ANIMAL FEED SAFETY SYSTEM PUBLIC MEETING

CROWNE PLAZA HOTEL

655 NORTH 108TH AVENUE

OMAHA, NEBRASKA

APRIL 5 AND 6, 2005

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INDEX CONTINUED

INDEX CONTINUED

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APRIL 5, 2005

INTRODUCTION BY GEORGE GRABER, Ph.D.

DR. GRABER: I think we're gonna -- we're gonna start. We've got a tight schedule, and there'll be some time for visiting a little later this morning, and then this afternoon, you'll have plenty of time to talk to each other.

My name is George Graber, and I'm the Deputy Director of the Office of Surveillance & Compliance in the Center for Veterinary Medicine, FDA. What I want to do for the next few minutes is just run over some logistics, some administrative issues, and then Dan McChesney will give the introductory -- or the welcoming remarks.

First, and probably foremost, for those of you who have cell phones with you, could you please turn off the ringer? It would be much appreciated.

Second of all, you should have -- Each of you should have your, your packets, your infor -- you know, the red, red folder, and what I want to do is just go through some of the items that are in that folder.

Next -- Okay. There's -- In the folder, you should have a CVM update, that came out in February, announcing this meeting. There are also copies of the Federal Register notices of March 31st of last year and February 7th of this year. The notice of March 31st of 2004 gave you the docket number and also identified the, the definitions for risk-based and comprehensive that we have added to the docket -- the FDA docket, and also, provided the basic elements of a process-control system. So these were put out for public display. They were draft comments -- or draft documents for, for you to consider.

You'll also find, in the packets, some information dealing with risk. Some of the slides that'll be used today are included in the packet because they had not been released previously.

There is also the, the framework document, which we -- most of what we're gonna be talking about this morning, this draft document that's, I think, eight -- seven or eight pages.

There is also -- This afternoon,

everyone, with a few exceptions, will be assigned to different breakout groups, and, and you see that on your badge, what your breakout group number is. Within your packet, there's a listing of the breakout groups and the -- and the diagram in the hotel for where these breakout groups will be.

You'll be meeting at lunch, and lunch will be served in the Regency Room, which is around -- somewhere towards the back of the hotel, and the breakout groups will be -- will be eating together, so there'll be cards on the -- on the placard -- on the tables indicating what your breakout -- where your breakout group will be having lunch.

There's also a list of, of registrants for the meeting, at least as of the end of last month. If everyone had showed up, we would have had somewhere around 210 people here registered. We don't anticipate that, as, in most cases, things come up, and we're not anticipating everyone will be here, but looking at the size of the room, it looks like we have pretty close to a full house. There are some seats right up here in the front row, believe

it or not. They got bird's-eye view of the -- of the slides, and --

There's also speaker bios, number -- The people who will speak, just about everyone is, is a member of the Animal Feed Safety System Team, and rather than go through and introduce speakers, other than their name and what they're gonna be talking about, if you want to read anything about the backgrounds of the people, that's -- it's in the -- it's in your packet.

There's also comment cards and an evaluation form, form to fill out at the end of the -- at the end of the -- tomorrow, and the comment cards, you can fill out comments and questions and stuff. There are boxes in the back of the room, on the table, to put both the cards and the forms in.

(A cell phone rings.)

DR. GRABER: There's our first cell phone. Okay. Where is the hook?

Okay. The -- There's also a sheet identifying -- There's a reception this evening from 6 to 7:30. It's in the Regency Room. It's a cash bar, but there should be plenty of

food there.

And then the last item I've identified is the meeting agenda, and like I said, this morning there'll be presentations by the members of the Animal Feed Safety System Team covering the framework and then each of the components that we've identified in the framework and then, also, the discussions on risk and, and also the risk-ranking method that we're utilizing -- or considering to be utilizing. And there will also be some discussion about the definitions of risk-based and also comprehensive.

There will be -- At the end of the morning, there will be a time set aside -- there is a time set aside for introduction to the breakout groups, so you'll get a lot more background about what's gonna be expected of you and how that's -- and how that's all gonna occur.

And if time permits this morning, between speakers, we will entertain a few questions. There are people scattered throughout the, the room here with mikes, so if you raise your hand, at this time -- and if you

raise your hand, then we'll turn to you, and you'll ask your question. Just identify yourself, name and affiliation, and ask the question. And I'm not guaranteeing we'll have time, but if we do, we'll take -- we'll take a question or two.

Like I said, this afternoon we're gonna have breakout groups. You'll have a series of questions that you're gonna be working on. Again, lunch will be served. So looking forward to, to hearing your reports, which will be done tomorrow, tomorrow morning. We'll have a full schedule tomorrow morning, and then there'll -- at -- some time for some open discussion before we close the meeting a little after 12.

Okay. I think I've covered everything I wanted to cover. I think -- One, one thing I didn't mention, the, the names of the facilitators are also in your packet. The facilitator for 2B, the name needs to be changed. The, the new person's name is Natalie Vacanti, V-A-C-A-N-T-I. And, in fact, the facilitators are here. Maybe they can stand for a minute, you can recognize who they are.

They're the younger people, and in my case, the much younger people. Okay. That's to get everybody to come to the breakout rooms, so anyhow . . .

Okay. The welcoming remarks will be given by Dr. Dan McChesney, who is the director of the Office of Surveillance & Compliance in the Center for Veterinary Medicine. Dan?

WELCOME BY DANIEL McCHESNEY, Ph.D.

DR. McCHESNEY: Good morning. Just start with the next slide. We know who I am.

What we'd like to do this morning is welcome you to Omaha. And many of you may ask why Omaha, since we did this, oh, a year or so ago, year and a half ago, and we did it in Washington, D.C., and all the familiar faces from Washington were there, all the trade associations were there, but we decided, since this Animal Feed Safety System is going to focus, really, on the animal feed industry, that it might actually be wise to come to someplace in the country where the animal feed industry is actually located. There is not much of it in Washington, D.C., although there

is some rural parts, not much. So we're here in Omaha with the idea of hoping to have participation from producers in the feed industry, and basically, looking at the registrants, I think we have accomplished that.

The focus of the meeting, as George already said, is really the framework document that was developed at -- with the comments from the first public meeting and then a method for risk method discussion of how we might look at risk. Next slide.

Reasons we're here. Well, animals are -- We all know animals are important to our society for two reasons: one, when they're pets; and two, we eat 'em, which is an interesting concept between both of those. Food and feed are important to animal health. I think we need a more uniform way of addressing safety issues. In the past, we've sort of done it on an ad hoc basis. When a safety issue came up, we'd decide how we deal with it, what -- how we proceed. We actually need some way to look more uniformly at that, have some things in place for what we're going to do, what actions we're going to take. And I

think one, one example of where that's played out is in the response on the -- for BSE in the -- on the feed side of the house, but also on the animal side of the house.

Between FDA and U.S. Department of Agriculture, we have lots of plans laid out of how to respond to -- when there's been a notification of a BSE incident like we saw up in the state of Washington or the Canadian animals, how to attract the feed, how we talk to each other. So that's a very well-laid-out system, with very defined things of who we're going to be contacting. We need to look at doing that for the other, other types of contaminants.

And we, first of all -- Most importantly, we need to better utilize the resources of both FDA, the states and the involved industries. And up here -- This picture on the top here is from a CVM picnic we had last April, and just -- I think it's a little microcosm of what we have here today. All the people here are actually CVM employees, and it's hard to see in the back, but they're all sort of pointed in one direction. They're

all sort of looking ahead, and I think that's what we have with the group here today. The Animal Feed Safety people that are here, the FDA folks and the state folks that were involved all sort of have a vision of where the Animal Feed Safety should go. It's not a totally common vision, but they're all at least looking in the same direction.

I think most of the rest of the audience is sort of reflected by the dogs down here, who are -- There's some looking in every direction. I mean, this one is completely turned around, obviously totally opposed to the whole system, and there are just a bunch of 'em, all going individual directions, with all different opinions, and then we have this little black fella sitting out front here who seems to be willing to listen to all sides, and I think that's what we're looking for this morning. I think most of the folks in the audience have lots of opinions that we want to gather, but you need to be willing to listen to each other and not come, you know, with your own position and just state it and keep stating your position. So we ask you to be open to it,

sort of like this fella sitting here. And at the end of the day, maybe we'll all sort of be looking, you know, sort of forward, maybe even if we're looking out the side of our eyes, but at least we'll be looking forward. Next slide.

The next three slides just sort of go to the fact of why do we need something and what's happened over the years for feed-contamination-type issues. And we're not going to go through each of these, but the important point is to just look at the diversity of the things that we have up here. So we have mercury. We have salmonella bacteria. We have P -- PBBs, PCBs. Monensin down here at 94 is an (inaudible). Monensin is a drug -- an approved drug, and in this case, it was used in the appropriate manner and resulted in about 600 cattle being dead in the Midwest here, and as it turned out, when we did do an investigation, we found out that the animals were being fed distillers' dried grains, which turned out not to be the problem, but mixed in with that was a fermentation byproduct from the pharmaceutical industry, which is not part of the definition of

"distillers' dried grains," and it turned out to potentiate the uptake of monensin and killed 6 to 700 cows. So a preventable problem. Just had to lead out -- leave out the pharmaceutical byproduct, but still, where you can take an improved product, use that approved dose and have bad results. Next slide.

