose; that is to improve the recall process, effectiveness and to maximize the public health safety. Mr. Phil Derfler will discuss today's meeting in more detail with you shortly. However, I'll briefly point out that today's agenda will

be divided into two main sections. And during the afternoon -- excuse me, during the morning we will focus on the current recall process that is in place and during the afternoon we'll have a series of interesting panel discussions to determine how the system can be made more effective. The recall process makes me think of the personal motto from one of the nation's early pioneers, Davy Crockett. Let me step back a few years to the lessons in my high school class and in history we talked a little bit about Crockett's environment. Davy Crockett was born a few years after the American Revolution in the wild Tennessee frontier. His formal education amounted to only 100 days of study in the classroom. He learned most of his lessons in life through the harsh and wild frontier environment of the early 19th century. He faced death and hardship on numerous occasions, fighting the creek war, suffering a bout with malaria, a gun powder explosion which destroyed his business, crossing a raging, flooded river, narrowly escaping a sinking boat on the Mississippi River and assault at gunpoint by his political opponent for a Congressional seat, just to name a few. You see, with such a harsh environment and

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there is little room to err and to err with judgment, which is why Crockett's personal motto was "Be always sure you're right, then go ahead." Our world is vastly different from Crockett's. However, like the wild frontier there's little room for error in public health.

To protect public health, Crockett's motto, "Be always sure you're right and then go ahead," equally applies to our recall process. If we go ahead and recall the wrong product, based purely on speculations, then we haven't protected the public's health. Errors in judgment are costly to everyone involved in the process, especially to the public. Crockett's maxim is certainly applicable to help fulfill the vision I have outlined for FSIS. I'm committed to making FSIS a world-class, public health agency that is a model for other public health institutions. FSIS already has a solid foundation in place from a long proud history of protecting public health for nearly 100 years. Just as FSIS and its predecessors have done over the past century, the agency continues to evolve in a changing environment to carry out its public health mission. I see us now at the cusp of evolving into a model public health agency, especially after the implementation of the landmark

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pathogen reduction HASIP [ph] rule, which required preventage systems to control hazards and new microbiological testing and created a huge program shift for both government and industry. HASIP is a solid foundation on which we can build Food Safety improvements. Our new policies for e-coli 157:H7 and listeria monocytogenes are examples of how we can build on HASIP now and in the future. We will see further improvements as we upgrade our work force and training.

I'm very proud to be part of a dynamic food team at USDA. The appointment of gifted scientists, Under Secretary Dr. Murano, and Deputy Under Secretary Dr. Pierson to lead Food Safety policies based on science will help us become the model public health agency we seek to obtain. We stand at this cusp today and I'm clearly going to outline what I expect from our employees, as well as the industry we will regulate and what we need to do to make public health priority number one. We're holding ourselves accountable to the American people just as we are holding industry accountable for having validated systems in place to ensure food safety. Let me talk for a few minutes specifically about recalls, since that's why we're here

today. Results -- or excuse me, recalls present a unique dichotomy to us as we stand on the verge of achieving our public health vision. They are not our number one strategy or cure all to achieve this vision.

On the other hand, recalls are a critical tool for us to carry out our public health mission. What is the optimal balance? Because I answer that, let's examine -- before we answer that let's examine how recalls should not be the cure all. A recall of the product due to contamination tells us that there's a failure in the system and it should be a glaring stop sign, warning us to go back to the repair shop to fix the system. The repair can not be a band aid approach. The fix needs to be a long term repair based on science or else the public's health will continue to be placed at risk. Public health needs to be at the core of industry's operations. Simply recalling a product on a continual basis does not take us to a higher level of food safety.

And I imagine it can not be the most effective way to run a business as well. On the other hand, some recalls are necessary for FSIS to carry out its public health mission. It is our utmost duty to work with industry in recalling a product when contamination is found. Anyone

who believes the stereotype that government workers are ruled by a time clock and don't put in more than the required eight hours a day would quickly be shocked if they were to observe the FSIS team from the inside. Many of our employees worked more than 24 hours straight without sleep in the name of protecting the public's health during the massive recall of ready to eat turkey and chicken products in October. And that was during a holiday weekend as well. However, not all recalls are related to possible contamination. We believe it's very important to inform consumers from the public health standpoint whenever products are mislabeled, out of concerns for adverse reactions to ingredients not listed on the product. Now back to the earlier question, what is the optimal balance? I look forward to the day when recalls become a rare occurrence. I know recalls will continue and will be important to have them as a tool on hand to use readily in order to protect public health. But they should be a last resort. We must strive to prevent recalls from happening in the first place. When we get to that point, we know that industry and government are operating efficiently in their exclusive, yet complimentary roles of protecting public health.

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The dichotomy of recalls is an interesting one. But given what we do on a regular basis with them we have taken internal steps to make our operations more effective. These include improvements that are establishing a memorandum of understanding with states so that we can share distribution lists with them, adding representatives from USDA Food and Nutrition Service and the Agricultural Marketing Service on recall committee meetings, notifying suppliers to a further processing facility both verbally and in writing when a positive E-coli O157:H7 sample is discovered in ground beef supplied to that facility, and moving the recall management division to the office of field operations so that recalls can be conducted in a faster and more efficient manner. There are steps we have taken to improve the effectiveness of the recall process and help us evolve into a model public health agency. However, we are also looking for external recommendations to help us achieve our vision. In my short time here in Washington and getting to know many of you, I know all of you are deeply committed to improving food safety; that's why all of us are here today. And with recalls as one tool to improve food safety I do look forward to

the many diverse ideas you have to improve our effectiveness. I'd like to turn the program now over to Mr. Derfler.

MR. DERFLER: Thank you, Dr. McKee. I'm going to start by going and giving you a brief overview of the meeting and then we'll move on. This morning we're going to talk about the recall process. And the purpose of this part of the meeting is really three-fold. First of all, to give you all a frame of reference into what you're going to hear today would fit. Second of all, it is to educate so that people understand both how FSIS, some other federal agencies, industry and the states approach recalls, and finally it is for us to learn in comparing what we do and how the states approach it and other federal agencies approach it. Ideas for how to improve our process may well be generated. The morning is going to start off with me, and I'm going to talk about our authority to do recalls and under the current law. We will then talk about how FSIS approaches recalls and how we work with the CDC when necessary and when outbreaks drive the recall. After that we will have a talk on how a company responds to a request for a recall and how it goes through its own recall process.

Then we'll have a discussion about how FSIS works with the states, particularly in light of our new rule, which empowers us to share recall data with the states. Then we're going to have a break. Well, somewhere in there there's a break, I'm sorry. But then we're going to talk about how other agencies handle recalls. We're going to hear from both FDA and from the Consumer Product Safety Commission. After that, there will be a question and answer period. And one of the ways that you can provide your questions, out by the registration desk there's slips of paper for you to put your questions down on. And we would really encourage you to use that mechanism because those are the ones we're going to look to first and we'll only have, at most, a half an hour before we break for lunch. This afternoon we're going to turn to the questions, some of the questions and some of the suggestions that are presented to us about how the recall process can be improved. First question we're going to take is a major one and that is should the agency be given mandatory recall authority. We'll have the panel, both -- excuse me, of Congressional staffers, consumer representatives and industry representatives to discuss that question.

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After that we're going to talk about how public notification should be provided. Is the agency's current method of doing it appropriate? Are there ways to improve that process? After that we'll have a break and then there'll be a final panel that will discuss some other new ideas to recalls. When products should be allowed to enter commerce, whether FSIS should change the role that it plays in recalls and whether recall plans should be required of all plans. So that's how the day shapes up. And now I'd like to turn to the question of what's our authority to do recalls. As you've heard from Dr. Murano and Dr. McKee, we at FSIS consider ourselves to be a public health regulatory agency. We're empowered to ensure that the meat, poultry, and egg products in commerce are safe and wholesome as well as properly labeled. And we have a range of regulatory tools available to us for making sure that this is the case. What I want to talk is how recalls fit within those tools. The statement that FSIS is a public health regulatory agency bears some analysis. To say that FSIS is a regulatory agency is to say that it is an administrative agency that is charged with protecting the public from harm from meat, poultry

and egg products. As an administrative agency, FSIS is ultimately a creature of Congress. Its powers are limited to those that Congress has extended to it and the statutes that the agency acts to enforce. Thus, even though FSIS is the agency charged with protecting the public health from harm from meat, poultry, and egg products, it is not able to simply do whatever -- take whatever action it believes will best serve the public health. FSIS does not get to choose from an unlimited menu of options with the right to pick the one that is most protective. Rather, FSIS must look at the range of options that Congress has authorized it to take and decide which, if any, is justified based on the available evidence. Thus, that the question is not what action should FSIS take but what actions can FSIS take.

We need to turn then to the statutes under which FSIS works. FSIS is charged with administering the Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act. Under these statutes, FSIS inspects products before they enter commerce, decides whether they should enter commerce, and takes action to prevent them from entering commerce if there's reason to believe that the products may be injurious to

health, if they're unhealthful or if they're otherwise adulterated or misbranded, if their labeling is not correct. FSIS has a range of tools available to it to prevent products that may be adulterated or misbranded from entering commerce. It can retain the product in the plant, withhold the mark of inspection from the product so that it can not enter or move in commerce, or suspend and ultimately withdraw inspection at the plant.

Our focus today though is what FSIS can do when it becomes aware that there is reason to believe that product has already entered commerce that is adulterated or misbranded. The statutes that FSIS administers give it two complimentary courses of action. First, FSIS can detain the product for up to 20 days. In a detention, an FSIS compliance officer goes to where the product is located and puts a detained tag on the product.

Detaining product means that the product can not be moved. During the period that the product is detained, FSIS gets to develop and consider the available evidence and to decide whether it will bring a seizure action against the product. The seizure action is the second course of action open to the agency. Seizure is an action in the United States District Court by FSIS

against an article of food that is a meat, poultry or egg product on the grounds that the product was prepared, sold or transported or otherwise distributed in violation of the relevant law and thus should be removed from commerce so that it will not reach consumers. In a seizure the court takes control of the product until the case is adjudicated. If the government prevails in this action, the food is condemned and disposed of in an appropriate way, usually by destruction. If not, if the government does not prevail, then it moves on to the consumer. Remember we're talking about action against product that has been distributed in commerce. That means that a single lot of product may be dispersed to tens or hundreds of locations and that there may only be a small amount of product in any one place. Or the product may even have reached the consumer. In such circumstances, detention and seizure may not be practical. FSIS only has 175 compliance officers; there's a limit to what they can accomplish. It would be extremely difficult for them to identify all the places where the product is likely to be and to get to all of those places to detain the product. Despite this difficulty, when there's reason

to believe that meat, poultry, or egg products in commerce violate the law, the agency considers it extremely important to find a way to get that product out of commercial channels as quickly as possible. To deal with the problems presented by distributed product, FSIS and other agencies, like FDA and the Consumer Product Safety Commission, have developed the concept of a recall. Earlier I tried to emphasize that FSIS is a creature of Congress and of the authorities that Congress extended to it. Let me now be clear and answer the question with which I had started. There is no explicit authority to request a recall in the Meat Inspection Act, the Poultry Products Inspection Act or the Egg Products Inspection Act. Nevertheless, a recall ties back to the statutes under which FSIS functions, as I will explain. A recall is a voluntary action. FSIS asks that the company that introduced the product into commerce take action to remove the product from commerce. If the firm agrees, it contacts its consignees and asks them to collect the product and remove it from commerce as quickly as possible. The collection effort may include notice to consumers through a press release, shelf statement or even direct

contact, to return the product at the store to which they purchased it as quickly as possible. A recall, obviously can be a quick and efficient way to remove product that there is reason to believe is adulterated or misbranded from commerce. It is in the interest of the company to recall product because it helps the company limit its product liability and to minimize negative publicity. It also saves FSIS resources and most importantly, it helps to protect the consumer from product that can cause serious illness or other adverse effects. When FSIS asks the company to recall a product, there is the implicit threat that if the company does not, FSIS will institute detention and seizure action against the product. It is this implicit threat that ties the seizure back -- ties the recall back to the statutes. The threat means though that before FSIS asks for a recall, it must have some reason to believe that the product is adulterated or misbranded, unless that there is reason to believe that FSIS would prevail in a seizure action should it be necessary to bring one. So that is where we start. With the fact that FSIS does not have the authority to require a recall but that when FSIS asks a firm to do a

recall there is a fairly strong implied threat that the agency is prepared to act if the firm does not. So now we turn to how FSIS approaches recalls in an operational sense. How it learns that there is a need for one, how it decides whether or not to request a recall and what it does when it does request a recall. We will have two presentations on how FSIS goes about doing these things.

The first will be presented by Dr. Armia Tawadrous. And he will talk about how FSIS approaches the recall process. Dr. Tawadrous began his career in FSIS as an IIC, SBMO in a poultry plant in 1986. Since that time he has served the agency as a circuit supervisor as well as in various headquarters positions. He began working on recalls in 1997 and became director of the recall management division in 2001. Given his extensive experience with recalls, Dr. Tawadrous is well qualified to talk to us today about the agency's approach to recalls. Dr. Tawadrous?

DR. TAWADROUS: Thanks, Phil. Good morning. Okay. My name is Armia Tawadrous and I'm a naturalized citizen, needless to say, with my accent. Nineteen years ago when I applied to be a naturalized citizen, I wanted to be a full-fledged American and believe in the

melting pot theory, so I tried to change my name and guess what, I hear the song, Jeremiah was a Bullfrog. And that's what Armia is, it's Jeremiah in English. Anyway that's me. I thought the coffee might not be strong this morning. So we have fun in recalls, it's not all bad. Anyway, okay, as eloquently Dr. McKee and Dr. Murano has stated this morning this is a basis, what we do, recalls. Basically that's our goals and how do we move and function. And this is the main driving force to recalls and the important basis where we put all our action and decisions on, which is public health. FSIS stated and acted in its policies in the past and we said we are a public health regulatory agency, and as such we treat our recalls with the same emphasis. Class II and I is a good example of how we do public health in these recalls. Class III's were no public health even though we don't pose any public health, yet we are regulatory in nature as Mr. Derfler has stated. Simply defined, it's a voluntary removal of product in the marketplace that's in violation of the Act. Whatever prospective Act, Meat, Egg Product Act or Poultry, Egg Product Inspection Act. Why do we recall? As Mr. Derfler said we have and Dr. McKee stated in his speech,

that we don't have recalls as only means to deal with issues in the agency. It's just one of those enforcement tools that we have as a safety net when all fails and we have to do that. And by doing that it's a very fast and effective means to bring product from the market place that's been deemed to be either adulterated or misbranded. Who does recalls? Simply because it's voluntary in nature, it's the manufacturers and the distributors and FSIS ensure that the product is being carried out as it should be. Because we don't have, as you heard this morning, a regulatory authority to have recalls. However, having stated that, we can initiate recalls by requesting from the industry to do so. Whenever we have a need and we have substantiated proof that we have an adulterated product out there, we'll bring it to the industry's attention and they work accordingly. What triggers recalls? So many things can cause a recall to occur. The first one is consumer complaint that can happen. We have a system in place in the last few years which is centralized and very effective, whereby all complaints from the field and from the industry are pulled under one umbrella here in the Office of Public Health and Science. And through

that by working closely with them we do look into cases and situations and that can be a trigger for recall. The second one, which is actually -- I'm proud to say that it's been so many times and so many people in this room on their own volition, pick up the phone and say I do have a problem, I want to recall. And that's probably constituted like one-fourth of our recalls that's coming directly from the industry, coming to us either through the quality control, through their monitoring system, through the local HASIP methodology or procedures through which they deem a product that has been in the market, need to come back, recontact us and we work with them. But the bulk of recalls, it does happen because of the fact we have a very effective microbiological testing program through which we have a lot of positive samples that come indicating that a problem, either E-coli, Listeria monocytogenes or some other pathogens. A lot of recalls can come to our attention through the local inspectors who through their hazard effectiveness check we do find some problems through labeling or other issues, bring it to our attention, and that can be a triggering mechanism for recall. And Dr. Kristin Holt, who's going to follow me,

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she will speak about the illnesses, outbreak investigation and others as a trigger for recall. So that's basically the main problems and it comes to our attention and we deal with it. When a problem comes to our attention, as I stated previously, right away we deal with it and immediately we go to the industry and bring it to their attention. Some, granted, come to our attention through the industry. Either way, we act and work directly with them. And we send them a classical several pages that most of you know called recall worksheets, that's on our websites, basically to seek product information to help us in determining the scope and the depth and how we can go with the recall process.

Basically the recall worksheets includes all these items that you see. When the product was produced, what dates we are dealing with, the specific product name because we want to communicate to the public the specific problem and not to cause confusion, how much was produced, how much was held at the plant, how much in distribution centers, how much in the market place, how far did it go to a wholesale level, to a consumer level, to a retail level and we take care of any issues related to school lunch programs, child nutrition and

any product that went to the military or exported overseas. Additionally, to these recall worksheets that we request from the industry to complete to assist us in making a credible decision, we do ask for the hazard flow charts and the laboratory reports that could be because of a local third party laboratory that an industries are relying on to base their recalls and he has to put SSOT [ph] record that could have contributed to the issue, to the problem, any production record and naturally, distribution records that will aid us later on in doing what we call the effective check. As soon as we receive the recall worksheets and the information from the industry, we distribute it to our recall committee members so everybody will have a chance to look at the information, digest it before we have a meaningful discussion of how to proceed further. And there will come a time right after that to convene the recall committee, which we chair it, and our division, which is the recall management division and includes a lot of members depending which issue we are dealing with. And most of these are experts in multi-departmental and multiple interagency people that we work with. Mainly we work with the field, which is our

district offices where the problem has occurred. Also when we deal with microbiological issues we have to deal with our folks from the lab so that the microbiology division, seeking their expertise. If we have issues dealing with toxic agents or residues or things of that nature, we do have experts and all these are from FSIS.

In addition, when we have issues for public health that Dr. Holt will address you later, we deal with our medical doctors who are members of the Health Hazard Evaluation Board, which we resort to them quite a few time when we have a lack of precedence in a previous situation to seek their help to analyze for us the public health risks and the needs to have public health determination. Of course, our compliance folks are an important part of the committee because they help us to enforce the decisions and to ensure the effect of the check, which I'll address later. We have a lot of good partners who work with us from the media office, the congressional public affairs. They are a hard working bunch like the rest of us. They do work on very specific details in order to make sure when we communicate a recall to the outside it's specific, it's targeted, and it created the benefit that we intended

from having public health notification so the public not only would be notified, but also would be educated about the problem. As many of you have seen our press releases and others, it has steps of what to do and what's the causes, what's the consequences, what should you do, take it from the refrigerator, return it, don't eat it, dispose of, and so forth, which is served as a notification in addition to being an education to promote the public health issues. As Mr. Derfler stated, we have folks from his shop, which is the Office of Public Policy to help us, to keep us on the legal track to ensure that all our recalls are based on our charge as mandated by Congress and our Act, if it's the Federal Meat Act or the Poultry Inspection Act or the Egg Product Act. And we also have a lot of technical experts in addition to the core group that we have from our technical service center. If we have issues with child and nutrition programs or anything dealing with the school lunch, we have our partners, USDA from an early marketing service, food nutrition service and when we're dealing with a lot of issues for illnesses, outbreaks and what have you, we deal with the states public health representatives, the AG and Market

Departments, our partners in FDA and the CDC and others.

So as you can see, it's a multi-departmental interagency effort that we all work together. After we get together, everybody has the facts as stated by the industry to us, we do toss it around, evaluate the hazard, try to find what level we're going to go to, what classification and so forth. And that's basically what we do. At that time we're still in the process of making a recommendation of a recall because we haven't had a chance to formally engage the industry with us. So once we do finalize the firm recall strategy then it's time to get in touch with the particular industry and do the classification. Classes are known, as most of you see, Class I, Class II, Class III and I eluded to that earlier. Class I and Class II basically are the same except for the words that are highlighted in yellow, for the word reasonable. Because with Class I we wanted to see in any given population if they are exposed to that particular product, what is the consequences of adverse public health reactions or death. A good example to that, all pathogens, with no exception, underprocessing, which tell us that the product hasn't been deemed the desirable lethality so

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they fit into that and a lot of the undeclared allergens, which falls under the Class I, like the peanuts and the soybean and others. Class II is the same thing like Class I. It's involving public health risk but the chances for that to happen it's not reasonable but remote possibility. So given a room like this we all can be exposed to the same product, maybe one or two can show adverse consequences versus 50 or 60 percent. And a prime example to that, again, undeclared allergens, which with low dose or an unknown allergen that might not cause a lethal effect or an undesirable public health consequence but rather just a reaction. Class III, as I stated before, even though they have no public impact yet, they are regulatory in nature and as such we give it the same importance we do to public health. And basically those are materials like MSG and in very low quantities or misbranding, instead of putting turkey hotdog they put beef and things of that nature. Once we've done our thinking and we've deliberated among ourselves as experts in all these previous fields, we engage the industry. Of course, the industry's being engaged previously by sending us the recall worksheet and after they're completed if we have

questions, but we get a chance that the industries experts have a chance to meet with our experts and discuss the issues, answers, questions and we have any concerns being taken care of. So as you can see, being a voluntary process we give the industry the upper hand during this time in order for them to do it voluntarily with the understanding that we have a problem and we have a public health issue in order to deal with the problem. Once that happens we do request and ask the industry to go ahead and inform the consignees. And 99.9 percent of the case they already have done that because this is the first issue we wanted. We don't want to wait a few hours until we make it formally because it takes time, of course, until everything gets together. So we do advise them from the get-go, go ahead and verbally notify your consignees, they do that.

But then we ask them in addition to that to make sure that you send in writing to confirm that your consignees had a chance to receive it and understand it. So by the time we have the committee in action the product has already been stopped from being further distributed and some of it's on its way coming back. And we try to act as quickly and expeditiously as possible but at the same

time we're prudent in how to approach it. So this is my slogan usually, work expeditiously but prudently. And that can happen by telephone, by fax, by whatever possible means. Of course, we have to identify the exact lots as we need because we don't want the consumer out there to be totally lost when we say hotdogs from such and such plant. That could mean anything and everything. So we tried to be specific in order to be targeting a particular problem, not to be atrocious and irresponsible in our approach. But meanwhile we're achieving the public health consideration that we are working for. As you know, we have to explain the reason for the recall, the hazards involved in order to make it an educational and worthwhile process. It's not like intimidating or shoving things down the throat of anybody, but rather, we work in a very cohesive manner.

Of course, we will discuss when the product comes back, how it comes back, how we dispose of and how we deal with. And as I mentioned before, our CPA folks, the media, they work a very important control with us because we do have two forms of public notification. We have the press release, which is for every recall and we something called recall notification report, which many

of you, if not all of you in this room, do receive it. We have over 500 organizations and public health, state AG departments, CDC, our partner USDA and FNS and others. We do receive that for every and each recall. So everybody is being made aware of the fact that we have an issue with the details in it. In addition to that the press release goes to all the targeted areas where the recalls need to be advertised and that could be the print, the TV, the radio and others. Now as Dr. McKee had eluded and Dr. Pierson later on will discuss that in details we have MOU's with certain states and they do work with us so with that in place we share the distribution record with them whenever requested. Again, I can't say enough of that as I stated before. The whole thing is based on one specific goal to enhance, to promote, and to protect and ensure that public health is in place. And that leads me to this slide, which is the urgency of recalls. We do work very, very, very fast. You know I have a little one and I watch some cartoon called Speedy Gonzales. I know you know that and I always liked this guy. He runs around just fast telling the rat to eat the cheese. So sometimes we think of ourselves with a bunch of Speedy

Gonzales's. Everybody just as soon as the phone has information comes we do move and we do move very, very quickly. And as Dr. McKee stated we do spend a lot of sleepless hours and we are 24/7 wired up to take care of this mission. And we're proud to do that. And our reason for moving and acting quickly is two tiered. Basically to stop further distribution, as I said, and whatever is out there to come back as soon as possible.

Again, maybe I sound like a broken record but I want to drill this point more and more and more that again we're doing that because of our basic concept that we do that for the sake of promoting and protecting public health.

The only time that it elapsed between knowing an issue, if it's a lab notification, if it's a problem if it's and epi-illness, whatever the reason it could be is to allow the industry to obtain and gather all relevant and specific information related to the recall case in order to have a meaningful and credible public notification process and that's the only time we spent. A lot of times we have two or three o'clock notification from the lab. We end up eight, nine, ten o'clock in the evening to make sure that people in the west coast are able to see that before they have their dinner. So it's a

serious commitment. We take it seriously in all levels, it's not only our levels but all these folks that work with us that I mentioned that join us in the recall committee and I'm proud to say all our superiors that are here and down here, they all share this in that commitment. How many times I woke up my superiors at two, three o'clock in the morning to discuss an issue or to look at a document to make sure we are on the right track. So it's really a total commitment, not only on my level but all and everybody else who is involved in that process. Class III's, even though they're not public health related, but yet they have the same importance and we try to make them in the same day as Class I and Class II's. Of course, we have to conclude the issue quickly and that's been discussed earlier. When we are with the recall committee and studying the firm's E-coli strategy, we try to know how they're going to return the product, how we can make sure it's been done properly, we are adhering to the plan, that they told us they wanted to do it and as a result we have what's called the recall effectiveness check and that's very important. We are dealing with our folks and the compliance field and once that happens and we know at

the end that all means has been exhausted and no more avenues that any E-coli is out there and everything came back, everything's accounted for except, of course, what's consumed, then we do ask the industry to write us a letter stating this is what happened. And our folks from the compliance in the field, they already verified that fact. When that happens, we formally terminate and close the recall and remove it from the active cases to the archived cases. I just wanted to run by you what we've done in the fiscal year for 2002. This is basically the amount of recalls we have by type. As you can see we have the line shared for Listeria, we have for E-coli, we have for misbranding, undetected substances, strange materials, processed division, among other reasons. So as you can see we encompass a whole lot of issues and we deal effectively with a whole lot of issues that come our way. Considering the source, as I said, so many ways can come our way. We had an import issue actually came from APHIS because it might be surprising, some people say, how APHIS would be involved in that. But a lot of import issue that it comes on the border, it comes to our attention and then we have outbreaks and we have illnesses, we have photo-ops,

things come from our folks, which is the IIC, you go to the IIC or it could come from the industry themselves as you can see or from monitoring. So here we are, we come by the source. Again by the Classes, as you can see the lines share comes for Class I and that again emphasizes what I said previously, it's a public health consideration that we go after. Class II's, Class III's in this case is a little bit high because most of you probably remember a corned beef issues last year and that's what had Class III's to be that high. But normally with the Classes, Class I versus II versus III.

There are two other things that I wanted to -- a couple more to go I hope I'm within my time. A lot of folks do mix up recalls with the market withdrawal and maybe the way it's defined and the directive left some room for probably lack of understanding. But basically a recall, it's not a market withdrawal by any means. We can not substitute one for the other. A market withdrawal, in its simplest term, mostly something has nothing to do with the Act, no violation of the Act, which means it's not a Class I or II or III. And no public health hazards, of course, so it becomes a violation of a local company when quality control issues that the company had

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committed itself to. So that's why we call it market withdrawal. So it has nothing to do with recalls. Given that we still require that even if a company has a market withdrawal they let us know so our compliance folks can do effectiveness check on the market withdrawals the same way that we do in the regular recalls. So I just wanted to make sure that the definition is known so there would be no misunderstanding. Stock recovery, on the other hand, which has nothing to do with recalls or market withdrawals. When the product hasn't been offered for sale it's still under the total control of the company, hasn't gone anywhere, we don't touch that because we know that the industry has total control over it. I hope I gave you a great, quick synopsis on what we do. There is a lot more details that I could get in to, but for the sake of time, this is basically how we do run our recall process. I thank you very much.

MR. DERFLER: Thank you, Dr. Tawadrous, for your comprehensive and very informative talk. Next, because we're a public health regulatory agency, we thought it was important to emphasize how we work together with the Center for Disease Control and

Prevention and our other public health partners. And to give that talk we're having Dr. Kristin Holt. Dr. Holt has served as an FSIS veterinary medical officer since 1983. For 10 years she served as an in-plant supervisor at various poultry slaughter plants in Georgia. Dr. Holt has served in field operations as assistant area supervisor, circuit supervisor and deputy district manager. In July of 2002 she jointed the Office of Public Health and Science where she assumed the role of USDA's FSIS liaison to the Centers for Disease Control and Prevention. Dr. Holt?

DR. HOLT: Thank you, Phil. Just one minor correction. 2001 was when I went to the new position.

MR. DERFLER: Yeah, I just read that wrong.

