UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD AND DRUG ADMINISTRATION

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JOINT FOOD SAFETY AND INSPECTION SERVICE AND FOOD AND DRUG ADMINISTRATION MEETING

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REGULATORY APPROACH RELATING TO JURISDICTION OVER CERTAIN FOOD PRODUCTS THAT CONTAIN MEAT AND POULTRY

THURSDAY,

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PRESENT:

DR. STEVEN SOLOMON, MODERATOR, Morning Presentation

DR. RICHARD RAYMOND

DR. ROBERT BRACKETT

BRYCE QUICK, MODERATOR, Public Comment Sessions

DR. ROBERT POST

KAREN CARSON

PHILIP DERFLER

DR. SOLOMON: Good morning, welcome to today's Food and Drug Administration and Food Safety Inspection Service joint public meeting on possible changes to the regulatory jurisdiction of certain food products containing meat and poultry. I'm Steve Solomon. I'm from the FDA's Office of Regulatory Affairs. I'm going to serve as your moderator for the opening sessions today.

Just a couple logistics and housekeeping items just to cover very quickly. We would appreciate if you have the breakfast back there, continental breakfast, please help yourselves. We would appreciate if you would turn off or put onto silent mode; cell phones, other electronic devices as a courtesy to everyone. Restrooms, if you have not found them yet, if you go out the doors to the right here, they're right to your right; both men's and women's bathrooms are there.

You should have picked up a package of information outside. If not, there will be additional packages out there.

This is a public meeting. People have signed up for giving comments to them. We will be taking them in the order people signed up. A number of people have pre-registered. They will be the first folks that are signed up. There is still plenty of opportunity for others

that wish to sign up. If you go to the registration desk outside and there's a list out there. You can find your name on the registration list and you can sign up and we can fit additional folks on to give public comment today.

With that I'll come back with some additional introductions and some additional details about today's program. But we're fortunate to have with us today, Dr. Richard Raymond who would like to give us some welcoming comments. Dr. Raymond was appointed Undersecretary of Agriculture for Food Safety in July of this year and is responsible for overseeing the policies and programs of the Food Safety Inspection Service. Thank you, we'll welcome Dr. Raymond.

DR. RAYMOND: Thank you, Steve. Good morning to everybody. It's great to be here even if it's a little cold. Before I go any further, however, I want to take a moment to thank those that have taken on the responsibility of setting up this very important meeting and making this public meeting a reality today. And I want to thank everyone here for juggling their busy schedules and making the necessary arrangements to bring FSIS and FDA together with our important Food Safety partners. I think that's a real accomplishment to get this group together today.

I'd like specifically to thank Karen

Carson and Mary Ann Allen from the FDA for taking the lead on the preparations and the logistics for today's meeting. And everybody else from FSIS and FDA who worked on this meeting so diligently. I'd also like to thank those of you who are Food Safety partners who have braved the Chicago December. It may not be the best timing but we wanted to get this done.

But we look forward to you sharing your input, your concerns and ideas with us at today's meeting, and for having a few flight delays to get here. And hopefully we'll all get out this evening without further delays on the east coast, for those who are traveling that direction. Your participation is vital. I greatly appreciate it. Mr. Brackett deeply appreciates it. Our secretaries deeply appreciate it.

So why are we here today? Both FSIS and FDA are here to discuss and to solicit public comment on developing a more consistent regulatory approach concerning jurisdiction over certain food products that contain meat and poultry, as you know. As everybody knows here, the FSIS and FDA do have the regulatory jurisdiction over the nation's food supply. The FSIS has the authority over meat and poultry and processed egg products. The FDA has the authority over all foods not under FSIS's jurisdiction.

Contrary to what some people have said about this meeting, it is not about bagel dogs and pepperoni pizza. And we're not here to debate whether or not we should have a single food safety agency. We are here instead to listen to you talk about how we can improve governmental efficiencies and effectiveness by bringing some clarity and consistency to the regulatory structure that many of us inherited that was already here when we came.

We intend to keep today's meeting very focused on these important topics. After all, we are here because FSIS and FDA had a working group established about a year ago to examine the agency's regulatory approach to jurisdictional issues. And they recently concluded with some decisions that were made in the past that just do not appear to be consistent or even based on transparent reasoning. Both agencies, the FSIS and FDA, agree that we can do better, that we should do better and that we will do better.

Talking to some of you earlier this morning, I guess this hadn't been a one year project. Some of you who have been around in this industry for a while said they heard it ten years ago and you heard it 20 years ago. I'm, in five months, tired of hearing it already. So hopefully

we can get some ideas on how we can move that forward.

Improving our efficiency means working together to find out we can accomplish our own regulatory work in the best manner possible. We have some ideas on how we can do that and we're going to share them with you but we need your input as well. I'm going to let Karen Carson talk a little bit later about the specific recommendations that the working group has come up with. I will say that I think improving efficiency will result in a more streamlined regulatory approach for the agencies to use when making future decisions about jurisdiction also.

However, improving the efficiency of the decision making process will not matter if the public continues to have doubts about the results of this product or the efficiencies of the federal government. Changes do need to be made to ensure that future decisions are also transparent and consistent with the intent of the Federal Meat Inspection Act and the Poultry Products Inspection Acts. I strongly believe that to be effective we must ensure that agency officials, stakeholders and the public can all trust in the accuracy and the completeness of answers to jurisdictional questions.

To identify how we can increase the consistency and sharpen the clarity of our regulatory

approach we first need to take time to reevaluate what we have done in the past, what we are doing today and what needs to be done differently in the future. That is exactly what the FSIS And FDA working group has done. I am looking forward to hearing your comments, perspectives and input on their recommendations. I believe your participation will be invaluable to us as we work to improve the efficiency and the effectiveness of our approach to jurisdictional issues within the regulatory framework that currently exists today.

Before I go, I do want to point out that this meeting is taking place before any new regulations have been written. It's a new way of doing business. My secretary believes in transparency and openness. I believe in that also. I've worked for him long enough to know this can work. That's why we're here today. We have not written regs, there's nothing in our back pocket, there's no secrets. This was done purposefully to signal that we are intent on approaching this whole issue through an open and an inclusive process to get buy-in and support. I can assure you that no decisions on any changes will be made until we have received full feedback and conducted public notice and comment rule making.

In closing, I want to point out that today

is just the beginning of this process. As I said, we want to hear your ideas, your experience, your input on this topic to help us decide what steps to take next. The important of this topic to Mr. Brackett and myself is so great that that's why we're both here today and we'll be here all day listening to your comments.

We have lots of staff with us taking notes and that will help. But we need to hear it personally. You can only get so much from reading transcripts. You can get a lot more by listening to people and watching, the passion in their voices. And that's why Bob and I are here today with you for the entire day. Your participation is crucial, it's appreciated and, once again, I thank you all for coming, and I look forward to the next six hours.

DR. SOLOMON: Thank you, Dr. Raymond. Just to briefly review the packet of information that you have with you. In that package you have a copy of the agenda for today, which I will just briefly go over.

We're going to have some additional opening comments from Dr. Bob Brackett from the Center for Food Safety And Applied Nutrition, and Mr. Bryce Quick from the Deputy Administrator, Food Safety Inspection Service. After that we're going to get into the meat of the presentations. You have copies of those slides in your

packet with you today.

Additional information that's in your packet will include the Federal Register Notice that issued announcing this public meeting, and questions and answers that may provide additional clarification about the information in that Federal Register Notice, and the biography information including all the speakers and members of the panel. So I'm not going to go into a great deal of detail about those. I encourage you to take a look at that.

Just for information you should know that this meeting is being recorded and there will be transcripts of this meeting available after the meeting for anyone that wants it. Once again, the public portion, after the presentations, will begin after the final presentations by the agencies. At those times the people that have pre-registered will be the first ones. Anyone else that wants to speak today, once again, I would strongly encourage everyone to sign up. If you go out to the registration desk they'll give you assistance in signing up to be able to speak today.

And with that, I'd like to introduce for opening comments, Dr. Bob Brackett. He's the Center Director from the Center for Food Safety and Applied

Nutrition. Bob's coming up on his second anniversary as Center Director. So I'll turn it over to him.

DR. BRACKETT: Thank you, Steve. And I'd also first off like to add my welcome to Dr. Raymond and thank him for joining us here to discuss this, you know, possible regulatory approach to dual jurisdiction over some of the certain food products that you'll hear more about today.

This is a very important meeting, this joint meeting, because it illustrates the continuing cooperation between FDA and FSIS in providing the U.S. consumer and industry with a comprehensive, consistent food regulatory program. And I'd also like to expand a little bit on Dr. Raymond's comment about improving efficiency and effectiveness. I believe that our efforts here today will ultimately enhance the efficiency and effectiveness of the regulatory system as a whole.

And you might ask, well how is that going to happen. And it's done so by clarifying for industry, for consumers and for others who regulates what and which agency, industry a consumer should be consulting on a multitude of issues related to meat and poultry containing products; ranging from complying with regulatory requirements to obtaining consumer information to food safety and food defense.

I think there are certain food categories where a more rational, practical approach would be less confusing for the industry and as well as consumers and would contribute overall to the efficiency of the regulatory system. So that's why we think it's important.

Each agency expends quite a few resources in a manner to achieve maximum efficiency. And public health protection within the regulatory framework that we have at this point, that's dictated by the laws under which we function. So, if we can find a way to make our task easier and better than what we're doing now, so much the better.

The history of the various regulatory decisions that have resulted in similar products being under jurisdiction of different agencies, actually, is quite interesting. But it is also quite confusing to some. We, just like you, spend a lot of our valuable time and resources sorting out product jurisdiction, resources that we could be applying in a better manner to food safety and food defense and consumer outreach.

I think there are food categories where a more rational, practical approach would be less confusing to the industry and consumers and contribute to the overall efficiency of the regulatory system.

So what we're presenting today and, as Dr.

Raymond pointed out, really asking for your comments, is an approach that the working group felt was a rational, practical way to differentiate products under FSIS jurisdiction, from products that would be under FDA jurisdiction. What products clearly fall under the purview of FSIS? Which are clearly FDA regulated products? These are the sort of questions that we're asking.

While I agree that this meeting is not about bagel dogs and pepperoni pizza these products provide us with stepping stones to a rational, practical and transparent approach to increasing the efficiency of the regulatory systems. And so we are looking, as Dr. Raymond said, this as the first step in heading down that path.

I look forward to the discussion and to the continued collaboration with FSIS as we go forward to enhance the U.S. Food Regulatory System. Thanks.

DR. SOLOMON: Thank you, Dr. Brackett. Now to give some opening remarks from the Food Safety Inspection Service, I would like to welcome Mr. Bryce Quick. He's the Deputy Administrator for the Food Safety Inspection Service. He was appointed in September of this year and he's been with the Food Safety Inspection Service since 2001.

MR. QUICK: Thank you, Steven. I'll keep my

remarks short so we can get to the meet of the program. Good morning and welcome to this very important meeting. I want to echo what Dr. Raymond and Dr. Brackett said in thanking you all for making the trek, in some cases, from coast to coast. Your input on the ideas that we want to share today are very important to us. This is about you. This is about the consumer. So we do look forward to hearing what you have to say.