Salmonella and pet treats coming in. We have a real concern about salmonella in pet products because they come into the home, they're direct to consumer. So that's one.

We all know fumonisin, the horse deaths. Those of us in FDA and usually in Kentucky, we make a big point of this every three or four years 'cause we kill 30 or 40 horses. You don't feed 'em grain -- You don't feed 'em corn screenings because of the potential for fumonisin. Everybody learns from that, and then three years later we kill a bunch more horses in the same -- in the same state or adjacent states because they're back to feeding corn screening. So we just need to kind of keep things in perspective.

BSE, we all know about that. I think we've addressed that fairly well. Next slide.

Dioxins, surely a problem that we've known about. One of my most -- One of the most favorite quotes I've heard in this came from someone who is not actually in the room but was not a state or federal person, nor a producer, and when I mentioned that dioxin was a problem, 'cause we had a problem with boil clay trace minerals and baghouse dust, the comment was, Well, we've only had three -- we've only had three problems with dioxin over the past 10 or 15 years, and I said, That's true, but each of those problems were preventable if the company had actually tested for 'em or not used the product. So, you know, ignorance is not an excuse for not doing something that's right and safe, so we're trying -- We need to try to get away from that. That's why we're looking at a total system here.

More recently, several horses died in Puerto Rico. Really never did figure out why that happened, and even more recently, didn't -- so recent it didn't make the slide, several cows died in Hawaii for no real apparent reason. We looked at all the feed and everything else and really could not put a

handle on why it is. So there are surely things out there that we do not know about. Next slide.

And I think this is almost the last slide. What we saw -- Those of you that attended the first public meeting -- and there's a number of you in this room -- Dr. Sundlof, our Center director, said at that time, The feedback you provide is absolutely critical to making this system work, and that's true, and if we think back to, like, the, the slide with the dogs and the people on it, that's sort of the feedback we're looking for today.

We need your active participation. I know breakout groups can sort of be trying and things like that, where you're actually forced into a group and, you know, forced to interact with people and provide your opinions as to put -- sitting in a room with 200 other folks and just sort of being an anonymous person here. So we -- I really encourage you to actively participate in this. We want your views. We need your ideas. The people that are in the groups with you surely can, you know, help you

draw those out. You can draw theirs out. We need your feedback in order to develop -- further develop the Animal Feed Safety System, and the only way we're gonna get that is if you actively participate today. Sitting there is not what we need. Next slide.

And finally, I'd like to thank you to (sic) coming to this meeting, and I don't have the agenda, so I don't know who I should introduce next. George?

FRAMEWORK BY GEORGE GRABER, Ph.D.

DR. GRABER: In my haste to, to introduce Dan, I missed the last slide. Some important information on there, so -- Okay. As I indicated, there'll be a facilitator for each of the -- each of the breakout groups, and the people facilitating are an organization here in, in Omaha called planitOmaha, and those were the people who stood up in the back of the room.

One thing I did want to point out is, is that we are taping this session this morning and tomorrow morning's session, and that information then will be transcribed and placed on the docket for the -- the FDA docket for

this meeting, and in your packet, there's a card that identi -- Inside the bottom -- Inside your packet, there's a little -- one of the business cards that has the docket number on it. Should you wish to submit comments at the docket, you could do that at any time. There's no closing point -- no closing period, at this -- at this particular stage, with regard to that docket.

Now, one thing we will not be doing, we will not be taping the programs -- the breakout groups this afternoon, so there is -- there is no tape recorders in there, so people are free to speak. Nobody is taking notes other than yourself, other than the group in terms of reporting back, so . . .

Okay. Let's move on to -- I'm gonna go through the framework document a little bit now. We'll be taking a break, I guess, around 9:50, and we'll have coffee and -- outside there, so for those of you who need the caffeine, if you can wait a little bit, appreciate it.

Okay. Dan went into this a little bit, why this public meeting, and one of the

things we had said at the meeting in Herndon, Virginia, back in September of 2003, that we wanted to make this as transparent a process as possible, and that -- You know, that becomes somewhat difficult for, for the federal system to comply with that, but one of the reasons for having this meeting, one of the reasons for putting the draft documents up on the -- in the docket were, in fact, to get -- solicit comments.

And so we are presenting, in stages, the work products that we have developed as a group, and I'm a firm believer that while this -- the work products that you have in your packet and you're gonna hear about today may represent close to the best product we can develop, we don't think it's the best product that will be eventually developed, because we don't have everyone else's input at this point. So that's -- It's fairly important for us to get that input and ideas and concepts, so --

And one of the things -- One of the reasons for coming out here, as Dan mentioned, was to get -- to get a wider section of people to come especially, and one of the things we

tried to do at -- by coming out here is, is -- We've always had good attendance from the feed side. We were trying to get more producer groups to this meeting, and we think we've gotten a few to come to this meeting that, that hadn't been at the meeting in Virginia, so . . . And we also can -- You know, we want to see continued stakeholder input. Again, that's why the information about submitting comments at a docket, because, you know, even now, this thing isn't over when this program is over. We're gonna continue to work on this. Okay. Next slide.

Again, the objective of the Animal Feed Safety System is to develop a comprehensive risk-based system for feed manufacturer distribution and use, with the goal in mind of minimizing the risk to both human and to animal health. It's a long-term project. It's one that we started two years ago, and right now, the, the work is supposed to be completed in the year 2007 -- fiscal year 2007. A lot of that'll depend on what, what products we eventually decide to work on, and you've got some indication of that in your

packet.

The Animal Feed Safety System Team is made up of 22 members. They're -- On the next slide is the list of all the people. 20 of the 22 members are here at the meeting. You'll -- There's -- gonna be making presentations from -- some are making presentations from here this morning. They will also be in your breakout groups, and they represent -- A lot of the people are from the Center for Veterinary Medicine. We have somebody from the Office of the Commissioner, who is serving on the team, and several people from our Office of Regulatory Affairs representing the Kansas City district and, and also San Francisco, and we have several -- two state people on the -- on the team representing Kentucky and, and Wisconsin. Okay. Next slide.

Again, the idea is to develop a comprehensive system that's -- that covers -- It's just -- It's not just regulations that it covers. It ties together issues dealing with policy, guidance, programs in general. One thing I, I believe there, there seemed to be at least a great deal of misunderstanding is that

we're not really starting from scratch. I mean, we're not starting from a -- with a blank sheet of paper. We've been in the business of -- "we" being FDA -- been in the business of regulating animal feed for many, many, many years and have a long history here, and the states, likewise, have had a long history of regulating animal feeds, but what we're trying to do is identifying the gaps that exist, the things that aren't in place at the present time, to make the system more comprehensive. Again, that's why the definition of "comprehensive" is, is very important. And the idea of -- also, to introduce the concept of risk into, into decision-making within the agency. Again, that's not new. The agency has always used risk, but we're trying to do it in a little bit more systematic manner now.

In the -- In the framework document that's in your packet, we've identified seven, seven operating principles that we thought was important to, to put down on a piece of paper to ensure that -- ourselves that we were clear about what it is -- where we were going and what our responsibilities are, but the -- It's

the industry's responsibility. It always has been. And I know -- You've said it yourself for, for years, for -- responsible for, for making a safe product and distributing a safe product and using a safe product. That's not the FDA's or the states' responsibilities. Our responsibilities are to ensure that process is working. Do that through various ways. Regulations is just one way. Guidance documents, education, conducting inspections. The oversight capacity is, is what the government's responsibilities are.

Within the Animal Feed Safety System, while we're speaking almost entirely of it being an FDA program, I think just about everybody in this room recognizes the responsibilities and the -- and the cooperation that, that the states and the agency have, and it's very important that we continue to have a real strong, robust federal/state cooperative program. It's really paramount.

We're also talking about that the program will continue to have the various basic features that exist today. There may -- The ratios of some of these may change, there may

be greater emphasis in some areas than others, but we'll continue to do inspections. We'll continue to do label reviews. We'll continue to check for guarantees. We'll do sampling and checking for contaminants. But like I said, within the Animal Feed Safety System, you may end up with more focus on safety and less on, on economics, but that doesn't necessarily mean that economic issues are gonna disappear.

We've indicated also that we're gonna -- You know, the agency has -- does not have finite resources, very limited number of resources, and the idea is to try to focus our resources on, on those issues that are the most -- offer the most risk to, to human and to animal health, and we hope to be using the risk-based decision-making, and you'll hear more about that today, about -- a little bit more about how we're gonna go about doing that. And where feasible, we -- we're going to introduce feed security measures as they relate to the counterterrorism ex -- situation that we're currently going through and will continue to, to happen in front of us for -- probably for years and years to come.

Okay. The four components -- what I'll call "structural components" of the Animal Feed Safety System -- deal with having safe ingredients, ones that are -- been found to be acceptable for use. There are limits that are established for the various contaminants that could find their way into animal feed. The -- We have a processing control, an important component of, of the system, and then from the agency's aspect, there is the regulatory oversight. So these are sort of the four cornerstones of, of the Animal Feed Safety System.