DR. HOLT: I don't know if that was on the paper or not. Good morning. I've been invited to spend a few minutes describing how FSIS works with CDC and other public health agencies. I'm going to start with a brief overview and I will describe public health activities related to food born diseases that are performed by CDC and state and local public health agencies and departments. I will also describe FSIS public health activities that compliment the activities

of these agencies and I will talk of how FSIS interacts with CDC and the state and local health departments. The public health agencies, such as CDC and the state and local health departments and health agencies perform surveillance for food born disease. They also respond to reports of illness or outbreaks and they investigate using various tools such as epidemiologic studies, environmental assessments and laboratory testing. Prevention of illness is a very important public health activity both in responding to an outbreak to keep more people from getting sick and in the long term by applying new knowledge gained during an outbreak. Several of the other earlier speakers talked about FSIS and its public health mission. Our FSIS mission statement is posted on our website on our home page and that is our mission statement and clearly you can see that we identify ourselves as a public health agency. So along those lines I have a list here of some of the FSIS public health activities as they relate to food born disease. FSIS public health activities function in parallel to the activities of the CDC and state and local health agencies. What you will not see it on this list, surveillance because FSIS is not out tracking

human illness; that's the role of the CDC and the state and local health departments. However, FSIS does have reaching communication that keeps us aware of current events, outbreaks and also long-term trends in food born disease. You might consider this may be kind of an informal surveillance of the surveillance systems they have or maybe a secondary surveillance but we technically do not do human health surveillance. FSIS -- oops, would you mind going back? FSIS works in parallel with public health agencies and our activities are complimentary to the activities when people are investigating outbreaks. We are involved when an FSIS regulated product is suspected or implicated as the vehicle for infection. And prevention is also very important for FSIS and you don't see, I guess, any mention of recalls at this point. So some of you may be wondering if your copy hadn't kicked in or maybe my copy hasn't kicked in but recall does fit here in the FSIS public health activities. And on the next line you can see where recalls fit. It fits in a long array of things that we are doing. We have to work towards prevention of food born disease. We continually revise policy as we get smarter, do things more science based,

have information come in from risk assessments. We need to continue to enhance the skill of our employees to do our jobs better, smarter, faster, science based. We need to continue our food safety education efforts. We need to keep open communications with consumers and consumer advocacy groups and we need to foster industry initiatives. Focus on trying to lower pathogen levels on products. We work closely with the USDA agricultural research service, and they do research. We do not do research. But we share, I guess, our wish list with them where we recognize the gaps in knowledge, gaps in the science. And of course, prevention. The immediate preventative action that we do is work with industry to achieve the recall of adulterated product and alert consumers. Arma had a better list, I guess, of categories, the types of recalls that we have. But I kind of in my mind, just from my experience, kind of sort things out to basically two areas. The bulk of the recalls are related to the finding of an adulterant in an intact sample. And then there are recalls that are, you know, kind of outside that scope where we gather information from different sources and a recall is issued. Laboratory confirmations come from many areas.

They don't just come from FSIS laboratories. And as Armia had spoken in earlier industry alerts, sometimes that they have a positive in their product and state agriculture or state consumer protection departments are out collecting intact products in the market place. And industry and FSIS gets alerted that they found a pathogen in an impact product and a recall will follow.

Sometimes state public health departments are out testing food, too. And some sources of information for the recalls that are not based on that intact sample having the pathogen in it. We make it information from the CDC, from the state or local health department investigating an illness. We're partnering with them in an investigation of an outbreak. We also have information that comes into the picture. And then industry, when they are aware that one of their products is suspected or implicated in illness they also have information that lends to this picture, it leads us to a recall. Public health agencies give us a little information that kind of points us in the direction of a specific product. They might tell us what the consumers purchased, when they ate it, when they got sick, and maybe the state health department may also give us some

information about maybe a sample that they tested that came from, maybe, the consumer's freezer. So returning to public health agency activities, want to take a little time to go over surveillance. And again this is an activity that the CDC and the state local health departments do. A quick definition, surveillance is the systematic ongoing collection, collation and analysis of data and the timely dissemination of information to those who need to know so that action can be taken. And you can pick out, I guess a surveillance definition that suits your needs because there are a few of them out there. And I like this one because it's action oriented. That there's not just a collection of data and it just sits there, but someone takes it and uses it. So that's why I like that definition. Again, who's doing surveillance, the state and local public health agencies and CDC. A little refresher for many of you. You've probably seen this before. It's the CDC slide of the surveillance pyramid and if you start at the bottom the population is exposed to say a food with a particular pathogen on it but not everyone becomes sick. For those who become ill then not everyone goes to the doctor. And for those who go to the doctor, the doctor

doesn't always collect a specimen. But if the specimen is collected then it goes to the laboratory and it might depend on what they're testing for. Norwok [ph] virus testing is a little more involved and there's not as much testing in that area, so no one was testing for that and that was the etiologic agent that made the person sick that might be missed and someone might report a negative finding. So once it's collected that information needs to be reported, that culture confirmed case goes into the surveillance system and then it's there in the database. And as you can see this is kind of, I guess another description, I see this as kind of the tip of the iceberg. So surveillance is actually not capturing data on everyone in this country who's sick, which I'm sure many of you know. Talking a little bit about CDC I just want to emphasize that the grassroots level of surveillance and outbreak investigations going on every day in this country at the state and local health agency level and that basically they're doing everything CDC is doing. They're doing surveillance, outbreak investigations and prevention and that basically the bulk of the outbreaks are investigated at the state or local level. This is just a list of some

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of the CDC surveillance activities and this may not be a comprehensive list. But basically the CDC keeps tabs on outbreaks, clusters of illness. And every week the CDC food born and diarrheal disease branch meets and they go over kind of the latest outbreaks or clusters. This meeting's led by usually the outbreak branch, excuse me, the outbreak unit within that branch. PulseNet [ph] is another system that allows for the early detection of outbreaks and that's the program led by CDC which FSIS, FDA and the majority of states are partners in. Another detection method that CDC uses to pick up outbreaks is salmonella outbreak detection algorithm, which is a statistical algorithm where the data goes in as far as the state health department as far as salmonella serum types that isolated. There's kind of a statistical assessment comparing baseline or routine background levels. And if a cluster comes in and is above that, then there's a flag, and they call it a soda flag. And that's a way for somebody to stop and say hey, maybe there's something going on here. It's similar to PulseNet in that's it's an early detection method. And FoodNet is a CDC project partnering with nine states, soon to be 10 and FSIS has been in FoodNet from its

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inception and the FDA is also a partner there. That project is involving active surveillance and since they have active surveillance, it's a mechanism where a lot of outbreaks are picked up. The states will formally report all the data related to their outbreak investigations via an electronic method, through the electronic food born outbreak reporting system, or E-4's, and that data usually comes in a little slower. And another activity CDC has is to collect reportable disease information through the National Electronic Disease Surveillance System, or NEDSS. One of the areas that FSIS works very closely with CDC is this kind of keeping their fingers on what's happening right now aspects of food born disease. And FSIS is fortunate to be invited to join the CDC's weekly meeting. And this meeting again is led by the outbreaks unit. There's discussions at this meeting about sporadic illness or illness clusters or something that's deemed a true outbreak, the soda flags are assessed. There's also just general discussions about transerum types, salmonella, and serum types and others. Any microbial resistance discussed, farm to table food safety discussed. So it's a very interesting meeting to

attend. Along with the outbreaks branch, excuse me, the outbreak unit, individuals can lead the discussion running through discussions about the outbreaks or clusters. Other people join in to the discussions, the PulseNet folks are there, the FoodNet folks are there. Since Norwok-like viruses get to people via food very frequently, a recent addition to the meeting is the viral folks will come in. The CDC Food Safety Office representative or representatives are there. And there are three agency liaisons that were actually housed at the CDC Food Safety Office. One of the liaisons and Clifford Perre [ph], is FDA's SISA [ph] liaison and Thomas Gomez is the USDA APHIS liaison. We're all housed in the same office. And we all are invited to the CDC weekly food born outbreak meeting. One of the things that kind of typically happens at the meeting is discussions about a cluster starting up. Frequently, early on, no one knows what the vehicle is. Or maybe the suspect vehicle is, you know, picked initially but more data comes in and the states maybe shift their perspective and say well, it's not the eggs it's the chicken or you know, it's not the hamburger it's the lettuce. And so basically the FDA liaison and I, we

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kind of sit there and listen. And sometimes the outbreak activity, I guess, both our regulatory agencies will jump in and respond to. We can't do it until the human health folks kind of sort out what type of product it really is. And so we basically sit back and wait for them to kind of point us in the right direction of, okay, we think it's lettuce and then Clifford will take it or we think it's ground beef and then it comes to me.

And I kind of tease Clifford that when we get busy with an outbreak and another one's looming, I say well you know, we're kind of busy right now, why don't you take that one. And fortunately sometimes it just works out that way. But basically FDA, I think, I don't know exactly how they work because I don't work for FDA, I never have, but they do things similar to the way we do.

It becomes lettuce and then they go off and trace back and et cetera, et cetera. And I guess possibly eventually a recall. I want to talk just briefly about PulseNet, which is a molecular subtyping network for the food born disease system. I mentioned earlier that it's an early warning system. The CDC maintains the database, includes the PFGE patterns for food, environmental samples, human specimens. CDC administers

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this program. FSIS was one of the original participants in PulseNet and I'd say definitely on at least a daily basis our Athens laboratory submits PFGE patterns from poultry isolets to CDC to PulseNet. Almost all the states have participating laboratories in PulseNet and FDA, also just similar to FSIS in food isolet patterns.

I don't know if this is a great gel or not, some microbiologists might corner me after the meeting and say oh, that was a terrible gel, but basically an isolet's identified, say it's listeria, salmonella O157 and it's cut, the DNA is cut with what they call restriction enzymes. And it allows the DNA particles to fragment out. And the pulse feel is, basically the machine is a flat table top model and the isolet goes in, it's been cut with the enzymes and a electric field just kind of pulses and then it runs here and it shifts around and it runs here and it allows the DNA fragments to drag out and kind of accumulate based on their size.

And so you have this stringing out of the DNA and that's what you'll see with the pans there. So here is what's considered to be an indistinguishable patterns between human pattern or human isolet pattern and a food isolet pattern. I'm sorry, one more thing I wanted to

mention though that this early detection mechanism has been very important because we don't always have that kind of classic church supper outbreak or everybody goes to the same restaurant in town and everybody's sick after they go there. Foods are distributed, you know, over many states or people can go to a conference at a hotel and then they can all go home and get sick. And everybody's scattered around. And so when you have that, you know, church supper type thing, it's really obvious. You pick up the outbreak readily, everybody's sick. And you say ah, everybody went to this meal and you can pull it together quicker. So the PFGE patterns allow people to kind of look and see what matches up. And if you see these matches and it allows for someone to go in and look a little closer and say well, why do they all match? Is there anyway to pull them all together? And sometimes there is, it may be a common food that is the source of the illness. But a PFGE match in itself doesn't automatically mean that that person got sick from that food. Again, FSIS does not do surveillance but we do have a lot of communication with the public health agencies. FSIS has seven epidemiology officers stationed through the country. They're

essentially our eyes and our ears, letting us know what's going on as far as food born disease is concerned. They allow us to know things quicker. They allow us to know more things. I can give you one example of a real success. We had a local health department pick up on a catered event at a hospital where people got O157 after eating some burgers at a grill out, kind of a special event at the hospital for the employees. And the local health department had picked it up and let us know. And immediately we dispatched a compliance officer to find out if we could find some product. Well, sure enough the caterer had some product, it was intact, frozen product. And a recall fell out of that but that was a very quick response, a very immediate response whereby we were kind of in the loop early and the people had this product in their freezer, which is possible because this was a frozen product. The recall notice got out and the consumers were warned. FSIS has had a liaison at CDC since January of 1994. The first liaison was Phyllis Farling [ph], who's now with our laboratory program in Athens and I moved into the position in July of 2001. Our microbial outbreaks and special pathogens branch is

our PFGE lab and they have a lot of direct connections with PulseNet folks and state laboratories. So we get a lot of interaction with public health agencies that way, too. FSIS has a consumer complaint monitoring system where people may call us and say I ate a certain food, I think it made me sick. What we do when we get those types of calls is we make sure that the local or state public health agencies know about this because sometimes the consumers are not picked up in their system. They're calling us and so we make sure we communicate with them. Compliance officers frequently get called by the public health agencies to say, you know, we think there's a food involved in some illness and so sometimes information comes to FSIS that way. Continuing on to talk about outbreak investigations on the public health side with the CDC or the state and local health officials, they're doing epidemiologic studies, environmental assessments and lab testing. You have to communicate very closely during outbreak investigations. It's a really key item there. But relative to an outbreak investigation, if an adulterated product is in the market place and it's making people sick then the actual endpoint of an outbreak investigation is a

recall. The health officials are doing epidemiologic studies to try to refine what they know. They may do descriptive epidemiology to figure out who was sick, where were they sick, when were they sick. They may do formal studies or case control studies or cohort study.

Sometimes there's not enough people to do either the case control study or the cohort study and sometimes all we have is the descriptive epi and maybe individual purchased information. So in parallel to the outbreak investigations performed by the CDC and state and local health agencies, FSIS performs complimentary activities when an FSIS regulated product is suspected or implicated as a vehicle for infection. One of the first things we do usually is hear that people ate the certain food and we get the information about what that food was, we do a trace back. We have to be very careful to make sure that the information we're given meshes with the distribution of that product. An example of, I guess, I'll call it a trace forward is there was a cluster of O157 cases in the state and they were aware of a PFGE match to recent recall of ground beef that was distributed nationwide. It was a fairly common PFGE pattern and when we looked at the distribution of that

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ground beef related to that recall, that ground beef actually did not go to that state. And so the information is very important that it meshes. And then of course later as more information came in and the investigation continued actually it was another company's ground beef that was associated with the illnesses. So it's just important to make sure all the connections are there. While we're involved in an outbreak investigation we've got our laboratories working pretty hard, kind of 24/7, too, like Armia's staff, testing product or environmental samples. You know, just the basic detecting what is the etiologic agent and is it listeria, is it O157, is it there in the product during the PFGE analysis. Any microbial susceptibilities sometimes shed some light on the information. There's been an emergence of multi-drug resistant salmonella new port and so frequently when people are looking at salmonella new port outbreaks the next questions, well, is it the multi-drug resistant strain or not? And it helps kind of differentiate among all the new ports that are out there, a way to kind of separate them out and better refine them. Part of FSIS outbreak investigation activities includes going into

plants and doing a public health assessment. If the trace back leads us to a certain plant, we go in, we're looking just to a basic regulatory compliance, we're doing an environmental assessment, we're doing a microbiological assessment, looking at the FSIS micro records. We're looking at the plant micro records, we're testing product. Environmental sampling is also done. But the key to prevention is if there is adulterated product in the marketplace to have the product recalled and to alert consumers. And again we get sources of information from many areas. We try to essentially put the pieces of the puzzle together to know what product needs to be recalled, much product needs to be recalled, what's the extent of the adulteration? Is it one days production, is it more than a days production and so that decision is done by basically pulling in a lot of information from different areas because we are not dealing with a situation where we just have that intact product has the pathogen in it. We're having to kind of put the pieces of the puzzle together from all the different areas in response to the outbreak investigation. We're pulling the information from the human side, what they got from their

epidemiologic study, what the trace back tells us, what the in plant assessment told us and what the lab testing tells us, both from the human side and the food side. In the long list of preventive actions I'm sure that's not a list of everything that we do but they're all very important and I think basically all prevention should be taken in light of the farm to table continuum, could we implement things in any area along the continuum, not just doing recall. We need to continue to do all activities to prevent food born illness. In closing, just kind of listing out again the different activities that we do and this will kind of show you how we do things in parallel with the public health agencies. Even though we are not doing surveillance but we're keeping tabs on the surveillance that the public health community is doing. We are doing outbreak investigations paralleled with the public health agencies. We're not doing exactly the same things but sometimes in a way we are with the environmental assessment, similar to an in plant assessment. We're doing laboratory testing. We're not doing testing of human specimens but our food or environmental testing is a companion to what they found on the human side. Again

we both have a goal of prevention. Thank you.

MR. DERFLER: Thank you, Dr. Holt. I think you gave real concrete evidence of our commitment of public health. Okay. So now FSIS has decided that it's necessary to request a recall, what does a plant do? To talk about that, to talk about the anatomy of a recall from a plant point of view we're going to have Dr. Angie Siemens. Dr. Siemens is Vice-President of Food Safety for the Smithfield Packing Company in Smithfield, Virginia. Her responsibilities include quality assurance, technical services and consumer relations. She is the recall coordinator for the Smithfield Packing Company. Prior to her tenure at Smithfield she's worked for Oscar Meyer Foods division in Madison, Wisconsin. She's also worked as a food technologist for the Beatrice Cheese and served a year as a Congressional Science Fellow to the US House of Representative Committee on Agriculture. Dr. Siemens?

DR. SIEMENS: Are we on? I'm too close to the screen to sit and do this and I'm better here anyway walking around instead of sitting. I'm going to do a little broader than what Phil introduced because I have a problem with some of the language that talks about the

fact that the FSIS decided we have a recall and then they go tell us to do it. There is a lot of things that we as industry do and I think there's some more that we would like to do in advance of having a recall. A recall's reactionary. There is some preparation steps that are required. So as part of my presentation -- go to the next slide -- I want to talk about basically four steps and the first one and our responsibility as industry is plan, plan, plan and then practice that plan. Recall is reactionary. You know, once either we decide or FSIS in coordination with FSIS decides that we are going to have a recall, you'd better have a plan in place to execute that properly. Know who the point people are, et cetera. So there's a lot of advance planning, a lot of resources used very much in the beginning before you actually get to the process. There's a whole set of decision steps. Dr. Tawadrous talked about the FSIS section for the decision steps. I want to talk a little bit from my perspective what I deal with daily and other members of the industry deal with from a decision standpoint. Then there's the execution. And I've talked to a lot of folks in the industry. The first two steps are 90 percent of the

process and when it really comes down to it, you want to prevent, you want to be prepared, and then you've got to make a proper decision based on the right data.

Executing the actual recall itself, getting the product back is a set of very straightforward series of steps from that standpoint. The last part of it is the assessment. It's not acceptable to have a recall. FSIS described it as a failure and in the industries mind it is absolutely correct, it is a failure. You need to go back and find out one, why you had the recall and then secondly, what could you have done better during the steps of the recall from that standpoint. There is an assessment face to this. So I'm going to kind of walk through these. In terms of the planning, recall plan, simply a written practice, refined set of directions for the company and its managers to facilitate the response when a crisis occurs. Not too difficult. You know you think you don't know what's going to come up in a recall. You don't know the conditions but there are a set of standards that you should have in place that you can modify fairly easily to the individual decision. Part of that recall plan -- next slide. The components of it, I'm going to talk about the first five kind of

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together and then we'll jump into the procedures in the second section. You should have a purpose for your plan. What does it mean to the company? An objective in a scope. You should have your recall team identified and even more than that recall team, who is your decision makers. How many of you have sat in on teams and sat in on team activities in a stressful situation and they don't have a decision maker, you know, in that whole part of it. You get lots of recommendations and no one's going to step forward. So you can predetermine your decision maker. Most of the time in the company it's the general manager, the CEO that has the ultimate responsibility to finally make in the final decisions. You need to know that in advance. Definitions, responsibilities, we tend to have different definitions sometimes than FSIS has. So if you've got those outlined in advance then everyone knows what the definition of a market withdrawal is, what a stock recovery is. A lot of the definitions will help in your communications. Responsibilities, we'll talk a little bit about that and then I'll get into the procedures of the second part. Let's start with the first piece of this on purpose and objective and scope. Next slide,

purpose. You've heard FSIS's purpose for dealing with recalls. We share that same purpose. In our case it's our position in regarding the consumer protection and establishment system for handling product withdrawals and recalls throughout the production and distribution system. That's a common goal with FSIS. We as an industry have an additional goal. We have to be in business from that standpoint. I'm not going to hide it from anybody but we need to provide a prompt response that meets our needs to maintain our integrity, our customer trust, our continued dedication to quality. Another way of phrasing that up is I have to reduce my company's liability. And that is not exclusive of the overall goal of protecting consumer health. And we often hear that people separate those two and say I can't do the second and accomplish the first. I don't believe that. You know, to maintain and reduce my liability is in the consumer's interest from that standpoint. So that's the purpose of recall plan and how you move forward. Next slide. On the recall team I've got nine different functions. This will vary and this could be anywhere from three people to twenty people depending on what company you go into. What size

company they have, what resources they have, but I think this is a general list of those kinds of folks that are involved from an industry side on a recall situation. The general manager or CEO, different titles. You should have a recall coordinator. That recall coordinator shouldn't be running the transportation department. That recall coordinator shouldn't be answering the media phone calls. There is a lot information that you'll see later that comes in at one time. That coordinator should be a coordinator, simply moving information around. And it's a huge piece of how a successful recall works. Operations manager, logistics manager, straightforward, public relations, technical risk advisors. These don't have to be inside people. Put an epidemiologist on retainer from that standpoint. Have a toxicologist on retainer or have their phone call and have an agreement in advance. Hey, can I call you for information from that standpoint. Plan ahead for those type of contacts. Marketing manager, legal counsel, trade relations, liaison. We have to talk to our customers first and foremost. We have got to satisfy our customer needs in effectively moving this through the system as we go forward. Now

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the next slide talks about -- this is a center of everybody involved. Now I've got some repeats on here and I put these little balls on here on purpose because this is a juggling act. You've got a lot of bouncing balls where you're walking through a recall. Logistics has got information. Operations has got information. Plant management's got information. Your regional sales force, the folks in the field have information. Or you have to get information to these folks. And this is not a sequential process. You don't do task one, complete it, then go to task two. There's very little of that in a recall process. You are bringing information in and sending information out parallel. You know, multiple things going on at the same time. Your finance, your technical risk advisors, your information technology, your key to success, the support functions. From my standpoint these folks won't talk about the finance group. It's not their responsibility. I have a responsibility as a recall coordinator to be sure that if we have insurance coverage that we have to get credit memos back to our customers because they're not going to return that product for free. They expect to be paid. That's a part of what we have to do as we're going

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through this and have to be prepared to handle. Investor relations, public relations, consumer relations, gosh, communication and lots of different venues for communication and folks that do it. Sales and marketing, legal counsel and then your CEO, president, general manager, your decision maker right there at the top from that standpoint. I'm going to talk through some of these, how these folks fit in to recalls as we go through. So the next slide. The definitions I'm not going to get into too much. Responsibilities I'm going to talk about as part of the standard procedures. FSIS has defined in their FSIS directive a number of definitions. If you don't agree with those definitions, you'd better make sure that up front that you get on to the same page if you don't agree. Because one of the biggest issues that we run into is a communication problem. We think we're talking about one thing, they think they're talking about another. Get your definition straight. Let's go into the procedures. Decision steps and then the recall procedure steps themselves. And the decision steps are the next slide. I'm going to start all the way back from when, say I get a phone call from a customer

stating they got ill. All right or I get a hospital saying, you know, something comes in. In our case it comes to consumer affairs. It will go to a number of different folks. The FSIS has talked about that they have their consumer line. Each of the industry folks have some type of mechanism of bringing the information in from consumers from outside sources. Have an avenue from where you go with that information. In our case you have a number of things that comes in lots of different ways, that runs through our consumer affairs department. They're going to gather some facts pretty quickly. Believe it or not there are a lot of folks that call in with bogus claims. It is a function of our society and we have to sort the real issues out from the bogus claims. We're chasing our tail a lot of times and wasting a lot of resources. I'll throw an incident out, we had a gentleman that had constantly called us. We had sold product, he had fed it to his kids and the neighbor's kids, would never produced any hospital reports. After multiple phone calls back and trying to contact him this gentleman was a drug addict on a scam. That's not uncommon on things that we get, so we have to sort through so we don't overreact but we also don't

want to underreact. It's a matter of making proper decisions and gathering information that you walk through. Because we want to find those legitimate claims as we walk through the process. We'll go down through a decision process, is there a death or serious illness involved, actual health hazard, adulterated or misbranded? If the answer to that is no, we go through our normal complaint process, which is we're investigating, you know, and respond back to the customer. From that standpoint we will not take any further action relative to product. If the answer is yes though, we still have a couple more decisions to make though. In the next slide, we'll contact the recall coordinator at that point. If there's some validity to what's going on, at that point we're going to gather some additional facts that my consumer affairs group would not be able to get a hold of. If there's enough information there that says whoops, there's something not quite right in my HASIP documents, you know, something matches up or we've got two or three, you know, linked complaints that we're uncomfortable with. You continue to gather facts and if you start putting that pieces together, the decision is made by

the recall coordinator in our case, to pull the full team together for an evaluation. We may have already pulled in technical advisors. There's a number of things that can be done as you go through. At that time, in many cases, if you've gotten that point and you think there's some validity to it, we're already putting a hold on product moving, if we believe that that product is within our control from that standpoint. I know there's a lot of people that talk about recall notices are not put out fast enough. Well, from my observations of recalls, the majority of product that comes back is the stuff that's in the pipeline. It doesn't come back from the ultimate consumer. So I don't necessarily need a public health notice to stop the product from moving into the system from that standpoint. The press release is not vital to me to start a recall and to help eliminate some potential public health effects. If I can stop it in the pipeline, I've made major progress towards eliminating some risk. We'll do the physical distribution, we'll continue to obtain further information from production QA, consumer sources, et cetera, et cetera and then you walk on down, you may at that point decide that hey, the

complaint that we had, which happened to be internal and there was a question on our HASIP documents, we have all that product under our control. It's setting in a cold storage warehouse in which they don't release it without our control. We'll go grab that and then there's no consumers at risk. And that's our stock recovery. And then that product is handled internally. If it happens to get into our customer's warehouses and we know that we delivered the truck two days ago and we call the customer and all 200 cases are sitting in their warehouse and we can account for our full production, we'll initiate a market withdrawal at that point. We've not involved, you know, at this point, any consumers because none of the product made it to the consumers. Now if we're going through this whole process and we know that there's a health hazard or a regulatory issue and it's out of any of our control and our immediate customer's control, you have to go to a recall. You need to notify the public that it's out there from that standpoint. So you've got a decision process. Now this thing can get turned upside down when the information comes from FSIS and you have illnesses, you know, in many cases. In terms of how the decision process is

done because the product you know is already in the field. A lot of times it is multiple days down stream of the production from that standpoint. So a lot of these don't apply. The closer you are to production date the more successful we are because you have control of more of the product. The further you get down the more difficult it is, these three, four, or five months after production, real difficult. Because a lot of it is way out of the pipeline by that time. That's a decision flow chart. We're going to get into a lot of discussion this afternoon about who does this, what information is shared with whom in terms of decision process. I'm not going to get into that this morning. But I think industry has a big role to play in that decision process. We have a lot of valuable information. I have learned in working through these "special situations", you have to set everybody down together with the information because questions come up, boom, boom, boom, boom. And you don't want to wait to call somebody to bring you the information and then go boom, boom, boom again. It's not an efficient process to have segments of this making independent decisions. They need to be together to make decisions from that

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standpoint. All right. We've initiated a voluntary recall. I've got five steps here I alluded to before and I put at the top of the list, communicate to appropriate parties. That is the hardest thing to do in this whole process. And assure that it's accurate, timely, information is getting to the receiver. That's an issue as you walk through it. You identify, locate product. You actually retrieve the product. You have to make plans to go get it. It isn't good enough to find it, you've got to go get it. And then you have to document. And that's a huge piece and one of the, I think, the difficulties that people don't follow through on necessarily is the whole documentation piece. And there's a lot of documentation required from our customers, which we don't have control over. You know, if they've got 10 cases and they decide they're going to throw it away and don't have anybody witness that, I don't have a lot of control over that. I can give them instructions but we've got to account for, if we knew the 10 cases were there, we have to know they have to come back. And then you assess the process. I talked a little bit but that before. The recall team and recall coordinator needs to work this whole process. In the

next slide I'm talking about communications. I'm not going to get into a lot of detail because I know there's a lot of discussion relative to communication in this afternoon's section. These folks worried about getting information out to the consumers. I have a multitude of other concerns on communication that I have to deal with in running a recall. We work with a press release, media contacts, it's all typed, getting to the customer. But we also have customer and consumer calls coming in. It is amazing to me that I can write a draft press release, send it to USDA, and it comes out with different numbers and then by the time it gets to the local paper in Birmingham, Alabama, the numbers don't look anything like what I started with. We spent most of the time -- I had a very small Class III recall, we spent most of our time correcting media information in this segment of our consumer calls. And it's not difficult but information to copy from one page to the next but every editor seems to think they need an editorial license to write it a little differently and they make mistakes when they transfer it from one piece to the next. It was amazing that the corrections we had to make on a very small Class III recall. I don't know

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the details in the larger recalls but I know in a small recall they can't be doing accurate information by the time it gets to a local level. I don't know a more efficient process though. I know there's a lot of debate on how do you get that information right to the bottom source and I think we've got to work on that whole part of it. Recall notification and government notification are all part of the communication pieces. Now, I didn't put on there internal communication. They will screw up more things by not even communicating properly internally. That -- and that's part of your preparation plan. You've got to know who needs to be contacted and how and when and the right information, so that you can run with as most efficient. And you can do it. You know, it's just a lot of planned preparation. All these folks are involved along with the team. I identify and locate the product, while we're doing all this communication piece, yeah, we're trying to find product at the same time, you know, from that whole standpoint. You've got to know the precise volume of the suspect lot. Now there's all those questions under you, do you go broader, do you stay narrow, what is involved relative to the lot involved? Why does a small

recall end up being a large recall? You know, from that standpoint, and I think there's some discussions on that this afternoon. One of the things that I ran into in this effort to get a press release out, we have to have a number. Well, I'm not sure all the decision process is complete in our effort to drive that press release. Even though there's probably product coming out of the pipeline at that point, so I think there's a timing issue in some of the accuracy of the reporting of suspect lot from that standpoint. We need to know the precise distribution pattern. We need to know where this product went. We need to know -- and my vernacular when we talk about product being moved and I have some difficulty with the agency with this, I move product in case quantities, all right? And I have a lot of what I call catch weight items. There's not 12 ounces to every package that I put in that case. So our transfer and translation into pounds, a lot of times, ends up confusing the issue. But I'm going to work with my customers on case count because that's how we do business, you know, a lot of times. So there's some frustration, I know, on FSIS's part sometimes on I have to have pounds. You've got to translate this to pounds.