I'd like to emphasize what Dr. Raymond and Brackett both said, and that is that this really isn't the norm for us as an agency or both of our agencies. We are gathering public comment before we do any proposed rule. And, as Dr. Raymond said, this is all about being open and transparent. This meeting is also a very good example of how we, as agencies; FSIS, FDA, and other sister agencies in food safety are working more closely together than ever to collaborate on issues of importance to food safety.

We, in 1999, as another example of this, signed a memorandum of understanding the FDA to share information about establishments. The agencies continue to work together to ensure the food safety of products. Earlier this year we also joined forces with FDA on food security awareness training. This training was developed jointly by FSIS, FDA, AMS and the Food Nutrition Service.

So whether it's the topic of jurisdiction, BSE, Food Defense, we do take the charge to work together very seriously.

And on that note, I look forward to hearing what you have to say and appreciate you being here.

DR. SOLOMON: Thank you very much. At this time we want to give a combined presentation by both the Food Safety Inspection Service and FDA of the working groups results. We're going to outline kind of the history of this issue and the current thought process that the groups put together. I'd like to introduce Dr. Robert Post. He's the Director of Labeling and Consumer Protection Staff from the Food Safety Inspection Service. And he's going to be combining the presentation with Karen Carson from the Food and Drug Administration, who's the Director of the Executive Operations Staff.

DR. POST: Thank you, Steve. Well, good morning, I'm glad to be here as part of the FSIS representation on this important issue. The issue of amenability has been studies continuously for all the years that I've been with FSIS. And that's why I've been given the opportunity to talk about how we got to this point.

A public meeting to share and get your feedback on an approach that FSIS and FDA have jointly

developed to make, consistent, transparent, and rational decisions about the jurisdiction of certain products that contain meat and poultry ingredients.

Well, as you may know, the FSIS and FDA both have regulatory authority over the food supply. Under the Federal Meat Inspection Act, or the FMIA, and the Poultry Products Inspection Act and the Egg Products Inspection Act, FSIS was given the authority to, over food products for human consumption that are made in part or in whole from any portion from meat, poultry and processed egg products.

Under the Federal Food, Drug and Cosmetic Act, the FDCA, FDA was given the authority over other foods, all other foods, in fact, including dairy, bread and grain products and vegetables and other produce.

Generally, all foods with meat and poultry ingredients are under FSIS purview. And this is based on the language in the FMIA and PPIA that I just provided. The implementing regulations specifically define what constitutes a meat product and a poultry product. A meat food product is defined as any product capable of use as human food, which is made wholly or in part from any meat or other portion of the carcass of any amenable species. And that historically has included cattle, sheep, swine,

goats and equine. A similar definition for poultry products exists in the PPIA.

The statutes go on to direct the secretary to examine and inspect all meat food products and poultry products prepared for commerce for human food to ensure that they are safe, wholesome and accurately labeled. However, the FMIA and the PPIA and the implementing regulations provide factors that are to be considered in making jurisdictional decisions. These factors include the amount of meat or poultry ingredients used to make the food products, whether the product is represented as a meat or poultry product. And that is whether a term that refers to meat or poultry is used on labeling, and, whether the product has been historically perceived by consumers as a product of the meat or poultry industries.

Generally, the first factor is known as the relatively small proportion of meat or poultry factor. Foods made with two percent or more cooked or greater than three percent raw meat or poultry are generally viewed as meat or poultry products. And that's based on the relatively small proportion factor.

The second factor is known as the labeling factor. And it relates to the features used on labeling that relate to meat and poultry.

The third factor is called the consumer perception factor and relates to consumer expectations and the contributions of the meat or poultry ingredients to the product's basic identity and characteristics.

Now, there is one additional condition that the statutes and the regulations provide and that, in applying these factors, and that is the secretary must be assured that meat and poultry ingredients are not adulterated and must be USDA inspected or come from an eligible inspected source.

Now these factors have been used in USDA rule making in the past for some specific exemptions, mostly for poultry products in the poultry, in the Federal Poultry Products Inspection Regulations. For example, specific exemptions from the definition of poultry exist for poultry broth, poultry bullion cubes, poultry gravies, and poultry containing closed face sandwiches.

However, the acts and regulations do not restrict using these factors only in rule making. For example, about five decades ago USDA made a policy determination that similar to poultry sandwiches in the regulations meat containing closed face sandwiches are not under its jurisdiction.

Over the years FSIS has examined food

product formulations and product labeling and applied the factors that I just mentioned to make what have been known as amenability decisions. Amenability has come to mean whether or not a product is subject to FSIS jurisdiction.

For many years, up to the late '70's the decisions about jurisdiction were clear and simple. And that's probably because the marketplace was not yet driven by trends to make new convenience foods and updated versions of traditional products.

As the interest by industry and marketing different products containing meat and poultry grew so did manufacturer's requests to reconsider the regulatory jurisdiction over which products were produced. Requests for decisions have been accompanied by product formulations, processing procedures and product labeling. And in some cases, background information on the marketing history of the product has also been included.

Amenability decisions have been made over the years on a wide array of products and product categories. And I'll list a few of these examples. Dough filled products with meat or poultry; for example, turnovers, roll-ups and rollovers and pizza rolls and pierogies and calzones and bagel dogs; bakery products, such as crackers with bacon, and pepperoni rolls.

Other products have also been questioned. Seafood products such as shrimp and scallop wrapped in bacon. We've also responded to a craze about soups and stews, soup bases, dried soup mixes, meat broths, meat and poultry stocks and extracts, bullion cubes and bullion seasonings, bean with meat and meat food products, the list goes on; livestock, blood and blood derivatives, ramen noodle meals, cheese or cheese products with meat, gravies and sauces, and salad dressings.

And what we call non-traditional sandwiches; variations of the traditional closed face sandwich that are composed, for example, of waffles or pancakes between which meat or poultry ingredients are placed.

In most of these cases the relatively small proportion factor that considers the threshold levels of meat and poultry in the product formulation and the labeling, the product labeling factor, are fairly easy to understand and were applied. With most of the examples I listed decisions were based on these factors.

In some limited cases, however, the consideration of a product's jurisdiction was presented as a matter of historical consumer perception, not a matter of the amount of meat or poultry in a product or its labeling.

With regard to the consumer perception

factor, FSIS has made decisions on a case by case basis. Mostly in response to situations involving compliance and enforcement. Although this case by case approach resulted in decisions that made sense at the time they were made, in retrospect some of the amenability decisions do not appear to be consistent with other product decisions. And the reasoning behind various decisions was not fully articulated.

For example, the reasoning behind a decision in 1979 that a product labeled as a bagel dog, which is composed of a ready to eat hotdog wrapped in bagel dough, which is baked, was not meat product, was not fully explained. The rationale can partly, can be partly explained by the notion that the product was viewed as a closed face sandwich and thus was not under FSIS' jurisdiction.

However, the rationale did not explain why bagel dogs were different than other products that were similarly formulated. For example, corn dogs and meat turnovers that were, and continue to be, products under FSIS jurisdiction.

Other examples of amenability decisions that relied on the consumer perception factor followed in the 1980's. For example, it was determined that pepperoni

rolls which is a product composed of pieces of pepperoni that are distributed in dough or bread dough and then baked was not a meat product. In this case the decision was based on the view that the product was one of the bakery industry. In contrast, products composed on bread dough into which meat, cheese and vegetables are stuffed or filled have always been deemed to be meat products.

To further complicate this situation the reliability of the decisions about bagel dogs and pepperoni rolls has been challenged by changes in marketing trends. Such as the desire to market bagel dogs and pepperoni rolls with cheese, poultry and other ingredients that were not considered in the original jurisdiction decisions.

FSIS has received responses or requests, rather, in recent years to categorize the jurisdiction of newer versions of bagel dogs and pepperoni rolls in the same way that it characterized the original products.

A similar situation exists for sandwiches. The original exemption for traditional closed face sandwiches defined it as a product composed on meat and poultry and other ingredients between two slices of bread, biscuit or bun of the type usually prepared in bakeries.

The definition has been challenged by marketing trends producing new sandwich products such as

wrap sandwiches in which meat and poultry and vegetables are rolled in a tortilla. And waffle, pancake, and french toast sandwiches composed of a sausage patty between two waffles, two pancakes and two slices of french toast.

However, in these cases the FSIS response has been that without a clear rationale for the original decisions, confusion would only be compounded further by perpetuating the flawed basis contained in the original decisions.

Other examples that exist to, that have added to industry and consumer confusion about the reasoning used with respect to various decisions about which agency has jurisdiction over certain food products containing meat and country product are available for review. For example, natural casings used for making sausages were determined in the 1950's to be packaging materials and thus under FDA's jurisdiction. Because they're actually meat byproducts the original decision is easily questioned.

Another example of inconsistent decisions relates to dried soup mixes. Dried chicken noodle soup, for example, and powdered beef and vegetable soups. Those are examples. The decision for dried meat soup mixes was that it was not amenable. While the decision for poultry

soup mixes was that it was amenable. This is most likely attributed to the fact that these two products developed in two different industries at different points in time. Although the rationale is absent from the decisions.

In fact, looking at the inquiries that FSIS received regularly about amenability of food products we noted that in addition to sandwiches, casings and dried soup mixes, certain other products had been the subject of confusion over the years. Cheese products, for example, bread products, reaction and processed flavors, pizzas, salad dressings, all containing meat and poultry ingredients have been sources of confusion.

As I mentioned, the issue of amenability has not been static. There have been studies, a variety of studies over the years that have been conducted by FSIS and also other organizations. Studies conducted by Congress and by the general accounting office. Now while these studies concluded that a clearer basis is needed to support amenability decisions, particularly as they relate to the consumer perception factor, a responsive approach to do that had not been successfully developed or recommended.

Over the past year, as you heard, FSIS and FDA, and FSIS and FDA working group met to jointly address this challenge. In an effort to alleviate the confusion

that consumers and manufacturers have expressed about the classification of food products, FSIS and FDA conducted an in-depth examination of the historic decisions about regulatory jurisdiction made by FSIS.

From July, 2004 to May, 2005 an FSIS and FDA working group met to explorer the issue of developing a consistent and logical approach for making sound, clear and transparent decisions about product categorization and agency jurisdiction. As a result of the working group's findings the agencies are presenting an approach to making unambiguous decisions that will be described by the next speaker, Karen Carson. Thank you.

MS. CARSON: Good morning. I'm going to give you an overview of the approach our joint working group devised, an approach to dealing with these types of products.

To reiterate, our work was targeted to confusion, to reducing it. That's the issue we dealt with. We heard a rather loud, clear message that it isn't clear which agency has jurisdiction over some types of products that contain meat and poultry as an ingredient. And it is not clear why and how decisions have been made about jurisdiction. It's not clear to industries, not clear to consumers, as well as others.

So the issue is one of clarity. It's an issue, one of efficiency, making the regulatory process as a whole more efficient, and accountability. I want to emphasize that it is not an issue of food safety. We, I'm sorry, I didn't see that.