And from the viewpoint of regulation, and just using this, this as an example, you have -- For ingredient acceptability, you have -- In the Code of Federal Regulations, Title 21 is the Food and Drug section of the code. CFR stands for the Code of Federal Regulations, and Part 573 has the issues dealing with, with food additives, and it has the listing of, of the food additives that are approved and gone through a formal review process. And then this section here, 21 CFR 73, has all the color additives that are

approved for use in human food and animal feed. Then there is -- An example here, there's the prohibitive proteins regulations dealing with prevention and spread of -- potentially, of BSE.

For contaminant limits, salmonella, there's a regulation for salmonella in the Code of Federal Regulations, again, part 535, and that's -- For those, those of you who don't know, that, essentially, has been on the books for over 30 years.

And then we have process control regulations, the medicated feeds. "G" -- Good manufacturing practice regulations are in 21 CFR 225, and low-acid canning regulations are in the human foods section of the Code of Federal Regulations.

So these are examples, at least for the first three structural components on the regulation side, again, indicating that, you know, there are things in place already. I mean, again, we're starting from scratch.

And as Dan mentioned, the -- and I've said before, the first public meeting we had back in September of, of 2003 was in the

Washington area, in Herndon, Virginia, and we had, probably, a comparable turnout for that. There was -- It was quite rewarding. We had what I thought were some excellent presentations and great feedback from, from the breakout groups, and, and we utilize that in, in developing the draft definitions for comprehensive and risk-based and the essential elements of any process control system that we, again, announced back in 2004, and then this meeting here, we're, we're looking for a repeat in terms of productivity.

And, and I know that the framework document, you've had an opportunity to look at and, and read. Whether you've taken that opportunity is another story, but the risk-ranking situation, you'll be -- hear some of that this morning for the first time, so stay tuned. Be alert.

The four structural components and the terminology that we've used in the framework document is -- are the ingredients in the approval process: limits for animal feed contaminants, process control for the production of feed ingredients and mixed feed,

and then the regulatory oversight component. And the basic framework or the basic format for each one of these components that are in the -- in, in -- again, in your handout, we have an objective, a scope, a short description of that particular component and then what I call the process prescriptions. Where -- In the Code of Federal Regulations or in the AAFCO book or wherever, where can you find the information that we're talking about? Where, where are the processes that lead to, for example, safe animal feeds? And then there -- Where are they -- Where are they described -- The process for going -- for, for developing safe animal feeds, for example, then the listings, where are those listings? Where can you find the listings of, say, feed ingredients? And then last but not least is the gaps -- the things that we've identified as, as -- at least at this stage, that need to be developed in order to make the system comprehensive.

Again, these are drafts. We're really looking forward to a good discussion about, about the gaps section, and that's, to a large extent, what the breakout groups will be

focusing on. There are some specific questions and, again, presentations this morning -- later this morning we'll be getting to, to give you some insight as to what those gaps are and how to go about working on the breakout groups.

Okay. Timewise, let's see where we are. We may have time for a question or two. Let's see. 9:02. Yeah. We got a couple questions -- couple time -- minutes. I'm sorry. We got a couple minutes. Barbara? Somebody right behind you.

MR. NORTHRUP: Arnold Northrup, Garvey Processing. I agree that we're not starting from scratch, those of us in the feed industry, but some of those brought in by the term "comprehensive" are really starting from scratch, producers, as well as transporters, and I'm wondering how you're gonna catch them up to speed and who's gonna do it.

DR. GRABER: Well, I think this is a start. We're obviously -- You know, we've got some people here at the meeting. We're gonna have to work at that to, to get some of these groups to come to the table, and we're gonna have to devise some means for doing that,

and, and that may be some of the work that comes out of the breakout groups today, as well.

Question, Tim?

MR. HERMAN: Yeah. Tim Herman, Office of the State Chemist. How do you feel that the gaps identified by AFSS line up or align with the recent GAO report?

DR. GRABER: Which, which GAO report?

MR. HERMAN: As it pertains to BSE and the gaps that were identified there.

DR. GRABER: BSE? You're talking about the BSE report, or are you talking about the Animal Feed Safe -- animal feeds?

MR. HERMAN: Well, the one that was on the front page of --

DR. GRABER: Oh, okay.

MR. HERMAN: -- Feedstuffs here --

DR. GRABER: Okay.

MR. HERMAN: -- last issue.

DR. GRABER: Last, last issue? Yeah, I haven't seen that issue. Okay. Well,

I -- You know, I think the -- There is a group, you know, within the agency. Obviously, it's working on, on BSE, and that group will continue to work on BSE, and whatever gaps were identified there, we'll try to fill, but for the most part, we thought that the, the gaps that -- or at least the issues that were identified by GAO, the agency has been working on. We didn't totally agree with all the, the items identified by GAO, and, and we -- and our responses, which are part of the record, part of the GAO report, do identify where we agreed and where we disagreed, so . . . This particular group is not gonna be focusing purely on BSE. The Animal Feed Safety Group is, is working on some other areas.

Got a question up front here? Hold -- Wait up a second, sir.

MALE VOICE: In this global economy, how can you walk this narrow line between emotional response and scientific-based -- risk-based responses?

DR. GRABER: You got any clues? I, I think -- I think you -- I think we have to -- You know, we have to be realistic. We're

gonna try to be as, as scientifically oriented as we possibly can, but I think we all have to recognize that there are other factors that weigh into decision-making, and, and that's just the reality of things in this democratic society. There are political issues. There are trade issues. I mean, the BSE is an example of one that -- where all these other factors play a role. But I think, for the most part, you know, as -- at least -- at least from, from where I'm standing, we're gonna try to be as scientifically oriented in our decision-making as we can.

Okay. We've reached 9:05, and the next presentation is by Shannon Jordre, who is with our Division of Compliance, and he's going to be covering the "comprehensive" definition. Shannon?

"COMPREHENSIVE" DEFINITION

BY SHANNON JORDRE

MR. JORDRE: Go ahead. Oh, thank you, Ferris. Well, I can see there'll already probably be some questions about the definition for "comprehensive," and so if we get some time, we'll, we'll try to respond to

those more specifically.

I'd also like to take this opportunity to welcome everyone to Omaha. Thank you for, for coming to our meeting. As you know, this group, the Animal Feed Safety System Team, has been working for a couple years now, and we've, we've been referring to our program as a "comprehensive" or as an "umbrella-type" program, a way to approach feed safety. Well, I worked with a small team of people to try and flesh out what we mean by "comprehensive," and that's what I'm gonna report on today.

Webster's -- As you can see on the screen, Webster's defines "comprehensive" as covering completely or broadly and inclusive. The Webster's definition is really very simple, and although it's simple, it really doesn't say anything about animal feed or feed safety, so we try to customize this definition a little bit to suit our purposes here. Go ahead, Ferris.

And just to -- And to throw in a little humor here, here is a group of inspectors touring a feed mill, and they're

wondering if their hard hats provide comprehensive protection from the pigeons that are sitting up on the tower at that feed mill, and -- not unlike the -- kind of, the, the program we're discussing here. We've got -- We've got all kinds of rules, hard hats in place, if it were, but do they cover everything? And that's what we're trying to -- trying to work out here. Go ahead.

So what is a comprehensive Animal Feed Safety System? We did public a draft definition on March 31st, 2004, in the Federal Register, and through this series of slides, I'll try to lay out the, the concepts we thought should be incorporated in a draft definition, make a few comments about each of those concepts and, and perhaps highlight some of the comments that we've received to date.

So the Animal Feed Safety System, or AFSS, as we call it, comprehensively would apply to the whole range of feed products, including all ingredients and all finished feeds, and as we just heard a minute ago, some feeds and some feed ingredients are produced outside of our traditional feed-controlled

jurisdiction. Other materials may never make it into commercial commerce, for example, and may not be subject to state feed laws. In order to provide a seamless system, it will be necessary for us to identify exactly where our authority stops and where the authority of other regulatory agencies start. Some of these other agencies might be USDA, EPA, the Department of Transportation and, of course, the state regulatory agencies that we work with all the time. Go ahead.

The Animal Feed Safety System would require the use of ingredients that are approved and/or recognized by an established mechanism of an appropriate regulatory agency, so this would be FDA, this would be the state feed-control agencies. You cannot have safe feed without safe ingredients, and how does someone know whether an ingredient is safe unless it has gone through some type of -- some type of approval or recognition process? We intended for this concept to include ingredients that have been approved by FDA, those, those ingredients that have been defined and are listed in the AAFCO publication, and we

know there is a number of other processes that are also available.

We did receive some comments. People said, Well, don't forget about grass notification and things, and we haven't. We've -- Just in generic term, we feel that those processes were already recognized by FDA. We don't need to, at this stage, anyway, go into too much more detail. Go ahead.

Facilities and equipment. We think the AFSS would cover the complete range and variety of facilities involved in animal feed production. This concept would apply across the board, from small on-farm feed manufacturing operations to large multinational corporations. All facilities and equipment that would be used to manufacture and distribute feed would be covered.