We're not going to be accurate always on pounds because we know our range and our average for our case counts but on any given day can I give you an accurate number of what I sent to customer X? Not always from that standpoint. There's some things that we need to work on in terms of communication. Product internally to be contained. People get so wound up sometimes in trying to find a product from a customer they forget what's sitting in your warehouse. So you have got to make sure that your internal folks, when it's sitting in your own warehouse, go out and cane that product down, you know, from that whole standpoint. We've run into several issues where there's been a secondary recall or there's been a recall based off of an emphasized monitoring sample because the product accidentally was shipped when it shouldn't have been. You know, we tend to forget some of that stuff that's in our own back doors sometimes. So you have to have a procedure to make sure you capture that product as well. And then one of the other issues is you don't always know how much is going to come back, so you should prearrange with some warehouse locations. I would not bring it back into your own plant, but set it in some locations to bring

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product back to. Because I tell you when you bring product back you're not -- you know, if I do a bologna recall in Smithfield product I'm going to get Oscar Meyer, I'm going to get Sara Lee product, I'm going to get code dates that aren't even close to the dates I'm asking to be recalled. And there's different reasons for that. Retailers are not going to go to their inventory in many cases and sort out the dates that I'm looking for. They're going to go to their retailers, if it's at the retail level, and they're going to say whatever you have in inventory you pull out of there. You don't have time to sort it. And they're telling us you take it and you're going to pay us for all of it, because we're not going to sort all of it. And if it happens that, you know, we had product come back in banana crates. All right. They're just pulling it off a shelf, throwing it in a box, we're picking it up and bringing it back. You have to sort through that to understand what's been returned and not returned that actually applies to the recall. You know, this is the reality of the whole thing. So you need to have a system to be able to handle that when it comes back. So I know these guys get frustrated when I don't have my

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numbers put together to show what I produce, what I shipped and what I returned in as timely a fashion as they would like but there's -- you know, I have banana crates to go through. It does take a little bit of time to walk through, finding out what you have returned. All these folks are involved, you know, quality assurance, plant management, your operations management. There's a lot of other functions that stop when you're going through this process. Now unfortunately we're still producing products, so we've got to use our resources efficiently, effectively, while still producing products now. You know, it depends on the case and the standpoint. Information technology people can walk on the water during these processes. They are key to making sure we've got the right information, collection information as we go through the process. In the next part of it at the same time these guys are asking for a whole bunch of numbers. And they want them accurate when they come in there. I get challenged when we're walking through it because the truck that we thought delivered it at 4:00 a.m. this morning didn't make it, so therefore it's on a truck I can bring back and I don't need to bring it back. There's a lot of,

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you know, nonabsolutes when we're trying to put these numbers together from that standpoint. But we do the best we can in terms of making sure we get the information back to them and they talked about the recall worksheets before but there seems to be more tension than I think is necessary as we're trying to put this information together. And how close to accurate do you need it sometimes knowing this is an imprecise process many times. It's a reality. Trucks don't deliver on time. Cases get damaged. So instead of 1,000 cases being delivered they dropped a pallet. And I wish I could get jack drivers to stop dropping pallets in warehouses, but they do. So you know, you pull 55 cases out of that shipment. Those things are realities that tend to mess your numbers up as you're going through the process. So you're dealing with the communications with FSIS and trying to put those numbers in the format that they're requesting. On the next part of it at the same time, on the next slide, you are also dealing with how do I get the information. I know I have 10 customers -- and let's do a small recall -- 10 customers that received product. Now this varies from company to company on how this process occurs. This is

how I do it. There are also a huge amount of variations on how our customers want to receive the information and how they want to handle it. Our program has to be flexible enough to accommodate our customers. So there is not in my case a one-way serves everybody function when we're trying to deal with our customers. In our case we use an outside sales force and brokerage firms. They're the ones that maintain the databases on their contacts with their customer because a lot of our sales force are set up where they have a primary customer and they know the contacts and they really know that business. We will notify our sales force, the sales force then notifies the company. And we do have some safeguards so there's not a drop the ball process. I'll go through that in a second. We also do follow-up contacts. Be sure that, you know, did they actually receive the information? We'll visit stores to be sure that there's not anything left on the shelf. We won't hit all of them but we'll hit our primary customers from that standpoint and then part of our function in finance is we have to issue credit. We've got to have, you know, those folks are going to want to be paid for not having that product in the system. So that's part of

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our process as we go through. But I want to reiterate we have customers that you deal with one corporate manager.

You don't send information any place else. We have other customers that if I'm drop shipping to the stores, I'm going to deal with the 20 stores directly. All right? You do a different process with those folks and there's a different requirement as you're going through.

So there is -- you've got to be flexible and know how your customers want this information in case it happens and how you're going to deal with them. In terms of notifying our sales force, a pretty straight forward process on the next slide. What we do in our case is you have to indicate the urgency. And a lot of this is in the FSIS directive 80.80. That's a nice write-up that they have in there and the discussion we had earlier. You know, half the page to say recall or urgent notice of some kind. I don't know about you, but my desk is out of control right now. And I know a lot of our brokerage folks, our sales folks, our customers, they're folks where their desk is out of control. So if they don't have something on there where this paper is special, they're not necessarily going to see it. So what we do is there's a receipt confirmation instruction

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on each piece of paper that goes out in this process. And what it says either you call us back or you sign this, date this, put the time on it that you received it and send it back to me. And if I don't get a response back from my sales force, because, you know, sales guys and the whole thing I get sideways with them any way. They go on vacation and don't tell anybody. So okay, there's no one as a back-up. We've got to know that. We've got to know who went on vacation and if I don't get anything back we have got to be on the phone finding out where they're at or who needs to do this in place of them if they're not available on that standpoint. And then you've got to have clear instructions. A whole communication piece. Who do they need to contact? What product was sent to the customers they need to contact with logistics information? Do you tell the store to put it in a shelf, put it in the back room, hold it for further disposition or have you already got it figured out? And one of the things I do applaud the USDA on is this less than 10 case count. A lot of times we've been able to work with them if there's less than 10 cases, a very small quantity, we'll ask the retail store to have someone document that it was destroyed with witness

program from that standpoint and that it was destroyed, send us back the documentation. That's a lot more efficient use of resources to destroy it right there, get it documented, than me have to spend a lot of time with a truck running all over the place and trying to worry about whether I picked those 10 cases up. We've got a system. And I applaud them for that piece of it because it has really helped. Because believe it or not we don't sell pallet loads to everybody. I wish I did. I'd love to send 2,000 pounds to every customer I sell it to. In our last recall I had 13 states involved. Ten of those states were involved because I sent product to commissaries and no one of the commissary received more than three cases. That was it. But we had to list all 13 states in the press release. Okay? We have a lot of product that's sent in two case quantities. And it's going to be more so as we move forward. Just in time deliveries, as the information systems get better between customers and suppliers, we do a lot of two, three, four case deliveries each day from that standpoint. So that is really a time saver and I think an efficiency saver being able to document and destroy it onsite. So that's got to be determined. Sales force

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does the same thing with the customer on the next slide. Customer, they get a notice as well. And a lot of times you'll send the press release and they'll want to know why or you'll send them a document covered letter from that whole standpoint. But I request return receipt from the customer back to the recall team. I don't want it going back to the sales force. I need the document that that sales force did their job in contacting the customer. All right? And you pull two or three people off their normal jobs, they're tracking to be sure that everybody got contacted. If they didn't react, we have to find out why. Again with the same thing I talked about on the clear instructions, as you go through it. On the next part of it -- I'm trying to what my next slide is. Oh. The whole disposition. You should have a disposition predetermined. You've got to have recorded receipts and documentation. You've got to recount because your customer -- and I have to be careful with the retail group here -- customer probably isn't going to count this many times. They're throwing it in a banana crate and sending it back. And I don't blame them. This is an event that is really not excusable from our standpoint being a supplier to a

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customer. We are creating issues for them. They're going to accomplish the task but they may not count all the boxes accurately. We deal with it, you know, from that standpoint. Conduct the internal effectiveness checks, you know, we've got a sales force out in some of these stores to be sure that a store has heard and they're actually off the shelf. From that standpoint, that's in addition -- I don't even worry what they're doing. I'm doing this on my own. I talked about the reconciliation. There is a difference between manufacturing records and shipping records internally. They don't always match. You need to make sure those match and then you have to match with what comes back. You need to walk those through. If you produced, you know, 100 cases and you shipped 75 and you can't find the other 25, you need to find out what happened to it from that standpoint. And if your systems are like mine, you know, I have a set of production records, I have a set of shipping records, you've got to find it through the process. It's an exercise. It takes you a while to sit down and put those pieces together. And then hopefully you can terminate the recall here. Once you feel comfortable that you've made all your contacts

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and if you set your plan right, it should not be, you know, a five-month process, you know, from that standpoint. It could be shorter. Again, closer to the production date, the quicker this works. Further away it takes longer, from that standpoint. So the first thing you do is assessment. Huge, you know, on that whole part. It's not unlike you go back and have the plans and you say what in the world happened. You've got to make sure while this whole process is going on there's a plant component working to figure out what happened. You don't do the recall and you say oh, by the way, I've got to fix the process. You have got to be, you know, you have to decide whether that line shuts down, if there are more products, the possibility there's a lot of analysis going on in the plant at the same time. I know there's been some discussion on, okay do I have my resources working towards trying to identify this problem or do I accommodate the FSIS end that's investigating at the same time? My folks are doing multi-tasks at that time. You know, I think there's got to be some cooperation sometimes when they send people into the plants. While I'm trying to do investigations, they're doing investigations, we're

trying to make sure we've got the right product count; there's a lot of things going on. And are we using our resources at the right time effectively? We've got to evaluate, you know, this is not FSIS's point. But it is from my standpoint. I've got to evaluate my company liability. How do I, you know, what is my public relations damage? What is my customer damage? From that standpoint, how do we make it better moving forward? You know, that's an ongoing part of the assessment. As you continue to improve those things you improve the fact that you don't have recalls. The plan, plan, plan, prepare section, everyone should have some documented mock recalls. You have a third party come in and say okay, here's your scenario. I want to know if you can find products, I want to know if you can react to media responses. You can do it internally, external, whatever. But you don't write a plan and then don't practice it. Because once you get into these things it's a whole different world, and write down on a piece of paper that I'm going to call X. You may not remember to call X in a moment of stress from that standpoint. So you've got to do the mock recalls. In summary, I know we're way over our break here. But in summary I

have the same goal everybody else does. I don't need a recallable event. It is a stress situation I don't need. This business is stressful enough as it is. So the goal is not to get into a situation, no question. The recall process is complex. Once you get into that reactionary mode it is very complex. It's multiple task. They have to be accomplished at the same time. It is very resource intensive from that standpoint. And you'd better plan, if you can not resource your recall then you need to figure out what you're not going to produce that day. It's very simple. Your priority should be to the recall from that standpoint and where are your resources or what's not going to get done, if you have to pull your folks out of their general day to day business. Preparation is essential, and the whole hinge pin of this thing is the cooperation and communication with all parties involved, you know, from that standpoint. I can't complete a recall if my customer says I'm not going to do it. I don't have control. I don't have their distribution records. You know, working with FSIS and their decision making process. From that standpoint, it can work very, very smoothly if you plan, prepare, you know who, what, when,

where, how, you know, the basics as you go through. That's my presentation on once we get into it, how we do it. Phil?

MR. DERFLER: Thank you very much on your really helpful talking, Dr. Siemens. You might not realize it but we're actually on time. We just started a half an hour late. So that there's any chance of having questions and answers at the end of the day I'm going to cut five minutes off the break, so we'll come back at 10:35. Thank you.

[Off the record]

[On the record]

MR. DERFLER: We're at the point in the agenda where we're going to talk about FSIS's relation to the states as we work through recalls. They'll be two presentations made. The first will be by Dr. Kenneth Petersen. Dr. Petersen is assistant deputy administrator in the FSIS office of field operations. In that role his responsibilities includes the supervision of five district offices, including the recall management division. After we hear from Dr.

Peterson, we will here from Ms. Shirley Bohm. Ms. Bohm is the director of the dairy and food inspection division with the Minnesota Department of Agriculture. And she's also a member of the Minnesota Food Safety Task Force. And currently she is president of the Association of Food and Drug Officials. She is responsible for the division of dairy and food inspections food protection activities for all dairy and food products processed and sold in retail stores and under Minnesota law. Her regulatory activities includes inspections and food sampling at grocery stores, farmer's markets, processing plants, distributors, dairy farms, both milk tankers and cheese and milk bottling plants. So I'd now like to introduce to you Dr. Kenneth Petersen.

DR. PETERSEN: Okay. Good morning and welcome back from your break, even though Phil cut it short. I want to spend a little time talking about what we're doing with states and the recall process and why this is important. First slide. First just to revisit two things from this morning. Why are we doing a recall? Once we do a recall why is that critical? And that's because we want to get these products back. They're out

in commerce, they're potentially adulterated and as you heard I think more than once, they're particularly concerned of that may be a risk to public health. But we also have some obligations of products that may be misbranded or otherwise adulterated. And then we also communicate that the recall is happening. And we do that through the RNR process, the recall notification reports. Those are posted on our web sites and then we have the e-mail distributions that were mentioned to officials in all 50 states. This would be either Departments of Health, Departments of Agriculture but we do contact the officials in each state. We also contact some of our sister agencies within USDA, FNS, AMS and even the Foreign Agricultural Service for example, as well as our friends in other federal agencies, FDA, CDC, EPA, what have you. These folks get the information that the recall has in fact happened. And we do a press release for a more public end for all recalls and then the firm, as we heard from Ms. Siemens, notifies each of its consignees about the recall. So we're looking to get it back and we tell people what's going on. While we have some historical relationships, working relationships, of course, with states and other Federal

agencies, particularly related to food born disease outbreaks and even during recalls we have these relationships in place. We also have good local relationships with our district offices. These are the offices that have the authority for inspectional activities of meat, poultry and egg products out beyond the beltway. So they have good relationships with their friends in State agencies. Sometimes they're even located in the same building. And certainly states have an interest in being directly responsive to their local constituencies. Whether they be media or perhaps some of the retail outlets that they directly regulate. So there is other information sharing going on beyond just notification during the recall. And yet historically when we've shared information with State agencies, we deem that information sharing in the same status as we did with information sharing with the public. And the statutory citation you see here, five US code, et cetera, is a Freedom of Depredation Act. And so what I'm referring to here is if we provided information under this provision of the statute, if we provide information to an individual, we are obligated to share that information to others who request it. So if we

provided some information to a state, here we're getting close to particularly distribution lists. Historically if we provided those to states, we felt we believe we were obligated to share that information with other who would ask for that information. So frankly we did not share those distribution lists for that reason, as well as some others you will see in a minute. And yet that's probably a conflict with our half the farm detail approach, which is certainly supported by our interests in having a theme with food safety system. It's impossible to have the food safety system unless you are effectively communicating with those who you should be.

So what are the distribution lists and why are they important to various players? Distribution lists essentially show where and when a product was shipped by a firm. And here, of course, we're talking about the firms that we directly regulate. These lists are confidential information. They are valuable to a firm.

They are valuable to their competitors. So we had concerns that unprotected release of the lists would impede their willingness to voluntarily share them during a recall. If we're always rethinking if they have a question in their mind, if the plants are

questioning why they would give this information, and it would at a minimum delay the process. And as you heard timeliness and moving forward with the recalls is certainly important. And so some of that delay, whether it be intentional or otherwise could certainly have a negative public health impact because we're not getting the products back as quickly as we would like. So we initiated the rule making to address this disparity between us, not sharing some of those distribution lists. And this was in a final rule published on April 24, sharing recall distribution lists and state and other federal government agencies. That had an effective date at the end of July 2002 and essentially it update a portion of our regulations by adding a new addition to an existing regulatory site we had. It added nine code federal regulations, 390.9, which discusses sharing information with state and federal partners. That's a new section under our existing part 390, that's 9CFR part 390, freedom of information and public information, that's essentially part of our regulations so we supplemented that with the ruling. So what does it do? It enables us to share distribution lists provided that, let's talk here about state

agencies. That the state agencies have such authority to protect the list from public disclosure. Again this is confidential information. They need to have the ability to maintain that confidentiality. And they need to also have a written commitment not to disclose the information without permission from either the firm, who ultimately owns these lists or from us because we may have knowledge that they may no longer be confidential.

So they need to protect this information. We're sharing the information for Class I and II recalls only.

Because those are the recalls that are done in the interest of public health. The release of information is to protect the public health. And it is limited to events evolving around a recall. And we think this will improve public health protection and cooperation especially among those State agencies and Federal agencies that actually enforce these food safety statutes. And the states can then use the lists to help facilitate the recall process. They know where the firms are located. They have additional resources to go do some of the recall effectiveness checks that you've heard about. They may, in fact, regulate some of these firms. So again they may have some local relationships

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that we should be using, rather than have a Federal officer go in and do some of the similar activities. But depending on the part of the country, they may in fact be better located to do some of these effectiveness checks than we are. But it does not diminish the public's right to general information. It only relates to the information involving around a recall and involving around the sharing of the distribution lists during a recall. So do we have any other MOU's? Yes. Again the effective date was late July and these four states, California, Connecticut, Georgia and New Hampshire, we have in fact entered into MOU agreements with where they have met the stipulations of the regulation and others are pending. So really these helped at the one points. States certainly want to be responsible to local constituencies. And previously when we had a recall of the states, they get calls, say from the media asking where are you looking for the product? Where do you think the product is? And they would have to say, let me check with FSIS. That's not the best way for them to interact with their local partners. So this helps with that. It helps them be more responsive and then as I said it helps get things

moving more quickly as far as the effectiveness checks so we can get it back as quickly as feasible.

MS. BOHM: First off, I wanted to thank everyone and FSIS for the invitation to come and speak today. I'm here representing the Association Food and Drug Officials, State and Local, State Agriculture and Health Departments and Local Food Inspection Programs and also the Minnesota Department of Agriculture. I'm going to just give you a little overview of what AFDO does. It's an association of state and Federal and local regulators, academics and industry associates who are interested in promoting a uniformed science based approach to food, drug and cosmetic law. And we accomplish that in a lot of different ways but we feel that collaborative training and education effort and things that support that training effort including everything from our reports to commenting on Federal regulations and Federal activities. We accomplish it through partnerships, through conferences and training and things like that. We promote and you've heard this before, a seamless food safety system that identifies and acknowledges individual roles in protecting the public health and food safety. And they think public

health is most obviously our primary concern. AFDO promotes two way communication among all of our members and participants and in any activities that we do in the Food Safety System in this case. I wanted to also explain what kind of a relationship that AFDO has with FSIS. It's a very good one and we've been improving that over the years so that FSIS liaisons to our board and the FSIS members in AFDO are a very important part of our organization. They advise us on things that are going on in the meat, poultry and egg industries and with regulations that relate to those industries. They also partner with us and support and I'll have to say financially as well, which is very important. A lot of training and education efforts in these areas. In the last few years we've had some satellite broadcasts on retail meat and poultry processing. We've had a recall workshop, several years ago that illuminated some of the issues that needed resolution. So were the things that were being done well, of course, too. We also have another, just for your information, we have another recall workshop to update everyone on what's been going on in the area of recalls and the changes that are taking place at the conference coming up in June. FSIS

has also provided some grants to AFDO and to states for training the area of processing, retail meat and poultry processing and also to some states for Safety Task Forces in the same area. You can see that there really is a lot of interaction between AFDO and FSIS and it's been very valuable, I think, in supporting the regulatory concerns that we all have as well as some of the industry that regulators who interact with them, who do inspection and take part in recall situations and things like that are knowledgeable about what's going on in the meat and poultry processing industry. Other activities that FSIS does that helps support this relationship and these quality knowledgeable regulators is they provide technical information through the technical services center and the meat and poultry hot line. They also have, as has been mentioned already, epidemiologist located in various district offices around the country that do get involved in recalls and food born outbreak investigations that are generally conducted at the State and Local level. There's a long tradition of FSIS and AFDO working together and it is a good one. And I think there is no reason to believe that that won't continue on into the

future and get even better. I wanted to talk a little bit about the recall process at the state level. Now I'll be sharing mostly what happens in Minnesota but it also is a very close type of process that occurs in other states as well. We base our recall requests and again this is a voluntary situation. We based the request on the Minnesota Food Safety Law, which is very close to the Federal Food, Drug and Cosmetic Act. It's generally based on either the confirmation of adulterated and contaminate and/or food epidemiologically implicated in a food born outbreak. And if there is a public notification required, if we're not doing a withdrawal or something like that, we do have specific information just as FSIS does. It's included in the press release, in the news release that goes out to the public. It would include a minimum of common name and brand and lots, plural or singular, that are identified with the reason for the recall, the risk to the consumer, because that's a very important piece of information, particularly if it involves a susceptible consumers who are very young or very old are at greater risk. And also the instructions for the consumer because the press release is targeting the

consumer. What they should do with the product if they still have some of it. Wholesale and retail facilities and that would be stores or food services, restaurants for example, distributors or warehouses that may have some of the product are identified and if they're known that they have served the product or handled the product. This is in conjunction with the recalling firm. It takes time, as we heard a little earlier to trace back from that initial distributor who receives that product from the plant to the next distributor, the next distributor, the next distributor, maybe another one and maybe by the time we get to the retail level to where a store or a restaurant has received that product.

Food supply chains is very complex. And I have to make a point here that State and Local agencies believe that because of their present onsite, for example, in Minnesota we have about 70 inspectors in the Department of Agriculture. About the same number as the Department of Health who do food inspections. And then we have several hundred at the local level who are all on site and willing and able to help the recall process and to help speed it up so that all of us together can be more responsive to the needs of our constituents, and our

citizens and our city or county or state. We also, during this initial and pretty early on in the investigation and in the recall process have just as the plant is having, we have our own groups of individuals from various agencies and organizations and they're often at different levels of government, get together to discuss how to handle the recall situation. And at that time when the press release goes out if those people, not only the people who are at the table and involved in the recall but also we bring states or other agencies at other levels would receive, we make sure that they also receive a copy of that, if there is potential for that product to be distributed in their areas or they have some interest in some way in the product recall. In an investigation, in the recall investigation for example, there would be a record of review with the operators of the plant or records that are provided by the plant. Now this is generally not and this does not happen with a federally inspected plant, of course. Because those records are given to FSIS and not to the State or Local agencies that are involved. This would be a plant that has a recall that's regulated by the State Health or Ag Department. The records are reviewed and of course at

that time one of the most important pieces of information that we're all looking for are the distributors who first received that product. The depths of the effectiveness check and we've touched on that a couple of times already today, is determined by the risk to the consumer. So that can be speeded up by doing some telephoning as well as onsite visits. This is where the utility of having State and Local agencies involved really, I think, you know, is most beneficial. And can simultaneously be checking many, many sites. Particularly when it gets to the retail level because you have a very large number often of facilities that receive that product and there are a couple of compliance officers, for example, who are located in the State of Minnesota, have to trace back to all of these facilities. It takes quite a long time. Going on to some really important things that most State and Local agencies try to do after not only a recall situation but any kind of a food born or recall investigation is to take the lessons learned, not only for the recall process itself but as we trace back and do the effectiveness checks but also in the investigation of the sanitation and processes that go on in the plant to

see if we can identify what contributed to that problem and to take that information and sanitize it, of course, because there's no need and we don't share specifics. But to take that lesson learned or lessons learned and incorporate it back into our inspection programs so that our inspectors are able to recognize similar situations to prevent them from contributing to a similar kind of problem. I think we've heard that earlier that that is also an important part of the industry recall process and that you want to identify what the issue is so that it doesn't occur again in the future. You know, there are some situations and I'll speak first about Minnesota and then about some other states. For example, when the recall originates in another state and either FSIS is doing that investigation or if it's not a meat, poultry or egg product it would be investigated by the state agency who's responsible in that state. We may or may not be notified of the distribution list from them. At this time Minnesota has not signed on of the MOU's. It's take us about five months to see if we can propose an amendment to our Data Practices Act, which is equivalent to the Federal Frequent Information Act, to allow us to protect that information. We're a very open

state or a very transparent state in that the Data Practices Act requires us to provide a lot of information to the public upon request. So being able to hold that information private has been the hold up in us doing that, signing that agreement. Let me go back a step. If we do receive that information and the media contacts us or anyone contacts us, we are obligated to provide that information after the certification of that recall or that investigation is completed. We can certify the information while the investigation or the recall process goes on, which means we can protect it but after it's finished, after the recall is completed, then the certification is lifted and we are then at that time required to provide it to the insurance agents or the media or anyone else who asks for it. We do make sure that wherever possible we contact the other state or the other agency that's initiated the investigation to see if we can verify that nay product's been distributed in Minnesota and our state. I do know that it would be, it's very uncomfortable to tell the media or your commission or your legislature that you don't have any information about the distribution in your state. It's very difficult to say I don't know. So

being able to have FSIS share that information in one way or another would be a really important step in not only facilitating the recall of a product that endangers the public's health but in keeping things a little more comfortable and a little more even keel, because sometimes when legislatures don't have access or don't have information that they would like to have right now they may overreact and there may be some outcome to that that none of us may like very much. As I said we are looking at getting pretty close now hopefully to sign the agreement. Of course, that's a legislative proposal that's being done and then it's up to the legislature to decide. It's out of our hands. We won't make that decision, whether we can or can't mend our Practice's Act. Many states are in the same boat. There are, I think, four states now who have signed it. But it's still most states have an equivalent to the Federal Freedom of Information Act that makes their information pretty open. I wanted to say that as I mentioned earlier that our relationship not only was out there but with the State agencies who do wholesale and retail food processing inspections because it has really improved considerably over the last few years. Some of things

that I think are real important are the electronic notification of recalls to State and Local agencies. There's an online recall achieves that provide historic information and that's real useful in a lot of investigations. Basing their decisions on epidemiological statistics is also, which are science based, are very important steps. FSIS have taken that step. We're seeing analytical methodology such as PFG fingerprinting and ribotyping is also another way that they're incorporating science in their decision making and that's very useful and I think moving with the times here. When you share information with State and Local agencies in a timely manner you really overcome some of the problems that can occur that a plan or FSIS can't always address in a real timely manner. Sometimes that person who's supposed to get the phone call about a recall is on vacation. Or sometimes they misplace that letter. Or sometimes they ask somebody to respond back and they don't and it sits there and it gets buried under some papers. So I have to say tat I wish everyone was as prepared as Smithfield with their recall plan but they aren't. I can say that with personal experience. So any help that's available to increase the speed that

a product is totally recalled or accounted for and that includes systems from State and Local Agencies. I can only recommend to FSIS that they find a way to make that happen. The sharing distribution information also allows stores to inform their customers about the recalled product because whatever the product is and it's identified in a press release by brand, by lot number and a really good specific information, accurate information that doesn't always sink in. And people just equate that to every other product or similar product or maybe not even similar product that they have in their own refrigerator or freezer. And getting this information that a particular retail store or a restaurant handled that product or sold that product is really important because people will go back to that store where they bought it to that restaurant they ate and ask, did you have that? Did you see me that? Is this some of that stuff that was recalled? And if the store has not received that notification yet, you know, it does damage to the entire industry, to the entire food chain. So being able to speed up the process would be really useful in a lot of different ways, for a lot of different people. And I think I also have to mention

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it's really important that having an open process really promotes consumer confidence in that product and in that entire food industry. So I think that really says a lot and while there are some understandable objections from the industry about sharing distribution lists and things like that I think the consumer confidence in our food supply is a very important statement. We do have some, I feel there are still some things that could be improved upon. There is some duplication of effectiveness checks by multiple agencies. In some states the local agency actually contract the plant themselves to get the information about distribution. And in some cases get that information. So they are out there doing, blasting out their people, their state and/or locals to do the effectiveness checks all the way down the supply chain to accomplish that more quickly. And then you'll have the industry and the plant sending their staff. You'll have FSIS sending their staff and it's kind of a, you know, resources are scarce, no matter where you sit they're scarce and it really would be useful to, if we could eliminate this and work in partnership so that we each have a role and our responsibility, we know what it is, and we can resolve

these issues a lot faster. I wanted to make a comment about the retail sampling of ground beef. The FSIS does do sampling not only in processing plants that they regulate but they also go into retail stores. And I think part of what they're doing is sending a message to the store and other stores, which is an important message that there are issues that they need to be aware of when they grind ground beef. And if they aren't in compliance then there may be a recall. And a national recall notice for 50 pounds of ground beef is kind of unnecessary. There are some ways that we can accomplish the same thing of doing some sampling at the retail level, doing that education that should be a part of the recall sampling and the recall numbers. And that can be done at the state or local level. Then I have to add and I'm sure everyone here in this room has this added on to whatever your responsibilities were before, security is an issue now. And security of the meat and poultry supply is just as important as food safety. And in fact they go hand and hand and because of the concerns and the fact that we all have scarce resources and after some of the budget cuts that we're facing we'll have even scarcer resources. I think this means

that this speak to the problem that we really need to martial our resources, don't duplicate and be as appreciative as we possibly can. Finally a couple of recommendations and commendations as well. We need a rapid and accurate decision making process on whether to do a recall or not do a recall. Whether to provide information or not to provide it to our food safety partners. And we need to strengthen the recall process because of accidental or intentional. And this is where our concerns of bioterrorism comes in. Intentional causes by using all possible resources to protect the public health. New technologies, partnerships and whatever we can possibly do, including working with AFDO. Anyway thank you very much and I appreciated the opportunity to talk to you.