We believe that the combined efforts of FSIS and FDA continue to ensure the safety of the American food supply. So we set out to find a solution that would provide consistency and predictability in determining whether FSIS or FDA have jurisdiction. We looked at the wide breadth of products that potentially fall into this group of foods, foods that might be under, similar foods that could be under the jurisdiction of both agencies. We also considered other joint activities such as the proposed rule on general principals related to food standards modernization, and factored that into our deliberations to the extent possible.

The bottom line is that we recognize the advantages to industry, consumers and our agencies of building consistency and predictability about agency jurisdiction over similar products. The result of our work is published in the Federal Register on November 7th, the public meeting notice for this particular meeting.

These are the types of products, this is a

list of products under consideration and the suggested approach. Dr. Post has discussed how decisions about jurisdiction have come about and the complications and challenges that modern variations on those products present in making jurisdiction decisions today. The original jurisdiction decisions are not satisfactory to meet today's marketing needs.

We are not questioning the clarity of decisions made based on the principal of amount of meat or poultry in a food. The confusion has come about from using the consumer perception factor. After extensive discussion we homed, we were able to home the factors to consider in determining jurisdiction down to one: what is the contribution of the meat or poultry ingredient to the identity of the food? Does the meat or poultry characterize the food? That is, is the product readily recognized as a meat or a poultry product? Are the pieces of meat or poultry easily discernable when you look at the product? Or is the meat or poultry ingredient there to flavor the food? Can you not really see the pieces of meat or poultry? Do they not characterize the product?

Taking the list of products shown and applying the concept it's possible to divide the products in our list into these two categories. People eat closed

face sandwiches for either the meat or the poultry ingredient, not for the bread around it. In contrast, pizzas for the most part have meat or poultry to flavor the product. The predominance of the ingredients are the dough, tomatoes, cheese, other ingredients.

We recognize the application of this concept to these products may result in changes in jurisdiction for certain foods and categories of foods and that's why we're here today, to discuss the impact of these potential changes.

This chart shows how jurisdiction over these products is rated today. This chart also points out the dichotomy that currently exists among similar types of products. For example, hotdogs wrapped in bagel dough are FDA's, hotdogs wrapped in corn bread are USDA's. Dried meat soups under FDA jurisdiction, dried poultry soups under USDA's.

This chart also is an illustration of the confusion that has resulted from historical decisions about consumer perception and the need for more reasoned approach to determining jurisdiction.

So applying the approach based on determination of contribution of the meat or poultry ingredient to the basic nature of the product, changes in

jurisdiction will occur. Products will move both ways. Some come into FDA from FSIS jurisdiction, some moving to FSIS jurisdiction from FDA jurisdiction.

These potential jurisdictional changes will affect firms and establishments as well as FDA and FSIS. We do not anticipate that the changes will result in major overhauls of production facilities or processing operations or significantly alter marketing approaches or change product formulations in order to meet regulatory requirements of one agency or the other. It is likely that there will be administrative, inspection and labeling requirements that must be accommodated, however.

This is why we are here today, to hear from you what the impact of this approach and these possible changes will be.

The FR Notice articulated eight specific questions that we are asking you to give us information about. What I've listed on this slide as kind of an overview of very general questions. They're broad scope questions that we must consider before deciding how or if to move forward with this approach. It is critical that we have the kind of information you can provide us on whether this approach is reasonable, on the impact on the industry and on consumer's reaction.

Our next steps, in determining what the next steps will be, we will evaluate information provided at this meeting, the information we get in comments as well as other information. Based on that we will identify options available to us and determine whether the next logical step is rule making to implement this approach. This will all be done with your input and participation hopefully.

Thank you very much for your intention. I look forward to hearing your comments. One thing I would like to point out to you, the docket is an open docket. There's no end date for accepting comments, however, we would like you to get comments in as soon as you can. Thank you.

DR. SOLOMON: Okay, we have a short opportunity if there are things that need to be clarified on the presentations. This is not the time yet for your comments. But if anyone does need some clarification on Dr. Post's or Karen Carson's presentation on it, now is the opportunity. If you would go up to speak to one of the microphones to ask any questions.

MS. SMITH DeWAAL: Caroline Smith, the Well Center for Science in the Public Interest. Karen, could you put your slide up with the current jurisdictional split? Okay, my question is on the issue of cheese and

cheese products and on the issue of pizza. Can you talk about what FSIS' current inspection resource is in those particular categories and what the shift would be? I may have a follow up.

DR. POST: Well, in a general way I can respond by saying that there is an exemption for cheese products composed of up to 50 percent meat, like a cheese ball and a cheese log. It's been very specific to that product and that's a historical decision.

Otherwise, FSIS inspection occurs wherever more than two percent cooked or more than three percent or more raw meat or poultry is used to make the pizzas. And I don't have those fixed numbers right now in terms of how many establishments those are. And then in cheese products where slices of pepperoni are mixed with shredded cheese, for example, in those situations FSIS also has its inspection presence today.

MS. SMITH DeWAAL: I'm asking because these are two product areas where the possibility for risk is higher than perhaps in the soup areas. And you may be taking inspectors, FSIS inspectors, out of plants which are inspected on a daily basis and moving them to FDA jurisdiction which, on average, they're inspecting about every five years. Bob, is that currently correct? So

you're really reducing the level of inspection significantly for those two product categories.

DR. POST: I just have one point also. In the packet of materials that was provided there is a specific question with an estimate of the number of establishments involved in various food category operations. So you might look at the question 11.

DR. SOLOMON: Any other clarifications, once again, on the presentations you just heard? Okay, with that we're running ahead of schedule. I think we'll extend the break and when we come back from that, we'll go to 11:00 o'clock, and then we'll come back and go to the public comment.

Once again, anyone that is not signed up we would encourage you to go to the registration desk and sign up. We'll take individuals in the order that they sign up for the sessions. So we'll start again at 11:00.

MR. QUICK: It's going to be an open mic. We have about 15 people that have signed up to speak or give comments. As we indicated earlier, there will be about five minutes per speaker.

Before we go any further I want to draw your attention to the screen. There is a mistake in the Federal Register Notice. If you are submitting comments for the

record the e-mail address, this is very important. It should go to FSIS.regulationscomments@FSISUSDA.gov. The FSIS. (dot) is missing so it's very important if you're submitting electronically.

I want to quickly review, in the Federal Register there are eight basic questions that FDA and FSIS are asking for comments. And it's on page 67-493. The first question is, is the approach that is suggested by the agencies a reasonable one, if not, why not? Second, are there are other food products or product categories that have been the subject of historical regulatory jurisdictional decisions by FSIS which were based on a consumer perception factor that should be considered by the agencies?

The third, how many firms or establishments would be affected for each product and product category? What is the volume of production for each product or product category? The next, would there be modifications and equipment, facility design, labeling, record keeping or processing and reporting responsibilities that are needed in order for current operations to continue making the products that are the subject of the suggested changes and what are they?

The next, what would the administrative,

operational, marketing and labeling costs be associated with changes in product jurisdiction? What would be a reasonable process and time frame within which to implement any changes in jurisdiction? And lastly, what would be consumer's views of the subject products under the suggested approach? More particularly, what affect would changing regulation jurisdiction have on consumer's perceptions of the subject products? For example, what would consumer's reaction be to the fact that dried chicken soup mix is regulated by FDA?

So if you could base, I'm sorry, there's one more. And that's, what affects would there be, if any, on the way subject products are marketed? And if you can address these questions in your comments as much as possible we'd be very appreciative.

The first speaker that signed up is Lamas Hendricks from Sara Lee Corporation. And you can either come up to the microphone here or you can address it from there. There is a five minute timer that's being controlled from the back. If you do it from out here I'll just stand up at about three minutes so you know that your time is starting to wind down.

MR. HENDRICKS: Don't worry, I'll try and make it quick. I will say, my name is Lamar Hendricks. I work for

Sara Lee Corporation and we will provide formal comments on these issues of amenability.

I do appreciate the agencies attempting to clarify where products fall. I don't think this is a safety issue. I agree with that comment. FDA and USDA has a good history of providing safe products to the consumer.

I agree there's confusion and no clear rationale to the current determination of amenability. And I've worked a lot with over the years, probably since the early '70's with Robert and his staff and some of the other folks within FDA to determine whether the products are amenable or not.

Today I would like to give you several examples before I finish my comments. And these are some of the examples that create confusion within where products fall as far as whether they're amenable or not. And my first example is a sausage patty. We produce sausage and luncheon meat specialty items, a great deal of them. So if we have two sausage patties and one is wrapped in a waffle and one is wrapped in a pancake; one is amenable and one is not amenable. Why? That doesn't make much sense. So I think there is a definite need for clarification.

Did the mic go out? Maybe somebody didn't like my comment. Anyway, that's a good starting point.

And the other example I would like to provide is the hotdog in the bun situation. A hotdog in a bun is not amenable. But a hotdog in a bun with chili on it is amenable. Now there's some other clarification of that. That hotdog in the bun with chili, it depends on the amount of chili as to whether or not it's amenable or not.

So those are, and I can go on for hours. But it clearly demonstrates a need for determination of where these products fall. And I think what's needed? I think we need a clear, very clear point of differentiation between whether products should be amenable or not amenable.

I do, I do agree that we're not talking about food safety here. But I do have a couple of comments that might provide some guidance on where this clear definition is. I think it should, I think you should look at risk. And I think risk should be minimal for items already inspected. And this will be in our comments as well.

These products that are already inspected that have gone through a process, a lethality process that determines them to be safe under House of Plans and the responsibility of those plans follow all the way to the customer and user. So when products that are cooked,

processed, inspected and passed, when they move further into the food chain or the manufacturing ability, whether it be sandwiches or hotdogs or whatever, these products don't need to be re-inspected again. They don't. It's, it's not a good use of resources. And there's no reason to believe that they improve the safety because they're re-inspected once that hotdog goes into a bun with a dollop of chili or something on it.

I think that our plans are constantly reviewed by both industry, FSIS. So when those products reach that lethality step and they go through a final house of plan, those products should move on to whether someone wants to further process them into a sandwich or some other lasagna or pizza or whatever. So that's just what I believe.

I think that if we do this it will provide a clear differentiation from where products need to be determined to be amenable or not amenable. And I thank you for your time.

MR. QUICK: Thank you, Mr. Hendricks. I failed to mention we do, you know everybody up on the panel. We did have one more and that is Mr. Phil Derfler from FSIS' policy office. And the panelists up here will, of experts, can answer questions if you want to pose questions.

The next person we'd like to invite up is Mr. Lloyd Hontz from the Food Product Association.

MR. HOLTZ: Thank you and good morning. I am Lloyd Holtz, senior director of food inspection issues with the Food Products Association which represents the broad food industry on scientific and public affairs issues including those involving food safety.

FDA appreciates this opportunity to comment on this joint agency effort to rectify long term inconsistencies in regard to the regulatory jurisdiction of certain food products that contain meat and poultry ingredients. Many FDA members are subject to the regulatory oversight of both FDA and FSIS and, therefore, have a very keen interest in this subject, especially since we believe the results of this effort could not only clear away the confusion but also, and perhaps more importantly, could contribute to improve public health protection by helping to focus limited USDA and industry resources where risks are the greatest. And that's being done within the extent of the exemption allowances under the meat and poultry statutes.