Now, historically, some of these industry segments have not systematically been regulated, and some of these operations may not be aware of the requirements that are already in place that they are supposed to be meeting, so we do recognize that there will probably be quite a bit of an educational component to the

Animal Feed Safety System, and I think, in general, the comments that we did receive pretty much agreed with us, although they did say we need to make it a little more clear that we're gonna cover transportation, make sure that you talk -- that we're -- we plan to cover the farm, as well. Go ahead.

Flexible. The AFSS should have the flexibility to be process- or product-oriented, depending on the situation. I guess our team felt that we can't predict the development of new processes or new products, and it is not our intent for the AFSS to be overly prescriptive, and, and we don't intend to dictate a particular approach, such as HACCP or any other particular approach across the board, but we're not sure what other types of control systems may be available, so we're very interested in receiving your comments on this particular component. Even within our team, we're -- we had some discussion back and forth as to what, what is process-oriented -- or -- Well, we know -- We, we think we know what the process-oriented controls look like, but product-oriented, we had some discussion as to

what that might mean. So we're very open to your comments on that.

All animals. The AFSS should address feeds produced for food and nonfood animals. And why, might you ask? 'Cause we're not eating cats and dogs or other pets. Well, it, it boils down to simplicity, at least from our perspective. Most of the feed ingredients are used in a wide variety of species' feeds, and for consistency and ease of implementation, we feel that the AFSS should apply, across the board, to all feeds.

Hazards. The AFSS should cover all known hazards and be applicable to hazards not yet identified. And if there was some heartburn expressed in the comments, this was probably where most of it got expressed, and I don't say that in a bad way. People did express their nervousness with our use of the terminology "hazards not yet identified." Well, how can you -- You know, how can you make us address hazards that have not iden -- been identified yet? And someone else said, Well, if you mention the word "all hazards," aren't you being kind of absolute? And that's a good

point. I guess our intent here is that we just -- we just want the AFS -- the AFSS to be as robust as possible, to be well designed, to accommodate as wide a range of potential hazards as possible.

Now, the question has come up: What about acts of vandalism or terrorism, things like that? And although we certainly may not be able to anticipate or stop every act of terrorism, for example, we do think that if we have the AFSS in place, it certainly should provide some degree of mitigation and help the situation.

Health protection. The AFSS would address both animal and human health issues. The system we have in place now seems to do a pretty good job of protecting human and animal health once the problem has been identified; however, we think -- we think we could develop a more systematic approach that may allow you to predict where problems may occur and help prevent those problems from occurring.

Regulatory oversight. The AFSS would acknowledge and coordinate regulatory oversight at all levels, including local, state, tribal

and federal, any agency who is involved in feed safety. As, as a follow-up to this, it will be necessary to identify the agencies involved and the extent of their authority, and, and we feel it will be important to coordinate with these agencies rather than to dictate to them.

We did receive several comments that suggested that we not forget that there is currently a program in the works that we call Voluntary Self-Inspection, or VSIP for short, and we're working on trying to get the pilot for that going. And we certainly don't intempt -- or intend, I should say -- We don't intend to, to, to bypass that, that project.

We have received some additional comments, and I guess I should say we have not been inundated with comments, those of you who have looked at the docket. We have not received a vast number of comments, but the comments we have received have been excellent. Very, very good comments. We did receive some additional comments from a few people. I, I thought I would note these, these two comments in particular: That we should conduct research to ensure hazard determination is based on

sound science; and that we should facilitate access to diagnostic tests that will support the AFSS. These are not things that we wrote into the program, but certainly, they're things that we have to keep in mind, and that's one of the things that we hope to get out of this meeting, as well as people commenting to the docket. Please send us your, your ideas. These are very valuable comments.

So thank you for your attention this morning, and we do appreciate your help as we journey into this new territory. We're on time.

DR. GRABER: Yeah, we're on time, but we'll take -- I'll take one question, if we have one.

Okay. Next on the program is Dr. Barry Hooberman. He is with risk -- he's a risk assessment manager in the Office of New Animal Drug Evaluation in CVM. He is going to be talking -- The agenda has him down talking about "risk-based" definition and risk ranking. He'll probably be covering more on the risk and risk ranking, and the "risk-based" definition will be covered a little later this morning in

Karen Ekelman's presentation. Anyhow. Barry?

"RISK-BASED" DEFINITION AND RISK RANKING

BY BARRY HOOBERMAN, Ph.D.

DR. HOOBERMAN: Okay. Thanks, George. And since this is the first time a lot of this will be presented, I'm sure there's going to be more than a few questions. Go ahead. And, and that's part of the purpose of this talk, is to try and set a background or a framework for the whole risk assessment process and trying to set it up for the breakout groups that will happen later this afternoon to answer a lot of your questions. So this is a brief overview of what I'm gonna try and talk about today, and we'll try and answer these questions: Why are we doing this? What about risk? What is it? What's risk assessment and risk ranking? And then: How are we going to apply a risk-ranking approach to the Animal Feed Safety System?

You've heard of this before, but I pointed out a few things in here that are particularly interesting for this talk: to develop and implement a comprehensive risk-based preventive Animal Feed Safety System

that minimizes, reduces or eliminates the risk to animal and human health. So we have already heard a little bit about the comprehensive aspects. I'm gonna talk about the risk-based, and part of the advantages of a risk-based approach that we're using is that we'll cover a preventative or preventive approach, and, of course, the goal is to eliminate the risk to both animal and human health.

So why a risk-based approach? I'm a firm believer in the first point, which is that risk assessment provides a structure. It -- All it is is a logical process for collecting, organizing and analyzing information to inform a risk decision. This is what often is referred to as a sidespace decision-making. A risk-assessment approach also can be used as a forecasting process, and this is the prevention -- or the preventive approach we talked about before: trying to prevent illnesses, predict where illnesses, adverse health risks could occur. And again, I think it provides a structure to -- for discussions between decision-makers, stakeholders and the public so everybody is on common ground and can have a

good discussion. Keep going.

So just to point out what risk assessment is, everybody goes through this every day. You're gonna ask yourself: Can I cross the street safely? And just to point out a few things, the -- in this scenario, the cars are the hazards that you want to avoid. Exposure means when you walk out in the street, you're gonna be exposing yourself to the hazards, and, of course, there are consequences if you don't do that properly, which -- and that is a tombstone down there. That's not to say death is the only consequence.

So putting that in more of a formatted approach, risk assessment poses four simple questions: What can go wrong, and we call that the hazard identification; what are the consequences, which we call the consequence assessment; how can it happen, which is the exposure assessment; and then what is the likelihood that what could go wrong does go wrong, and that's where we put it all together and try and come up with an estimate of risk. And you can put that in an equation format.

Risk is a function -- some function

of hazard and exposure. Again, the hazards here we're talking about are the health consequences, which are composed of two components there: the severity of the health consequences, which can be anything from slight skin irritation to decreased feed consumption in animals to death; and then there's also something called potency, which is: How much of, of the exposure to the hazardous substance do you have to have in order to cause the illness? And then the exposure side of the equation just talks about: How, how are the routes of exposure? How are you gonna be exposed, and what's the likelihood that you are gonna be exposed? And that can range anything from improbable to common.

And, of course, risk assessment is not the end of the story. Layered on top of that is risk management. In other words, somebody is gonna decide: What are we gonna do about the risks that you've talked about? Risk management asks these kind of questions: What can be done, what options are available, what kind of risk trade-offs in terms of risk benefits and costs, and what are the impacts of

current management decisions on future options? Now, you can put that all together in what we call risk analysis, and here's a brief sketch. First, you define the problem, which is kind of your hazard identification. You do your risk assessment, and we -- Being bureaucrats, we have to write a report, so you write your risk assessment report, which may outline a few options for the risk managers to determine what they want to do. The risk management makes some decisions, and then the final aspect of risk analysis is to communicate what those risks are and what the risk management decisions were to the -- all interested stakeholders.

And, of course, an important feature is once you implement the risk management decisions, it is iterate to process as more data becomes available. You can repeat the risk-assessment approach. In this case, they installed a walk/do-not-walk sign, but nevertheless, the person crossing the street still has got to do some figuring out if they can do that safely or not, and then you can determine how effective that risk management

decision was, and if not, then you go back through the cycle, and you come up with something else, hopefully, that will reduce the risk of being hit by a car.

So now we're talking about what risk ranking is, so you can identify a bunch of risks from individual hazards, and those are represented by all the different circles. You have different-sized risks. And then you go through, and, and when you rank the risk, as you see here, the -- rank in terms of worst risks on the top, the bigger circles, to the lower risks.

And, of course, there's another aspect to this. Should go -- There we go. Risk management is gonna weigh in, in the order that the risk assessors may put things in, in terms of lower to greater risks. When it comes to actually doing something about it, the risk managers may determine a different order, depending on, on what kind of values they have, cost-benefit analysis, those kind of things, so the management order could be different than the straight risk order.

Okay. Now we're gonna move into what

we want to talk about, which is the risk-ranking procedure, and I just want to put up this caution: That a lot of times you hear about risk assessment, you hear a specific risk, like one in a million or something like that. We are not doing that. The risks that we are ranking are relative risks, and that's what we are concerned with, so nobody is gonna say, The risk of this particular hazard, dioxin or BSE in this particular feed, is one in a hundred thousand. We are not doing that. All we are talking about is relative risks.