MR. DERFLER: I'd like to thank Ms. Bohm and Dr. Petersen for their helpful talk. I want to remind you that if you have questions you can get a piece of paper out by the desk to write them down. Again you want to put down the name of the person who you've heard from this morning that the question would be addressed to. It would help me a lot. Now we're going to fill in the last piece in the recall process and that is the

other Federal agencies and how they act. We're going to hear from both the Food and Drug Administration and the Product Safety Commission. First we'll hear from Mr. Willie Bryant of the Food and Drug Administration. Mr. Bryant is the senior recall officer at the Food and Drug Administration. He has been with FDA since 1963 when he joined the Baltimore District Office staff as an investigator. He worked as an investigator from 1972 when he became the recall officer in the Baltimore District Office and then later he came to headquarters and joined the emergency operations staff of which he is still affiliated. From the Consumer Product Safety Commission we will hear from Mr. Marc Schoem. Mr. Schoem is the director of recalls and compliance division of the Office of Compliance at the Consumer Safety Product Commission. He's responsible for directing headquarters and commission field office investigations of a potentially defective, nonregulative and volatile regulated consumer products. Additionally, Mr. Schoem directs the negotiation and implementation of voluntary product recalls to ensure timely notification and correction of hazardous products. He joined the CPSC in 1974 and has had a distinguished career there

since. Under his direction they did put together an award winning program on fast track product recalls that was recognized for innovations in American government. So first I would like to present Mr. Bryant.

MR. BRYANT: Good morning. It's good to have an opportunity to speak to you this morning. My boss sends her apologies. Sandra Woodstone is my division director and she was scheduled to speak to you and she is detailed to an upper management position at the current time and she had multiple responsibilities for today so she couldn't make it and asked me to fill in. When we're talking about, excuse me -- that's fine. We were talking about recall situations, recognize that the FDA is the premier organization with respect to recalls and that we've been doing recalls since back into the 50's, back into the 40's even. And since I've been with the FDA, USDA and CPSC both have come to our office and looked to us for guidance when they were developing their systems. So we've netted a long time. We have a very complicated situation in that rather than just handling a simple commodity we have multiple commodities. So I want to give you just a brief rundown on our organization from headquarters and the standpoint

with respect to recalls. First we have five centers. We have the center for drug evaluation research, which handles, of course, RSOTC trucks, set up for device evaluation and research, a medical device can be anything from a tongue depressor to a multi-million dollar magnetic resonance device. It's extremely complicated the things that they handle. They also have the lasers, the radiation devices, such as televisions. We have a set up for biologic evaluation and research, which is responsible for all the blood making operations, blood products, especially blood products for vaccines and for human tissues, set up for food safety and product nutrition, which that's not just foods that they handle but they also handle cosmetics, your dietary supplements. That's a part of their responsibility. And you have to set up a veterinarian medicine that has a responsibility for animal feeds, for pet foods and also veterinary drugs. Each of these five centers have their own recall staff consisting of one to four persons. These recall personnel also have medical and scientific staff available to them in determining health hazards associated with the recall products. The overall responsibility for recall operations is under

the authority for associate commissioner for regulatory failures and the Office of Regulatory Failures. And under the Office of Regulatory Failures we have our field offices. We have 20 district offices, each located in a major city across the United States. Each of these district offices has their own recall coordinator who works with regulated industry to handle recall activities within the geographical boundaries of that district office. And then we have the headquarters component, which is the office of enforcement division of compliance management operations, which I'm a part of. At the moment we have two people responsible for overseeing and providing guidance and direction to all centers and the district office personnel related to recall activities. So when you hear folks speak of being under staffed and overwhelmed, you're in the right ballgame when you're looking at FDA, I assure you. I know at this point Dr. Petersen probably went through classifications and definitions and things so since CPSC and FDA brought it up, I'm going to just run through that briefly. With FDA a recall means a firm's removal or crash of a marketed product, that the Food and Drug Administration considers to be in violation with the

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laws it administers and against which the agency would initiate the legal action. That's the key here as to what makes that a recall. Would we in fact take some regulatory action against the product if the firm did not elect to voluntarily recall? In FDA all recalls are classified with a numerical designation of one, two and three. This is assigned by the centers. Each center recall staff that's done to indicate the relative degree of health hazard that's presented by the product on the recall. It's based on a health hazard evaluation conducted by agency scientists and health professionals.

This is done in one of two ways. We have a data base set up in the center for devices and so when we have similar situations or identical situations where we already have a precedence set we can use that precedent data base to determine what their classification would be. Our field people have access to this data base as well as the center of scientific staff. We are hoping that other centers will also come on board and develop similar precedent data bases that can be utilized by the field people so that when a recall situation comes up they immediately can look at this precedent and recognize what the classification

will be. This is turn will help the field people work with regulated industry and explain the significance of the problem in determining the recall strategy. The other considerations within the health hazard are if the disease or industry has already occurred from use of the product, whether any existing conditions could contribute to a clinic situation that could expose individuals to a health hazard. When we do an assessment of the hazard to various segments of the population, we want to know who is most likely to be effected by the problem with this product. And that includes infants, children, elderly, pregnant woman, immune compromised folks and especially the population at greatest risk. So we use the worst case scenario basically in determining what the health hazard is, also we run into industry where they'll say well, this is a Class II. And when it makes it to the general public it's a Class II but there's a special population out there that has access to this drug or this product and ay be using it and they're the ones we have to be concerned out. The allergen products, for example, is a good explanation of that in that maybe one percent of the population is allergic to nuts. But when we look at

food recalls, undeclared allergens, we have to consider that one percent or half of one percent of the population that are exclusively sensitive to those products. We also look at the degree of seriousness and health hazard to which the population at risk would be exposed, the likelihood of recurrence of the hazard. Another word, we look at the volume of the product that's on the market, the potential population that could possibly be affected and that has some effect, also, on the significance of the hazard. We assess the immediate and on range consequence of the hazard. Classifications, I'm pretty sure Dr. Tawadrous gave you this warning. So briefly, class I, reasonable probability that the use or exposure to a volatile product will cause serious adverse consequences or death. An example might be listeria in a rated food. Class II the use or exposure to a volatile product that can cause temporarily, medically reversible adverse health consequences. Where the probability of serious or the Class I definition is remote. An example would be it got in rated foods. And Class III, the situation where a use or exposure to a volatile product is not likely to cause adverse health consequences and we have

again a food example of fermentation of salad dressing or incorrect serving size situation. Recall authorities, the general public believes that FDA and USDA and probably CPSC have authority to order recalls and we know on the news we hear that FDA today recalled such and such or USDA today recalled so many million pounds of beef or maybe it was just 60 pounds, if that be the case. But regardless, recall authorities are very limited and FDA authority is limited to only in the earlier foods to have authority for infant formulas. In fact, the law requires that if infant formula doesn't meet certain specifications, that it must recall. So it's more of the law requirement than giving FDA the authority to order the recall there. Section 518.A of the medical devices regulations gives FDA the authority to order recalls of certain medical devices when there is a life threatening situation and there is no other way to eliminate the problem. And then in the center for biologics, they have the authority to order recalls of human tissues and certain biological products under the public health services act. But that particular has never been done. We have authorities there but we've never had to use it. And what I missed at the top, the

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important part is 99.9 percent of all recalls, which are regulated for the FDA are voluntary on the part of industry. We do have a procedure where we have an FDA requested recall, which is a formal house procedure where a recommendation comes into headquarters after and firm has been advised of the problem and elects not to recall the product, then a recommendation comes into my field office. It's reviewed by the center and by our office and it goes to the Social Commission for Regulatory Failures, which is in my letter. It's a request though, requesting that the firm recall the product immediately but advising them that the agency is prepared to take regulatory action should they decide not to. Our role in recalls, we're to provide guidance to the recalling firm in the development of it's recall strategy, including the method and the content of it's notifications. We want to determine the health hazard if there's any and we want to classify that recall based on that hazard. We want to monitor the progress of the recall, verify the perfect disposition of the recall product and assure that corrective actions have been made within the firm to prevent recurrence. And lastly we want to assure that our recalls are appropriately

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publicized. Contrary to USDA policy, FDA does not issue press releases for all recalls. This past year there were 4,000 recalled products for FDA related products. And there were approximately 2,000 separate recall actions that brought back those products. There were some situations a recall may include two or more products other than just a single product. So we were putting out press releases for 2,000 recalls a year. For one thing the press wouldn't pick them out or wouldn't carry them and the public would ignore them. So we were more selective. We do try to issue press releases on all Class I situations, when the product is expected to be in the hands of the consumer. The exceptions would be where a situation like Dr. Siemens mentioned earlier where we determined that the product has been contained within a warehouse. None of it's actually been released to the public and there would be no value in putting out that information. We do consider press releases for Class II situations, particularly things like infant formula recalls and food born outbreaks. When you don't put out press about the infant formulas and baby foods and problems, the public gets upset real quick. They expect that information to

be out there and certainly we want to do whatever's necessary to make sure that the public is notified of these significant situations even though they're not life threatening. We have model press releases that are posted on FDA's web site so that industry can go to that and see how their press releases should be written. Our district coordinators will work with industry, will bring those press releases into headquarters to the central recall staff to the Office of Public Affairs for review. But if they meet the model that's on the web site then there's no need for further review. We can go with it as is. Now the firms are given an option, even on Class I situations. The firms are given an option to issue press themselves. In most cases they do. We simply review that press release and if we find that it's inaccurate, it's not doing the job, we will reissue it or if the firm does not issue it at the beginning we'll be glad to do that. The FDA web site at www.FDA.gov provides access to all the recall information that's currently available. There is a document, referred to as the FDA enforcement report, which covers all recalls classified by FDA during the previous week. This is up on the web site, easy to

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find. The web site also lists all press releases issued by FDA and recalling firms. I have a few people that will send the recalling firms, press releases in and the Office of Public Affairs will also put them up on the web site. There's a problem with the FDA enforcement report. Some of you probably are well aware of it. And that touches back to what I said in that the enforcement report covers recalls that were classified during the previous week. Unfortunately, our classification process is not instantaneous. In fact, it's rather lengthy sometimes and that's something we're working very hard to improve. But sometimes, for example, biologic's recalls, if you'll look at the enforce reports you might find that biologic recalls that are classified may be six month to a year behind the actual time that the recall took place. So these are situations where a blood bank supervisor reviews a blood donor's donation records and determines in reviewing the records that possibly the interviewer skipped a question or that the amount of time that they used to swab your arm wasn't 60 seconds or it wasn't documented. A lot of things. Some very significant, some minor but the blood bank would then immediately

contact the hospital to which they shipped the product and then they bring it back. Even though the likelihood that there's any problem with that particular blood or blood product is extremely remote, we will not take any chances and bring it back. What the process of the blood bank doing this and notifying the FDA and the FDA headquarters notifying the field people and them having the resources and time to follow up and get these into the system, sometimes takes several months before that happens. So what we're looking to do is to develop a new system, something that will provide transparency, that will provide the agency with recall information in more real time. So we have a new system. The recall enterprise system that will, in the near future, post recalls on the web site, hopefully in real time. I'll give you a brief report on how that happened. Mr. Cannon, in January of 2000, when we started the recall engineering project, the purpose of the project was to improve efficiency in FDA's recall process and one of the primary purposes was to expedite timely notification as I just mentioned. And what were the reason for this? Well, we had a lot of reason. Food safety and nutrition, for example, is very concerned that food

recalls are not being publicized in a timely manner. In fact they might be looking over USDA's shoulder and seeing that USDA compliance staff is able to obtain information within 24 to 48 hours, I guess, and get it up there on their web site. And that's something that we haven't been doing. And so they wanted to improve. Our field recall coordinators, also at a recall conference, pointed out that was one of the things that they wanted to see. They wanted a lot of changes in the way that recalls are processed within the agency. And then we had the association of food drug officials Mrs. Bohm just mentioned, they're working with FDA as well as USDA and as far as their remarks go you could change the title at the top of her page and said how AFDO works with FDA and it would have all been pretty much the same. Because it is a huge organization that works together. FDA is vitally involved. In fact, my boss, Sandra, is initially involved with Mrs. Bohm in working with that project. But after a series of recommendations to us I even went to see, there's always GAO. They came in and did a review of some food recall processes and they came back and said we could improve the process in a number of ways. Primarily it was

recording, it was time keeping, it was verifying kinds of things. It was nothing meaningful as far as I'm concerned but they were sort of adamant that we develop our data base and we maintain the information that they wanted. So that was another reason. And there was some Congressional interest also for changes in our recall system. So what about reengineering goals? We wanted to develop a uniform health hazard evaluation to be used by all centers. At the present time all five centers had slightly different health hazard forms. They had a basic guideline that's published in the CFR. But they had developed individually. So we wanted to come up with a uniform hazard evaluation form that'd be transparent that everyone could look at. The industry could see it. The district could be aware that it is we're looking at a health hazard and they could use that form also for their own health hazard evaluation. We want to improve the tallies of the latest submission, the classification and the publication of recalls. We wanted to streamline the recall process to make it less resource intensive where it was past. We want to develop an agency-wide data base, which could be used by all recall components of the agency to more efficiently

input track and disseminate the general force of recall activities. At the present time three of our five centers will have their own separate data bases. ORA, which I represent, has a data base, which we consider an agency data base but it doesn't have all the components that the different centers want. It has what ORA feels is necessary. So our goal was to evolve into a single data base, which would address the concerns of all the centers as well as the Office of Regulatory Failures and we provide everything that they needed, that way we could eliminate other data bases and just have one central one. We wanted to develop a recall internet site to provide recall information in public in real time. And we want to evolve and publish industry recall guidance. Okay. I'll start by our accomplishments. What have we done to accomplish our regulatory goals? The recall enterprise system is under way as of November 15. We are talking about phase one. It's going to be phase two, phase three and hopefully not phase four but it's a very complicated system, complicated in many respects by the fact that each of the centers have their own data bases and we're having to try to integrate data bases or at least make this a ready data base to talk to

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the others so that the centers could enter information in the central data base and it in turn would download into their own data base, which also handles many other things besides recalls. So they still have to maintain their data bases but they just want ours to talk to. Where from a technical standpoint and I'm totally not a technical person but that's very complicated. So the data base has been developed. We're still working to get the integration between the centers but the data base is there. The uniform health hazard form was completed some time ago and that's now in use in the centers. Now the district recall coordinators submit recalls and then the centers review them, classify them and they're terminated either by the centers or by the field depending on whether it's a Class I or a Class II, III. All this is done on one electronic document entered by updating it using the internet. It's really a much better system than the hodge-podge collection of things that we were doing before. And so I made a number of forms and other problems. And then the records to industry guidance, we have developed a document referred to as product recalls including removals and collections, industry guidance. This is

all inclusive, it covers all industry regulated by FDA.

So should you be in a particular company and you look at it you'll see that all things may not relate to your specific operation but we had to make it all inclusive so that regardless of what type of product you are manufacturing and distributing that these guidance would tell you what you needed to do. This guidance has been developed, it's at the point of issuing a notice of availability and that should be done within the next couple of weeks. There will also be on the FDA web site, there will be a lead to it from the web site. Okay. We do have the capability of publishing real time information on the web site. The system is currently working. It's being tested. The Office of Public Affairs wanted to look at it carefully to see if the information was coming up in an appropriate manner and it's accessible and user friendly to the public and so we're working on that at the moment and we expect implementation within about 60 days. And that's a guess, that's not a promise, okay? I mentioned the weekly enforcement report. The weekly enforcement report would disappear once the web site is on and all recall information is there. And it will have an

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extensive research capability that we believe the public can find whatever they want. You can search by dates of recalls. The last seven days, the last 30 days. You can put in a time frame. You can manufacture the product, the recalling firm. All those perimeters can go in to bring up whatever you may be looking for. So in a nut shell that's where we are with FDA's process.

MR. SCHOEM: I'm not really sure if it's better to go first in the morning or go right before lunch. I don't know which is the least desirable. Because I know you're always eager to get out. I'll get started while he's cleaning that up. I'm with the Consumer Product Safety Commission. Some of you may not realize that we are an independent Federal regulatory agency. We're responsible for the safety of some 15,000 different consumer products that are used in and around the home. Generally, any product that's not already regulated by another government agency comes within our domain. Okay. Example, some of the products we are involved in, everything from hair dryers, halogen lamps, toys. You know, products all the way to the local amusement rides, fire sprinklers they find in buildings, all types of consumer products. And like I said there

are about 15,000 different products that we have jurisdiction over. Just to give you an idea of how big we are and how small we are we have about 480 person staff with a budget of about 55, 56 million dollars. We're headed by three commissions that are appointed by the President with the advise and consent of the Senate.

And right now we are fully staffed. We have three commissioners. We have the new chairman, Hal Stratton, who came from the New Mexico Attorney General's Office.

He's been with us for about three months now. How do we carry out all of the responsibilities? We can issue mandatory standards. We can ban products. We can recall dangerous or violent products. We can seize products that violate mandatory standards and we can also seek Federal and criminal penalties, primarily where a company or industry fails to report certain information that they're obligated to report. The Office of Compliance, from which I'm at is responsible for enforcement of employer rules and regulations that are administered by the agency. We have five Acts that we administer. The Consumer Product Safety Act, the Federal Hazardous Substances Act, the Poison Protection Packaging Act, Flammable Fabrics Act and the

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Refrigerator Safety Act. A number of those Acts came from other agencies. Many of the people 30 years ago, when the agency was formed, came from Food and Drug, came from the Federal Trade Commission. So a lot of the practices and procedures that we had in place were brought over from these predecessor agencies. We do have specific reporting requirement though for industry. Manufacturers, distributors, and retailers are obligated to report under what we call Section 15 of a Consumer Product Safety Act, where they have a defect that present an unreasonable risk of injury. So we do receive about 350 reports a year from industry. We think we ought to be getting a heck of a lot more reports. We think that only touches the surface. As a result we don't rely only upon the reports that are made under Section 15 in order to determine whether or not there's a defect that exists in a product or if a product is volatile and there's a lack of conform to our regulations. So we initial several hundred investigations on our own using some of the same type of source information that you all use, the Department of Agriculture uses, Food and Drug uses. We rely upon consumer complaints. We have a hot line. We have

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60,000 actual complaints a year from our hot line. About 150,000 calls, it used to 700,000 because we have a web site now, we're now getting about eight million hits from our web site so we're getting a lot more electronic mail complaints than we were previously. Also copasetic to the size of the agency, we're just like the Office of Compliance. We have about 45 people in the Office of Compliance. Exactly about 17 compliance officers and we also have other support, about seven or eight compliance officers around the country in our field offices. So we have about 21/22 compliance officers that are handling the reports, investigating potential product defects and then also negotiating recalls. We also have a staff of about 13 or 14 attorneys that support the compliance officers. Where there is an order or there's an authority to recall a product or for the companies or industry to recall a product they do have that obligation to report product defects. As a result of that reporting mechanism, we get into whether or not a corrective action plan or recall is necessary. So we handle a lot of products. There are really two types of recalls that the agency now does. What we're calling just the

tradition recalls, which has dropped off substantially since the advent of our fast track product recall program. In the traditional sense, the firm would report under Section 15 where the staff would initiate an investigation on their own based upon some lead, some information that indicates a consumer product contains a defect and they present a significant risk. We obtain full report information from the company and this is generally done within a 10 to 15 day working period. Independently we have our own technical staff. We have manufacturers, engineering scientists, epidemiologist, economist, mechanical and electrical engineers, structural engineers. We have a laboratory who independently will look at the product that's being reported or the product that's under investigation to determine whether or not that defect does exist. And if that defect does exist, really what we're looking for is it a significant hazard? Does it rise to a level where we would ask a company to take some type of voluntary corrective action? We look at the number of products that are in distribution. We look at the severity of the list. We'll look at the likelihood of injury. We'll look at the volatile population. How is the

product being used? Who's it being used by? For a children's product, a child may not necessarily be able to protect themselves like an adult. So that will all be taken into the mix. Whether or not we would then ask the company to conduct a voluntary corrective action plan. In both the fast track and I'm getting to the fast track recalls, and traditional method, we go to the company and receive from them a voluntary corrective action. Like FDA about 99.9 percent of the recalls that the agency conduct is voluntary. In a voluntary, of course, you always have that clout that if they don't do it we have certain enforcement tools that we can go and use against them should it be necessary. That's one of the reasons why we have those compliance officers and attorneys working recall cases or investigation cases. In August of 1997, although it should be 1995, we initiated a fast track recall program, my pilot project in August of 1995. It was a staff initiated concept. Our then chairman asked for staff ideas on how to improve the process throughout the whole agency. And we felt that there was a deterrent to companies coming in reporting under Section 15 that they had a product defect. Especially when the company reported on Section

15, had a product defect and wanted to do a voluntary recall. Often times we set them down and we said wait, we've got to investigate. We've got to make a technical assessment of whether or not the report you're making and whether or not the defect you have in your product rises to a substantial hazard level. If it rises to that level, then you can do your recall, otherwise we're going to close it out. So companies thought that they were being penalized when they wanted to come in and do a recall. So what we worked out was that if the company reports under Section 15 and they can conduct an adequate consumer level recall within 20 working day of the report, the staff would not assess whether or not a substantial hazard existed. So we would free up our chemical resources and we would also free up the company from having to provide us a lot of documented and detailed information on what the problem was. We were going based upon what the company's represented. That if the company reported a particular problem, we got some minimal information on what the defect is and what the risk is. We worked primarily with what the remedy was going to be. How to notify consumers, how to notify the distribution chain and also how to fix the problem.

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We wanted some assurance that the same problem would not reappear once they fixed or once the remedy was worked out. So since August of 1995 about three quarters of our reports that come in now are under the fast track program. And we've had over 1,000 recalls under fast track with about one hundred million products being recalled. The average time for a recall under fast track is about six days, which has been reduced by several months. Because in a traditional method you have to do that typical assessment and it might take 10 to 12 weeks just to confirm that a defect does or does not exist. So generally a fast track recall gets out within six days. That may not be the public notice. That's actually the first notice outside the recalling company. Generally to the retailer or the distributor. Where's the recall? We find the recall material. And our experience over the years has been that this industry does not like the term recall. We like the word recall because we think it send both the media and consumers a message that is important to the matter that needs to be taken care of. A recall, as we define it, is any repairable product, any replacement of a product or any refund in a product. Assuming the company comes

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in and we've gone to them, we've made either a determination or they come in under fast track, we ask them to submit a voluntary corrective action plan. And the corrective action plan really has two components. It's the notification component as well as the remedy component. And the notification is targeted to the distribution chain and the product owner to inform them not only of the hazard but also what the remedy is. And the notification that we seek from companies is really linked to the hazard and the risk presented by that particular defect. Rather than a number system we use a letter system, Class A, B, C. Class A is the most grievous, serious injury where death could occur, death is likely. Class B, mid-level, Class C is a lower level. Under fast track we don't do a designation, although we know internally what we think it might be because that thing guides us in the company and what type of notice we're going to seek from them. Okay. In the traditional method of a recall we will classify it, we will send them a letter saying we've made a preliminary determination and then we'll seek a corrective action plan that's appropriate with that particular classification. When we've asked a company,

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we're working with the company on a voluntary recall, there are only four steps as we see it. We ask them to stop the production. Along with that we'll stop production or else we'll stop distribution. We'll ask them to stop the retail sales. And then we'll ask them to come up with an adequate consumer notification plan.

Each one of these and we'll move on to each one, has some unique steps. For production, for the manufacturer, for the employer, we'll isolate the inventory on the particular defect or products and we'll ask them to come up with a plan on how they are planning to fix that and also, maybe more importantly, how are they planning on disposing of it. We track everything the recalling company does from A to Z, from the beginning to the end. We don't leave it up to the individual recalling company to really do anything on their own. Most companies that we have worked with over a number of years, know there are certain formulas that we look at, know that there are patterns that we look at. So they're pretty prepared when they come in to give us a corrective action plan that's comprehensive. What the agency looks at, the staff looks at every step of the phase and how the company intends to recall the

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product, repair the product from various phases from manufacturing. So it's all subject to CPSC approval. With respect to the distribution we'll look at the notice that's going to go out to distributors, we'll work with the individual recalling company on that notice to ensure that it contains clear and precise language. We'll ask them what their plan is to isolate the inventory. How they're going to plan on getting it back, what they're going to do with it, how they're going to correct it. And again it's subject to CPSC review. With respect to retailers, we'll look at the recalling company's plan. Generally we work with manufacturers or importers of products, so they've got to go to the retailer and seek assistance from the retailer. We have jurisdiction and authority of the retailers as well, so the retailer, if they don't work with the manufacturer, we'll open an independent case against them. But generally retailers are willing and cooperative and they work with the recalling company. But we'll take steps to assure that the retailer has stopped selling the product, they've isolate the product again as well and see how they're going to fit into the whole formula of remedy and also notification. With

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respect to considering an application, which we primarily target, that's one of our priorities and how to reach the consumer. The bottom line is to reach as many owners of a recall product as possible and provide them sufficient incentive for them to stop using the defective product and take advantage of particular remedy that's being offered by the recalling company. With respect to consumer notification, the manufacturer or the recalling company has the obligation really to come in with the voluntary, corrective, action plan. We ask them what do you intend to do although my staff will certainly recommend certain steps be taken, depending upon what the risk of level is, what the hazard level is. And generally every recall that we do will have a joint press release. That's issued by the CPSC and the company. We have a quirky law that Congress imposed upon us called 6B of the Consumer Product Safety Act in that we're allowed to release any information to the public or to any outside party that identifies a manufacturer or brand name unless it has first been cleared by that particular company. So we can't just go out and issue a warning. We can't just go out and issue a press release that this product is bad. So we are

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almost compelled to work individually with each company on the specific words and language and any type of joint notice that goes out. As a result it's a give and take negotiating process that goes on with respect to every recall where there's a press release. The only time when we would not seek a recall press release generally is when we're dealing with a company like Cosco or BJ Warehouse or a catalogue company or JC Penney catalogue where they have the name and address of each and every owner of the product with them to work with that particular company on looking how to best reach that person with direct mail. Generally every recall we do where it's sold in retail store we'll have a recall poster. And again the recall poster has a certain designated type and size language. Although it's more by procedures and experience that we've gotten to there.