FDA appreciates the effort undertaken by the joint working group to identify many long term inconsistencies and the designation of products as amenable

or not amenable through FSIS inspection. We concur with the working group's determination that while many historic case by case jurisdictional decisions may have made more sense at one point in time they no longer tend to be rationally justified. For this reason FDA is very supportive of the approach taken, at least to the extent that it is a substantive effort to identify inconsistencies and to set a rational basis for rectifying past anomalies and for making future determinations.

Let me say right at this point and let me emphasize that the safety of the products under discussion is not at issue. I agree wholeheartedly with the panelists and with the previous speaker. American consumers have good reason to be highly confident in the safety, wholesomeness and proper labeling or meat and poultry containing food products regardless of whether they are manufactured under the regulatory purview of FSIS or FDA. We believe that in large measure subjecting previously FSIS inspected meat or poultry to subsequent FSIS inspection during the manufacture of further processed products is unnecessary and is an inefficient use of limited inspection resources which could be utilized in areas which present a more significant risk to public health.

We note that this is not a new idea and our

written comments will reference a report from more than 20 years ago from the agency where they recognized that for many of these same types of products the continuous inspection requirements under the FMI and the PPI appear an inappropriate allocation of limited USDA inspection resources and industry resources as well.

Despite substantial advances in recent years, FSIS inspection remains more intense and in general more prescriptive than FDA regulation. As a result, the cost to the public for delivering FSIS inspection is substantially more than for FDA oversight. In addition, FSIS inspected facilities incur significant costs that FDA regulated facilities do not face.

We suggest that in the absence of a clearly defined need for the greater level of inspectional intensity inherent in the FSIS inspection system that options for jurisdictional discretion provided within the meat and poultry acts should be exercised to their fullest. With this in mind, it makes sense to us to transfer from FSIS through FDA inspectional jurisdiction of those products that contain previously inspected FS meat or poultry ingredients and for which there is no reasonable expectation that a daily FSIS inspection presence is required to assure their safe manufacture.

For the same fundamental reasons, it does not make sense to us to suddenly subject to daily FSIS inspection, any products which have been safely produced under FDA oversight. Consumers are primarily concerned with the, that their food is safe, not about which agency has overseen its production.

For example, bagel dogs produced from an inspected component and subsequently modified by a pastry wrap, these have been successfully and safely produced under FDA oversight for years. In our view, this argues very forcibly for maintaining these products under FDA purview.

In today's climate, with broad recognition of the need for risk based allocation of inspection resources, we trust that optimizing the effectiveness of limited inspection resources will be a primary consideration as the two agencies embark on an open and transparent process to properly utilize existing statutory options for exempting certain meat and poultry products from FSIS inspection.

Thank you for the opportunity to comment. We will have much for expansive, written comments that will be submitted.

MR. QUICK: Thank you. Well, Caroline, I was

going to offer the microphone to you since you were standing up anyway. So would you like to, we'd like to invite Ms. Caroline Smith DeWaal from the Consumer Science in the Public Interest to address the group now.

MS. SMITH DeWAAL: Thank you, that's the Center for Science in the Public Interest.

MR. QUICK: Sorry.

MS. SMITH DeWAAL: Thanks so much, Bryce. I wasn't quite ready, but I'm ready now. First of all, I really want to support the effort that USDA and FDA have undertaken in starting to grapple with this issue.

There are many ways where we could rationalize inspection. And I was looking at e-mails today and saw a write up actually by Doug Powell up in Canada about the recent outbreaks from vegetables, for example. Dole lettuce, packaged lettuce where 18 people became ill in Minnesota and Oregon from E-coli 015787. And I know that FDA is grappling with this issue. But the reality is, FDA doesn't have jurisdiction on the farm either, neither does FSIS.

So the way we regulate food today sometimes results in over-regulation. But often, in many cases of high risk food also resulted in under-regulation. So I really embrace the beginning of the

process to rationalize these programs. I would also like to note that the Farm Bill, last year the last Farm Bill, which was passed several years ago, actually urged the Bush administration, had language for the Bush administration to actually create an advisory committee on regulatory jurisdiction issues of the food supply. So this issue has been recognized by Congress and it's good that you're starting this process. But we would urge you to go further.

Part of what you'll see, I think in my comments and comments of other groups that are here, reflects a Hobson's choice. It's a very difficult choice between well, does the food need to be inspected every day or once every five years? Because that's the choice you're asking us to make. And it might be that for cheese balls or pepperoni pizza there might be a number somewhere between every day and once every five years that's really the right risk based number. But the choice you're asking us to make is, is it once a day or once every five years. That's the choice. So if we don't always come out with the exact, an answer based on risk, it's because you can't in this scenario.

We can't, you really can't stop the process just looking at bagel dogs and pepperoni pizza. One of the

things the new president of the Canadian Food Inspection Agency said recently, last week actually, in his visit to Washington is that we're forming meat inspection is really central, a central goal to his process. But he can't do it and still trade with the United States if we're going to have the system we have today. So really beginning this process, moving forward with it is important.

Now, I'm going to get to very specific remarks on kind of what you should be doing in this regulatory process now that you've started it. First of all, you need to, a clearly articulate standard that not only helps agencies put the food in the right place but also improves food safety. And that standard should be understandable, not only to the agencies, not only to the industry, but to the general public as well.

Again, anything that reduces inspection from once a day to once every five years is going to be difficult to communicate to the public. So you've really got to look at those categories of food where you're shifting jurisdiction to FDA and make sure you can explain that.

Certainly, the contribution of the meat and poultry ingredients is important, the weight, percentage of composition, consumer protection, those issues are all

important and I'm sure will be considered in the regulatory process. But you need to go further than that. You need to anticipate new food products and product variation. Because if you don't have a standard that works with the next new food product down the road then you don't have a standard that's going to stand up to the test of time.

You also need to be very careful on the issue, as I said, of transferring jurisdiction, especially going from a high inspection frequency to low. And finally, the issue of the level of quality assurance and food safety protections afforded by one agency should not be lessened as part of this process. We're getting to this issue I raised of explaining to the public why you're reducing inspection frequency.

Finally, I want to propose a somewhat radical idea. Maybe we should be labeling food by which agency is responsible for it. And that way consumers would know when there are outbreaks, when there are recalls, which agency was holding the bag. Thank you.

MR. QUICK: Thank you. Thank you, Caroline from the Center for Science in the Public Interest. The next --

DR. SOLOMON: If I could just, excuse me, Bryce. Just one point Caroline on that. FDA does have risk based inspection frequencies so it's not a general statement that

can be made on all products. High risk products are inspected on an annual basis.

MS. SMITH DeWAAL: Just so everyone understands could you review the inspection frequency for your highest risk products?

DR. SOLOMON: Highest risk we try to get to on an annual basis for the highest risk products.

MS. SMITH DeWAAL: So once a year. And how many food categories fit into that already?

DR. SOLOMON: I don't have all of them.

MS. SMITH DeWAAL: It's seafood. It would probably be eggs. Probably produce, vegetable, sandwiches. So you already have a number of categories. So I'm not sure these products would fit right into the one year. They're also having trouble getting their once a year based on my understanding.

MR. QUICK: Thank you. Our next speaker is from the Flavor and Extract Manufacturers Association in Washington, Mr. John Cox.

MR. COX: good morning. Thank you. My name is John Cox and I'm with the Law Offices of John Cox in Washington, D.C. I'm going to comment on behalf of two organizations today but I will keep my comments under five minutes.

I am representing the Flavor and Extract Manufacturer's Association, FEMA, but first I would like to comment on behalf of the American Spice Trade Association, ASTA.

ASTA represents the interest of approximately 300 members including companies that grow, dehydrate and process spices and seasoning blends. ASTA members create a wide variety of products such as seasoning blends, dried soup mixes and gravies, flavors and flavor bases that currently fall under FDA and FSIS jurisdiction.

ASTA supports this effort to provide clarify and consistency with respect to which of the two agencies has jurisdiction over certain types of food products that contain limited amounts of previously inspected meat and poultry as ingredients.

ASTA believes that there are several reasons to consolidate regulatory oversight over seasoning blends, dried soup mixes and gravies, flavors and flavor bases under a single federal agency, the U.S. Food and Drug Administration.

Three relevant statutes make it clear that flavors are not to be considered meat or poultry products. In addition, jurisdiction for regulations affecting flavors or additives lies with FDA. The products

manufactured and processed by ASTA members that are now sometimes under the jurisdiction of FSIS, seasoning blends, dried soup mixes and gravies, are similar in nature to flavors in that they are ingredients and not meat products. We believe that flavors and these other similar products fall outside the definition of meat, food product found in the Federal Meat Inspection Act and they also fall outside of the definition of poultry product found in the Poultry Products Inspection Act.

We also think that it is significant that in the Federal Food Drug and Cosmetic Act Congress has given authority to HHS, which was delegated to the FDA for establishing regulations affecting flavors, colors and spices. FDA has done so and the definitions for natural flavor found in the Code of Federal Regulations includes specific references to flavors containing ingredients derived from meat and poultry for the function of their flavor properties, not nutrient purposes.

An additional reason to consolidate would be the resulting predictability of requirements for the regulated industries. It's clear from the Federal Register Notice and the comments today that the agencies are aware that there is significant confusion under current provisions and practices.

ASTA will submit detailed comments to the open docket and, of course, will be available to answer any questions.

I would like to now comment on behalf of the Flavor and Extract Manufacturer's Association, FEMA. FEMA is the National Association of Flavor Manufacturers and they represent the vast majority of flavor companies in the U.S. FEMA also supports the effort to provide clarity and consistency with respect to which of the two agencies has jurisdiction over certain types of food products that contain limited amounts of previously inspected meat and poultry as ingredients.

FEMA concurs with all of the points offered by the Spice Association related to the basic nature of the products, statutory guidance and the need for consistency and predictability. As the agencies move forward FEMA would encourage you to adopt the following general principle when addressing this issue: that all flavors, flavor bases and seasoning blends shall be manufactured under the exclusive jurisdiction of the FDA. And that any meat or poultry product previously inspected by USDA may be used as an ingredient in flavors, flavor bases and seasoning blends without additional inspection by USDA. There will, of course, be details to be filled in but we

would encourage you to adopt this general principle moving forward.

FEMA will also submit detailed comments to the docket and, of course, we're available to answer any questions. I appreciate the opportunity to comment today and I thank you for your attention.

MR. QUICK: Thank you, Mr. Cox. Phil Derfler would like to ask a question.

MR. DERFLER: Can I ask you --

MR. QUICK: Can you come back to the mic?

MR. DERFLER: I'm sorry, you just, you asserted that the flavors are outside the definition of meat and poultry products. Can you just explain that please?

MR. COX: Yes. In our written comments we referenced the definition in the Federal Meat Inspection Act that says it's, excepting products which contain meat or other portions of such carcasses, only in a relatively small proportion or historically have not been considered by consumers of the meat food industry and which are exempted from definition as a meat food product by the secretary.

MR. DERFLER: Okay, so you think it comes within the small?

MR. COX: Yes.

MR. DERFLER: Okay, thanks.

MR. QUICK: Thank you. Dr. Post?