So we'll go through the four steps and the way we are going to implement them in our risk-ranking procedure. Of course, the first step is the hazard identification, answering the question: What can go wrong? What we've tried to do is go by the guiding principle on the bottom there, is we're trying to make it as simple as possible, 'cause we're realizing we're starting with the -- with what we're calling "the universe of risk," and there may be additional risks that become identified, but at this point, we've categorized the risks into chemical, biological or physical hazards,

and then within those categories, we're grouping them together to let us get a better handle on things and not be bogged down by the details of each specific risk, and then, of course, within the groups, we're trying to group further to talk about hazards with similar characteristics. And the next slide shows you kind of the approach we're taking.

We've talked about the three different types of categories: the intentional -- I'm sorry -- the physical, the microbiological, the chemical. I'll also say that we've divided 'em up into unintentional hazards and intentional hazards. Part of that is -- The intention, of course, is the agroterrorism that has generated a lot of publicity. And a lot of the identified risks in there actually mirror what's in the unintentional category.

Then -- As I said, so we have the three different types of risk in the un -- I'm sorry -- hazards in the unintentional category: physical, microbiological and chemical. Then, for instance, you can split out the microbiological into different groups. You

have bacteria, viruses, fungi, (inaudible) mycoplasma and others, and then within those groups, on the next slide, you can kind of group hazards into things with -- hazards with similar characteristic profiles, such as salmonella, and realizing that they are not the same but also realizing we are trying not to do individual risk assessments on every single hazard in every single feed. Okay. So that's the first step.

Moving into the second step is, now we're going to try and analyze: What are the consequences of exposure to these hazards? So the health-consequences step has two factors. I mentioned that before. The first is likelihood of the illness. If you're exposed to the hazardous agent, how likely is it that you will become ill? This was kind of the, the potency argument -- or statement that we talked about before. It may be referred to as "potency" of the hazardous agent, the amount of hazard required to cause the illness or adverse effect. The other component of health consequences is the severity of the illness. If you become ill, how severe is the illness?

Are you gonna die? Are you gonna -- Is it just gonna cause vomiting, or is it just gonna be a light skin irritation?

And before we move further, I'll say that we tried to put some of the background slides in all of your packets, just generally talking about the principles of risk assessment. I happened to pick up a packet today that did not have it, so if you don't have it, don't worry. All the slides are avail -- will be available on the Website, I think, from all the talks; right?

Okay. So the health-consequence score, we said, was a combination of likelihood and severity. You could combine 'em in this type of approach, where a high severity -- and, and the colors are slightly off, that was intended to be red in the upper square -- goes with a high likelihood, medium is not so much of a concern as the high highs, and lows are lower concern.

You can -- Go to the next slide. You can put it -- How is this gonna look numerically? We're gonna rank -- give it a health-consequence score from 1 to 5, and you

could say the 5s -- We've put a column of 5s on the right -- And this is just an example of how we're -- one approach to doing this. In this approach, we're saying, Well, if it's gonna cause a high severity or death, we're concerned about it no matter if it's a low probability of it happening or a medium probability of it happening or, of course, a high probability. We're gonna try and prevent deaths.

Then scores, if it's a -- Well, you can see the chart, but if it's a high likelihood, even though it's a low or medium severity, you can give it a 4, and then, of course, going all the way down to the bottom, if it's not very likely and it's a very low health effect, it's of least concern, and it'll get a score of 1. So the health-consequence scores will be developed for both animals and humans. We're concerned with both animal and human health.

The scores for the chemical agents may be based on existing health standards. I mean, there's a lot of ADIs that have been developed -- that's acceptable to acceptable daily intakes -- that come from FDA. EPA has

something called RFDs, which are their reference doses, which define a safe exposure level or other kinds of health standards, and there's a lot of those established already for many of the chemical agents that we're concerned with.

The scores for the physical agents are likely to be higher for animals and humans. In this case, you can almost look at animals as kind of a filter for the physical agents. It's never gonna make it to humans. I'm talking about rocks, glass. Those kind of things are not gonna pass into the human food supply. Or are unlikely to.

And then the scores for the biological agents are a more difficult challenge. There's a lot of work in trying to figure out how much of an exposure to E. coli is going to actually result in a health consequence, and how severe is that health consequence going to be? I mean, that's something we're still working on, as are a lot of people, not just us, but we will make a stab at it.

Moving to the third step in risk

assessment: How could it happen? This is the exposure assessment. This is a more difficult challenge than the health-consequences score. What we're trying to do here, the approach we're taking is to identify the source of each hazard entering the feed process. In other words, starting at the very beginning of the -- of the chain of manufacturing the feeds, what are the potential hazards that are going to be present, and at what levels? We're gonna work through the chain by following the second bullet point: Feed ingredients will be leaked -- linked to each hazard they may contain, resulting in a set of ingredient hazard pairs for each ingredients. In other words, we're gonna worry about -- From corn, we're gonna worry about aflatoxin. From clay, one of the hazards we're worried about is dioxin.

So for each one of these pairs, we're gonna start out with the initial -- trying to figure out what the initial level of hazard is and then feed ingredient or feed, and that's gonna depend on a number of conditions: environmental conditions, moisture content, those kind of things; human activities, which

would work for pesticides and things like that; the source and type of contaminant and the source and type of feed ingredient. All those will factor into what the initial level of the hazard is in the feed ingredient.

So we're gonna give it an initial exposure score based on what we think is there. Most of the -- We have -- We don't have a lot of data on these initial levels. We'll be relying a lot on expert opinion and input from knowledgeable sources, which may include you, in trying to estimate that initial exposure score. We do have data when available. Measure data, salmonella contamination data, we have some of that, but we'll rely on expert opinion.

And then we also realized that, as it goes through the feed manufacturing process, things may change in terms of things that may impact -- The processing may impact the levels of those hazards in the feed, so we're gonna apply a modifying factor to that initial exposure score. We're talking here things like, if it's a high-heat process, you may reduce or even eliminate the levels of the

bacterial contaminant, so we want to make sure we incorporate that, so we would be reducing that initial exposure score for that contaminant -- for bacterial contaminant in that process. Manufacturing processes include transportation, storage, steps and feed manufacturing and on-farm processes.

And I'll apply one last thing. We are gonna also -- Remember our simplified principle. We are gonna try and combine those manufacturing processes into groups, as best we can, that represent similar conditions of processing.

So then you'll come up with a final exposure score based on the initial exposure score modified by -- using modifying factors from the manufacturing processes. And we talked about the second example there, so next slide.

So finally, you have the fourth step in the risk assessment, which is estimating the risk. What's the likelihood that you're gonna have a sufficient hazard, in your final feed, that's gonna pose a high risk? So the way we're gonna get it is relative risk score.

Remember, we're only talking about relative risk. As for each of the ingredient hazard pairs we talked about, the consequence score, which is the health-effects score, will be multiplied by the exposure score to yield a relative risk score, and it doesn't necessarily have to be a multiplication. We are doing that so we get a big spread of scores, so we get differentiation between low risk and high risk. You could possibly just add 'em, you could do a number of other functions, but we're trying to maximize the spread. For example, the consequence scores and exposure scores may range from 1 to 5, so when you multiply, you have a range of relative scores from 1 to 25, and hopefully, that will give us a good spread.

And then, of course, the interesting factor is: How are we gonna use those relative scores -- risk scores? As you can see from the list, these are some of the things we're talking about. When you have a higher risk contaminant, I mean, do we need to establish limits for that? And in particular, which contaminants do we need to establish limits for? Do we need to develop analytical methods

for some of the higher-risk contaminants? If we find common higher-risk contaminants in a lot of feeds, perhaps we need to talk about trying to change the manufacturing process so that risks go down a little bit. And then, of course, do we need to develop better surveillance or sampling plans to ensure compliance with existing contaminant limits or ones that we may propose?

So just to summarize what we've done, we've identified the hazards by grouping as best we could. We come up with a consequence assessment using the -- a consequence score, which is a function of severity and likelihood, combination of those two factors. We've tried to come up with an exposure assessment by starting with an initial exposure score that's modified by factors in the manufacturing process that may reduce or increase that exposure to the hazardous agent and then combining 'em together to come up with our relative risk ranking.

Now, there's a lot of limitations to this approach, and I'm sure a lot of you have already identified them, but I'll just go

through a couple that are obvious to us. You could either take two approaches: You could take a top-down or a bottom-up approach. A top-down approach would say, for example, that you start with an observed health effect, like we know people are getting sick from a specific contaminant, and we know the incidents of that sickness. We could work our way from there -- go through the feed supply to try and consider the source, or you could also take it down a notch, and you say you start with your final feeds, and we know there's a high contaminant level in a final feed, and we want to identify the risk, work through -- work -- what's causing that high-risk feed to occur.