There's nothing but statute that they have to do a recall poster. It's generally up there for about 120 days. We ask that it be posted in some conspicuous locations. Depending on the product that is being recalled we also will work with the company on specialty posters. If it's a children's product, generally we'll ask them to do a notice of pediatrician offices. The

same recall poster located in stores would then find it's way to pediatricians. We would probably have care professions when we go to repair centers if it's a hand-me-down type product or a second use type product when they very well ask the recalling company to also provide posters to thrift stores around the country. Also required for every recall is if the company has a web site, we require that they put notice of that recall on their web site. And it can't be hidden away somewhere where the consumer has to find it. We ask them to put a recall or safety information or some type of icon or button on the home page so that you see it right away. This is a battle that we have been fighting with a lot of companies over the last couple years because the marketing people get involved and they don't want to mess up their web site. But in order for them to get a letter from us that says their recalls acceptable they're going to have to follow through and do certain things. It may not happen with the first recall they do but they put on notice that the next time they come in they're going to have to do a web site notice. In there, the Class A hazards where death has occurred, significant injuries have occurred, and one comes to

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mind, some of you might remember the Burger King Pok'e'mon Ball that was recalled five, six, maybe longer seven, eight years ago. We had at least two infant deaths where the half of the ball was put over the child's nose and mouth. We work with Burger King on a lot of extra publicity. We did provide a recall poster or a press release. They did take advertisements, they did some special magazine advertisements as well as advertising supplements. So we'll look at whether or not there's an appropriate need for newspaper advertising. We also require that companies in recalling a product have an 800 number so consumers can reach them. If they have a web site, we'll ask to try to make that, interactive so consumers can register on the web site to obtain the remedy. We'll also remind companies that they have to look within the company themselves and they might be able to identify some of their customers that way. People who have purchase a set of warranties or called their 800 customer services. They may very well be able to get their name off somebody who purchased a recall product. Other types of notice that we've been doing over the last seven, eight, nine years, we hold press conferences where there's a

Class A recall. We'll hold the press conference and invite the media out. And again it's generally cooperative in that it's a voluntary corrective action plan. Companies don't always like the fact that we're holding press conferences announcing the recall. But at the same time what we're trying to do is get as much publicity to the media and consumers. Our previous chairman was famous for going on the Today show and Good Morning America about every six to eight to ten weeks to announce recalls. Our present chairman has already appeared on both CNN and Today show and Good Morning America, I think in the three months he's been here, several times. So again we view the morning news shows as a very good avenue to try to get publicity out on recalls. One of our biggest challenge has been over the years and continues to be how to get consumers and not only consumers but how to get the media to react to recalls. With all the Federal agencies issuing recalls we're always looking for some other way and we're doing it more collectively to try to get to the media to get to consumers. Some other types of notices that consumers have been doing lately to try to get word to owners, putting product inserts in other products that

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may be related. Vacuum cleaner bags, when a vacuum cleaner that was recalled so they put the notice of the recall in the vacuum cleaner bags. Tray liners, food bags, Burger King did that for a period of several months. Whenever you went into a Burger King store not only did you see the poster but in the bags, the carry out bags, as well as the tray liners, you saw notice of that particular recall. And then we also may do television ads, radio ads and some other things. We encourage companies to come up with consumer incentives, to get consumers to return the product. Because everybody's busy and not everybody wants to avail themselves to the remedy. So some of the companies will come up with gift certificates or cash bounties. Will try to make it as easy as possible for the consumer to return the product. Send them a preaddressed stamped shipping box, that way they don't have to box it up and do anything. Put the burden back on the recalling company rather than the consumer. Telephone numbers, I said we have an 800 number that the company has to use. The second phase is a consumer remedy. And the remedy is proposed by the recalling company. Whether it's a repair or a replacement or a refund but the agency will

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look at every part of that proposal. If it's a refrigerator, we're not going to accept the recalling company telling the consumer to return the refrigerator to the store. But we will look at whether or not the consumer can make the repair themselves safely. We'll look at whether or not in-service store personnel can go into the home and do that particular repair. So we work out all phases of the remedy, whether it's a repair, replacement or refund. Generally, phone calls are 800, consumers call an 800 number and they find out information about the particular program. We do work with the recalling company to coordinate the public notice and the distribution notice with the retailers. Generally the recalling company doesn't want to go to the retailer until the day before to tell them about the recall. I don't know if that's been your experience. But we try to get at least a weeks notice. All the retailer, we try to get posters up in the stores prior to the public notice so really the public notice isn't the first kick-off, it's really the end result of the recall program. We do monitor recalls as well. Each recalling company is required to provide to us a monthly progress report giving us a number of corrections,

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replacements, refunds done that previous month. We also are looking at how the consumer learned about the recall. We ask the company's to find that out. It's not always possible if it's not a live operator but that generally will help us in future recalls. We also conduct, after these checks, we do a limited number of effectiveness checks at both the retailer and consumer level to be sure that the manufacturer has gotten the word out to the distribution chain. We'll monitor the media reporting of the recall to assure that it's gotten the message out. We'll also monitor reports of limitation and if there's any additional reports of incidents or injuries, we'll monitor that as well. Here's the last four fiscal years, the number of recalls that we've done. These are both for regulated products that violate one of our regulations as well as nonregulated products that are defective. So last fiscal year we had about 386 recalls, which was one of the largest numbers over the last 10 year period involving some 50 million different products. And the numbers have been going up increasingly. That's why we think that there probably are more reports that we ought to be receiving every year. Here is some more

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information, www.cpsc.gov. It's got a lot of information under industry, the industry icon. We've got a recall handbook that really is the, you just go into our search engine, it will give you all the information under recall handbook on how to conduct a recall. It's not only our procedures but it's also what a company can do to set their company up to avoid, hopefully, prevent recalls. In any event they need one they can find out how to do it there. The only other thing I'm going to say is that the agency now is looking at consumer recall effectiveness. When the chairman came in a few months ago one of the things he asked us to look at and what he's designated as a priority for him is looking at how consumers receive notice and whether or not we ought to be doing more. As a result we've got a pass course that's now meeting, looking at the first phase was conducting a literature service to see what exists out there on recall effectiveness, how consumers receive information, maybe there's other ways that they ought to receiving information and then we'll be looking internally at the data bases that our compliance office has on these thousands of recalls we've done since the early '70's to see whether or not

there's something we can glean from any of their progress reports or any reports from companies on maybe a better way to conduct recalls. So this is a good process, I think, that you're going through and we're certainly interested in hearing what you've come up with. Thank you.

MR. DERFLER: Okay. I'd like to thank Mr. Schoem for his fast track speech and I'd like to thank Mr. Bryant. Although we don't necessarily agree as to that the premier recalling agency is. We have no time for questions. I'm sorry. What? No, I'm sorry. We'll give you an opportunity at the end of the day. I know and at the end of the day...

MS. DEWAAL: At this presentation this morning and no opportunity to ask questions.

MR. DERFLER: At the end of the day they'll be an opportunity to ask questions. No. At the end of the day there'll be an opportunity for questions. We'll reconvene at one o'clock. Thank you. What?

MS. DEWAAL: When the question and answer period is right after lunch, do you ask the ten speakers who we heard from this morning to be available...

MR. DERFLER: The problem...

MS. DEWAAL: This is not a public lecture.

MR. DERFLER: I understand.

MS. DEWAAL: This is a public meeting.

MR. DERFLER: And I'm really sorry that we're running so late.

MS. DEWAAL: We can delay lunch by half an hour.

MR. DERFLER: The problem is we've got a full schedule for this afternoon that's scheduled to run until 5:10 anyway. I mean we can have an opportunity...

MS. DEWAAL: If we're not allowed to ask questions, why should we be here?

MR. DERFLER: You have an opportunity to ask questions and I will ask all the speakers to be here this afternoon so they're available at the end of the day to answer questions.

MS. DEWAAL: So you will give us an hour for all the questions that everybody has?

MR. DERFLER: We'll have an opportunity to ask questions until we run out of time.

MS. DEWAAL: Okay. But we have a lot of questions for these speakers.

MR. DERFLER: I understand and...

MS. DEWAAL: There's a lot of people here and we have a lot of questions. And we would ask if you can't assure that they'll be here that we do it directly after lunch or we'll ask right now.

MR. DERFLER: Well, I'll ask the people who were here, spoke this morning, if you can't come, if you will identify yourself to me and I will let you know and we can see about you getting in touch with them. Thank you. We'll meet after lunch.

MS. DEWAAL: This is a public meeting.

MR. DERFLER: I understand and I'm not trying to do that but we have to move it on. Okay?

[Off the record]

[On the record]

MR. DERFLER: Okay. We said that we'd get started at one o'clock and so we're going to get started. I need Angie. Okay. We've got four written questions and I said before that we were gong to start with the written questions. Okay. Let me just, hold on a second, back up a second. Shortly before lunch time I received the request for questions even though we said

that it was the end of, it was time to break. Cooler heads have prevailed and after some deliberation we decided that we will provide a question period now. And then they'll be a question period at the end of the day.

So we're going to start now. I've invited all the panelists who appeared this morning and we're going to start with the first question that we got. We have four written questions and I'll do the best I can to answer them and then at the end of the four written questions we will provide an opportunity for people to come to the microphone to ask questions. And then we'll move on into the afternoon session of the agenda. Okay. First question, regarding in-house table trim, generated from multiple whole subprimals for in-house grinding. In the event of a positive E-coli infection sample found by USDA sampling of raw ground beef to what extent would FSIS consider light raw materials used in production of other lots. IE other table trim generated by similar whole cuts. Is only the sampled lot subject to a recall or is it carried out into other lots with similar raw materials? If so, how is the source of contamination investigated? And I give that question to Dr. Tawadrous.

DR. TAWADROUS: Okay. First of all, we have a policy of clean up to clean up. And we'll see what this sample represents from clean up to clean up, is it the same grinder or different grinds, multiple sources. And we do limited to that. However, we have a three step possibility whenever we have a clean source. If we do have a clean source, yes, we do trace back, we do follow-ups. But we try, as we said this morning, we do things expeditiously but prudently and we have to work from the perimeter of our policy and the Act. I was saying that is there was a problem we do have assessment on a case by case basis and we have our teams in the field. We can go to the establishment and look for other sources and problems if need to be. Now this is just a general outline for situations like that.

MR. DERFLER: Okay. The second question that we got is, if FSIS requests a recall yet the firm does not recall does FSIS still provide public notification of possible public health concerns. To my knowledge this has only happened once. And in that instance we did issue a press release notifying the public of the concern involved of the product in question. So the answer is yes. The next question is in the event of a

recall of any type what, if any, responsibility does the distributor have selling that recalled product? Does the main responsibility and liability lie on the manufacturer issuing the recall? And I think I'm going to turn in the first instance to Dr. Siemens and then see if anyone else has any further comments.

DR. SIEMENS: I guess some of it is in return of liability. I look at it two ways. I think someone needs to answer the regulatory part of this. And there's probably regulatory applications. But from my standpoint it still has my brand name on it going through a distributor. So what I need to do to protect the company's liability is if I've got an uncooperative distributor I need to work some way with someone to work through that issue because I still have products with my name that can put the company in liability. So we're going to try and work through whatever means necessary to be sure that we can work with that distributor and work it through. I'm going to turn it over to Dr. Tawadrous for the regulatory piece.

DR. TAWADROUS: For every recall, as I mentioned today in my presentation, we do make it incumbent on the recalling firm to notify their

consignees verbally full up in writing. And that writing will say in the event of a sub-distribution to an additional distributor or sub-distributor, the letter that the company A is writing to distributor in it. We made it incumbent upon those to notify any sub-distributors. And our compliance on the go from the recall effectiveness check, we do make sure that the first level has notified the second level in writing and verbally as well in that particular situation. And it can go to either third and fourth level and it did happen.

MR. DERFLER: Okay. Does anybody else have any comments that they'd like to...

MR. SCHOEM: I'd like to make a comment.

MR. DERFLER: Sure.

MR. SCHOEM: The FDA recall guidelines that mentioned earlier, published 1978, has a particular Section, part 15F, we believe that discussed the further responsibilities. It indicates that the distributor of the product has the same responsibility to subrecall and get that product off the market as does the manufacturer. So we expect first the manufacturer's notification to the distributors to have a statement in

there that we're requesting that you subrecall to the retail level, to your customers. And as Dr. Tawadrous says, if it happens to be a large distributor, goes to secondary wholesalers it doesn't matter. We want to continue down through chain until the product reaches the retail level. And then we expect the manufacturer or the recalling firm to conduct effectiveness checks and be assured that his distributors have, in fact, initiated recalls down to the retail level. And if it's a Class I situation or significant situation where the FDA is conducting audit checks, we will also not only contact the direct accounts but we will expect the direct accounts to have subrecalled and we will actually go out and visit some of the companies of the distributors to be certain that they, in fact, have done what they're supposed to do. For the CPSC, since our authority extends to the whole distribution chain, we too could go directly to the distributor but we prefer to work with the manufacturer of the imported product and let them take a lead in notifying the distribution chain but then we're involved at looking at all aspects of the notice that goes down to them. If we find that there's a recalcitrance by anybody in the distribution

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chain to follow what the manufacturer is requesting then we have the ability to independently open a case against that distributor and make a preliminary determination of hazard, since they also distributed the products into commerce and ask them to submit their own corrective action plan. Generally that doesn't happen. The distributors and the retailers would generally follow what the manufacturer is requesting them to do.

MR. DERFLER: Does anybody else want to comment? Thank you. There's one more question and then we'll open it up for questions from the floor. As I'm reading this it's a little bit hard to decipher but I'll do the best I can. Dr. Tawadrous mentioned that information from in-plant inspectors can serve as a basis to trigger a recall. Over the past two days there have been news accounts concerning an inspector assigned to the Wampler plant who had been trying to alert FSIS supervision about serious sanitation problems at that plant, whose concerns were either ignored or not pursued. Dr. Murano, undersecretary for Food Safety has tried to minimize these, and I can't read this word I'm sorry, allegations by stating that the inspector should have turned the information to the USDA inspector

generals. At a 2001 hearing before the Senate Agriculture Committee Roger Viadaro [ph], who was the USDA inspector general at that time, testified that FSIS approach to investigating employee allegations that the inspector general receives on his whistle blower hot lien was a sham. Often times FSIS turned over the information to the person against whom the allegations were being made with no independent investigation by the agency. Has FSIS approach changed and has that policy been communicated to its employees? I would say first of all this isn't relevant to this meeting but second of all I think Dr. Murano yesterday in the papers made it very clear that we'd take these allegations very seriously and they've been handed over to the inspector general for investigation. Are there any questions that people would like to raise from the floor? Could you please identify yourself for the record and ask your question? If you're addressing it to anyone, go ahead.

MS. DEWAAL: Thank you. Caroline Smith DeWaal with the Center for Science in the public interest. Thank you very much for reconsidering your initial decision and deciding to hold the questions right now. I know there are at least four of us who have questions,

two of them aren't here right now. So I'm sorry for the miscommunication and I'm hoping they'll arrive while the other Q and A is going on. My question is actually to Dr. Murano. Is it on?

MR. DERFLER: That's okay. The acoustics are good. We can hear you well.

MS. DEWAAL: Okay. Thank you. Now I'll have to talk quietly. My question is about the decision that the USDA made not to have CDC participate in this meeting. This is a significant meeting and we're very glad that the department is having it. And I think the presentations this morning have been quite excellent and enlightening and especially from CPSC and some of the other government agencies that do have a mandatory authority. But with both FDA and FSIS there is a critical that CPC played in many recalls and while you have a speaker, Dr. Holt, from FSIS who talked about the liaisons. It think that's quite distinct from the role that CDC played in actually investigating the outbreaks and then trying to identify the food source, which becomes quite critical to your recall decisions. And in fact in the Billmore situation and the Sarah Lee situation they actually, CDC and FSIS were both asked by

the company whether they should recall the meat that had killed four to six people and ultimately ended up killing over 20. So it's very important I think and a gap in this meeting that the independent CDC was not asked to come here and talk about their unique and independent role.

DR. MURANO: Well, all I can tell you is certainly when we planned this meeting the purpose as Phil Derfler stated very well. One was to inform everyone attending what our process is and so forth and also what other agencies do as you heard this morning. But also certainly to get people's input on knowing then what the recall process is, recommendations and what we can do to improve it. I'm sure there's a lot of other people we could put in the program. I assure everyone here that we value at USDA our relationship with CDC tremendously. So much so that Dr. McKee and Dr. Holt went down to Atlanta about a week ago, Dr. McKee, to visit with their people there to talk about collaboration that took place with our two agencies as a result of the listeria outbreak. It was certainly a collaboration that we valued and that we learned a lot both sides, CDC and FSIS has learned a lot about what we

could do together and how that process is improved when we work well together. I personally went to Atlanta myself on Friday and visited with Dr. Guberting [ph], the director of CDC. So there is a commitment on the part of USDA and I think on the part of CDC from Dr. Guberting's conversation with me to, you know, work very closely with us. So I do believe that Dr. Holt's presentation was very good. She certainly presented what CDC does very well. I'm sure this will not be the only recall meeting we will have and I'm certain that that will be taken into consideration for the next time to see if maybe we can broaden the scope of the meeting itself.

MR. DERFLER: Any other questions from the floor?

MS. ESKIN: Hi. I'm Sandra Eskin and cover food safety issues for AARP. My question is to Dr. Siemens and anyone else who may have information. You mentioned in your discussion about the recall process that you were frustrated because the media often get it wrong, the information that needs to reach the consumers. And I was wondering if your company or if you have any other companies that have ever used point

of purchase notification or even paid advertising, which is apparently done sometimes with CPSC regulated products. Have you tried either of these methods to notify consumers about product recalls?

MS. SIEMENS: Well, I think that there have been some reports, you know, I don't have a lot of these that I personally get involved in. You know, you have to say that. I think the Federal thing's been done. As we build more relationships with our customers, getting that information out and as our customers become more sophisticated in getting information from, you know, their particular corporate office into their point of purchase in retail. I don't control the retail establishment so we've got to build a partnership. And I think a lot of it is going on with the companies we are working on. They want to get the product off and they want to be sure that they're not caught in the middle of a liability piece because they just happen to be holding product produced that we need to get out of the consumer's hand. I know there have been some efforts with some of the organizations in moving in some host seats. Again, I don't control what goes on in this level but I think if there's anyone from the retail

industry it's probably a better question for them. Secondly I know there have been some paid advertisements that have gone out historically on some of the large ones. Again you're dealing with trying to figure out what the target audience is depending on what the distribution of the product is. And you know if you just understand marketing and advertising in general it is a limited response to advertising. It is another incident and what we probably need to think about is the multiple approaches to getting to the consumer, you know, risk. I did not mention, I want to, the Allergy Network I think has done a tremendous job and I know there have been several companies there that had to do this but several companies have worked directly with Allergy Network to distribute via their e-mail list of those folks that have, you know, severe allergy situations. And I want to commend them for their work that they do in being proactive for their constituent from that standpoint and getting the word out especially when an allergen is involved. So there are multiple levels that we're going to have to consider depending on what the distribution is, what's the severity is of that.

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MS. KRISTIN: Hi, I'm Charlotte Kristin from the Center for Science in the Public Interest. First of all thank you for the opportunity to ask the questions of the panelists immediately after the morning panels. I think for all of us who might have other commitments it's certainly important that we're able to do this and we do appreciate this opportunity. I have two questions for Dr. Petersen regarding the agency's decisions about not releasing information to the states. I want to understand your analysis that one of the reasons you should not release distribution lists to the states is because of concern that in the future that the companies might not cooperate with the agency again. I fail to see the justification for that and I think that in fact that argument cries out for mandatory recall authority for the department. If you were having to withhold important information so that you can ensure that companies work with you in the future, you're doing a disservice to yourself and to the public. Can you explain to me how you can justify that policy and not demand mandatory recall authority?

DR. PETERSEN: You have to remember the information we're talking about the company's giving us

is proprietary information. And so it is under the Foyee's Statutes there are exemptions to releasing that information publicly. So it is protected. And what we want is for the companies to be as rapidly forthcoming with that information. And it's really not then an issue for us. But then that comment that I made is put forward as one of the reasons that, there were others but that was really one of the reasons that we decided that we had to move with the MOU. So we took away any questions revolving around that Foyee Exemption of that proprietary information. So we haven't experienced any delay but I don't want a company to even have a question in their mind where could this information go? Because it is protected and by giving it to people who are meeting the company's expectations that the information will in fact be protected. So we're simply making sure that we're fulfilling obligations under that statute. They should understand that information when they give it to us will be handled in an appropriate and confidential way.

MS. KRISTEN: But I think that that interpretation misread the Foyee Exemption. I think that you're making the assumption that, number one,

Foyee is not based on what a company's expectations are.

The Foyee Exemptions are meant to be read narrowly.

The whole purpose of Foyee was not to protect business records. In fact, it was to get information out to the

public therefore the exemptions are meant to be read

narrowly. And you haven't found any substantial

competitive harm from releasing this information to the

states nor have you shown that this information isn't

customarily released. I mean the fact is that we have

products in supermarkets that have P numbers in them.

We've had members of industry stand up in public meeting

and say that everybody knows who's doing business with

whom anyway. So there's no reason to protect these.

And we're moving, the industry's moving toward a branded

product. I don't see this argument that this is so

secretive. I mean there has been Foyee cases in which

customer lists have been released and I maintain that

the agency has not made a strong argument for keeping

this information from the states. And if you think you

don't have the appropriate authority to allow yourself

to release this information to the states you need to be

on the Hill demanding mandatory recall authority.

Because you're saying you're public health agency but

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you're not acting that way. Thank you.

MR. DERFLER: Okay. We have three minutes left. We said we'd give 30 minutes and there's about three minutes left. So this will be the last question.

MR. KOHL: Terry Kohl, public citizen. First, Phil, I want to apologize for your having to struggle with my penmanship but I'm also sorry that you don't see the relevance of the question for this meeting. Because you have a 7,000 plus special work force out there. And if those employees do not feel that they can communicate their concerns properly and internally within your system, then you're forcing them to go to the outside. And I think that it's tragedy that it's come to this where we have to go to newspapers. We have to go to whistle blower groups to have the employees try to do their jobs.

MR. DERFLER: Thank you. We believe that we've created an environment in which most employees feel free to come forward and write in ours and that's the way we're working it. I wanted to say thank you to all the members of the panel who are up here. Not only for their presentations but for willingness to come back and answer your questions. We're now going to exit the

stage and start with the afternoon panel. Thank you very much.

[Off the record]

[On the record]

MR. QUICK: We'll go ahead and get started while we're shifting. Hello and welcome to our next panel discussion. I'm Bryce Quick, acting assistant administrator for communications and outreach for FSIS.

As you can see we have a distinguished panel here today to talk about mandatory recalls, something we were just discussing. The title is mandatory recall authority, what are the implications. And what we've done is invited three of our core constituencies at FSIS from the Congressional Section, the Consumer Advocacy Sector and Industry to come in and share some of their views on mandatory recall. This morning we've heard A to Z, the recall process at FSIS. And as Phil described for you we do not have mandatory recall authority per say now but the system, we do have the detention and seizure authority. But despite this we want to discuss some of the alternatives that are out there that have been

discussed. This issue has been in the public eye for some time and we've invited these panels particularly because they have been involved in food safety for a number of years. And I will introduce each of them individually as they speak. But you'll see that their views are different but they all share a very strong passion for food safety. The first panel, what we're going to do, if we can keep all remarks between five and seven minutes. We're trying to shave back a couple of minutes from each presentation so that we can have Q & A at the end of the day. So five to seven minutes. Our first panelist is Mr. Eric Juzenas. And Eric currently works as counsel for the Majority staff at the Senate Agriculture Committee, Agriculture and Forestry Committee. He covers food safety, pesticides, varied research and applied technologies for the committee. Prior to working for the committee Mr. Juzenas was acting director for scientific and professional affairs and the health policy analyst for the American Public Health Association. Eric, do you want to come on up? I guess that's all right. Okay.

MR. JUZENAS: Thank you, Bryce.

MR. QUICK: Let me get this up here.

MR. JUZENAS: Actually it's okay down there. And thank you for having me here today. I suppose the reason I was asked to come here today is that Senator Hartkin is one of the people that was actually introduced legislation addressing recall authority. Not just at the US Department of Agriculture but also the Food and Drug Administration. In one sense I think that legislation has understood and technically speaking it's not what is called the mandatory recall bill. It's actually a bill that addresses enforcement more generally. And it is known as the Taking Care of Enforcement and Recall for Meat, Poultry and Food Act, or the Safer Act, it's sometimes called shortly. I think that the deep question when considering this legislation is not just to look at the current system and trying to make a judgment about how well it's functioning but really to take a look at it and make a judgment of what might be needed in the future. If recent events have taught us anything it's that none of us can predict necessarily what the future threats or the future incidents might be when it comes to food safety or indeed any other area of public safety. And as consumers of the stock market are painfully aware, past

performance is no guarantee of future returns. And that nobody can really guarantee that there will ever be another case where a company doesn't refuse to recall a product or drag it's feet or otherwise delay in making a recall. And while this happens very infrequently, whether it's FDA regulated products or USDA regulated products, there have been cases where companies have refused to recall a product even in the case of an ongoing food born outbreak that was associated with that product. It seems sometimes, particularly with the Federal Meat and Inspection Act and the Poultry Product Inspection Act that they've been encased, I don't know, in some kind of frost that defies all attempts to either thaw it out or renew it. We've gotten more in the habit of amending the Federal Food, Drug and Cosmetic Act, which you seem to do on a regular basis. But amendments to the Federal Meat and Inspection Act and the Poultry Products Inspection Act have really been infrequent. And that is unfortunate because when you look at what inspectors were originally looking for when the original piece was developed in the Meat Inspection Act earlier this last century, it was to try and identify invisible material that might be on carcasses. The organic weapon

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inspection. We now have a systems particularly after 1996 where visual inspection is still important but you also strong element where you have a real system approach to food safety. And the question becomes are the enforcement options tat are presently in the Federal Meat Inspection Act and the Poultry Products Inspection Act really sufficient to meet that system's approach. Senator Hartkin and Congresswoman Rivers and many others don't believe it's sufficient and that's why they introduce the Safer Act. The Safer Act has three key parts and that's why I say it's somewhat of a misnomer just to call it the mandatory recall bill. In fact, I'd venture a guess that it's not really the mandatory recall portion that probably engenders the most concern from the industry. The first portion of this bill is, of course, the authority to mandate the company recall of meat, poultry or food products, whether those are FDA regulated products or USDA regulated products. The second is a requirement that companies notify USDA or DHHS and that's two H's not one H, if they know their product is adulterated. And then lastly the authority to level fines for violations of food safety regulations. Now where this runs, quickly, I think that

probably a lot has been said today about the authority to recall products. I know that one of the criticisms that has been raised about that is that is USDA going to take over all aspects of a recall and what might that mean in terms of USDA exposure to the liability, what might that mean in terms of managing the recall process with companies. I would venture to bet that most companies are going to still elect to meet the voluntary recall request and maintain some control over that recall process. I think where mandatory recall will come in on those rare instances where you do actually have a company that wants to argue with USDA or FDA or delay or refuse to meet a recall, a voluntary recall request. And the notification, I think that one of the problems it has that have come clear in a lot of recalls is just trying to trace the food up and down the food chain. And while the provisions in the bill may not wholesale change the USDA's underlying authority, it does offer some tweaks that will make it easier and strengthen the secretary's hand when it comes to trying to get information from distributors or retailers and then share that with the appropriate parties. Hopefully, voluntarily on the part of the companies but

if the companies do not provide that information then it provides alternatives and recourses for USDA to compel it. The last is the authority to level civil fines for violations of food safety loss, I'm sorry, food safety regulations. And this is where, I think, that we really come to what the changes in 1996 really mean in terms of the overall enforcement structure. Relying purely on withdrawing inspection or suspending inspection really makes a lot of sense. When you think about organoleptic inspection as it was traditionally done, they're looking for visible contamination of the product. They see it on the product, it's adulterated. You withdrawal inspection, you stop the line until the problem is taken care of. When you look at HASIP and you look at things like NR's what you really see are kind of a whole series of steps and regulations that are deigned to reduce the risk that contamination or adulteration might occur. And when you have an NR, you have a series of NR's. Even if you have a repeated series of NR's the inspector, USDA had orders, they're trying to make a decision. Does the risk of potential contamination or adulteration rise to the point where they actually need to shut the plant down. Nowhere is this probably

demonstrated more greatly than in -- do I have more time left? Okay. When you look at the traditional practice of when things get bad enough, USDA will issue a withdrawal of inspection or suspension inspection and then they'll hold it in advance. And I think probably no other regulatory action captures this idea of trying to assess what the risk of contamination and adulteration is than that. You've got a situation that's serious enough that you can contemplate shutting it down if it's not address but yet maybe it hasn't reached the point where you do want to shut the plant down, cause those economic problems, the economic blotch to the company. Sometimes these advances go on for over a year as was found by the general accounting office. In future stuff the penalties provide intermediate incentive for companies to address those NR's and address those repeat noncompliance before you get to the plant. And take the history and the evidence the GAL found on just how often you have to withdrawal inspection or suspension, the inspection held in advance really speaks that there is a need for interim measures to address the noncompliance if the company's has a plan or in their sanitary operating procedures. You may not

shut them down but say look, if you guys don't take care of this you are going to be subject to a fine. I think that just to end on one more aspect, none of the criticism of course that is made of levying or giving USDA penalty authority is, well, is it necessary? They already have the authority to shut down the plant if they really find a problem. I think that anybody who looks at the situation will realize that it's not that simple. And when you look at violating food safety regulations and trying to make that assessment of what the risk is of creating a situation where adulteration or contamination might occur. This is just a situation where there are penalties and a lot of other facets of public regulation. And in fact I think it is the sole penalty authority that will give USDA the strongest enforcement tool to help deal with some of this repeat noncompliance and actually target their enforcement measure directly towards where there are deficiencies in the systems and to deal with plants that sometimes will drag this out. And I think back when I was a kid and I'm older than I look but spanking was still quite prevalent. And spanking always started out with that threat. Well, you're going to get a spanking.

Sometimes when dad got home, sometimes mom would do it.

But you kind of always knew how far you could push them before it actually occurred. And I think a lot of plants know the same. They know the inspectors in the plant, they know the headquarters people. And they know how long they can keep pushing on some of these issues before actually forcing USDA to go in there and shut them down. And unfortunately sometimes the withdrawal of inspection or suspension inspection actually only occurs despite repeated noncompliance and after a food born outbreak. And I think that that's the piece that we all want to change. Thank you.

MR. QUICK: I want to personally thank Eric. He was only given about 24 hours to put together the very thoughtful presentation. So thank you again. Our next panelist is John Bode, who is a principle in the DC law firm of Molson, Frank and Weda. Prior to entering private practice Mr. Bode held three presidential appointments at USDA so most of your are familiar with Mr. Bode. This was during the Reagan administrations and the first Bush administrations including the assistant secretary for food and consumer services.

MR. BODE: Thank you, Bryce. It's a pleasure

to be here and I'm honored to be part of this panel discussion. And I'll try to stay on strict -- I want to say I appreciate the fact that this meeting was convened. It's very commendable that it was and I think very commendable that it's so well attended. And I'm honored to be part of this panel. Let me just try to address a couple of points Eric made. I have the highest regard and respect for Eric. We disagree on some of these points, which is why it's good to talk. I think before talking about mandatory recall so much. Let me say a little bit about as 2803, the safer legislation. I agree with Eric that the mandatory recall provision in that legislation are probably the least of industry concerns or ought to be the least of industry concerns. It does have notification authority that would make any person who works in the production or distribution of food subject to criminal penalties. They can be subject to criminal prosecution if they fail to report to FDA or FSIS, according to the product. If they had reason to believe that a food produce may be adulterated or in some cases misbranded. Also that legislation would authorize civil money activities as Eric described. It seems to me that you look at it with

those penalties being renewed on a daily basis, incur violation that could easily equal an amount far in excess of the value of the establishment. And also he didn't mention it but as I saw the legislation, correct me if I'm wrong, there was also authority in that bill for withdrawal of inspection, FSIS withdrawal of inspection upon the second violation of a regulation promogated under the Act. So second NR in the history of an establishment could serve as basis for suspending inspection. I think that legislation would create such a vast rant of authority in discretion in the hands of the agency regarding the liability, just the continued operation of any establishment in the meat and poultry industry that it would have a severe destabilizing effect on the regulatory environment and constitute a powerful disincentive to participation in the industry and certainly have an adverse effect on consumer prices causing them to go up. And would not be advisable. Let me tell you a little bit about mandatory recall because I'd like to focus on that. That legislation is simply not necessary. And I think that's implicit. In Eric's comments, focusing on future needs instead of really trying to talk about any demonstrated need in the past.