DR. POST: A clarifying question. Is this on? Okay, the definition of seasonings, I mean, will you provide that in your comments, describe what you mean by seasonings and other types of ingredients that you're talking about? That would help us.

MR. COX: Certainly.

DR. POST: Because there are flavor bases, there are soup bases, there are a lot of names that are used and it would help to understand the full realm of the products you're dealing with.

MR. COX: Certainly.

MR. QUICK: Any further questions from the panel? Okay, thank you. Our next commented, Mr. Dwight Grenawalt of Summit Hill Flavors in Middlesex, New Jersey.

MR. COOK: Good morning. I'm not Dwight Grenawalt, but I'm going to speak for Dwight Grenawalt. My name is Charlie Cook and firstly I would like to extend my appreciation to both agencies for holding this meeting to discuss possible changes to the regulatory jurisdiction of flavoring agents containing meat and poultry.

Based on my personal experience, it appears that at least for the past 45 years the agencies have used

a mystical Ouija board in determining amenability of certain products. This hearing is deja vu, as over the past 30 years I have had discussions with Irv Fried, Bill Dennis, Bob Hibbitt, the late, Ron Brewington, and of course, Rob Post. And every time after each one of those discussions I have left shaking my head wondering how the decision was being made.

Allow me to digress for one minute. As I indicated, my name was Charlie Cook. And I'm representing clients that manufacture natural flavors, flavor bases that are derived from meat, poultry, seafood, eggs and vegetables. My clients strongly support the recommendations that flavors, flavor bases and similar products derived from meat, poultry, seafood, vegetables, legumes, and grains that fall under the definition of natural flavors in 21-CRF, Part 101.22 be administered by the Food and Drug Administration.

This section clearly states that the term, natural flavor or natural flavoring means the essential oils, oleo resins, essence or extractive, protein hydrolysates, distillates or any product of roasting, heating of enzymolysis which contains the flavor constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark,

root, leaf, et cetera, including meat, seafood, poultry, eggs and dairy products or fermentation thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence of extractives from plants listed in Section 182.

The above clearly defines my client's products. Based on this language alone it is clear that for the past 80 years it has been the intent of Congress to have FDA regulate these products. A review of the relevant statutes on product amenability defines meat food product as list defined by Rob with one addition. And it clearly states, excepting products which contain meat or other portions of such carcasses only in a relatively small portion or, as I underline, historically have not been considered by consumers as products of the meat food industry.

To verify our belief that flavor bases, pastes, powders, et cetera were not perceived by consumers to be a product of the meat food industry. My clients supported a research study administered by an independent research firm which showed clearly that 30 percent of the respondents perceived these products not to be, excuse me, that 70 percent of the respondents perceived these products not to be historical products of the meat food industry.

For a minute, please allow me to address some of the specific questions posed in the hearing notice. The approach suggested by the agencies in classifying natural flavors as amenable to FDA oversight is correct and complies with the intent of Congress.

FDA has extorted regulatory oversights of these products for approximately 50 years with no problem. Because of the very low food risk associated with these products, continuous inspector presence is not justified.

For my client alone the cost of modifying equipment, facilities, labeling, record keeping, that were required if the jurisdiction was moved to FDA would approximately be 15 percent of the annual gross sales. Compliance to SSOP documentation would cost in excess of $175,000 for a firm that is classified as very small.

Additionally, the cost associated with putting an inspector to these plants would be significant. Inspectors would have to be trained in a whole new way of inspecting a different classification of products.

In summary, we strongly support the recommendation that the manufacture, inspection and labeling of natural flavors derived from meat, poultry, eggs remain under the jurisdiction of the Food and Drug Administration.

We appreciate the opportunity to comment and we will be adding additional, written comments at the appropriate time.

MR. QUICK: Thank you, Mr. Cook. Our next commenter is Mr. Terry Burkhardt from the Wisconsin Department of Agriculture.

MR. BURKHARDT: Thank you and good morning. I am the Director of the State Meat Inspection Program in Wisconsin. And I applaud FSIS and FDA for taking a stab at trying to simplify or modify the current situation related to amenability of products.

Earlier in my career I worked as a label reviewer and had many discussions related to the amenability of products and the amount of meat necessary to meet a published standard of identity.

The current regulations create many instances where both FDA and FSIS have joint responsibility in establishment because of meat and non-meat products that are produced. Any change in the regulation should be designed to avoid duplication of resources between agencies. It is extremely difficult for establishments to deal with two different regulatory agencies in the production of their products.

We believe that distinction should be made

along product lines and not be solely based upon the amount of meat and poultry in a product. We also believe that the risk of the particular product category should also be taken into consideration when determining which agency should regulate the production, considering that FSIS has mandatory HASSOP for establishments under their jurisdiction and daily inspection.

We agree with the proposal that all meat sandwich type products, closed, open, wraps, dough covered, meat products should fall under the jurisdiction of FSIS. We also agree with the proposal that all pizza type products should fall under the jurisdiction of FDA. That would include all meat and non-meat type pizzas, all variations, deep dish, stuffed crust, et cetera.

We agree with the concept regarding considering the contribution of meat and poultry ingredients to the identity of the food. With that in mind we believe that products such as egg rolls, pasties, burritos and soups that contain meat food products should now fall under the jurisdiction of FDA. It does seem more reasonable to determine that meat food products containing more than 50 percent meat fall under FSIS jurisdiction and products containing less than 50 percent fall under FDA jurisdiction.

In Wisconsin we have 60 state inspected establishments that produce meat pieces for wholesale distribution. Changing the regulations would have a significant impact on those businesses as well as impacting all other state inspected meat establishments.

The current prohibition on shipment of state inspected products in interstate commerce comes into consideration with any proposed rule change. For example, if FDA assumes the jurisdiction over pizza or other commodities those businesses and those products automatically gain access to the interstate market. On the flip side, sandwich produces who previously were under the jurisdiction of FDA or a state food inspection program would now fall under FSIS or state meat inspection authority. If the rules change all sandwich production would need to fall under FSIS authority in order to maintain their interstate market.

In Wisconsin we have about 25 establishments that produce sandwiches for commercial distribution. These businesses are now regulated by the state's food inspection program. The proposal would directly impact those businesses. Most of those sandwich production facilities are small businesses and would have difficulty in complying with the extensive FSIS regulations.

We believe that the interstate shipment issue is closely related to the amenability issue and should be seriously considered with changes in amenability of products. It would be terribly disruptive for businesses to lose their interstate market simply because the jurisdiction over their product has changed.

In our state the Wisconsin meat processors would be in an uproar if suddenly pizzas were allowed to move freely in interstate commerce while their sausage production products were still limited for in-state distribution. It wouldn't seem right considering that the same inspection system had previously been in place for both pizza and sausage production under state inspection.

We don't believe that consumer's perception would be impacted by these changes. However, many establishments would experience a significant difference between FSIS and FDA oversight for mandatory HASSOP and daily inspection to voluntary HASSOP and random inspection. There could be a significant change in the way that products are marketed as a result of the proposal. Companies with products that now become eligible for interstate commerce would significantly expand their marketing to include internet sales. On the other side, however, products that now become amenable to FSIS

jurisdiction or state meat inspection jurisdiction now are limited to in-state sales if inspected by the state meat inspection program.

As a final note, considering the amenability door is slightly open we recommend you open the door completely and address some other amenability issues; particularly the issue of amenable species. We believe that species such as buffalo, farm raised deer, captive game birds and other specifies commonly used for food be considered as species requiring mandatory inspection at government expense. It does not seem reasonable for FSIS to consider cattle as a species that mandates ante and post mortem inspection and not require buffalo when both species provide the same risk to consumers. Thank you very much.

MR. QUICK: Thank you, Mr. Burkhardt. Okay, our next commenter, we would like to ask Mr. Dennis Johnson from the law firm of Olsson, Frank & Weeda in Washington who will be representing the National Frozen Pizza Institute.

MR. GARFIELD: Obviously I'm not Dennis Johnson. I have a little more hair right now. Thank you. I am Robert Garfield, executive director of the National Frozen Pizza Institute. And with me today, somewhere in the room, there he is, is Dennis Johnson of Olsson, Frank & Weeda,

NFPI's legal counsel.

The frozen pizza industry appreciates the opportunity to comment on the approach by federal agencies; the Food and Drug Administration and the Food Safety Inspection Service, that would be taken in regard to regulation of frozen pizza.

NFPI is the national trade association representing the interest of the $3.8 billion frozen pizza business. I note that frozen pizza retail and food service pizza sales represent only about 14 percent of the $28 billion pizza business in the United States. The majority of the pizza business represents restaurants that are not actively regulated by FDA or FSIS.

NFPI generally supports the concept of regulating all frozen pizza products under the jurisdiction of FDA although eh Institute withholds unconditional support for the concept until certain implementation concerns are addressed. I will briefly mention some of these concerns in my comments.

Frozen pizza is a product that is characterized by dough, a dough base, or crust, a sauce and toppings. The toppings include any number of ingredients including cheese, meat, vegetables, mushrooms, seafood and fruit.

Since the recision of the standard of identity for frozen pizza in 2003 there has been an explosion of new products in the marketplace and topping combinations. Products include margarita pizza that contains special sauces, spices, mozzarella and grana cheese. Hawaiian style pizza that includes flavors, bacon, cheese and pineapple. Low-fat pepperoni pizza that contains lower fat and calories per serving and low carbohydrate pizzas.

Moreover, according to Mintel International, new product introductions have increased from an average of 84 new products during 1999 to 2002 to 111 products for each of 2003 and 2004. According to Mintel the, and I quote, "the elimination of the standard of identity for pizza in August, 2003 opened the door for packaged pizza makers to put just about anything they could imagine on the top of a pizza." Finally, while some may still argue that pizza is characterized by the meat on the product it is important to note that restaurants historically allowed consumers to choose the price, toppings equally regardless if the topping is pepperoni, mushrooms or green peppers.

NFPI believes that differences between meat topped and non-meat topped pizzas is not and should not be a determinate factor for regulatory jurisdiction. And I

want to emphasize this, regarding food safety, use of previously inspected and passed meat and poultry on a frozen, not ready-to-eat pizza product poses no safety issues unique to meat products.

Moreover, the concept of previously inspected meat and poultry as an ingredient in an assembled processed product is not unique to frozen retail and food service pizza. This concept is repeated thousands of times a day in school pizza kiosks, institutions, restaurants without strict regulatory oversight. Indeed, to the best of our knowledge, there has never been any human illness attributed to frozen pizza.

Although NFPI supports regulatory consistency this issue cannot be viewed in isolation from practical considerations. Given meat topped pizza has always been regulated by FSIS, other requirements have evolved. If regulatory jurisdiction is transferred from FSIS to FDA there are a variety of implementation issues that need to be addressed. I will briefly summarize these.

Exports; as we understand foreign government requirements currently USDA inspection is required to export meat products regardless of whether USDA deems the product to be amenable to continuous federal inspection. If the FSIS inspectors are withdrawn how will exports be

handled and who will issue export certificates? Would this require the services of an FSIS inspector? Certainly NFPI believes this deserves consideration by FDA, FSIS and USDA's foreign agricultural service.