So -- One of the benefits of that kind of approach is that it does focus on the point of concern that's closest to what we're worried about, is the health effect. The problems with that approach is that we don't have a lot of data to support it. We don't have -- And this is a credit to everybody, that we don't have a lot of health effects from animal feeds, and we don't have a lot of data on potential hazards in final feeds. So that,

that really limits the usefulness of this kind of approach, and this kind of approach also would be difficult to use as a preventive tool, which is, of course, one of our goals of the Animal Feed Safety System. It's a hit or miss. I mean, it's a one-shot deal. We're worried about this specific hazard, and let's find it, and -- as opposed to a bottom-up approach, which is one of the -- we are -- decided to implement, where you start with the sources of hazards, and you work through the system to come up with your relative risk to health. The benefits of this approach is that you do get to incorporate the complexity of this system. It also makes it more difficult to do, but it does incorporate the complexity. It does permit isolation of specific problems. If something crops up, you can go back through everything you've laid out and figure out where that problem could be -- the source of that problem could be, and therefore, it does allow a preventive approach.

The problems is (sic) that it requires a lot of risk assessment for each hazard, and like I said, we're trying to group

the hazards, so we don't have to do that many, but it is a more involved process, but that is a function of the complexity of the whole system.

Another limitation to using a risk-ranking method and the one that we are implementing, which is a -- You can call it a semiquantitative method, in that we're scaling things on a factor of 1 to 5. This kind of approach or methodology pushes most of the insignments into the middle of the range. You're gonna get a lot of things, we said, from 1 to 25. You're gonna end up with a lot of 9s and 12s. A lot of things are gonna come out as 3s (sic) times 3 is 9 or 4 times 4 is 12 -- 16, in that middle range. So you don't have a lot of distinguishment between intermediate risks. For example, how do you handle kind of a serious acute effect, like a severed finger, versus a mild chronic effect, which is a long-time health effect? They might come out with a similar score, and that's something that is a feature of this type of approach or a negative aspect of this type of approach.

It also doesn't distinguish between a

high-exposure/low-consequence event versus a low-exposure/high-consequence. The -- When you multiply 'em, those two things are gonna come out the same. That's why we're working hard to try and make sure we have a range and we can differentiate between those kind of scenarios.

And then a final limitation is one that's common to risk assessment, is data, or lack of data. This is primarily an issue in the exposure side of things. We don't have a lot of measured data for many of the hazards, so -- which means we're gonna have a strong reliance on expert opinion, not that there's anything wrong with that. Expert opinion is a form of data. It's just a matter of getting quality expert opinion, people who really know. I'm not one of those people, but we have a lot of people in CVM who are experts, and a lot of people out there, I'm sure, are experts and will be able to weigh in on the process. So that's an overview of our risk-ranking approach.

DR. GRABER: We've got some time for questions for, for Barry. Can we get the mike -- Hold on one second.

DR. HOOBERMAN: Unfortunately, I went too fast, leaving time for questions, so . . . Sorry.

MS. WAGSTROM: Hi. I'm Liz Wagstrom of the National Pork Board. I have a couple questions. One, in your hazard identification, as you group and, and et cetera, are you gonna look at risk by species of animal fed? We know that there are risks in feed of something that may be a risk to cattle that may not be a risk when it's fed to pigs.

DR. HOOBERMAN: Yes. Yes. I mean, it's not really in the hazard I.D. step. Oh, I'm sorry. Yes. It's not really in the hazard I.D. step. It'll follow through the chain to when we get to the final feeds in ranking the relative risk of feeds. That, that factor will come in. That -- The hazards --

MS. WAGSTROM: Thank you.

DR. HOOBERMAN: -- that are not there in the starting material will -- of course, will not be present in the final feed for that species, so that's where that would get incorporated.

MS. WAGSTROM: Okay.

DR. HOOBERMAN: Did that answer your question?

MS. WAGSTROM: Somewhat, although there may be a hazard there that isn't a hazard for that species; i.e., we know that E. coli 0157, there may be some evidence that feed in cattle may, you know, be a problem in herds that, you know, have contaminated feed. E. coli 0157, while we don't want it in our pig feed, has not been shown to be a hazard when fed to pigs, so --

DR. HOOBERMAN: Sure. And we're not -- Let's not confuse "hazard" and "risk." And just to go --

MS. WAGSTROM: Okay.

DR. HOOBERMAN: -- through this again --

MS. WAGSTROM: Sure. Okay.

DR. HOOBERMAN: -- so the hazard is E. coli, but the risk will be low because the --

MS. WAGSTROM: Sure. Okay.

DR. HOOBERMAN: -- health consequences in that species --

MS. WAGSTROM: Gotcha. Okay.

DR. HOOBERMAN: -- will be low, so we'll work it through.

MS. WAGSTROM: Okay. Cool. Second is, in your exposure assessment, am I understanding that you're trying to link pairs; i.e., corn and aflatoxin? Are you gonna take, then, an average of aflatoxin found in corn, realizing that the risk is the very small percentage that may have high levels versus the vast majority that may have low levels?

DR. HOOBERMAN: Yes. I mean, that is a difficult approach that we're still working on, is how to incorporate seasonality and all those kind of factors into coming up with that initial exposure score.

MS. WAGSTROM: Okay. And within the exposure assessment, will you have any distribution as -- Will you look at your manufacturing? There may be a lower risk for a person with a 1- or 2-ton mixer feeding a small group of animals versus feed and interstate commerce. Will that be in your assessment, as well?

DR. HOOBERMAN: We will try and do that.

MS. WAGSTROM: Great. Thank you.

DR. HOOBERMAN: (Inaudible) our best efforts at that, yes, recognizing that it could be a consideration.

MR. SHERWOOD: I'm Greg Sherwood with Aurora Cooperative Elevator Company at Aurora, Nebraska. The question I have is the use of the term "contaminant." You talked about -- You've used two terminologies already: One was "hazards" in your feed, and the other was "contaminants" in your feed, and the one of the world organizations uses the term "adulterated feed," I think, and I'm a little bit curious to know -- In a world that will sue a company over a hot cup of coffee, I'm a little bit nervous about the use of "contaminant" out there, especially in a low-level environment. It looks to me, from a feed manufacturer's standpoint, that we could lose in court, when we didn't really lose, just because somebody used the terminology "contaminants," when it was really an adulterated feed or a foreign substance that doesn't necessarily go through the feed to the

human.

DR. HOOBERMAN: I understand what you're saying. I'm gonna defer a little bit to Karen, who will be talking about contaminants specifically later this morning, but that -- I mean, it's a contaminant because we don't want it there; right? That's a definition of "contaminant"?

MR. SHERWOOD: So as a -- Okay.

DR. HOOBERMAN: And, and --

MR. SHERWOOD: Okay.

DR. HOOBERMAN: -- there's a reason we don't want it there.

MR. SHERWOOD: Okay. Oats -- Let's see. Copper in sheep feed is a contaminant; right?

DR. HOOBERMAN: Okay.

MR. SHERWOOD: It -- The copper in beef feed is not a contaminant, right --

DR. HOOBERMAN: Right, at --

MR. SHERWOOD: -- at a certain level?

DR. HOOBERMAN: Karen is talking to me up front, so she's gonna be the best person to respond to that question, 'cause she

will be talking later about contaminants; okay?

MR. SHERWOOD: Okay.

DR. HOOBERMAN: Thanks. One more? Do we have time?

DR. GRABER: Oh, yeah. We got two more.

DR. HOOBERMAN: Okay, two more.

MR. ROACH: Yes. My name is Steve Roach. I'm with Food Animal Concerns Trust, and I was -- just wanted to make a comment about the way you described the risk communication. In your -- In your diagram, you had -- you all finished the job and then you need to communicate the risk --

DR. HOOBERMAN: Right.

MR. ROACH: -- and in one of the principles of risk assessment, is there actually needs to be communication through the risk-assessment period, you know, and -- so that you can have inpoll -- input from state polls --

DR. HOOBERMAN: Yeah, I --

MR. ROACH: -- which is the purpose of this (inaudible).

DR. HOOBERMAN: Well, there's a

lot of debate about the extent of that, but you're absolutely right. I mean, it's always good to get input, as you work your way through the risk assessment, from all interested parties. Absolutely correct.

MR. ROACH: And, I guess, in -- sort of related to that is also -- Again, you mentioned a little bit about the lack of data in the end, but that also needs to be incorporated into the risk assessment, because we -- You -- A lot of times the problem is, is that we aren't able to characterize a risk very well. That's really the challenge of risk assessment. If we understood the risk perfectly, then we would know exactly what to do, and I think the --

DR. HOOBERMAN: Right.

MR. ROACH: Again, a lot of times risk assessment is described as a very deterministic process, when, actually, you have to decide all throughout based on the data you have, and a lot of time you don't have it.

DR. HOOBERMAN: Yes, yes, you're right. Although, we are doing the semiquantitative. We're not going through the

full quantitative, where you can put distributions on uncertainty and all those kind of factors, but yes, we will recognize that, and that's part of making your risk assessment a transparent process, is pointing out those kind of deficiencies in the data and where they create uncertainty in your results. Any others? Thank you.

DR. GRABER: Okay. We're gonna take a half-hour break. Be back here at -- sharply at 10:20, and we're gonna spend the rest of the morning going through the structural components.