We don't have a demonstrated need. There is not experienced, decades of experience, thousands of recalls, there is not a basis to believe that we have a need for mandatory recall authority. And the reason for that is clarity, it makes a lot of sense that we wouldn't need it. There are legal imperatives as well as business imperatives. I understand Phil Derfler did a great job this morning reviewing the legal context so let me just very briefly say FSIS has authority, of course, to use publicity and that is a very powerful tool. They have authority to retain product in inspecting establishments. They have access to records and they can detain product wherever meat and poultry products are. And of course they have seizure authority. So if a product is seized upon filing a complaint by a US attorney and of course they can go to court and enjoy a distribution. Those are a very effective set of tools in going about action and that is part, just a small part, of why companies have such a stellar record of complying, cooperating when recalls are warranted. It should also be noted that that's just one. There's also criminal liability. Persons who enter adulterated food in interstate commerce are

subject to criminal prosecution under the Meat and Poultry Inspection Acts. And that includes individual prosecution of individuals, responsible individuals, and finally there are very significant tort liabilities. I don't like that the metaphor, preparing companies to small children who are trying to push to get away with as much as they can. I think that it implies that companies in the meat and poultry industries are working to minimize good safety efforts. And that is very much at odds with my entire experience and the way that the industry has proven to work over many years. And so let me note that there are also business imperatives. Many companies have more tied up in the value of their brand name than they do in their physical assets. And so to wreak that by behaving irresponsibly as we're told they might anytime in the future just doesn't make sense. Final note, this legislation could actually be harmful because we're throwing out a recall system that is working in starting anew. In doing so by creating an adversarial relationship between a company and the agency it's likely to be slower and I would note that we have, there are very real due process concerns about the mandatory recall provisions in the cycle legislation

because it does not provide for a hearing until after the recall is done and then no meaningful way to provide relief if the recall is ordered in error. I do think we can make recalls better. We can do more to improve our efforts to identify problems and to implement the recalls more effectively, especially as information technology advances and we can do a much better job in communicating about recalls by being precise about what our objective is with the public communication so that it is on target. Dr. Bohm from Minnesota made that point this morning. I'll stop there. Thank you.

MR. QUICK: Thank you, John. The third panelist I've got to thank as well. She has agreed graciously to fill in for another speaker who called in sick this morning so Ms. Caroline DeWaal Smith will be pulling double duty today. She is the director of the Food Safety for the Center for Science and Public Interest, CSPI. CSPI is a nonprofit advocacy in education organization focusing on food safety, nutrition and alcohol issues. They're supported personally by 800,000 subscribers and to it's nutrition action newsletter. And added to that Ms. DeWaal is the co-author of Is Our Food Safe?, a consumer's guide to

protecting your health and the environment. She's currently on the editorial board of the food and drug lab journal and a member of the International Association of Food Protection.

MS. DEWAAL: Good afternoon. I have spent too much time in scientific conferences so I'm probably the only lawyer with the power point presentation. I also wrote a very long speech in preparation for this meeting. And could you pick that original you can put it on the web site, you can put it in the transcript but we have done a lot of research on this issue and we would like our views to be considered by anyone looking at the transcript of this meeting. December of 2002 may well become known as the USDA's summer of recalls. The past six months have clearly demonstrated the weaknesses in the USDA's current voluntary recall policy. The recalls have affected numerous meat and poultry processors and repeatedly sent consumers to their refrigerators in search of plants, numbers and production dates. There are a number of lessons to illustrate the need for a mandatory recall policy. First, too many recalls are initiated only after people become ill. With outbreaks and recalls signal a failure

in the HASIP system to prevent well known food hazards from entering the food supply in the first place. And FSIS must initiate earlier testing programs to ensure that meat and poultry companies are focused on finding and fixing contaminated products in the plant rather than releasing and recalling them after they're in consumer's homes. On going testing for hazards like E-coli, 0157.H7 and listeria at the plant level would mean that the USDA wouldn't have to wait days for test results to come in before taking action as they had to do this summer with the Con-Agra recall. The agency would have a better basis to prevent recalls and could act more quickly when a recall was needed. Second, too many recalls begin with an announcement that grossly underestimates the amount of products that poses a risk to the public. Each new recall announcement appears to be just the beginning of an arduous process of further investigation followed by additional announcements that dramatically increase the recall size. Under a voluntary recall policy, here are just a few examples of the ones that my staff gathered for me. Under voluntary recall policy consumers all too frequently minimize the size of the initial recall. Once USDA sends

investigators to the plant, the size of the recall sometimes increases by several orders of magnitude. But as we've seen numerous times days can elapse before the expansion is announced, during which time the hazardous products remain on the market. USDA should have the authority to find companies that had knowledge or information that should have led to a larger initial recall but that negligently understated the necessary product amount. Third the voluntary recall system leaves consumers and even some states without critical information to know if meat sold locally might be linked to the recall. In order to protect business records, USDA only shares a plant customer list with the states to promise not to release that information to the public. This approach seems countering intuitive as consumers urgently need to know if the meat in their refrigerator or freezer came from the implicated product. Some states have open record laws that prevent them from giving USDA the requisite assurances as we heard today. Last summer, for example, in Colorado, public health officials were barred from obtaining Con-Agra's distribution list from USDA, even though the Denver plant distributed widely in this state. FSIS

claims that it can't release this distribution information because it's protected under the Freedom of Information Act acceptance. However, as we've heard, this interpretation applies to fully open up business records too broadly. Since recalls are limited in their depth and scope it's questionable whether the release and names of the specific recipients of specific product at a specific time would be of any use to competitors. Competition not being allowed to use full exemptions to shield themselves from the consequences of introducing potentially adulterated food into the food supply by denying states and consumers critical information. At the consumer level an executive recall is one that motivates people to do something they wouldn't normally do, to question the safety of a product already in their refrigerator or cupboard. And recall messages must by necessity compete with other food safety messages that we're trying to get to consumers at the same time. With that in mind it is critical that government agencies, not food companies, be the principle source of information about food safety, including information on food poisoning outbreaks and recalled products. A government announcement is simply treated more seriously

by consumers and will garner more media tension than an announcement by a company. And I have two examples of this. I'm not going to go into them. I have lots of people asking questions about it but it is very clear, based on actual outbreak situations in the Schwan Ice Cream example is actually reported in the, I think, American Journal of Public Health or one interview journal, the researchers have documented this fact. A year after the Billmore outbreak the USDA announced a new recall policy indicating that the agency would send out a public announcement, when any company has initiated a Class I recall and you can see from the list there was clearly a jump in the number of announced recalls. We've done a little bit of analysis of this data. This shows the amount, again we're going 1994 through 2002. This is the amount of recovered product.

I will simply note that really the recovered product isn't a sign of how much product actually was not consumed as a result because many consumers simply discarded and some of the stores may simply discard it and not actually send it back to the company or report it back to the company. Finally, I did this only because I always want more information from my wonderful

staff. Charlotte Kristin prepared these slides. And this shows that salmonella, while there were jumps across the board in all categories and passages, salmonella reaches the one where USDA is doing more monitoring on an ongoing basis. Actually their jump was not as pronounced as the jump for listeria and E-coli, 157.H7. I'm wrapping up. CSPI in our written testimony has provided many suggestions for needed changes to FSIS's current recall policy. These improvements are only half measures and the meat industry promotes the myth that no changes are needed because no company has ever failed to comply with an FSIS recall request. In fact, a few years ago a poultry processor did fail to comply. In the end FSIS was forced to issue a press release warning the public that nearly 8,000 pounds of potentially adjudicated chicken were in the food supply and could not be recalled. In reality though we don't ever know under voluntary recall authority how many companies haven't complied because a recall is today, the result of a negotiation between the company and the government agency charged with protecting public health. And we have reports that indicate that in some instances the government itself may agree to a market

withdrawal, which can be done silently instead of a recall. So we believe this is one example that went public. There are many other examples. Clearly FSIS needs to urge Congress to give it the power to order contaminated food off the market. This is not a new or unique position for the department. In fact, USDA is still on record supporting mandatory recall authority and civil penalties following the large and Hudson recall in 1997. The USDA should not continue to operate with century old enforcement tools, especially as Congress is giving numerous other agencies include the Consumer Product Safety Commission and the Food and Drug Administration with modern tools. Mandatory recall and civil menarche's are necessary enforcement tools if the USDA is going to operate as the public health agency that we know it wants to be addressing food safety problems. And after this summer it is critical that USDA articulate its continued support for mandatory recall authority and make clear that its principle mission is to protect public health and not be industry's business interest. Thank you.

MR. QUICK: Thank you, Caroline. For those of us who have served on Capitol Hill we often times count

service on Capitol Hill in dog years. And if that's the case our next speaker has about 80 years under his belt.

Mr. Pete Thomson, it's hard for me to call mister because I shared an office with him for a number of years, bring in a number of years in expertise and safety and my personal theory is that he goes up to Sinclair's Jungle but that's just something I'll throw out there. He was a key negotiator on the farm bill. This last will end several before that. His current focus is life stock issues including marketing, country margin labeling, trade, food safety and appropriation's matters.

MR. THOMSON: I'm going to try to bring the average time of our panel down a little bit and keep my remarks very brief. First a disclaimer. I'm sure that you know that Chairman Combest has announced his retirement, so at the end of this month he'll no longer be chairman of the House or culture committee and our new chairman won't be named until January 8, though I'm sure we all have a pretty good idea who that's going to be. So I'm sort of a ship sailing without a flag today. I'm not really in a position to make any reassurances about what the committee will be doing in the next year

or the next Congress but I can talk a little bit about the past and maybe speculate about the future. So I'll again try to do that quite quickly. The fact of the matter is neither the Senate agriculture committee or House as agriculture committee has accepted the case that has been made that we need mandatory recall authority for FSIS. It's an idea that's been around for a long time, it's been discussed at length and then it falls on the case. I think mandatory authority is a solution in search of a problem. So the fact is whether to it is regarded by some or not, the fact is there hasn't been a voluntary recall that's ever been turned down. I've asked that question of every administration that's worked on Capitol Hill and gotten the same answer. Now there's been some fussing and some fighting and maybe some people regard that as negotiation and maybe some people regard that as conflict. But the fact of the matter is that at the end of the day the product is recalled. And if you had a mandatory recall authority you're still going to have fussing and fighting and you may have the unintended consequence of that fight going out of the regulatory regime and into the courts. And I don't think that serves the interest

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of public and it certainly doesn't improve public safety. So we have on the House agriculture committee 12 people that will be leaving the committee at the end of this Congress and judging by who we think is going to be joining the committee I don't anticipate the views of the committee as a whole are going to change, unless or until some additional arguments are brought to the table or a new prospective or the proposal's put together in a different way. Many a criticism has been discussed today about a recall practice that are valid and I think should be considered and part of today's meeting does that. I just don't see where those criticisms lead to the conclusion that you have to have mandatory recall authority. So I think I'll end it there. I'm interested in your questions.

MR. QUICK: Okay. We have about 10 minutes if you want to use the microphones up here to ask the panelists questions. And I'll try to moderate, unless we don't have any. Do you want to ask them? Okay. Here we go.

MS. THOMPSON: Hi, I'm Shawna Thompson with the National Meat Association and my question is for Ms. Smith DeWaal. Before you were talking about the idea

that sometimes they talk together and they have market withdrawals, the USDA and companies, instead of a voluntary recall, I was wondering, even if they did have mandatory recall are you saying that the USDA should just order mandatory recalls without communication with the companies? Are you talking about less communication between the government and the industry?

MS. DEWAAL: No. And thank you for your questions because I'd be happy to clarify that. The CSPI has always supported the bill that the Safer Meat and Poultry Foods Act supported by Senator Hartkin and others that requires mandatory recall only when the voluntary recall system fails. But this issue of market withdraws as opposed to recalls is a very important one because I was reviewing in preparation for today an article written in the Washington Post magazine, a cover story called, Outbreak, by Peter Pearl about a year after the Billmore outbreak. And he actually mentions the fact that in a discussion between the Sarah Lee company and the then administrator of the Food Safety and Inspection Service, the administrator said well we're not asking you to do a recall. We had people dying at that point from this product. We're not asking

you to do a recall. Maybe you should just consider a market withdraw. So I think that we'll never know how many of those have actually gone forward, where a recall is really what's appropriate. The other issue I would just raise is the issue of bioterrorism. When we are dealing with the potential threat to our food supply, which has been indicated by Secretary Thomson and others, someone may intentionally contaminate it. The idea is that we could rely on a voluntary recall seems absurd. The government will have to order a recall and rely on the states as well as the Federal agents to implement it.

MR. QUICK: I think Mr. Bode would like to make a comment as well.

MR. BODE: I'm just uncomfortable with the notion that somehow if there's a market withdrawal the consumer safety is not protected. I don't think that's accurate at all. Market withdraws are undertaken when a withdraw rather than recall is effected for recovering product. It concerns where the product is and what depth of action is required to take. If the impression were given, I'm not saying it was your intention to create that impression but I could see how someone could

get the point that a market withdraw is not protecting consumers. That's just all together inappropriate.

MS. DEWAAL: But I give a very specific example, Mr. Bode, which was the Sarah Lee outbreak, which had been going on from early summer, it was late December and the company was seeking help from the agency to decide whether to do the recall. The product was in the market. The product was on the store shelves and it was in consumer's refrigerators. In that instance...

MR. QUICK: The question is...

MS. DEWAAL: ...would a market withdraw be appropriate or a recall?

MR. BODE: And the principle is what product needs to be recovered? What product needs to be recovered and what action needs to be taken to do that? That was the guide of principle, so that in our case whether it results in a recall or results in lack of withdraw, the objective and I don't think this has every been questioned, was to recover product where there was an indication that product was adulterated. And that's what they were -- with prime outlook areas we don't have perfect information. We don't have perfect knowledge.

Science is not perfect. And what's going on in these situations is they're striving to find out what went wrong and how big is the problem and what do we need to do to recover. And as I tried to indicate in my remarks there are great incentives and that's why we have such strong aggressive response from industry in these situations for industry to recall all the product where there may be a problem.

MS. DEWAAL: I do think though that the point where I raised that issue on market withdraw was to make the point that we will never know how many companies have failed to comply with a recall request and have negotiated something lower. Even when product was in consumer's hands. And Pete mentioned that there's no need for this. Well, I respectfully disagree. There is a need and we will never know because of imperfect information in this negotiation how big the need is.

MR. QUICK: But...

MR. BODE: The US attorney had no action to seize product in that situation. That is where we're going.

MS. DEWAAL: Belmont is a clear example where a company did not comply with the recall process.

MR. QUICK: Pete, did you have comments?

MR. THOMSON: Hearing the example that you cited in Belmont, the conversation about whether to withdraw or recall. It's important to remember that even if the administrator has the mandatory recall authority that conversation could still take place.

MR. QUICK: We've got time for about one more question. Did anybody else -- Eric, did you want to make a comment on this?

MR. JUZENAS: No, although I would like to make a comment.

MR. QUICK: Okay. Good.

MR. JUZENAS: Be careful with that cell phone.

MS. DEWAAL: My next question is what is Eric's comment?

MR. JUZENAS: I just wanted to respond to John's comment. When I gave the example of spanking, of course, I was not telling you to abuse children. It was the experience in my family that people in general and kids including always want to do the right thing and they have a different interpretation of what the right thing is. And I think the fact that if you have debate over recall or even in ours, a lot of times there is

debate between USDA and the company about what the facts are. My point was that even though there may be an existing debate, a lot of times companies know how far they can go before USDA's going to come back and actually issue and make firm that withdraw of inspection.

MS. MITCHELL: My name is Karen Taylor Mitchell. I'm here representing Safe Tables are Priority, victims organization. I'm representing the victims of food born disease. One thing I would just like to bring up as a prelude to my question. I was interested to read in researching for this meeting that the USDA has noted that food born disease kills more people every year than the 15,000 products that face mandatory recall and regulations by the CPSC. My question, which doesn't really follow well from that but I tried, you had stated that mandatory recall was a solution in search of a problem. I think that all of the, by the definition that you used wouldn't all of the preparation and preparedness for bioterrorism be the same thing? What would we do if we found ourselves in a crisis situation and a company did refuse to recall the product. Do we want to be caught with our pants down

like that?

MR. QUICK: Well, all of this talk about spanking and pants down is disturbing me. And you need to meet me later. If you'd been in some of the meetings that I'd been in in the last year, doing bioterrorism legislation, legislation created by the Department of Homeland Security you'd have heard me making this similar arguments with some of the authority being asked for in those areas that the agriculture community is a very conservative community and I don't mean politically. I mean there's a considerable amount of worry about the law of unattended consequences and unless a very firm case is made for changing the way things are and a very careful understanding is arrived at as what will happen as a result of that change, that community is reluctant to act. And you know, we've had this discussion and we can go over that again about the tremendous compliance with voluntary recalls. But I worry about an example if mandatory recalls or an authority available to the administrator that the liability profile of the agency would change. And you could find, now you may find it may make you uncomfortable that you have a situation and certainly it

make some of the business folks here aware of a situation where we have scientists and administrators and folks from different agencies, different apartments in a room, kind of trying to sift through the data, the information and you can get a picture of the situation while they're trying to determine if they have to squeeze a voluntary recall out of somebody. I find that situation comforting. Because that means that experience is being brought to bear, intuition is being brought to bear. It's not strictly cut and dried empirical decision. It is guided by signs but it's also guided by other factors. I worry there was a mandatory recall authority you could have a situation where now you have somebody from OGC sitting there who's going to say unless you have absolute data that proves without any doubt whatsoever that I can win a court case on it that this is the plant that's responsible for our problem you can't issue a recall. Because at the time he will ultimately have to defend the agency from their decision if it's challenged later.

MS. MITCHELL: Should we then be seeking...

MR. QUICK: Okay. We're going to have to wrap this up. Eric is going to have the last word on this.

So he has 15 seconds to wrap up. We're going to have to move onto the next panel. Sorry.

MR. JUZENAS: I just wanted to say that I think in the case of mandatory recall legislation you're not going to see too much change, actually in a way that USDA handles it because again companies are still going to comply with the voluntary request. And I think Karen raises a valid point as what happens in the cases where you have a USDA company drag it's feet or some FDA companies that outright refuse, what do you do when you find yourself in that situation. But I think, you know, for the most part, most companies are going to comply with the voluntary request because they're going to want to be in control of the recall. They don't want USDA coming in and managing it.

MR. QUICK: Let's give a round of applause for our panels. Thank you very much.

MS. HULEBAK: Ladies and gentlemen, please take your seats unless you want me to do that again. Thank you. My name is Karen Hulebak. I'm deputy administrator for FSIS Office of Public Health and Science and I'm monitoring the next panel which focuses on the question when is public notification needed.

Clearly this panel, a copy of this panel specifically acknowledges the public's right to know, the public needs to know that potentially harmful products are on the market and are maybe in their homes. Discussions about public notification as a general matter have a long history. Opinions vary a lot about how much notification is too much. Should agencies notify about all issues or events or only the most high risk issues or events? In fact, our FDA speaker this morning, Mr. Bryant, suggested that FDA doesn't do press releases for all recalls because the public would begin to ignore them or the press would be overwhelmed, which frankly I didn't realize was possible. Another way of putting that observation is the question is there such a thing as notification or warning fatigue among the listening public, concerned consumers and others. What is the most important information to include in the public notification? With respect to what we are doing at FSIS currently with recalls these questions and others are the subject of this afternoon's panel. I'll introduce now our first speaker who is Dr. Alice Johnson. Dr. Johnson is president and CEO of the National Turkey Federation. He also serves on the FSIS national

Advisory Committee for Meat and Poultry Inspection. Dr. Johnson came to the National Turkey Federal from the National Food Processors Association, where she last served as vice-president for Food Safety Programs. Dr. Johnson also worked for 11 years with FSIS as a circuit supervisor, where she ensured compliance with Federal requirements in 27 meat and poultry processing facilities. She has a bachelor of science degree in biology from Fifer College and holds a doctor of veterinarian medicine from Testier Institute. Dr. Johnson?

DR. JOHNSON: All I have to do is press a button. That's good. Yeah, I appreciate the opportunity to be in this meeting and be on this panel.

And I'm going to go a little beyond public notification and talk a little bit about just communication in general in the recall process. I wish I could stand here and tell you that we would never have anymore recalls but unfortunately that's not going to happen. As hard as companies strive to prevent situations that might result in a possible recall they still may occur.

As you heard today a responsible company will have in place a recall plan and they will have conducted some

mock recalls to assure that the program they have in place is practical and achieves the objective. And we have to remember the objective. It's to get the product out of the marketplace. In a large part of what we see on the recalls is to protect the public health. Thank you. I'd like to talk a little bit to reinforce the commitment that industry does have with regard to having recall programs in place and being committed to move the recall process, if necessary, forward as fast as possible. And I'd like to do that using one of the standard old terms the survey says. Generally the grip of associations got together and surveyed their member companies to find out what were the practices currently in place within the industry, what were the experiences on recalls and what were the general thoughts that the member companies had regarding to the recall process. And of the responses, the responses received represented 502 establishments. Of those filling out the survey 100 percent of the companies said they had recall programs in place and 96 percent said that they did conduct mock recalls. And I won't go through all the names but you can see all the different groups that participated and surveyed their members. I'm going to refer to the

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survey with several points when we go to talking about the communication efforts. I think the important thing we all have to remember is that if a recall is determined necessary it's in everyone's interest to remove the product from the market place as rapidly as possible. When I say everyone, I mean the industry, the consumer and FSIS. FSIS exhausts a large amount of resources in the recall process. Dr. McKee was reading a statement in one of their trade publications just yesterday where you had made a statement that FSIS over the past few years based on recalls has exhausted extremely large intensive labor resources. It went on to say that FSIS works around the clock to make those things, meaning recalls, happen. This is true and I know that we have to compliment the recall staff for the long hours they put in. I know we've talked to them several night son a Friday night about 11:30 or even a Saturday morning at 2:00 or 3:00. So we do appreciate their efforts. Part of these long hours are because of the current procedures that USDA has in place with regard to the recall process. FSIS takes full responsibility in this case as for managing the recall process and the decision making. They do the

investigation, they look about the product involved to determine the scope and even do effective disc checks. I think of a recall process as the agency having the main process of managing under the current recall procedure and the plant just performing the mechanics. FSIS asks for information, the company provides the information, and then the company's responsible basically for retrieving a product once FSIS makes their decision. A lot of times companies feel that this process is made in a lot of secrecy and the USDA or FSIS during the decision making process is not very open and doesn't share information. Company feels that they are left out of the loop and actually in some cases feels that FSIS has withheld information. Doing the decision making process it could have been a value to the facility. A lot of times the companies say they share information with FSIS but there's very little information shared with the facilities. To this point, as part of the survey we ask the companies if you've ever been involved in a recall situation, in your opinion was FSIS forthcoming in providing all relevant information in a timely manner. While 66 percent said yes, 34 percent said no. Member companies reflected the frustration of

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not being involved in an FSIS key decision processes. Some of the comments that we received on the survey included that the information flow is generally from the company to FSIS. Agency and internal deliberations are generally not open to the companies. However, if the company finds an issue, has a decision making process in which they feel a recall is necessary, they will go to the agency and share all this information. And one company went to far to say that they felt like FSIS withholding information had actually made it difficult for the company to assess the situation in a timely manner. A simple solution for this would be to involve the company. The company should be involved in every aspect of their decision making process. There should be an information sharing. It shouldn't just a one-way flow of information. And companies should be allowed to conduct a health hazard evaluation or at least be a part of the FSIS process. After all, it is the company that has much of the information. An inclusion in the part of the company of the recall team only eliminate the time spent, going back and forth, gathering information. FSIS's sister agency, we heard from the Food and Drug Administration this morning, considers it the

responsibility of the company to conduct the health hazard evaluation. FSIS might want to consider this type of approach. Many companies have the expertise to do this. Companies that don't feel comfortable doing this could ask FSIS for their assistance. You can see that another survey question asks about whether companies would prefer to do their own health hazard evaluation, 81 percent said yes, 19 percent said no. There's also a question if necessary, would you get somebody, would you ask for help if you needed the expertise, 98 percent of the companies said yes. Companies could perform the evaluation, they could provide it along with the recall plan as outlined to FSIS and FSIS could agree or disagree with the information provided by the facility. If the agency was not comfortable with this approach then we strongly urge FSIS to assure companies are included in the decision making process, communicate with the company. This would allow for an open transparent process, which would lift the veil of secrecy that some folks feel is associated with the recall process and allow for faster decision making and then faster recalls when necessary. Another area of concern regarding the current FSIS

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practices includes the press releases that are issued. In asking on our survey, we asked companies if they felt like the FSIS issue press release had been entirely accurate, 58 percent said yes, 42 percent of the companies said no. We've had numerous occasions when the press release was not factual. Inaccurate information on product names, codes, even the wrong telephone numbers for responding to consumers have been released. If you look, 32 percent is a large percentage of error. Especially if you think a press release is related to a product that might have a food safety implication and the need to alert the consumers about hits. Company comments on this section included a coordination of the recall process being very frustrating, talking about the FSIS public affairs group not communicating, not notifying the recall group and allowing for reviewed error and one company in one of their responses cited in one incident where there was a large number of products listed that there were 12 instances of incorrect product descriptions. We would certainly encourage FSIS. A lot of companies feel that they can at least draft a press release and this is consistent with FDA's procedures. If a company is not

comfortable with drafting a press release then FSIS should, of course, submit one. I understand that there will be certain requirements that should be in the releases. FSIS currently has a template that they use.

I would think that that would be appropriate for companies to provide the information to FSIS. Again, FSIS would have every right to review that information and in reviewing that information they also could distribute and post the establishment release on their web site. This would of course, allow for the agency or government credibility that people need. Another area which we think would help as far as public notification in making sure that products of food safety concern are viewed seriously by consumers is to look at the terminology that's used in a recall situations. We would suggest that the term recall should be used only in food safety concerns. Right now the only distinction in a recall between a food safety and a nonfood safety is a roman numeral. As Dr. Hulebak had said there's a lot of information that's going outright now. A large number of releases and you wonder if consumers take all of them seriously. Because we heard from FDA they don't put out press releases in certain situations. We all

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recognize that food safety issues should be treated and given highest priority and we would recommend maintaining the term recall for those groups to highlight to the consumers the importance in coming up with a different terminology of like a product with compliant retrieval. We asked in our survey if the member thought that FSIS clearly defined recall classification and you can see the answers there. I want to again thank the recall staff. I will be the first to say I've had members call me late at night and go, Alice, the government's still working, is that normal? And we do appreciate the fact that you guys put in the long hours in working under current procedures that you put things forward. Hopefully those things can change and we can become more coordinated and better communicate with each other as well as the public. And I do appreciate the agency for giving me the opportunity to do this and exploring this whole process in such an open manner. Thanks.

MS. HULEBAK: Thank you, Dr. Johnson. Our next speaker in this afternoon's panel is Karen Taylor Mitchell. Ms. Mitchell is the executive director in STOP, Safe Tables are our Priority, a national

grassroots food safety organization established in 1993.

Prior to joining STOP, Ms. Mitchell consulted with a number of nonprofit organizations focusing on organizational development, fund raising and strategic management. She has led development departments for the Vermont Youth Conservation Corps, the Vermont Public Interest Research Group and managed global conference operations for the World Citizen Foundation. She holds a masters in public administration from Harvard University. Ms. Mitchell?

MS. MITCHELL: Hi. Well, I want to start by reiterating Alice's comments. The consumer groups and STOP in particular as a victim founded organization are very grateful for all of the time and effort that FSIS puts into the recall process, food safety in general, and especially into these emergency incidents. Same goes to the companies, I mean hearing that you guys are working around the clock to get food back into recall. We don't have perfect system yet, that's why we're all here working on it together. But it is so gratifying and so important to know that you're doing that. I want to tell you a little bit about STOP, just for the people that don't know out there what STOP is. STOP is an

organization that was founded by the victims of severe food born disease. In 1993, after the Jack in the Box E-coli outbreak, E-coli 157.H7, parents and loved ones of victims of food born disease got together and started this group to talk about things that weren't working. There's still a lot of things that aren't work and one of them is this recall process, and to be frank this recall forum. A month ago, USDA spokesperson publicly assured the audience that in case of a bioterrorism attack the standard recall process would go out the window. That's a quote, "go out the window". Another world what this USDA spokesperson said is that it's trashed in an emergency. I would say to you that we have an emergency right now. While we've been sitting here discussing recall process this morning, 500 people have been admitted to the hospital because of severe food born disease. Before the end of the day 14 people will die fro it. We have not talked today about the fact that the recall process is not working. I don't know what the figures are going to look like at the end of this year when we have had over 50 million pounds of contaminated meat recalled. But if Con-Agria's recall is going to be any indication of success, we're going to

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have reclaimed less than a third of it. It's not working and here some of what we're talking about is rearranging deck chairs on the Titanic when what we really need is to look at the recall process as a whole.