School food service products; under the Food and Nutrition Service child nutritional labeling regulations USDA inspection is required for products that bear CN labeling. How would this requirement change if all frozen pizza was inspected by FDA? Since pizza is the number one school lunch product and many schools require the CN labeling, the costs of separate FSIS inspection would be significant for many companies and might jeopardize their participation in the program.

Labeling --

MR. QUICK: How much more do you have?

MR. GARFIELD: Oh just, half page.

MR. QUICK: Okay.

MR. GARFIELD: Many pizzas are sold under private label. Hence, a single pizza company may have hundreds of labels which vary primarily in terms of the brand name. If jurisdiction is transferred to FDA these products cannot bear the mark of inspection. This would require a costly label change. How will the removal of the legends be accomplished if jurisdiction is transferred so as to

minimize costs, especially to small companies specializing in private label products? How could regulated companies use up label stocks with the mark of inspection if the inspectors are no longer at the facility?

Lastly, the scope of transfer. Let me focus brief remarks on the concept of what is a pizza as it has evolved over the years. As you know, there are dozens are variations, not only in terms of toppings, but in terms of presentation, such as when the crust folded over, totally enclosed in toppings. Many of these products are made by our members. And NFPI believes that, especially considering the recent recision of the Standard of Identity, these products are pizza. The question is how these pizzas will be defined and will they be determined to be non-amenable and what products will not.

I want to thank you on behalf of NFPI and the frozen pizza industry for our opportunity to express these issues. And we will follow up with written comments.

MR. QUICK: Thank you, Mr. Garfield. Of course, Dennis will suffer for that extra two minutes. Did you want to make comments? Okay, our next commenter will be Mr. Mark Nelson from the Grocery Manufacturer's Association in Washington.

MR. NELSON: Good morning, I'm Mark Nelson with

the Grocery Manufacturer's Association and on behalf of our members we're very pleased to offer our comments today and to contribute to the discussion. We will be elaborating on the comments that I present today and will submit them and we appreciated the updated e-mail address to use.

Before I start my comments I would want to emphasize again something that we heard earlier, that the proposed changes in the jurisdiction are just that, changes in the jurisdiction of inspection for the products for purposes of efficiency and consistency. And the proposals are not based on any actual or perceived food safety or public health issue.

Now my comments will focus on three topics. The first, GMA minutes and its members support the willingness of the FDA and FSIS to discuss changes in jurisdiction and appreciate their efforts to provide a clearer rationale for jurisdiction of the selected products.

Secondly, the agencies have provided a rationale for the proposed changes in jurisdiction. However, the agencies have not specifically provided principles to support the proposed changes.

Third, in their comments on jurisdictional changes the agencies have focused on the percent

contribution of the meat or poultry ingredients. But we believe there are also a number of other factors of equal or greater weight that should also be considered.

Now let me elaborate on those three points. First, again, GMA does support the willingness of the FDA and FSIS to discuss the changes in jurisdiction. However, we have noted that these changes in jurisdiction are simply for efficiency and operations. And these are worthwhile goals, but it's also important for the agencies that these, to recognize that the proposals are not based on any actual food safety or public health issue. All products that contain meat or poultry ingredients in a given category are already under the jurisdiction of either FDA or FSIS and both agencies inspect products that present public health risks if they were not properly managed.

Now in the experience of GMA member companies consumers do not in any significant way differentiate meat and poultry containing products by FDA or FSIS jurisdiction. With all due respect to the agencies it's not clear that any but a very few customers would understand the detailed and sometimes subtle aspects of agency jurisdictions. Consumers simply and reasonably expect any product for sale to be safe.

That being said, an important principle for

food regulation in general and not just for food standards is the appropriate allocation of resources in order to address real issues and assure removal of unnecessary inefficiency and overlap from the regulatory process.

Avoiding unnecessary or duplicative inspection frees resources for other food safety tasks. And it's safe to say that all consumers and tax payers expect the agencies to focus their resources effectively and efficiently using a science and risk based approach. Simply moving the furniture, simply changing jurisdiction is not enough. Therefore, GMA and its members support these jurisdictional changes that allow for better use of resources by the agencies and industry.

Second, the agencies have provided a rationale for each of the proposed changes in jurisdiction. However, the rationale is not supported by a set of principals that can apply to other products as well. This is not only inconsistent with the agency's earlier proposed rule on general principals published in the federal register in May of this year, but ultimately it does not contribute to a durable and rational assignment to one agency or another the food categories under consideration here or other similar product categories.

An example of an important principal is food

safety. The agencies have earlier proposed in the standard, in the context of the food standards monitorization to add 7-CFR 410-A-3 and 21-CFR 130.5-B-3 which would respectively hold that, "the food standards should protect the public" and "the food standards should promote honesty and fair dealing in the interest of consumers".

Here, fair dealing includes protecting consumers against unsafe foods. However, in its rationale on product jurisdiction the agencies appear to have focused on historical, sometimes ill-defined, definitional positions rather than the nature of the risks presented. For example, raw meat or poultry versus cooked meat or poultry. This results in some cases in the unnecessary double inspection of meat and poultry products when used as an ingredient in, or in an otherwise part of a prepared or packaged food product.

According to the proposed transfer of pizzas, cheeses and cheese products and breads and rolls and buns with less than 50 percent meat or poultry under the jurisdiction of FDA, the previously inspected meat and poultry ingredients would avoid being inspected twice. We wholeheartedly support that increase in efficiency.

Conversely, however, by proposing to move

closed face sandwiches and bagel dogs under the jurisdiction of FSIS the agencies are, in effect, requiring a second inspection of the previously inspected meat and poultry products. Changing the jurisdiction from FDA to FSIS would require significant added expense by the industry and added resource burden for FSIS without any clearly defined food safety problem that needs to be addressed.

Another example of an important principal is consumer perception and expectations.

MR. QUICK: How much more do you have left, Mr. Nelson?

MR. NELSON: I have three more large type pages.

MR. QUICK: Okay, I'm going to give you one more minute.

MR. NELSON: Thank you. Another, well then, let me skip to, you'll get all this in writing. Perhaps most importantly in our comments on jurisdictional changes the agencies have focused on the percent contribution of the meat or poultry ingredients.

In our estimation one factor that is more important that the simple percentage is the health or safety risk of the meat or poultry ingredient when it is used. Is it cooked or raw? How is it combined? Prepared?

Packaged with the other ingredients? In this regard the agency should consider, among others, the inefficiency that comes from a defective double inspection of meat and poultry products.

The agency should also consider the range or products beyond those identified in the current proposal that fall within the scope of the agency's reasons presented in the proposal. For example, why should soups or other retorted products with approximately ten percent previously inspected meat or poultry ingredients be subject to, in effect, a second inspection by FSIS when versions of the same products without meat or poultry are more than adequately covered by FDA jurisdiction in the same production facility?

Similarly, the agencies are proposing that salad dressings made with less than 50 percent meat or poultry be removed from FSIS to FDA jurisdiction. Why shouldn't jurisdiction for gravies which contain the same amount of meat or poultry as salad dressings be moved if the only difference is the type of food they are poured onto?

We recognize that the current discussion is intended to cover a limited range of products but the agencies do need to recognize that having initiated the

discussion questions will be asked about these and other products as well.

Let me close by saying that it's important to reiterate the changes in jurisdiction the agencies are discussing is just that, changes in jurisdiction. The proposals are not based on any actual or perceived food safety or public health issue. If the agencies advance the discussion to actual proposals to change the jurisdictions of the products clearly it should be done through the notice and comment rule making procedure.

And equally important, any formal changes to jurisdiction should be based on specific principals and relevant factors and not just on the percentage meat or poultry in the product. In the end, however, whichever agency has jurisdictional authority GMA member companies will continue to manufacture meat and poultry containing products that consumers can rely on to be safe and wholesome and to meet their expectations for product performance and quality. Thank you.

MR. QUICK: Thank you, Mr. Nelson.

MR. NELSON: Thank you for the extra time.

MR. QUICK: Can I ask by a show of hands, I've got eight more commenters signed up. Are there additional, anybody with an interest? Okay, we've got nine. I mean,

we can work through the lunch hour if you all are open to that. Okay, then we'll go ahead and do that.

Our next commenter is Tony Corbo, Mr. Tony Corbo of the Food and Water Watch. And Tony, just for, we're going to keep it very tight on five minutes. The shot caller will be employed at this point forward.

MR. CORBO: Okay, I'm Tony Corbo from the consumer organization, Food and Water Watch. First of all I want to thank the two agencies for holding this meeting. I think it's a very good approach to looking at any major regulatory changes that you're contemplating.

So I want to disagree a little bit in terms of some of the comments that were made earlier about the changes in jurisdiction not impacting food safety. Because I think and to amplify on what Caroline said earlier, I think there's going to be a perception by consumers that shifting some of the products from FSIS jurisdiction to FDA jurisdiction could be perceived to be as a diminution of intensity of inspection and food safety.

And what I want to do is I want to put a face to that a little bit. I have a set of comments that were submitted to the docket from an FSIS inspector who has worked for FSIS for 30 years and has been assigned to a frozen pizza plant for the last ten. And I just wanted to

state for the record, you know, just portions of it that seem to support my earlier comment about the level of inspection.

The establishment that I currently am assigned to technically comes under the jurisdiction of USDA, FDA, the Military Inspection Service and the Food Nutrition Service. USDA is the only government agency that conducts daily inspection procedures in this facility. During the first five years that I have been assigned to the present establishment FDA inspectors visited once. During the last five years FDA visits were increased to three.

If the jurisdiction of meat pizzas were removed from USDA consumer protection, to say the least, would not be the same. FSIS personnel inspect the entire plant premises including bakeries, production areas, packaging, storage facilities and outside areas daily. The bakery production systems are incorporated into the plant's standard sanitation operating procedures for operational as well as pre-operational activities.

As a direct result of daily FSIS inspection and the establishment's commitment, the plant operates under a high standard of operational and pre-operational sanitation that encompasses the entire premises. Although

traditional non-meat pizzas do not come under the FSIS jurisdiction, USDA inspects the facilities, equipment and utensils used in their production since meat and non-meat items can be produced simultaneously within the establishment or interchanged during the course of the day.

In addition, non-meat pizzas for the Child Nutrition Service, that is the school lunch program, are inspected by FSIS under a memorandum of understanding with the Food Nutrition Service that has been in effect since 1984. The operational sanitation procedures apply to all products produced in this establishment which benefit both the consumer and the manufacturer.

So as you contemplate these changes there are some significant issues that you're going to have to address in terms of, and in addition, to other inter-agency, inter-departmental agreements that have already been signed off on.

So I'm going to thank you very much for your time.

MR. QUICK: Thank you, Mr. Corbo, for your succinct testimony or comments. Our next speaker is Ms. Rosemary Mucklow from the National Meat Association.

MS. MUCKLOW: I hereby claim Mr. Corbo's leftover time.

DR. SOLOMON: He didn't yield it.

MS. MUCKLOW: I'm pleased to be here with you today. I particularly liked in the November notice that a letter was quoted that was written to me back in 1979 about bagel dogs by Mr. Irwin Fried, or he was otherwise known in my office as I. Fried.