(A break was taken from 9:50 a.m. to 10:20 a.m.)

DR. GRABER: The program is Dennis McCurdy. Dr. McCurdy will be -- is a member of the Division of Animal Feeds, a toxicologist/chemist. He's going to be covering the first component, the safe feed ingredient component. Dennis?

Oh, before I forget -- What was I gonna say? I forgot it already. Talk about a senior moment. Oh, yeah. The -- A number of the packets did not have some of the slides

that Barry Hooberman used. We apologize for that. We are making copies as you speak -- as I speak, and they will be available this afternoon in the registration area. So for those of you who do not have the slides -- copy of the slides -- there was about 8 to 10 of them -- 8 to 10 slides -- then just pick 'em up this afternoon. Okay. Dennis?

SAFE FEED INGREDIENTS

BY JOHN D. McCURDY, Ph.D.

DR. McCURDY: Good morning. Originally, George was programmed to put this on, but he was deluged with a lot of thing -- had a lot of things to do, so Karen Ekelman sent me an e-mail suggesting that I would -- I should volunteer for this, and that reminds me of a time back in 1968, where I said to someone, I'll do this for you, and I spent some time in a place that we don't want to go to, so so much for volunteering.

But how many remember the Big Fat Greek Wedding, which was on for -- TV for a while? And the father was always equating words with derivatization from the -- from the Greek? Well, how many people are Irish, Irish

descent? I know at least one person here is Irish descent. Anybody, anybody speak the old language -- study the old language? No. Well, the Irish have been all over the world, as far east as Japan, where you have the name Ohara (phonetic). In Japanese, it means big belly, "O" meaning big. But in the West, they came even further west, and we have Omaha. Now, the -- Now, the -- I broke my promise about joke-telling. I'm sorry. But the Omahas are in the west part of Ireland. It's a variation of -- variation of a name.

Anyway, so that's me. Some people call me "John," some people call me "Dennis," some people call me "Mack," you know. My wife has a pet name, but we won't go there either.

As, as Dr. Graber stated and that, that Shannon also stated, there are four components in the framework, and the first component that we're talking about, the agree -- and the approval process, and the approval process for feeds is to be sure that everything in the feed is safe, okay, for its intended purpose. And, and feeds, as you -- as you all know, are not just a source of nutrition. I

mean, there are a lot of things that (inaudible) feeds that come by way of color, color additives, approved food additives, things of tactical effect in -- under approved food additives, along with the grass substance items. So we might find something in a feed which may be an antioxidant or some kind of preservative, mold inhibitor, that may be in the feed. And, and so there are a lot of organizations and processes that may have some kind of an effect on feed and feed ingredients, because the scope of the whole thing is to make sure that all -- that the safety applies to all feed ingredients.

So we have the FDA, our lovely FDA, in which the various components of the Federal -- the Federal Code addresses drugs, food additives, color additives, grass substances, bioengineering things, which are on consultative agreements between the Center for Food Safety and Applied Nutrition and CVM, which are a biotechnology notification known as a BNF file, and that works wonderfully well -- has been working wonderfully well.

Other things going on in guidances

with FDA, things that are taken from bioengineer plants and animals that are used as drugs. We'll skip that, though. We'll come down to USDA and EPA also affecting things that may gone to (sic) -- into animal feed and into animals, vaccines for USDA; EPA, pesticides and other things, such as water treatment additives, that may find a way into animal feed. And, of course, the AAFCO definition process, we'll spend a little bit of time on it.

But these former procedures by the regulatory agencies are -- and you can read that -- are -- can be found in, in 21 CFR. For those of you who don't know what 21 CFR looks like, for our section, I have a copy. It's -- This year, its copy is red, so it's our little red book. You missed that one, huh? Okay. A little side humor.

So those -- You can find grass, grass notifications and what have you in 570, food additive petitions and its requirements in 571.1, and you can find them listed in 21 CFR 573. So that's the way it works; okay?

For color additives, CVM does not

look at color additives. That's done through the Color Additive Petition Group and CFSAN, but that you find everything in 5 -- in 21 CFR, Part 73, and those -- It has those listings for, for, for food and drug color additives, food, food color additives; okay? So -- And as a side note, if you're not well-versed on these things, the, the individual Websites for EPA, USDA and FDA are quite nice ways of spending coffee break time. And then we have also our informal, informal procedures, which result in nonbinding decisions, and we'll go into that part. Can we have the next slide, Abraham?

Since I am an individual to whom you send data for review and evaluation, the AAFCO definition process, which results in nonbinding decisions on, on we, the FDA, are placed in the official publication, and I have a copy of the OP if you want to see some of the things that we've done and what's required. Has included -- Does include a lot of things that are not -- or do not have a written regulation, which would be a food additive petition. Food additive petition would have to be submitted to the agency, or grass petition have to be

submitted to the agency. We would go ahead, and we would do a formal review and evaluation of manufacturing data and safety data and other things that may have to be done and go ahead and publish a regulation. The AAFCO definition process does not result in a formal regulation published in the -- in the Federal -- in Title 21 of the Federal Code. It will be in the official publication of the AAFCO. Can I have the next slide, Abraham?

Okay. So that leads to a major -- a major gap. That -- Not the only one identified -- or could be identified, but it's the one that we have identified, because we work so closely -- at least our shop does -- work so closely with, with AAFCO in preparation and defining of some of these feed-additive ingredients.

The difference between the AAFCO definition process and a full formal FAP, or food additive petition process, is one in, in -- in -- one in which we ask for similar kinds of data, but the review process is one in which we have relative -- relatively little safety concern about the material that's being added,

added to the feed; okay? If, in the process, we do discover situations or an issue where it's of, of, of safety concern, then, then, of course, the next -- the next move would be for a food additive petition, 'cause we wouldn't go -- we wouldn't go this route, but we've been very successful with this route over, over the number of -- over a number of years.

The -- What happens here is, though, the AAFCO is not the title -- not Title 21 of the Federal Code, so there is no federal regulation published -- written or published; okay? It only -- It only appears in the OP, but when we go to look at writing an Animal Feed Safety System as a formal title regulation, then these -- then this bounce -- this bounces up to each other.

So what we need to do and are planning to do is to go ahead and clarify, in a compliance policy guide, as to this relationship and this situation, and it has even, even a reference that maybe a regulation should be published, but then again, there may be a legal conundrum there, too, so . . . That's, that's the one, one gap we'll -- that

we've identified. I spend most of my time as a regulatory toxicologist and regulatory chemist -- chemist first, toxicologist second -- on evaluating these kinds of data, and in the recent time, I'm spending a lot of time on enzymes.

So there -- There's sort of a bounce-up for these things in the OP, which, in tactical, are not really recognized by the Federal Food, Drug and Cosmetic Act because there is -- there is no publication written. There is no regulation published -- written and published in the Title 21 CFR 573.

Is that the last one, Abraham? Yeah, that's it. So that's, that's the, the, the first component that we're looking at, at these processes and these ingredients and, and the non -- non-FDA-binding materials that are -- and chemicals that are -- find their way through the AAFCO official publication definition process. Got a question? Yeah, Ally (phonetic)?

MALE VOICE: (Inaudible) --

DR. GRABER: Whoa, whoa, whoa. Wait.

MALE VOICE: I'm sorry. Oh. I just wanted to mention that -- or if you have any comments, that ingredients definitions that are proposed to AAFCO also are reviewed by FDA. I think that's part of the process of the ingredients definition, that we make sure that that goes to FDA and FDA has a chance to review and make comments.

DR. McCURDY: Yes. And, and many times there's been some spirited discussion at the, the ingredient definition process at the AAF -- at AAFCO, so -- But that has work -- That has worked quite well in the past number of years.

Just one other -- One other thing just popped in my head. Okay. It does -- It does work. Here's an example of how it does work; okay? A number of years ago I was on a -- I was the primary viewer for toiliwell (phonetic), okay, to be used in animal feed as a source of linoleic and linoleic acids. Someone wasn't playing cricket. We asked AAFCO to have that definition withdrawn. That definition was withdrawn. Toiliwell is not supposed to be on -- to be used for an animal

feed. That did not require a notice of federal -- What do you call it?

(Inaudible.)

DR. McCURDY: Yeah. Yeah. So it was done (snaps) in a heartbeat, as opposed to going through a legal action. So it, it works well.

DR. GRABER: Okay. In a heartbeat. Okay. Karen --

MALE VOICE: (Inaudible.)

DR. GRABER: Okay. Next, next on the program is Karen Ekelman, who is a team leader for the Animal Feed Safety Team in the Division of Animal Feeds. She is gonna be covering limits for animal feed contaminants and also "risk-based" definition.

LIMITS FOR ANIMAL FEED CONTAMINANTS

BY KAREN EKELMAN, Ph.D.

DR. EKELMAN: Thank you, George. I asked George to wave at me at 12 minutes, but if I don't notice it, the rest of you are free to wave at me at 15; all right? Get me off the stand here.