Not just at various details but we really need more time and more effort. We need the CDC here to talk about the epidemiological triggers for it. We need a real comprehensive look at recalls. And so I hope this conversation has only just begun. Mosha's putting up slides for me. Mosha would you put up the first one, please? I want to introduce you to Amy Ermol [ph]. Amy was three years old when this picture was taken. It was taken after two surgeries. Imperidemiol [ph] dialysis because of hemoliticuremic [ph] syndrome because of E-coli, 157.H7 contaminated hot dog. She receive multiple drug transfusions and didn't sleep for two weeks because of the pain. So they gave her morphine, which caused her to suffer an allergic reaction. Her long term health, she is recovered, you'll be glad to know. At the age of four she was started on Cumadin for high blood pressure. That's an outcome of hemoliticuremic syndrome. I don't know if Mr. Bryant is still here for this morning but I did want to point out, too, that

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shigella is another cause of hemolytic uremic syndrome in addition to E-coli 157.H7. Mosha, would you put the next slide up please? I'd like to introduce you to Patti Metz. She doesn't look like our typical idea of a victim of food born disease. Patti was 40 years old when she became ill with hemolytic uremic syndrome, which is not unusual in adults. She spent 400 days in the hospital, 10 of them in intensive care. She only survived because she had numerous four and five hour plasma transfers to a tube inserted in her groin. The outcome for Patricia has been that she is no longer able to keep her job as a high school teacher. Her family believes her cognitive thinking has been effected by five weeks of constant pain. She describes that five weeks as real life torture, suffers daily headaches, is on daily medications and she doesn't eat beef anymore. One more slide. This is Kevin Kowalchek [ph]. Kevin was not one of the lucky ones. He died last summer. I'm going to talk now about what I'm actually signed to talk about is when recalls should happen. The clear answer is as soon as possible. The clear answer is immediately. The public has a right to know and should be notified each and every time there's a recall.

Anything less is just trying to hide things from the public. It's less than the very inadequate protection that we have right now. We've heard a lot today about the over bombardment of the public with information and how that's led to message fatigue and inaction. That's not a result of the amount of information that we are giving to people, it is a result of the fact that the information that we are giving to people is misleading and vague and mixed. I'll discuss that more in a little bit. But first of all I want to keep on the subject of when a recall should be triggered. We need to be doing a lot more with epidemiological evidence as a spark for recalls. We need to not wait for a test positive. In the Schwan's case that Caroline brought up, it was 10 days between the time that a recall was called and the test positive came back. They were able to make that recall based on the epidemiological evidence. They saved thousands of people from becoming sick by not waiting for that confirmation test. We need to be doing more of that. Epidemiology is a science. There needs to be scientists trained in epidemiology who are making these decisions and who are making decisions based on the public health and explaining them. You know,

epidemiology may not be something where you can get it down to an exact science but you can get it pretty certain that there is a specific product at fault. And that's something that really needs to be used more as we saw from the slides this morning. Incidents of illness and outbreaks together only sparked two recalls this past year. Surely with food we can do better. Public notification needs to happen on an immediate basis. And that has been discussed today. You know, there's been a lot of talk about the negotiating and the information swapping and things like that. The process just has to go faster, it just has to go faster. And I know that people are strained with what they're doing already but we need to continue streamlining the process. Mandatory recall would probably be a help in streamlining that process and that's the reason why we're so eager to see that past. Another thing about waiting, notification should go out. Notification should go to school districts immediately. Further than that we need to be getting those products off the shelves of school districts immediately. That is one of the highest risk groups. Its indirect control of the USDA. That needs to be an area of immediate action. Now I'd like to talk

about how we communicate recalls and I was please to find that I had so much overlap with Alice on this, as a matter of fact. Current press releases, we agree, aren't ideal. They're not going out with the messages that they should be and we are seeing consumer fatigue and we're not seeing the results that we want from them, obviously. We're sending out mixed messages in all sorts of ways. We're telling people here, you should have returned this meat but if you want to cook it and eat, here's how to cook it and eat it safely. And that really is giving people the wrong message and they don't know what to do after they get to the end of it. We also send out press releases repeatedly that say no illnesses have been associated with this product. Now if anybody can answer for me what purpose that serves other than making the company feel like its image is being protected out in the public, because it certainly doesn't help people understand their risk from this product. And I would argue that it's not really helping the company's image very much either. So we need to take that out of there. If we're going to be truthful in our press releases, we should be saying cooking 260 degrees can kill pathogens but because of the threat of

cross-contamination it is advised that you do not handle or eat this product. Consumers returning product to the store wrapped in a plastic bag will receive a refund. That's what we should be telling people. Thank you. USDA's own studies have repeatedly demonstrated that people are more likely to change their food handling behavior if they're fully informed about the health risks that they're facing. I haven't seen a press release yet that talks about children having strokes. I haven't seen a press release yet that has talked about hemolytic uremic syndrome resulting in diabetes, blindness, high blood pressure. I haven't seen reactive arthritis on any salmonella press releases. I haven't seen gemeberra syndrome on any press releases. But if we truly want to motivate consumers to properly handle recall product, what we're all talking about, consumers need to be equipped with the truth. I've agreed completely that the class system doesn't do anything to give consumers the information that they need. I'm not sure why we are identifying things in the public by class, we should be identifying them by high health hazard recall, allergen recall and something else, product retrieval, we call it to take Alice's line. As

a consumer I and probably you, would be much more likely to respond to something that came to you labeled high health hazard alert than something that says Class I recall. In a similar thing in order to know whether a recall applies to me as a consumer I need to know where that food has gone. I need to know if it's in the grocery store that I shop at. It's a very different thing for there to be a press release saying that E-coli is at large in 300 pounds of ground beef, floating around in the United States somewhere. This is being told E-coli contaminated meat has been distributed to the Safeway three blocks away from you. There's a difference. We need that distribution information going out. There's no substitute. No amount of press releases or public bombardment or anything is going to be the substitute for specific information for consumers where those products have gone so they can compare that with the likely unlabeled ground beef or meat or product that is in their freezer or refrigerator. A few more points, with regard to product identification, clearly it would make it much easier for consumers to return products. Also much easier for entire recall process to happen if there were traceable information on all ground

beef products. This type of labeling would facilitate more accurate and effective illness investigations and recalls. It would be faster and easier to identify the source of the illness. It would also be faster and easier to identify which of your companies were not the source of an illness. That's something that I would think would be of great value. Finally, STOP believes that production companies should offer double refunds to spark consumer's attention for Class I health hazards. There's a tried and true way of beating consumer fatigue. It's called double your money back coupons. We want to get people to pay attention to recalls, we can offer them an economic incentive to do that. Companies will come out looking like the good guys because they're working so hard to get that product back that they're putting, you know, a double refund out there. In long term it's going to save money for the companies. In closing I just want to remind you we've been talking about a lot of policy today. We've been talking about a lot of procedures today. I want to remind you what's behind the whole thing. Food born illness is a lot more than belly aches. STOP's victim members have suffered brain damage, strokes, heart attacks, kidney failure,

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liver failure, blindness due to food born disease. Our numbers stem between \$300,000 and \$500,000 to treat single cases of hemolytic uremic syndrome. Even those with health insurance have cause to worry because given the long term implications of food born diseases miss insurance payment or lose their employment. The person may never get medical coverage again. So the ramification is that these illnesses really do go on and on. The costs are not quantifiable. It's impossible to estimate the toll on marriages, on lives, on emotional state, on the economy from people who are not able to work because of nursing their children or themselves back to health. When we're thinking about recall process, I encourage you to keep in mind the people behind the numbers and the impact of even a single illness. Thanks.

MS. HULEBAK: Thank you, Ms. Taylor Mitchell.

Our next and last speaker is David Schmidt. The senior vice-president of the international food information counsel IFIC in Washington. Mr. Schmidt is also an ADJUN fellow with the Virginia Technical Center for Food and Nutrition Policy in Alexandria. Prior to joining IFIC in 1993, Mr. Schmidt served as a director of

external affairs for the Food Safety and Inspection Service. Mr. Schmidt?

MR. SCHMIDT: Thank you, Karen and afternoon.

And as she mentioned in my background I knew a little bit about these issues of recalls and thought I could escape my past, I guess, but I guess you never can. So when I was called to present at this meeting I said, well, gee, you know we're not that involved with recall notifications at IFIC. I'm not sure that I'm the right person to talk to you about this. And they said well, you know, you can provide some communications expertise on this. I said well, we could do that. And they said, by the way, Linda Swastina said you really need to do this. And Linda worked with me at the Information Legislative Affairs staff when I was there. And I guess I gave her a couple assignments during my tenure and she apparently now thinks that she can assign me things and that's done so successfully this afternoon. But anyway it's good to see many of my good colleagues on this and I guess this is a serious issue and I would certainly echo the comments that were made about how hard the agency staff works and I can certainly attest to that 10 years ago and have no doubt that they're only working

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harder, longer hours with all the news that I see on a daily basis related to recalls. But it's always been a dedicated team that really does want to do the right thing to get the right messages out there to the right people but I think there are legitimate questions. Are we doing this as effectively as we possibly could? Well, before I give you my perspective on this, I just want to give you a quick introduction to IFIC, if you were not aware of us before. But we are a nonprofit based here in Washington. Our mission is to communicate science based information on food safety and nutrition issues to those opinion leaders that we believe consumers are most likely to trust on these issues. And those are journalist, health professionals, government officials, and others involved in these issues. We are supported primarily by food, beverage and agricultural companies but we are unique as a Washington organization in that we don't lobby or provide regulatory advocacy on these issues. So one caveat in my presentation, I really don't have specific comments on how recall regulation ought to change. So I'll just give you some perspective that may be helpful to you in the process. We also have a very comprehensive web site at IFIC.org,

where we had a lot of consumer's survey information. I'm just going to give you one sample of that today. We also have a number of publications that consumers can go to get answers to questions about things like listeria and other food born illness questions and anything under the sun on food safety and nutrition. So I encourage you to go there as well. And then hopefully many of you are familiar with our food insight and this is an example of the new look, the current edition, featuring the illustrious Honorable Elsa Murano with my old boss, Lester Crawford. And the interview on a lot of the topics that we're dealing with, food born illness and not just my pathogens and the virus issues tat Dr. Crawford talks about that have been a big issue on the cruise ship stories that we're seeing in the news. So if anybody would like to be added to the subscription, just hand me a business card on the break and I'll be happy to do that. One of the things we do at IFIC as I mentioned is a lot of consumer research on different topics and this question here I'm giving you is a big survey that we do periodically on food biotechnology and we ask a series of open ended questions before we introduce the topic of biotechnology just to find out

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where consumers put certain issues in perspective. An this one we asked what, if anything, are you most concerned about when it comes to food safety but by and large we're seeing an increase in trend, the food paneling, the season contamination issues are by far top of mind with consumers. The latest survey in August of this year, nearly 40 percent cited disease and contamination and certainly related is nearly 35 percent on food handling and preparation. Other issues, again, we were looking for biotechnology in this overall survey, it's only at one percent. So we didn't prompt any of these answers. We took anything consumers gave us and grouped them by these categories. So I think you could certainly argue that all the media coverage of the numerous recalls that we've seen taking place have had an impact on consumers and this is a very top of mind, no doubt about it. Well, the question is have we come to a point in time where all of our decisions, simple as ordering lunch at a counter are coming down to risk benefit decision and this woman is contemplating whether to order the hamburger or tuna or egg salad based on the risk and benefits. But I think consumers are starting to ask themselves some of these questions and the better

we can inform them with the right information in the right context the better we're going to help them with those decisions. Because I think over concerning consumers with some information can have harmful effects when we're talking about specific recalls. The key is to get them the information about the recalled product as opposed to turning them off on perfectly safe products overall. So targeting that information is very critical. Now I think I'd also agree with the comments that we're seeing this consumer fatigue about the amount of information and it's really not just, I agree, it's not just the amount of information or how much FSIS is sending out. But it's the explosion and sources of information that's really taking place definitely over the 10 years that I've left the government. It's very different about how consumers tune in. We now have web sites, many more cable channels, satellite TV. It's not just three major networks and a daily newspaper so it's much more difficult to reach all the consumers you want to reach because they're much more segmented in how they get their information. We're also seeing, as part of this, greater turnover, just like many other industries, that reporters are turning over all the time. So you

have a media list that you're sending out your recall notifications and that probably changes on a monthly basis. Media outlets can't afford now to have food reporters, in many cases, as they're eliminated positions like that and then give general assignment reporters. So just because you've educated a reporter in the past on recall policy, you may have a completely different person in charge now. So you have to do, that the job of keeping up with all of that information. So some of perspective as I thought of that, thought of this with my experience in dealing with recalls and improving press releases 10 years ago, you know, one of the things that I was not aware of that I heard, I guess just maybe three years ago, that press releases are being sent now for all types of recalls and when I was there they were only going out for Class I recalls. And I think that really does raise some questions. Is that a proper risk focus? Because I do think that can contribute to consumers tuning out information. SO it's important, regardless, we do have to have a public health perspective on what is the risk that we're dealing with on this particular recall and make sure that we are doing what we can to reach that effected

populations as the first priority, not trying to paper the world and to reach everybody. Because that can be counterproductive in reaching the effected populations.

So one of the suggestions I would have and again I apologize for my former colleagues, if you thought of all these ideas. But supplementing media outreach with a very targeted constituent for notification process. You know, I think that was an excellent idea to get the messages out to schools, to make sure we're doing that in a comprehensive way. Obviously USDA has access to WIC agencies, woman, infants and children, to make sure that that group is very important obviously for listeria recall. So there are ways you can have a much more customized list of outreach then simply putting some press releases out tot the media. But the high profile alerts should be reserved for the highest public health threats. I don't think in cases of economic adulteration or ham, especially with a turkey but the product is otherwise perfectly safe with consumers that that deserves the high profile pres release that some reporters, who sees, you know, 100 press releases come across their desk in a day is going to get equal weight on a, you know, public health threat type listeria

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recall with a substitution for a ham or turkey. And I think you really need to rethink that decision. Are you contributing to an information overload there? Also, I would suggest varying the messages. And I think I looked at some recall language and it looked very familiar to what I used to approve in my 10 years with FSIS 10 years ago. But I think it does come across as a boiler plate. I know there's critical information that has to be there. But sometimes depending on the product that you are talking about, there's the bottom line, the media's going to pull out. As you know, with any story they're going to take a one-page press release and boil it down to a sentence or two. But maybe you could have a bottom line box in that press release that really gives the key information and what is the risk and who are the target groups. And just as a quick reminder of a motto that we've worked very well, together with FSIS and FDA and CDC and others and even the Association of Women's Health, obstetric and neonatal nurses on this patient tear sheet that gives information to pregnant woman about the risk of listeria in pregnancy. And this is a very targeted campaign. I'm obviously a little different than you do in a typical recall situation,

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there's a way of finding all of the affected groups on a particular issue and making sure that they have the information. And as we partnered with FSIS in getting this tear sheet out, we literally reached 200,000 health professionals and all these distributions, nurses, midwives, physician assistants, the obstetricians and gynecologists themselves, dietitians, anybody related. So there's a good change that if you've been pregnant the last few months that you have seen the fact sheet on the previous slide. So I think a similar approach needs to be used on recalls. It's very targeted to all the groups that can help get the message out. So finally I think in summary what we're really talking about with recalls you've got critical information that needs to reach the right people in the right way. So I would establish a recall registry, if we haven't done something like this, where groups, but the food allergy and asthma network could have some of their members register with FSIS or FDA so when there's a recall their members could be immediately notified electronically if they have previously signed up to do that. Other groups could offer to register as well. Make sure you have a customized list of journalist. You can obviously

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analyze who has been covering recalls in the past. Make sure you're really reaching the ones who are going to give notice to the story and then really try to reach out to other health professional groups and use the term deputize them in your effort to get the word out. Really say that you need help, this is public health information that needs to go to their constituents. So with that I look forward to joining the panel for further questions.

MS. HULEBAK: Thank you. Thank all of you. Thank all of you. We'll now take about 10 minutes for questions from the floor. Please identify yourself and your affiliation.

MR. WILLARD: Hi, I'm Tim Willard, I'm with the National Food Processors Association. And I guess I'd like to get comments from my former colleague Alice Johnson on an issue. Everyone here has noted the importance of getting information out with which we absolutely agree. But I would think that the food industry has a particular interest insuring that this particular information is accurate. It would not be fully useful to consumers if it is not accurate. I'd like Alice to comment on an issue that I think, I

remember companies have encountered on occasion, which is the fact that they are not able to review the release with USDA's draft before it goes out. And by review I do not mean negotiating it's language or any of the points, anything that would hold it up but taking a set period of time, perhaps 15 minutes to review specific facts, such as name of product, code lots, where it has been distributed, those sorts of things. I believe, if I'm correct, that there have been identified mistakes that have led to the need to do either further notification or where things have just been missed in that. So I'd like your comments on would that be a good way to go?

DR. JOHNSON: Yeah, I think when we looked at our survey we talked about the need for companies to have more input. If the agency chooses to draft the press release, then adding a memo, the company should be able to review it. We've had instances where something as simple as the number for the person to call that was released in the press release was wrong. And somebody was getting calls at three o'clock in the morning at their home instead of at the plant that was going to be answering questions got a little upset. We also have a

lot of cases where codes, product code is identified inappropriately and you can't really get the product off the market if you don't have the correct information. And we can sit here and give a list of the times that the system has not worked correctly and I know that there's one company that actually drafted a release and had the information right there for the agency to kind of just transcribe and it was actually transcribed wrong in the actual FSIS release. That doesn't get us anywhere in trying to get the product off the market. So as Tim said, it's not a matter of negotiation and of trying to change the recall that should be made perfectly clear; it's a matter of is the information factual, do you have the right product codes, have you identified the right products and brands. Because as everybody sitting out there from the industry can tell you, when you do a recall, even if the press release is right you get all sorts of product back, and sometimes it's really hard to -- for consumers to be able to sort through the information anyway. Ms. Dewaal?

MS. DEWAAL: Thank you. Caroline Smith Dewaal, Center for Science in the Public Interest. I have a question that I'd love to have each of your

panelists address. We've heard what I think of as three new ideas. They're clearly not new, but they would be new to this issue of consumer notification. The first is point of purchase consumer notification. The second was the bonuses or double your money back, we've heard it. And the third is direct advertising by the companies. We heard a complaint today that you can't rely on the media to get it right, that is, unless you draft the ad yourself. So I'm wondering if each of your panelists could comment on those techniques as ways to notify consumers about product recalls?

MR. SCHMIDT: I should have written all these down, Caroline.

MS. DEWAAL: So it is...

MR. SCHMIDT: I've got the double your money back...

MS. DEWAAL: Double your money back, and direct advertising and point of purchase notification. Those are the three.

MR. SCHMIDT: Okay. Well, see I think there's elements of those that would be a good idea. I think the first one that would probably be the most difficult is the double your money back. Obviously, in trying to

enforce something like that I can't imagine making something like that a mandatory government program. I think that for a company that wanted to really encourage the money back, that would be a great thing if they were willing to do that. That's obviously an economic decision that they've got to make. I think point of purchase at the retail level wouldn't make sense, you know, if they've gotten a message about the product they've removed from the market that shouldn't be there, so I'm assuming --how point of purchase would work essentially.

MS. MITCHELL: Can I clarify? Because in the Billmore outbreak we have instances with product with relatively long shelf life and the consumers, we actually had a family where the woman experienced a miscarriage of twins but the husband who shopped for them said that that thing, because he didn't read the newspapers and he was working two jobs and couldn't watch TV so he couldn't get the media notification. But if they had it at the store, he would have seen it and been able to take the product out of his refrigerator.

MR. SCHMIDT: Yeah, well, it would certainly be helpful if retailers were willing to have a section

where they could keep track of recalls because it would obviously not be maybe just one product, it may be a number at the time. So he could have a section like that, which would be a nice thing to do. But I wanted to make sure you weren't talking about other product recall. That could be quite confusing for consumers. SO I think the idea could work. The idea of a registry, whether any public health group had kind of a listing of active recalls so anybody could go to the site, USDA could keep something like that. And if the retailers wanted to do that as well or link to the other ones I think that would make sense overall.

MS. MITCHELL: And I would agree that it makes a lot of sense for us to have point of purchase notification. That's the place where a lot of people get their information. I would want to ensure that as Mr. Schmidt suggested it was a recall center that it was as some place as prominent as right on the aisle where those things are anyway. Because you know, I personally, just speaking from personal experience I rarely go over to the corner, where all the coupons and notices are hung up and review it for recalls. I think to ask people to do that looking for what happens to be

in your best regard or what may have been in their best regard for would be asking another step of them and what we're here to talk about really is taking away those extra steps and making it so that this process works. I think that we can go beyond that. I think that retailers are out there correcting information on their shoppers on what their purchases are. They're pushing coupons for competitive purchases and things like that.

We could have people, we could have retailers providing that information on the back on grocery receipts the way that they do coupons right now. We could have e-mails targeted to customer clubs and things like that. There are a lot of ways that we could really be doing more just to get the words out to the consumers. In terms of the double refunds, the idea is out there. I mean if people want the product back, if you truly want the product back and you want to keep people from getting sick, do what it takes. In the long run you're going to be the better for it. And that's what when I talk to people in the company they say we don't want that product out there because we won't be able to sell our product in the future. In the long run what you're do is going to benefit you. And in direct

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advertising I don't even know what to say except, go.

DR. JOHNSON: Okay, my turn. I suggested David start first because I was still, Caroline, still trying to write down everything, and I thought well evidently somebody else got it before I did. As far as looking at point of purchase advertising and I know that we have some folks from the Food Marketing Institute here and they want to talk about what the retailers normally do. As Karen said you can't really expect the consumer to go somewhere and look to see, okay, what products can I buy today. You know, the intent of a recall is to notify the retailers and the product is off the shelf. And I think that's really where the focus needs to be. If a retailer is going to post an announcement, it looks like to me it's easier for them to go ahead and get the product off the shelf. So just at first glance thinking of that I think that this should really be on, let's be sure it's off the shelf. And I know a lot of companies actually will hire folks or have their own sales folks go in and do effectiveness checks at retail leave to see did this guy really take it off the shelf? And I think that the benefit of posting somewhere and expecting the consumer, if people

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shop like I do it's a mad dash to the grocery store so that you can get home and move on with something else. It's going to be hard to get them to focus on a certain area where you have, here's your warning list or here's your recall list. To Karen's point, there's no one in the meat and poultry industry that wants product on the market place that's been determined to be unsafe. Bonus coupons, double refunds, because of the way recalls are handled and people returning product back to the grocery stores, my first thought with this would be that some of the retailers would have a lot of concern with trying to handle if you had a large amount of that type of incentive. If you had a large amount of product coming back, I'm not sure that the retailer, if they would have the resources to be able to handle, you know, just the mechanics of that. And you also have to remember as I said earlier, when you have a recall, not only do you get product that was actually involved in the recall, product that was coded, but you can get product that was totally unrelated, different brand, totally different product. So again the retailers are going to have to, you know, as this product comes back to the retail establishment, work through, you know, what's the right

product, what's this, what's that. And I just think that would be pretty resource intensive. Although I'm not saying there aren't ways to work through that. But that would just kind of be my first impression in trying to offer something like that.

MS. HULEBAK: Thank you very much. We'll now go to a break. Please be back in 15 minutes. Thank you.

[Off the record]

[On the record]

MR. DERFLER: Okay. We're going to start the third panel discussion. I want to start off this session by looking at the recalls that we have done over the last three years and the reason for those recalls. Actually, I want to focus on one reason in particular and that is FSIS verification sampling. FSIS periodically samples product before it enters commerce for E-coli, 157.H7 or for listeria monocytogenes to verify whether the establishment has a plan that's working and whether the product that the plant is producing is safe. In 2000, FSIS did 78 recalls and 43

of them, more than half, were because FSIS verification sampling found the product to be positive for the pathogen. In 2001, next, there were 66 recalls and 28, a little less than half, were the result of FSIS verification sampling. And this year, as of November 5, of 119 recalls, 45 were the result of FSIS verification sampling. FSIS recommends that plants hold the product until the testing results are back and most big plants do but a lot of small and very small plants do not. The question that is thus raised and I'd like to first consider here is this, should FSIS allow product that has been sampled for pathogen, whose presence would render the product adulterated to bear the mark of inspection before the test result is received. Placing the mark of inspection on the product means that the agency has found that the product is not adulterated. Should FSIS delay making this decision until the test results are back? This is the first question that I'd like the panel to consider. And first up I'd like to introduce Ms. Rosemary Mucklow. Ms. Mucklow is the executive director of the National Meat Association, National Industry Association representing meat packers, processors, wholesales, sausage makers, and related

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forms in the US meat industry. She's held her position since 1982 and has been associated with the meat industry for over 40 years. As executive director, Ms. Mucklow is responsible for the administration of the business affairs in the national meat association. Ms. Mucklow?

MS. MUCKLOW: Good afternoon. Okay. Let's break the microphone. There. You realize they had to bring me here kicking and screaming on the red eye to join you all today for this important meeting. So I missed the opening remarks and I apologize to Dr. Murano. I came in in the middle of Dr. McKee. I appreciate being included even if we are the last panel. And you indulge a little bit because they've got Christmas parties to go to. I'm honored to share with fellow panelist Shirley Bohm, current president of AFDO and I thought it was going to be Carol Tucker Foreman of the Consumer Federation of America but I understand she's gone home sick. I do hope she's not suffering from food born illness. We have Caroline Smith DeWaal in lieu. I know we've been challenged to respond to new approaches to recalls. And I also know that moderator of this session, Phil Derfler, has told me that his time

clock's been set to keep us within the time perimeters.

Before I get to the specific questions I'd like to say that it's time for us to pick some new approaches to recalls. Because I'm not in the least confident that the current policy is effective in it's objective and that objective as we've heard over and over again and feel I will be repetitive is that recalls are to protect the public health. Having been assisting companies when they're under extreme pressure to undertake a recall of their product, I come here today to tell you that it is one of the most stressful and difficult business experiences for a business. I listened to Dr. Siemens this morning. She was absolutely correct. They're a large business. There are many, many small businesses and the stress is huge. Business owners, business managers who learn product that they made in good faith is sufficiently harmful that they must get it back from the market is a huge step for them to take. It's unpleasant and counterproductive to go into a recall. But in my many years of experience I have never had to take a single person to my woodshed about the need to recall when they're presented with the facts. They've come willingly to that decision. We have an honorable

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industry that wants to do the right thing by their customers. There have been a lot of recalls in the last few years. Many times with more recalls than we ever did even just 10 years ago. Reminds me of the story of the little boy who was sent out to guard the flock of sheep just outside of the village boundary. He was told that if he sighted any wolves, he should cry out wolf so that the villagers, the other villagers, would come and help him fight them off so that they didn't destroy the sheep. He found it pretty lonely out there watching sheep, so he tested the shout. And the villagers came and who did this, they asked the boy because he was really quite lonely and he liked having company out there. And the danger when the wolves really came and he shouted wolf, the people didn't come to help him. Recalls have become so routine that the public is paying less and less attention to them. And if we really have a serious one, a really big one, a really critical one to protect public health they may not pay any attention.

I am hopeful that out of today's meeting we're we'll find a way to identify the critical list and I'm not sure there's such a word of recalls. So that those that are not a major threat do not lull our customers into

complacency when the day comes and we really cry wolf. Now to Phil's first question. I don't want to cross Phil. I find that he's pretty adversarial today. So I want to try to keep in time. Should the market inspection be upheld from products pending sample results? The short answer is no. Market inspection is evidence to a consumer that meat or poultry has been slaughtered and processed in a business that is under the oversight of the USDA, under the regulatory oversight. That oversight assures that USDA oversees and monitors the production activities at any time where that business is operating. Withholding the mark, pending receipt of the specific, single sample, laboratory test of a product, which is in no way representative of the entire market product isn't warranted. Further it is not the USDA's responsibility to make products safe for the consumer. That is the industry's responsibility. It is USDA's responsibility to make sure that official establishments that it in effect licenses to apply the mark of inspection, meet certain standards. Let's get one thing straight, please. The mark of inspection is not a seal of approval. It is as I stated, the evidence for companies

and people buying meat, which held that the meat has been slaughtered and processed by the company whose inspection number is associated with or inserted with the mark. To demonstrate that it has been handled under the mandates of the Federal Meat Inspection Act or the Poultry Products Inspection Act. Phil's second question.

MR. DERFLER: Now wait and we'll come back to the second question. I wanted to go through each question one at a time. I'm sorry.

MS. MUCKLOW: Oh, you mean I don't get to make my whole story all at once, huh? Sorry. Okay.

MR. DERFLER: There you go.

MS. MUCKLOW: You all know who's in charge.

MR. DERFLER: Hello. I'd next like to introduce Shirley Bohm from the Minnesota Department of Agriculture who I introduced this morning.

MS. BOHM: Rosemary was on a roll there. I hated to interrupt here. What I'm going to try to do is be -- full screen. I'm going to try to answer the question, should, establishment initiated recalls...

MS. MUCKLOW: Question number two, Shirl.

MS. BOHM: Okay. This one right?

MR. DERFLER: It's a good thing I'm tough.

MS. MUCKLOW: Yeah, I give up I'll go back to the first question.

MS. BOHM: Should the market inspection be withheld from products pending sample results? Well, I think under certain conditions. This should probably be determined on a case by case basis. Since we're looking at new approaches here, right? Based on risk to the consumer, there are some criteria that could be used if this was going to be a new way of looking at some ad recalls. Is there now in evidence from someplace that the product is adulterated or contaminated and that could be confirmed test from, for example, a state laboratory who has done the testing. Is there epi or epi statistics, for example that very clearly and firms implicate that particular product that could be considered adequate evidence to withhold the market at the time. Is it high risk product? There are some products that are very high risk. For example, foods that are destined for nursing homes, for examples, or school lunch programs or something like that, there's extra added risk because of the susceptible populations. Or is it a high risk adult with serious consequences if

it's consumed. And that could be, for example, E-coli with HUS or listeria monocytogenes or things that could cause definite miscarriage. So there are some condition if we're looking or trying to look at a new approach that the recall process could be changed. There are some, you know, other ways that we can look at it. Those are some possibilities though. Thank you.