I'm also pleased to tell you that I'm here today to speak for National Meat Association and for Southwest Meat Association and you do have a patchwork quilt of regulatory requirements in this area. And that's to be commended that you're going to try to figure it all out and do something about it. I don't think it's the top of the pile of issues we need to do something about, but I'm glad to be here, nonetheless, on the red eye.

We agree with the joint agency working group that a clearer approach is needed. Unfortunately the background information does not provide either a scientific or a practical approach with respect to what the application and the separation of each agency's jurisdiction.

We don't necessarily agree with the working group's finding that it makes sense to consider the contribution of the meat ingredient to the product. Rather we believe it makes sense to consider the way in which the

meat ingredient is handled in the production of the final consumable product. That is what is important to public heath.

We're of the opinion that the agencies need to evaluate for each product class the degree of public health risk that occurs because of the inclusion of a meat or poultry ingredient. Sandwich makers are case in point. At present they're appropriately regulated by FDA with concurrent jurisdictional oversight by state and county health departments. They are permitted only to use ready-to-eat meat and poultry food products that have been previously inspected and passed under the jurisdiction of FMIA and PPIA. If a sandwich maker is making his own roast turkey and putting that into a sealed sandwich package he better be under inspection.

However, applying this criteria of using only previously inspected and passed RTE products, some products currently under USDA inspection could appropriately be transferred to FDA. The bagel dog, which we're not meeting today about bagel dogs I was told, but the manufacturer is simply wrapping the inspected hot dog in a bagel and packaging it. And there's really no essential difference between that and the corn dog. They ought to be about the same.

Dried soup, apparently we've got a divergence on that. That certainly needs to be cleaned up. Pizza, we've got a divergence on that. The cheese on one side, the meat on the other. That doesn't make sense. As we regard sandwiches we submit that the presentation of the sandwich should be irrelevant as to the issue of amenability. If a product is sold as a sandwich, whether it's two slices of bread, whether the meat's placed in the bread and the bread's rolled around the meat, shouldn't make a difference from either a food safety perspective or a consumer expectation as to which regulatory agency has jurisdiction.

I raise a serious question with the estimated number of sandwich makers. I generously said there were maybe five to 10,000 in the United States. My guess is it's somewhere approaching 5,000. And if they've got that many in Wisconsin I think you could extrapolate that based upon levels of people living across the United States and probably get somewhere close to 5,000.

If you brought them under inspection it could double the number of establishments presently under USDA inspection and create serious competition for USDA's scarce inspection resources between traditional slaughter and processing establishments and the newly amenable

sandwich makers. Or it could require a very substantial expansion of USDA's inspection numbers and budget needs. NMA does not believe that there is any food safety justification for this very substantial reordering of food inspection and food inspector priorities.

In conclusion, he hasn't even stood up yet. In conclusion, it is time for the agencies to undertake a practical assessment of the risk and resource implications if sandwich makers and other firms using previously inspected products are brought under the more resource intensive USDA inspection. It's NMA's position that the establishment should only come under USDA jurisdiction where their use of a meat ingredient in their product creates a substantial additional risk and that the use of previously inspected cooked meat and poultry products in further processing will seldom, if ever, create such a risk.

I'd be glad to answer any questions you have or yield the microphone to the next speaker.

MR. QUICK: For ten more seconds.

MS. MUCKLOW: Yield, yield.

MR. QUICK: Thank you, Ms. Mucklow. Our next commenter is Mr. Mike Dunker with the Value Added Products.

MR. DUNKER: Well, good afternoon. We are in

afternoon. Sorry, it's at lunchtime, but I'm going to make this brief.

All these people that came before me, I think I'm under qualified here. They're all about associations. We're about manufacturing. I represent a company from Alva, Oklahoma called Value Added Products. We are owned by 780 individual wheat farmers. We make self rising pizza crust. At this particular moment in time we are taking our manufacturing from just making pizza crust into the topping part of the business.

Now, I'm an engineer by trade. I've built manufacturing plants all over the United States all my life, since I was 20 years old, well, 25 and got out of school. Anyways, when we started looking at the USDA and their qualifications or their construction standards, what we look at just for our little tiny, we have a small plant in Alva, Oklahoma. We did about $12 million worth of business last year. But we sell to every major distributor in the United States today.

When you look at the construction costs to build a USDA plant on our site it's 30 to 50 percent higher than it would be for an FDA approved plant. When you started looking at the operating costs of a USDA facility as compared to an FDA plant you're talking another, at

least ten percent more operating costs to operate these things.

Now as the CEO of the company my focus is on keeping capital dollars down and operating dollars down. The one thing I would like to address here is I think, Carol, we're probably going to argue about this, we are inspected to death. When you take an FDA plant that yes, you guys, the FDA does not come in every five years. But we're inspected twice a year by the state. We're inspected twice by ourselves by third party auditors. We're inspected by every major manufacturing distributor out there who have their own quality control standards. We are inspected to death.

Now, in meeting with the USDA inspectors from Oklahoma and from Kansas, we're trying to figure out how we're going to build our new production facility for toppings. I'm going to tell you, we can't get a straight answer. There's a different answer for all different situations. We need to have some way that we're going to be able to build our plant that we can have the correct answer what it needs to be. And if you go, I've been dealing with pizza topping plants for the last 20 years. If you go to Kentucky, get that inspector's opinion, it will be different that the guy in Kansas, I'll guarantee

you that.

Once every five years, well, I've built plants all over the United States and the FDA inspector's been there a lot earlier than five years. But the inspection, when the inspector is in our, in Oklahoma we have a lot of food manufacturing plants or a lot of meat processing plants. In northwest Oklahoma we have a lot of meat processing plants. What you guys are talking about the USDA or the FSIS inspection is the traveling inspector. He comes in for half hour, an hour a day. But he has to be there every day in order to make that thing run.

The, I don't understand why a guy coming in for one hour a day actually makes your plant more cleanable or your product even safer in the marketplace. I'll tell you, as the CEO of a company, we do not want to put any bad product in the marketplace. If we put a bad product in the marketplace, for a small eight to $12 million company like we are, it can actually put us out of business. We are very, very careful about what we're putting in the marketplace. And I'd like to thank you.

MR. QUICK: Thank you very much. Our next commenter is Mr. Mark Dopp from the American Meat Institute.

MR. DOPP: Good afternoon, my name is Mark Dopp

and I'm with the American Meat Institute. I would like to commend the agencies for holding this hearing today and offering the opportunity to comment on an issue that; one, has been around for quite some time and two, is obviously very significant to the meat industry. With your permission, the AMI will be submitting more detailed comments to the docket.

The issues and the questions raised in the Federal Register Notice are not new. As you've heard repeatedly this discussion is not about food safety. And I say that because whether processed under FDA or FSIS jurisdiction the regulatory systems in place ensure those products are safe. Rather, the issue presented is whether the existing exemptions to the meat and poultry inspection statutes and those being considered allow government inspection resources to be used and allocated as effectively as possible so that consumer safety and the public health are enhanced.

Interestingly, the notice supports the conclusion that the current criteria are antiquated and lack cohesiveness. Rather than engaging in an arbitrary and jurisdictional decision making we encourage the agencies to develop with the aid of public discussion, such as this meeting, objective criteria to guide amenability

determinations. These criteria should include: one, whether the product's meat or poultry component has been previously inspected by USDA. Two, the nature of any risk presented with respect to a particular product or product category. And three, the marketing and consumer expectations with respect to that product.

Using these types of criteria would, in our view, enable the agencies to move some products that have been inspected by USDA to FDA jurisdiction, such as when a ready-to-eat meat or poultry component of a food product has already been subject to FSIS inspection. Such a change, for example, would provide for a far more efficient utilization of inspection resources and be consistent with the risk based inspection system, a topic of considerable debate and interest at the most recent national advisory committee on meat and poultry inspection.

I'd like to raise two additional quick points, if I might. First, the agencies should carefully re-examine the meat or poultry content standards that have been used to establish a demarcation establishing jurisdiction. The definition of meat food product, which was up earlier, allows exemptions for products that contain, and I quote, "contain meat or other portions of such carcasses only in a relatively small proportion. This

language provides considerably greater discretion in making exemption determinations than the hard numbers tested historically has been used.

Second, AMI opposes the unnecessary inclusion within FSIS jurisdiction of products that although containing some meat component, have not traditionally been subjected to FSIS jurisdiction. There is no evidence that such changes are necessary and the problems, confusion and costs that would be attended to such changes, far outweigh the minimis, if any, benefits to public health that might ensure.

Thank you again for the opportunity to discuss the issue. We look forward to presenting our comments. And I'd be happy to answer questions.

MR. QUICK: Thank you, Mr. Dopp.

MR. DERFLER: Can I ask, hey Mark?

MR. QUICK: You want to come back up Mark?

MR. DOPP: You talked about ready-to-eat products that contain ready-to-eat meat and poultry. You're talking about products that are ready-to-eat or are you talking about products that contain meat and poultry that already been made ready-to-eat?

MR. DOPP: Let me give you an example. There are products in which the product is ready-to-eat and is simply

added as one ingredient into a kit, for example, package or products. Those types of, that's an example of what I'm talking about. Does that make sense?

MR. DERFLER: But you're talking about, but the meat and poultry component has already been processed?

MR. DOPP: Yes, yes, the meat and poultry component has been inspected, is ready-to-eat and is used as a component in a larger product.

MR. DERFLER: Okay, thank you.

MR. QUICK: Thank you, again. Our next commenter is Mr. Charles Leitzke with AFDO. You'll have to reintroduce your name, I'm sure, after that.

MR. LEITZKE: My name is Charles Leitzke. I'm with the Wisconsin Department of Agriculture, but this afternoon I'm representing the Association of Food and Drug Officials. We will be submitting written testimony also, so I will paraphrase some of this.

On behalf of the Association of Food and Drug Officials and its current president Marianne Aller, it's my pleasure to offer the organization's comments on FSIS's and FDA's plans to address the long-standing confusion of which agency has jurisdiction when certain food products contain meat or poultry.

AFDO represents state and local food safety

regulatory officials and is a close working partner to FSIS and FDA on food safety and defense matters. Furthermore, AFDO has long supported the concept of a nationally integrated food safety system and have promoted numerous projects in place today to advance this concept. We believe the examination beginning here today and to the jurisdiction of certain food categories can further strengthen the regulatory process, will better employ limited available resources and will resolve the number of long-standing criticisms of the Federal Food Safety agencies.

AFDO strongly supports this process and the approach taken by the FSIS/FDA working group for the following reasons. It will strengthen our national food safety system. Problems which exist at the federal agencies are problems for state agencies. Clarifying and rationalizing what federal agency has jurisdiction over foods like pizza and sandwiches result in more efficient and effective government regulations benefitting all parties.

It permits a risk based allocation of regulatory resources. We believe this effort is a logical cost saving step for better employing inspection resources to regulated industries. It is also a much improved way

for addressing inspection jurisdiction for lower risk versus higher risk food products.

It is a logical and more easily understandable approach to distinguishing products. We fully support the working group's recommendations as to which agency shall be awarded jurisdiction. Food products that primarily contain meat and poultry ingredients should be covered by resident type inspection under FSIS. While food products that contain meat and poultry ingredients for accentuating flavor only should be assigned to FDA. This rationale is best illustrated in our opinion with sandwiches which pose a potential Lysteria Monocytogenes hazard to consumers whether or not the sandwich is closed or open faced.

While AFDO recognizes the need for and importance of the jurisdictional examination we note that the changes being considered will have an impact on state and local food safety programs. We urge that these impacts be considered during the decision making process.

One, it is likely that the, some establishments that would be affected by the change are currently licensed and inspected by state and/or local regulatory agencies. Should these establishments become federally inspected plants under FSIS would state laws be

pre-empted and state programs lose licensing fees? What might FSIS do to ameliorate this impact?

AFDO has long supported the use of HASSOP by all food manufacturers and wonders what will happen to current FSIS establishments operating under a HASSOP plan that are then transferred to FDA jurisdiction where the requirement does not exist. It would seem appropriate that a HASSOP system that has been mandated and put into effect by a firm, it might seem inappropriate that HASSOP system which has been mandated and put into effect by a firm might no longer be required. AFDO requests clarification.

It would follow that rule changes for firms that are placed in under new federal jurisdiction will be inspected as well. Establishments complying with state required date coding, record keeping or processing schedules differ from those required by FSIS would have to make substantial changes.

A number of affected firms may be currently inspected by state authorities under FDA contracts. Transferring those firms to FSIS jurisdiction will impact such contracts.

This initiative could be an opportunity to look at new cooperative approaches to regulating food establishments subject to multiple jurisdictions. Food

establishments where meat or poultry or non-meat or poultry are produced in the same plant have always presented an awkward situation for regulators. Many of these plants are high risks types such as low-acid canned food manufacturers, acidified food plants and processes that cure with salt or smoke various types of food products.

Goals might be to prevent duplication of efforts and minimize the number of government food safety agencies with which small businesses must contend. At a minimum where the states are not pre-empted entirely and continue to have a role in regulating multiple product manufacturing establishments the federal agency should provide a mechanism for consulting with the states on the coordination of federal and state regulatory activities including compliance efforts with local retail food establishments.

AFDO is pleased to offer these comments to our federal partners and applaud any decision that would result in better utilization and integration of the limited yet very critical resources devoted to food safety. Thank you.

MR. QUICK: Thank you. Our next commenter will be Ms. Nancy Donley from Safe Tables Our Priority.

MS. DONLEY: Good afternoon. I'd just like to

say briefly that STOP, or there are some people in this room who may have not heard of us and I just want to say that we were founded by victims of families and victims of food borne illness in 1993. And we have worked since that time with all sectors interested in food safety which include government, industry, academia, and the public. We advocate policies that will improve the safety of America's food.

First of all, I'd like to thank Dr. Raymond and Dr. Brackett for holding this meeting. I think it's really, really a wonderful process that you're starting here to actually get input before promulgating a rule. It's a little bit of outside the box thinking and I really do appreciate it. And especially, I want to thank you for the location that you chose to have this meeting. And if this does get involved into public meetings and additional meetings I hope you continue to hold them here in Chicago.

That said, I'd just like to say that we certainly do understand the necessity for have a discussion such as this. It doesn't make a whole heck of a lot of sense to have inspectors from the two agencies criss-crossing one another's paths. Although, I don't know how often that does happen because the frequency of inspection is so different.

But any type of regulation that gets advanced on here I would like to say that we really hope that it is with the goal of enhancing and further protecting the public's health and safety first and foremost.

The issue was described today as being one of clarify, system efficiency and accountability. And I can totally agree with that. As I said earlier, it does make sense. However, I do take issue with the statement that this is not an issue of safety as has been stated here by many people today. If this was not perceived by our organization as an issue of safety, I frankly wouldn't be here today.

What we're looking at here basically boils down to an inspection, a level of inspection frequency. There is a huge, huge difference between FSIS's inspection frequency and FDA's. What would, in an ideal world what we would do is bring up, which I'm sure, Dr. Brackett you would like to be able to have your inspection frequency ratcheted up and with more, with more frequency.

But that's not what we're dealing with today. I would have to say that I have agreed also with some comments that consumers basically don't really care who's doing it, that it's not readily understood by the

public that FSIS is doing this or FDA. I'd also like to suggest that the public hasn't a clue of the difference of inspection frequency between the two agencies. I think if they understood that they're, that FDA inspected product was only being inspected at a frequency of on average once every five years they would be really, really outraged.

So to that discussion then I'd just like to say that anything that we do today that would be perceived, that could be perceived as a reduction in inspection for the food that we buy to feed our families would be a PR nightmare. That anything that we would take that is perceived now that is under FSIS jurisdiction that would then fall under FDA and, therefore, under a lesser level of inspection, this would not bode well to the public's perception.

Therefore, I would just like to conclude by saying that we would like to see that any food that contains a meat or a poultry ingredient fall under FSIS's jurisdiction. Thank you.

MR. QUICK: Thank you, Ms. Donley. I think we have one more coming up here. Did you want to come back up?

DR. RAYMOND: No, I, you can sit, Nancy. I just want to, for those who may not know Nancy Donley, she does

live in the Chicago area. And for most of you who probably don't know, since I took this job I've been trying to have monthly meetings with the Safe Food Coalition of which Nancy is a member and she always calls in on the phone. And when someone asked me at the last Safe Food Coalition why we were having this meeting in Chicago, I said, because I want to meet Nancy Donley finally. So, it's partly in jest but, Nancy, I do thank you for your comments.

And I just want to reassure you and everybody in the room any changes we may make after we've gathered all this information, and we haven't made any commitments yet to that, but any changes that Dr. Brackett and I may take forward to our secretaries first and foremost will be the public safety. If it's a reduction in inspection it would be only because we're convinced we can do a reduction in inspection for a particular product without any increased risk to the public safety or else we would not be here. But thank you for making that point and making sure we hear loud and clear.

MR. QUICK: Thank you. Our next commenter is Dr. Jill Holingsworth with the Food Marketing Institute.

DR. HOLLINGSWORTH: Thank you. I'm Dr. Jill Hollingsworth, vice president of Food Safety for the Food Marketing Institute. The Food Marketing Institute is a

trade association based in Washington that represents over 1500 retail and wholesale food stores.

We agree that there definitely is a need for a change and we're glad to be a part of this process where we're able to participate in what we see as a first step in the process. But one of the things that all of these discussions point out to us is that there is a need for a single food safety authority. And although we know that this is not a meeting to discuss that issue, nevertheless, were there a single authority for food safety there would not even be a need for this meeting.

The approach that was outlined today does not really resolve the confusion over the multiple and unclear jurisdictions for certain food products. The current approach applies subjective criteria on a case-by-case basis to individual food products, as I think Bob Post did a very good job pointing out.

The approach that was outlined today though, is no more than a new set of subjective criteria that are going to be applied also on a case-by-case basis. If a consumer is choosing to buy a pizza and they're trying to decide whether they want the meat lover's pizza or the vege pizza in either regard they're buying a pizza based on its flavor.

Likewise, if a consumer decides they want to buy a sandwich, whether they are buying tuna salad sandwich or chicken salad sandwich, they're still buying that sandwich based on its flavor.

Whether a meat and poultry product is based on its flavor or its characteristics it is still subjective to determination as to what the product should be and how it should be regulated.

Today's proposal then is to us just yet another approach that is based on how the product looks, how it tastes or how it is perceived. Whether these products are regulated by FS or FDA there is an expectation and an obligation that they are both equally safe.

Therefore, we feel that there needs to be an entire new approach to looking at this issue, not based on what the food looks like or tastes like or the perception, but rather such issues as, is there duplication of inspection effort? Is there a better or more appropriate use of resources in inspecting the food products? And whether these decisions are based on the demonstrated safety of the products.

We look forward to working with the agencies and hopefully with the working group also in looking at an entirely new approach and not just rearranging the duck

chairs. Thank you.

MR. QUICK: Thank you, Dr. Hollingsworth. did I have anymore speakers? Have I forgotten anyone? In the back of the room, you're withdrawing yours? Okay. Well, with that I'm going to ask Dr. Brackett to make some wrap up comments and then Dr. Raymond will follow.

DR. BRACKETT: Okay, well, first of all I do want to thank all of you because you are the reason that we actually came to this meeting. We do think that, as we expected, we heard divergent opinions about the effort that we've undertaken here and you will be included in this in the future.

I do think it has been, for that reason, a profitable day for us anyway and we'll be looking forward to hearing your written comments. And so my final saying to you is, again, thank you for participating with us in this effort.

DR. RAYMOND: I also want to thank you once again. But I want to make a couple comments that have gone through my mind as I'm sitting here listening today. One is I appreciate the brevity and look forward to the written reports to the docket.

Getting done, not that we intended to get done by this time of day, but it does allow me to catch an

earlier flight to Omaha and we're closing on our house tomorrow and my wife is moving to D.C. on Sunday, exactly five months to the day I took this job. So it's kind of a big week for me. I'm going to appreciate having a couple extra hours there.

And I want to throw that out partly because I've heard a lot of comments today about why would you do this, why would you do that, and why did this happen. And this is one time that I'm glad to say I've only been here five months. Don't ask me to lie. But Dr. Brackett and I certainly intend to go forward with the why we're going to do the next thing.

Several little issues that came up, but one that's just sitting her resonating in my mind. Back in Omaha where I lived we had a grocery store just a couple blocks away. And right next to the grocery store was a piece of establishment where we could call ahead and order a pizza that they would make but not bake. So we could order it, and I'm not going to give you the company's name, but we could order an Italian gourmet whatever, medium, and we'd go pick it up in 20 minutes. It was a nice pizza and all we had to do was throw it in the oven at home or we could throw it in the freezer and eat it another day.

And at the grocery store right next door, I

could go in there and buy a frozen pizza in a box that was inspected. And I'm not quite sure why it was more dangerous to make it in that particular industry to put it in a box, or the industry that wrapped it up in cellophane and I put in my own freezer.

So there are just a lot of inconsistencies and it's not going to be easy to get this done. And as Rosemary said, maybe this isn't the number one thing on our plates or tables, but it is an important thing. And I think if we can make people trust the FDA and the USDA that we can make intelligent decisions based on science and fact and input and come up with a better way to skin this cat then I think we've served the public well and the public safety will be always first and foremost in our minds.

One comment was made about the idea and the descriptions, perhaps a small amount of meat product is a better way to put it than the very prescriptive amount. But if you put the small amount and leave it there then that, next year someone may make another decision that ten years from now they'll say, why did they make that, what was the definition of a small amount. So those are things that we will also grapple with as we try to make this not just for the products today but, as we've seen in testimony, the new products that come out each year, we

need to make it apply in the future so we don't, so we aren't all back here, maybe not all of us, so somebody isn't back here, Nancy, in Chicago, ten or 20 years ago saying what about the lat ten years or products.

And with that I will just again thank you, as Dr. Brackett did, for coming and participating. It's certainly been informational for me and I know for others and we look forward to the written dockets submitted, to the docket. Thank you.

(Whereupon, at 12:43 p.m., the above matter was concluded.)

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