MR. DERFLER: And our third speaker will be Carolyn Smith DeWaal who you also met before. As Ms. Mucklow stated the scheduled speaking at the forum is ill today and so Carolyn graciously agreed to step in.

MS. DEWAAL: Thank you, Phil. And everyone here knows no one can really step in for Carol Tucker Foreman. I do want to apologize in advance because I don't feel like I'm prepared for this talk or even these small remarks in a way that I normally do as you saw earlier today. I think the issue of withholding market is an excellent concept. And I don't think that we can come to an answer today. I know I certainly can't deliver a definitive answer from consumer groups because we're still going over the pros and cons of this particular proposal. But what I am hearing and hearing it from industry as well is that ore and more companies

are moving to test and hold regimes. So in a way they're putting themselves under that provision of not selling the product, not marketing the product until, in fact, they are sure of those test results. Secondly I think that the withdraw of the inspection mark may be something very appropriate for the government in the event of companies that do not use interventions, that do not have a scientific program for ensuring the safety of their products. In the most recent listeria directive the government basically said show me, show me your plan, show me your data. If you can do that then we will give you credit for that assuming that you don't then run into problems. But the companies were unwilling to either put scientific programs in place or document those programs so the government withholding the inspection marked during an intensive testing program would be appropriate. Finally, when the government is testing in the plant for known edentates, we're talking about listeria monocytogenes and ready to eat meat products, salmonella in some ready to eat meat products and also E-coli, 0157.H7 in certain beef products. For those, if the test results comes back positive then in fact those products should not receive

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the mark of inspection because they're adulterated. It's a matter of the law. It's not even a matter of discrepancy for the agency. So I think that where the tests are being run in the plant the testing technology is getting faster. I heard from a plant yesterday that they're testing yogurt and they're running the test in about 18 hours. So it's not unreasonable to say that for those hazards that are defined adulterants withholding and where the tests are running in the plant withholding the mark of inspection is not only appropriate it's probably legally the requirement. Thank you.

MR. DERFLER: Are there any questions or comments about this from the audience? Yes, I have a question. Ms. Mucklow in particular, my understanding one of the reasons why the practice of allowing product to flow while we're pending the results of testing is because particularly small and very small plants have a hard time holding product or because they make only limited amounts of product it would create a significant economic hardship for them to do that. And I was wondering if you could just comment from your perspective on that.

MS. MUCKLOW: Okay. Certainly on a test and hold scheme that a company voluntarily takes on or for instance I had a call this week from a small grinder, a small company and he said to me, you know, you saved me a lot of grief a few years ago, he said because the inspector came in, took a sample of my ground beef and you told me that I was to stop my operation. I was to completely clean down and begin a new lot of product. And he said, I did that and my two competitors didn't and they had recalls and I didn't. I said well I guess that paid your dues for 10 years. And so you know he was back on again test and hold, when people chose to do that is a way of managing and certainly when the government says they're going to come and take a test, they give the company that opportunity to hold that product. And our member sand many others in this industry have chosen to hold that product as a result. And many of them are as grateful as that little guy that called me this week. When you do have a test and hold system and we are certainly encouraging people to undertake that test although I don't think it's the answer, necessarily, to everything, but it's an indicator. We had a story in our newsletter a couple of

weeks ago about this, about how people could actually complete that test while the product was in transit and complete the documentation before it was turned over to their customer. That is one of the alternatives. In a business where the product is a highly perishable product because my members don't want to be selling stale meat. It doesn't sell well, it doesn't taste as good as nice, fresh beef. Do you like to, if you're going to be using that product for ground beef, you want to grind it as fresh as possible. And because many of the very larger companies that produce a lot of that kind of product in more central locations, you're going to have two days of transportation to get it to the place where it's going to be ground and made available in a local store. And there are still many consumers, me included, that likes my meat ground fresh. It tastes better, thank you, and I'm going to continue arguing that. There are other alternatives, a variety of other alternatives but I still like my fresh meat. So I think the test and hold systems have validity. I have one member right now who every day sends me his update. He's a producer of combos. And he's had some pressure and every morning on my e-mail there's his list of what

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yesterday's combos reported. And he's doing pretty good for the testing that he's got in place. So yes, there's a lot more testing going on and if people are going to test then they need to manage that product and make sure that if they're waiting for a test that they don't have it out in the market place selling it because it comes back positive they have the obligation to get it back and they will get it back. I don't know anybody who has chosen not to do the honorable thing.

MR. DERFLER: Any comments from any of the other panel? Okay. Any questions or we'll go on to the second question. Could you just please...

MS. MUCKLOW: Why don't we just stay here, Phil. You don't need to get up and down all the time.

MR. DERFLER: I know. Whatever. She was going to say something else. Okay. Can you do that? There's a second trend in the data that I want to talk about and focus on and derive a question from it. Actually what I'm going to propose is not all that different from some of the things that Dr. Johnson talked about, which probably marks me on an industry shelf forever, but first of all in 2000, 17 recalls or about 20 percent were client initiated. Next one. In

2001, 19 recalls or almost 30 percent were plant initiated. And in 2002 42 or 35 have been plant initiated. Plant initiated recalls suggest an idea that was raised in a 1998, my recall working group that made some suggestions and that I'd sort of like to put forward again and as I said this idea does reflect or echo some of the ideas we've heard so far today. When the plant initiates a recall and what I mean by a planned initiated recall is since all recalls are voluntary that in circumstances where the plant undertakes the recall on its own, they have not been contacted by FSIS at all, and they decide to initiate the recall, the ideal in going forward is that FSIS's role would be one of verification instead of its normal actions. It would be up to the plant, not FSIS in the first instance to decide how to notify the public about the recall. It would be up to the plant to decide what product is covered and so forth. FSIS's goal would be to verify the adequacy of the plant's actions. If FSIS decided that they were adequate, FSIS would allow the recall to proceed. If FSIS decided they were not, the agency would step in, I assume you're talking press release for example or by asking the plant to expand the

scope of the recall. If the plant refused, FSIS would act. So the question I would like you to consider is whether it would be appropriate for FSIS to limit the role, its role, to that of verifier when a plant takes the initiative and recalls product from its own without being asked by the agency. Now I'd also like you to consider a second question in conjunction with this, would it affect your view in any way if FSIS required that all plants have recall plans as a prerequisite program. So that there would be some predictability as to how plants proceeded. We saw from data that Dr. Johnson presented that a great number of plants have recall plans. On the other hand it's been the agency's experience that on a number of instances plants have not and there's been a delay because they have not. So with that I'd first like to ask Caroline to reverse the order from the first question. I'd like Carol Smith DeWaal to address it first.

MS. DEWAAL: Hi. Okay. So Phil's asked us two questions. One is should FSIS's role be that of a verification agency not a recall agency and the second being would this be a better idea if they were required to have recall plans. Bottom line is no to both. FSIS

and I wish I had a slide to show it but FSIS has a critical role in announcing recalls. And we've talked about that earlier, we've heard about it but let me just give you two case studies to illustrate this. One is in 1994, the Schwan's ice cream outbreak. We've reference it today but I want to describe it right now. Schwan's ice cream had a tanker truck that came contaminated with salmonella and they produced a large volume of contaminated ice cream. According to the American Journal of Public Health, where they actually reported this case study, the outbreak caused 224,000 illnesses in 41 states. But it's relatively unique because Schwan home delivers so they knew who their customers were, they knew who had the contaminated product. We sent letters to their customers and instructed their delivery personnel to pick up the product and to exchange it with other product. This gave researchers the ability to reevaluate how consumers actually responded. They surveyed 179 households in Georgia that were Schwan's customers, representing over 600 consumers. Ninety-one percent of the households heard the warnings. So direct letter to the customer, that resulted in an over 90 percent, and heard the warning. They opened the letter

and looked at it. But among those, over 25 percent did not initially believe that the ice cream was contaminated. They didn't believe it. And then what we're finding was that in 31 percent of the households where they had the contaminated ice cream, people continued to eat it. And this just shows the hurdle that you have to overcome in a recall situation. People believe their food is safe. They believe that what they have gone and bought is safe and healthy for them. And so when you're delivering this information about recall you have a big hurdle to overcome. The second example was more deadly and that was the Sarah Lee outbreak we've also talked about earlier today. Again, December 22, 1998, Sarah Lee announced a recall. They were very responsible. No government agency would tell them they should do it. And they went ahead and did it. But unfortunately that was a big year for news and that information did not get out. Finally in January the company had to take out full page ads in newspapers just trying to get the information out that the products were recalled and people should continue to eat them. The reason they took that extraordinary measure is because people were continuing to die from this outbreak after

the company had recalled the product. Finally in late January USDA issued an announcement and the current recall policy where they announce every recall by a company is a result of that outbreak, which was tragic.

That the company's announcement was not enough to actually get the products off the shelves and out of consumer's refrigerator and to stop the outbreak. And then the key from the epidemiologic standpoint is have you stopped the outbreak. Bottom line is the hurdle you've got to get over is too high, the companies can not do it alone. And so when you're dealing with Class I recalls or allergens or anything that's going to make people sit you've got to have a government announcement if you want it to be effective. Thank you.

MR. DERFLER: Ms. Bohm?

MS. BOHM: Okay. I'll try this one again. Question here is should establishment initiated recalls with their own recall plan be approached differently from the agency's different approach. I think we've heard a lot of really, really good ideas today and I think maybe if we all admit it, we've all learned something and maybe we've changed our way of thinking, maybe just a little bit. I'll give you what I wanted to

put together before and maybe there is a little bit of room for changer. But if product is adulterated and they're both subject to recall, the recall process has to be treated the same whether it's identified by the establishment, whether it's identified by the state of a local or it's identified by FSIS, a consumer, a doctor, by CDC or by whoever. The situation is the same no matter who identifies that and there has to be a recall situation. The lack of recall control that the firm, the recalling firm has once the product leaves its facility. Once it goes off their loading dock, even though they're customers, even though you know that person personally at the distributor, even though they're your friend, it could be your mother-in-law, you still don't have the total control that you had when you had that product in your own plant. That leaves a hole in your system and sometimes you need to have the regulatory agency present. There are also possible miscommunications. Someone once said that somebody was on vacation or I guess buried under that pile of papers on your desk. Again there are some problems that occurred that aren't your fault. They're unintentional, they're accidental but they still happen and we all know

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that they happen and that's another case where, there sometimes you need some help. Whether it's from the state or a local or from FSIS compliance officers or whoever. So I really do believe that there is a need to have FSIS presence or regulatory agency presence here in the recall situations but I think that there is probably some rule to modify some of the recall processes that are being done. I think all of us would benefit from having the more streamlined and the most effective system possible. But people who are doing a good job they also, you know, need some reinforcement. So there's some possibility, there's some room for modifying the system in some ways that would allow for those people who are doing the good job to take the lead in conjunction with FSIS to go ahead and work the recall. My idea.

MR. DERFLER: Thank you very much. Now Ms. Mucklow.

MS. MUCKLOW: Phil, you can call me Rosemary, like everyone else in this room. Is that okay with you?

MR. DERFLER: Anything you say, ma'am.

MS. MUCKLOW: I'm not even going to give the rest of my presentation. I'm not sure what Phil meant

when he asked me that question. I wish he'd given me that later and he certainly didn't prepare me that he was going to do this musical chairs stuff. But that's okay. I can deal with that. The voluntary recall authority under the law give the USDA a big hammer. Believe me I know, it goes like this. Mr. XYZ company, we have evidence that you need to recall all of the ground beef you produced on December 1. We're prepared to have a press release to accomplish this and we're sending it out tonight on the wire service. If XYZ says, no, no, no, then USDA can initiate a detention and then a seizure action. It's there, it's in the law, it's not pretty. I think I've heard of only one company in my whole 40 years experience. I'm older than half of you. I've been in the business more years than half of you. I've only heard of one company that went through the no, no, no routine, in all of my years experience and they were not one of my members. Most people in the meat industry, most companies, have agreed to prepare themselves for the inevitable press calls the next morning after the USDA press release went out on the wire service. Perhaps there is some room here for the company to step up to the plate and take that

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responsibility and this is worth consideration. And I'm pleased to have heard the comments on that this afternoon. A recall that I was involved in earlier this year was announced by USDA and 7,500 pounds of ground beef, one day's production for the company, based on a single, random USDA sample that tested positive for H7.

Had the company known the sample had been taken by their inspectors, who forgot to tell them they were to hold the product and didn't. The product was made on Tuesday. The contamination was announced back to them on Thursday. The recall notice went out the following Monday. And I'm testimony here to Armia Tawadrous and his team because it was 6:30 my time in California, so it was 9:30 their time and I think they were all hissing at me through their teeth. The company had already accounted for 7,300 pounds of the production. About half of it had gone to a soup kitchen that cooked it 190 degrees Fahrenheit twice. So that's not a public health concern. The rest of it had gone to local, small restaurants and the company had recovered almost all of it except a couple hundred pounds. And the reason they didn't get the 200 pounds back was that the restaurants had cooked and served it and it had been consumed. A

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recall announced by USDA for 7,500 pounds grossly overstated the risk and I remember speaking with a senior official who's here in this audience today and the only thing that made sense was when that official said to me we can't change the policy on calculating the poundage that we state in the recall in the middle of a recall. And with that I conceded. I think those arguments late that Monday, 9:30, 10 o'clock Washington time are why I'm here today. The bottom line in respond to Phil's question is that there is a place for companies taking responsibility for a recall and I think we should try to explore and provide some real guidance about how they can do that and that the government can be there to back it up and to ask some questions if they want but to let that company take control of the product. Because it is the company that will eventually bear the heaviest burden. I was going to wind up by saying that Congress, I think they say I see the balance of my time but I know I don't have any left.

MR. DERFLER: This is an opportunity for people in the office to ask any questions that you wanted from people on the panel. I'll ask Ms. DeWaal a question.

MS. DEWAAL: You can call me Carol.

MR. DERFLER: Thank you.

MS. MUCKLOW: Why you, I thought that was a new versions.

MS. BOHM: You can call me Shirley, too.

MR. DERFLER: I guess one of the arguments that was put forward before by Dr. Johnson was that providing the, letting the firm have the first shot at this would provide an incentive for firms to more readily do recalls and particularly where time is of the essence as it often is the case with recalls in product in commerce that may present a risk to public health. Why doesn't that incentive that's offered by this idea outweigh the sort of concern you have, particularly where what we're positing is where FSIS stands ready to take whatever action is necessary, if the firm doesn't adequately respond.

MS. DEWAAL: I guess, Phil, I don't see what the new incentive is. I mean we've heard form the industry today, they are ready and willing to act. It's in their interest, it's their brands name. They have stated that they are going to do this so what is the incentive to let them take the lead. I mean you've

already said well largely they do take the lead, they have the distribution list. The only question is should the government put out a press release. Should the government's name go on top of a recall notice? And you know, this summer, for those of us who've been doing this too long like Shirley and like Rosemary, there is a little bit of de javu where we can learn from our mistakes. There is data. There is evidence about the effectiveness of just having the company put out the press release by itself. And it simply is not as effective. And when you are dealing with products that can result in HUS, that can result in severe cases of food poisoning, miscarriage or even run into milk food poisoning. The consumer deserves the best we can give them and that is the government notice. Now the one question, which I think Dr. Johnson raised, that I thought was very good, and maybe I'll call her Alice, which I thought was very good is this issue of, you know, what about the Class II's which are not allergens or the Class III's where there's no risk of human health. It may be a mislabeling issue. Should those have the same degree of urgency? And I think that's a legitimate question. I think that's one that we would

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certainly consider should the agency put forward a proposal to downgrade or modify the announcements made on those particular recalls. But I do believe that for Class I and allergen or human health hazard type Class II's that you need the government to be the voice.

MR. DERFLER: Thank you. Any other panel members wish to comment?

MS. MUCKLOW: I just told you that 7,500 pound recall that was really a 200 pound recall and the product was already consumed, we didn't protect any more public health. All we did was to alarm consumers by eating ground beef. I would rather see our energy put into teaching consumers and guiding them that they cook that ground beef properly. It's not a popular thing to say but it's one of the things that we need to understand.

MR. DERFLER: Any other, last call for questions of this panel from the audience. If you want come to the microphone and we'll recognize you. Can you state your name, please?

MR. BODE: My name is John Bode. I was involved in the Schwan's recall and I want to assure you there was an FDA notice, press release issued as well as

consumer advertising. There were extraordinary efforts there and it wasn't just the letter directly to consumers. And I guess my concern is that 31 percent consumer nonresponse after they got the notification. And I'd like to ask Caroline, if she would, comment on what this consumer nonresponse, after getting the notification in light of press releases from the government when no consumer response is expected, like Rosemary's example.

MS. DEWAAL: John, and I share that concern about the 31 percent who, you know, not only didn't believe it but actually then proceeded to eat the contaminated ice cream. That's horrific. But what it says to me, I mean, first of all number one, ice cream is an unusual food to carry a hazard. And so this idea, on the consumer level, I mean if you told me my ice cream was going to make me sick I may not believe you because it's such an unusual food. So I would love to see this study done with a different food where there's a better understanding of the health risk. I suspect we wouldn't see that level of noncompliance or nonresponse if it was hamburger or several seafood products where there's a much better understanding. But what my

concern is about that particular out break and the reason I use it, it's to inform us that even the best information to the consumer, you still have this incredible hurdle to overcome. And that's why the government notification in these becomes very critical.

Because the media, in the Sarah Lee outbreak the media didn't pick up the story. I think because, if I'm remembering my dates correctly, the issue of Monica Lewinski was all over the papers all over the country. And you just could not break through. And finally the company itself decides to do direct advertising. But you see relying on the media, unpaid media is risky because there may be news stories that are just going to totally eclipse any food safety story no matter how important it is to our consumers or your company.

MS. MUCKLOW: I hate to say it, we need a white house sex scandal to keep us on the front page of the newspaper. I don't know if I could stand that.

MR. DERFLER: Any other comments form the panel?

MR SEEWARD: I'm Luke Seeward with Food Safety. I just want to point out a clarification. First, I'd say low paid media rather than unpaid media

Caroline. But is there anything to prevent a firm from putting out a press release now? I mean I don't understand why, it seems to me that I do so, on occasion, see releases from both the firm and from USDA. What's the experience with that? I mean that would shed some light on this.

MS. MUCKLOW: Yeah, that sometimes does happen. Those who are very well organized, remember again this is a highly stressful moment. They need, usually, a small...

MR. SEEWARD: We're talking about 150/200 words. I mean, it's not, you know, like writing a term paper on it or something.

MS. MUCKLOW: I've seen the company get to the newspaper before the government. But it doesn't happen very often. I can think of a few specific examples and I'd just as soon not float a name here today but I remember a few. But I remember a few but they're very few and far between.

MR. SEEWARD: But I don't understand the issue though. If it's already being done or can be done, why isn't it being done?

MR. DERFLER: Let me explain the incentive. I

understand it from having talked to some industry people. If industry puts out a press release and that's the end of it then there's one notification and that's all that there is. But when there's a multiplicity of notifications in the media then it looks like the incident is of greater and greater significance. So the incentive would be that they would be the ones that would be able to provide the notice of the media and then there would not be a second government follow up unless their notification was inadequate. So that's the idea. And I'll now turn it over.

MS. DEWAAL: Thank you. And I'm somewhat speechless but the risk here is simply too great. You can not put protecting the reputation of the company ahead of protecting a woman from having a miscarriage, which happened in the Sarah Lee case after the recall was announced or protecting a child from getting HUS. We're simply, it's wrong headed and there may be some incentive buried in there and the companies can clearly put out recall notices. They could do point of purchase information that they get out to all their customers and I encourage the companies to do this. I encourage them voluntarily to take these actions. I mean don't leave

it up to the government to manage your recall. The companies do manage their recalls and they're very good at it. But you can not leave it to them. And it's an inappropriate job for government public health agency to think and I know we are just floating ideas here. But the company can do the same job and give it the same urgency that the government announcement does.

MR. DERFLER: Thank you. Were there any more questions or comments from the audience?

MS. MUCKLOW: All right. One last funny line if you are about to end or are you not finished yet?

MR. SEEWARD: Oh, no, I'm finished.

MS. MUCKLOW: I clipped a piece out of the Oakland Tribune. You know, I live in Berkley where our mayor, who just got sworn in, decided that one of the most effective ways that his opponent wouldn't win was to go and tear up the flyers urging the students on the campus to vote for his opponent. And so now he's going to be charged with petty theft but we've sworn him in as mayor any way. Any way there's a product warning publication in my local Oakland Tribune. The product warnings take on litigious fools and they're talking about the kinds of warnings that can go on through

products. And I thought a couple of them were kind of entertaining. On a hair dryer, do not use in the shower. Good idea. On a butane light, flame may cause fire. On an automobile windshield cover, never drive with the cover on your windshield. On a Batman Halloween costume box, cape does not enable wearer to fly. I guess you have another question.

MR. DERFLER: Do you have a question for the panel?

MS. HUSTY: I just got, is this an opportunity to ask general questions?

MR. DERFLER: We'll do that in a second.

MS. HUSTY: Okay.

MR. DERFLER: First what I wanted to do was thank the panel for their participation and their comments and thank you very much.

MS. MUCKLOW: Thank you, Phil.

MR. DERFLER: Sure. And now according to the agenda there is an opportunity, I mean, I'm not sure who's going to answer them but it's what it says.

MS. HUSTY: I would expect nothing less. This is Lynn Husty with the American Media Institute. I just have a general question. I notice the gentleman from

FDA earlier said that they have a form that's available to industry that kind of explains how they do their evaluation whether or not they're going to conduct a recall. Along those lines I've had several questions this year. It seems like recalls for allergens have really skyrocketed. And there's been a lot of questioning as to why some allergens are listed as Class I and Class II, Class III. I have a general understanding as to why that is from speaking with the agency people but I just thought it would be helpful if the agency could actually post something on their web site under allergens about how they come to that determination.

MR. DERFLER: Okay. Thank you for the suggestion. We recently did publish something on allergens with respect to food labeling but Dr. Tawadrous, who I had seen, do you want to address that question at all? I'm sorry. I put him on the spot. Are there any other -- no, forget it. We'll...

DR. TAWADROUS: I didn't hear the question.

MR. DERFLER: The question or the suggestion that was made is could we provide guidance on how we classify allergens between Class I and Class II and I

just wondered if you had any sort of insights as to the process.

DR. TAWADROUS: I'll be more than happy to. What we do, we have a risk analysis group and we do risk assessment for based on -- oh, I'm sorry. Okay. I thought I'm loud person to begin with. Okay. I'm short too. That compounds the problem I guess. That's a risk assessment I did. What we do we have a lot of risk analysts in our group. We hand him the case and we go over the percentages, the amounts so we know in the final product that's going to be consumed by the consumer how much of the allergen, percentagewise, who's the targeted audience, is it children, is it risky adults and so forth. And based on that they give us a risk analysis that it could be severe it could be fatal or it could be just a reaction. So if it's just a reaction which is not going to have any adverse health consequences that goes with in the Class II. If it's going to be more than that, it's Class I. I understand that if the agency finds every as one. That that can happen and then we go with the targeted audience who's going to consume the product, how much. For instance, if you say in a can, how many cans a child can eat in a

given day, unless he or she is a monster. You know. So that's just an example. So that's basically how we go by Class I versus Class II. I don't know if I made it clear or not.

MS. HUSTY: Is it possible just to have something, a brief description like you've just given us actually put on the web site though to explain to people because there seems to be a lot of miscommunication as to why my recall is Class II this other guy's with the same product, except his product was...

DR. TAWADROUS: Well, we do have our classification on the web and a definition is there. What kind of situation Class I versus Class II, whenever I did my presentation this morning, it's there. So we say the remote possibility versus a reasonable chance that the consumption of the product would likely cause an adverse health consequence or even death. I would rely on scientific literatures. So we do have research before we go through it. And we do have our experts on the committee along with the company experts to debate that. And a lot of times we go back and forth between Class I and II, based on the available information out there.

MS. HUSTY: I know that Dr. Post has given several presentations on it, but in a discussion with him about that in the labeling division, and he said he's given presentations at APTO [ph] and Effects Center and other places around the country to kind of explain the agency's thought process in going through and making this determination?

DR. TAWADROUS: Right.

MS. HUSTY: Is that possible? Something that we can just have access to?

DR. TAWADROUS: See recalls particularly it's not a cookie cutter approach as one size fits all. You have to go and analyze every situation by itself and look for all these factors that I mentioned and I think Mr. Bryant, he mentioned something similar to that that was in the through process too, who eats it, how much, and all that. Okay.

MR. DERFLER: We can look at the factor and consider it. Thank you, Armia. Thank you very much. Yes?

MR. TIMERLAND: Hi, Phil.

MR. DERFLER: Sure. My name's Bob Timberland. I have a question going back to press releases for a

second. I wonder if the agency might consider revising a policy which from time to time tends to compromise their potential accuracy. As has been discussed today when there's what we'll call normal, voluntary recalls, back and forth between the agency and the company which involves distribution list, labels, production dates and so on. And the agency work product is a press release.

Up until a few years ago the normal logical process was before that release was issued that document would be run by the company, initiating a recall simply to check that for accuracy before it was issued. For some unknown reason a few years ago someone in the Department decided that that was a problem that that was being too cozy with industry in some way and the policy now is that document, that press release in draft form is not shared with the company initiating the recall prior to its issuance. What can happen and in my experience has happened, is mistakes get made on that press release. Not intentionally but because the obvious quality control check that the company providing the initial information can give is removed from the process. I know of no reason for that policy. I've never heard a rational for it and I guess I would just ask A is there

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a rationale that I'm not aware of and B if there's not would the agency consider going back to the form process, not having to clear that document, it's still the agency's document but have a knowledgeable person on behalf of the company initiate a recall, check that document for accuracy prior to its issuance?

MR. DERFLER: Since this is a meeting of new ideas I'm going to part B and say that we can take it under advisement and we'll look at the possibility.

MR. TIMBERLAND: Going back to the first part of my question, is there a rationale for that policy that I'm not aware of? I've never heard one articulated.

MR. DERFLER: I'm not aware, you know, I have to admit I'm not close enough to the recall process to be able to give you an answer right now. And I don't know if anyone else is here that would like to step up.

So are there any other questions or comments or anything that anyone would like to offer? If not, it's my pleasure to introduce Dr. Merle Pierson, the deputy undersecretary for Food Safety, who will wrap up today's meeting.

MR. PIERSON: Well, thank you for staying the

duration of the meeting. It's always difficult to be the wrap-up person. I would tell you that I'm going to go through each presentation item by item and that would make you leave very quickly. I will tell you that I'm not going to do that. Actually I have one observation to make. In the front table there was this little sign that said reserved and I was thinking about our panelists and our speakers, they sure certainly did not epitomize this word did they? We're not at all reserved. I'll give that to you, Phil. You know today we certainly have all witnessed a very productive and informative session and I might say at times entertaining as well. It was a good meeting. I learned a lot from this meeting. I think there was a lot of good ideas. An important goals of these meeting was to listen to all those with an interest in the role recalls play in helping ensure safe and wholesome food supply. An effective recall system is very important to our public health mission. I want to thank all of you for your time and effort in developing presentations and for participating in this meeting. In particular, I want to thank, you know, the speakers and the panelists. It always takes a lot of time to put their presentations

together. Phil, for you as host it was a good job. Charlie, you know, Charlie, I can never pronounce your last name.

MR. OLIO: Olio.

MR. PIERSON: Olio, it just doesn't fit. The spelling just doesn't fit here. Armia Tawadrous, thank you very much for your good work. Mosha Dreyfus, visual aides and everything, there you are. Carol Fletcher, Andrea McNelli, Sheila Johnson, Mary Harris and the planning staff for their excellent work. And Shirley Bohm, thank you for the use of your computer. I hope you get it back. Was it a good one, Phil?

MR. DERFLER: I don't know.

MR. PIERSON: Okay. We certainly appreciate your input and now we have a significant amount of information, suggestions and comments to review, evaluate and I believe to further use in refining the recall process and improving that process. I want to say that I personally have been involved in refining the notification lists, et cetera and there's a very difficult process. I appreciate the hard work that our agency puts into determining recalls and the notifications. You know, our goal, by the way, relative

to all our meetings and the symposia that we're having over about a nine month period, has been to be inclusive and to hear from academia, industry, advocacy groups, Congress and the public. On applying the forefront of science to protecting public health as it is effected through meat, poultry and egg products. As the year comes to a close, I feel that we've been successful in being open and available to all of our constituents. And I might say I've just returned from the Netherlands and gave a presentation on what's being done in these public presentations and I might say the transparency of this process. And the Europeans were very complimentary, quite frankly. I'm not patting ourselves on the back, I'm just saying that they were surprised at how they're, you know, that these meetings are public discussion and public debate. And it's only through your participation that that happens. During these meetings we've learned a great deal and it will all make us more responsible and effective public health guardians. We look forward to continuing the meetings in the upcoming new year. I want to thank all the participants again for a discussion in the importance of the issue that was brought to us today. Thank you very

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much and have a good evening.

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Sarah Mowrer, Proofreader
York Stenographic Services, Inc.

Date:

Tim Wagner, Reporter
York Stenographic Services, Inc.