I want to talk by trying to -- start to talk by trying to address some of the

definitions that were raised earlier. Somebody asked, Well, what's adulterated? What's a contaminant? What do you mean by these terms you're using? In general, we're not trying to use legal terms here, but we're using "contaminant" to mean anything that's in the animal feed that you didn't want to be in that feed or didn't intend to be in that feed. It could be a nonhazardous contaminant. For instance, if you want to put rye in, and there are other grasses mixed with them, those could be contaminants, if you think you're buying rye and you get something you don't want. Those are unlikely to be hazardous contaminants. So a contaminant is anything you don't want there. A hazardous contaminant is something that might present a hazard if it is there, and those are what we're working on for our risk-based assessment.

Again, you might think that the risk assessment only applies to hazardous contaminants, but some of the questions that were raised were very perceptive. Somebody was talking about copper for sheep and goats. And so what Dennis McCurdy talked about, which is

our approved feed ingredients, they can also present hazards for certain species for which they are not approved or for species that are more sensitive than others. So the risk-ranking procedure is not only for some contaminants that we consider to be potentially hazardous but also for feed ingredients that may be hazardous when used in ways in which they were not intended or approved. I just wanted to make that clarification.

Today I'm going to talk about Component 2 of the Animal Feed Safety System, and if you're following along on your component there, it starts on page 3, and it's limits for animal feed contaminants. We chose the word "limits" very carefully because there are a number of mechanisms FDA and other organizations can use to recommend what safe limits would be, and we didn't want to imply that we had thought ahead of time about what we might use. So I'm gonna briefly discuss the objective and scope of this particular component, the three gaps that were identified, and then I'm going to switch a little bit and talk about what, what contaminants are you

talking about in terms of hazardous or potentially hazardous contaminants. If you remember, Barry said that we'd come up with 175 or so, and I'm sure, when you take a look at that list -- and you will get a chance to when we finalize it, and you will agree with most of the things that were on our starter list, and again, for what purpose we're doing this. Then I'm going to discuss a modification to the definition of "risk base" that we first made available in 2004, and I'm gonna summarize some of the comments we've received on risk issues, focusing on those ones that might be interesting to discuss in your breakout groups this afternoon. Next, please.

The objective of Component 2 states to use risk-based mechanisms to identify and develop limits for potentially hazardous contaminants in animal feed and feed ingredients. That's pretty straightforward. And we see from harvesting through use of -- through feeding, we need to consider the entire continuum. Next, please. Abraham, next please.

Component 2 does not -- Oh, go back

one. I'm sorry. It looked the same to me, but it was different.

The scope is, contaminants are toxic or deleterious biological, chemical or physical hazards that are inadvertently present in animal feed and feed ingredients, and I just have some pictures here. There's a whole bin of USDA-condemned poultry, and you wonder where they're gonna go, and there's a flooded field, and you wonder what's gonna happen with the crops in those fields if they're destined for human or animal consumption, and all of those are potential sources of hazards you need to think about. Next, please.

Component 2 does not -- or does apply to contaminants that may be inadvertently added to animal feed during its manufacture. The big example is the dioxins that are created by heating a set of substances to a certain temperature, and we did have one episode of those recently. However, Component 2 does not apply to unapproved or prohibited feed ingredients -- that's under Component 1 -- and it also does not apply to expected contaminants in approved feed ingredients that are likely to

be residues of starting materials or breakdown products produced during manufacture, and that's because the way in which these feed ingredients are approved includes review of manufacturing processes and potential contaminants, and usually, specifications will be set if there are contaminants or breakdown products in the manufacture of a feed ingredient that raise a -- either an identity concern or a safety concern, so these are not covered under what we're talking about under Component 2. Instead, they belong in Component 1. Next.

Three gaps were identified for Component 2. The first is that risk ranking will be used to help determine which contaminants present the greatest risk to animals and humans and to help decide how best to prevent, eliminate or control those risks. And the comments -- I summarized the comments, so if you made a comment and don't recognize it verbatim here, I, I summarized a number of them, but they were generally about the risk-ranking process, and they cautioned us that they should be done only for segments of

the feed industry that are not now controlled by CGMPs and to specify the process steps associated with risk, and, and those are all good points and points we need to take to heart. Next, please.

Gap 2 is the validated test methods for some feed contaminants may need to be developed (sic). It's a lot longer in your gap statement, but I tried to summarize it. Now, everyone knows if we come up with 10 contaminants or 20 contaminants, that somebody needs to control in feed under certain circumstances, that there are unlikely to be validated test methods for all of those in the particular feeds. It's also unlikely that FDA is going to have the resources to develop validated test methods for all high-risk contaminants, so this is a joint process.

The agency has had experience with setting criteria for test validation that may be done by third parties. In addition, we finally do -- and this is the first announcement of this -- have a new resource available to us. Dennis McCurdy, who is on the Animal Feed Safety System Team, is going to be

working with some individuals in our research group who have been given a little bit of bioterrorism money, and they are going to be working on developing some test methods for some hazardous contaminants in animal feed. We don't know how, how far they'll get or what they'll be able to do, but this is the first indication we've had that we may be able to have some resources devoted to this area, and so input from individuals about what they think we should be working on would be useful at this point. Comments for this were that we need to recognize that rapid, inexpensive and reliable test kits for most of these contaminants are not going to be available or, if available, are not validated, and that's a very legitimate concern. Next, please.

Gap 3 relates to agroterrorism. It says, By ranking the risk of potential agroterrorist agents that can be added to animal feed, we will enhance our ability to work with USDA to improve methods of preventing, coordinating responses to and investigating terrorist incidents involving the deliberate contamination of feed ingredients

with exotic animal diseases.

I don't know how many of you read your newspaper today that was delivered to your door, but there was an article on an exercise going on right now that involves CVM and the rest of FDA and a number of states, in which there was potential -- it's not real, it's, it's -- a potential release of a hazardous infectious agent from a car in New Jersey, and we were alerted that we were going to be involved in an exercise, but, of course, we didn't know what it was. So a number of people back at CVM now are working on their responses to this, and we consider this to be an important part of what we're doing, but, of course, we recognize that we can't rank the risk of potential agroterrorist agents the way we would for normal agents because we don't have exposure levels, so we're having to be fairly creative about that. And we had one commenter that agreed that this would be good to deal with this issue in the AF -- Animal Feed Safety System in some way. Next, please.

I just wanted to include some examples of, of some of the contaminants that

we are developing risk-ranking score fors (sic). There's salmonella, E. coli, staphylococcus and clostridia. Also, there are different -- We have identified not only salmonella but the specific subsets of salmonella that we consider important; insects, such as the blister beetle, and I bring that up because possibility of contamination with a blister beetle is one of the things that was considered and what George mentioned was the recent outbreak of horse deaths in Puerto Rico that we could not identify the source of; and the transmissible spongiform encephalopathy, such as BSE and CWE -- D are also going to be ranked. Next, please.

Chemicals, drugs approved for use in animal feed. Again, we will not set new limits on these drugs, but we will simply consider which drugs are most likely to be present at excess levels, based on our data, in what feeds and for what animals this is likely to be a problem and see if we need to have additional controls in place. Mycotoxins, such as aflatoxin and fumonisin; environmental contaminants, such as pesticides, dioxins,

PCPs, radionuclides and heavy metals; and, of course, the physical examples -- bone, glass, metal and plastic -- will likely pose risk to animals but not likely to pose risk to humans consuming the animals.

And you've seen some of these before, but we thought it would be a good idea to mention them again. What are we doing this risk ranking for in relation to feed contaminants? We want to determine which feed contaminants are present, that present the highest risk, and decide how best we can eliminate, prevent or control those risks. Next, please.

Now, I don't know if you recall -- And for many of you there should be available, in your folder, a -- one sheet that has the old "risk" definition on top and then -- -- and a new one on the bottom, and note that we are defining "risk-based" and not "risk." In other words, we're defining what "risk" means to us in the Animal Feed Safety System, but the second sentence attempted to find "risk" in a way that was understandable to people, and that was the one that caused the most concern.

So the entire definition is on your sheet, and if you don't have one, we'll make one available before the breakout groups, but that definition was -- said risk is a function of the likelihood of human or animal exposure to deleterious amounts of such hazards in feeds and the significance of the health consequences in response to those exposures. Next, please.

The comments we received are -- We should be a little more specific in what we're talking about. What about nonregulatory approaches? And I'm not gonna discuss that, but non -- Regulatory approaches includes a huge range of approaches, including education, and I think we'll talk about that when we talk about Component 4 today, but we also had the comment, comment several times -- the definition unclear -- what does risk as a function really mean in lay terms? And so we simply altered that part of our definition. Next page.

And we hope this under -- The risk resulting from the presence of these hazards in feeds is some combination of the likelihood of the human and animal exposure to the feed

hazard and the significance of the health consequences, and I think Barry explained quite well that we're going to modify these two scores, but you could do other things. You could add them. You could treat them in some other way. And, and it basically gets to: What do you want to do with the scores? And we want to spread them out so that we can make risk decisions, and multiplying is one way to do that. So that's just what we tried to correct, and you can look in your folder for the complete definition. The rest of the definition -- I think there's one minor point that's changed, but the rest remains relatively the same. Next, please.

And finally, these are some of the interesting comments we received on risk and risk ranking that you might want to consider as you go to your breakout groups. First, how would a risk-based approach affect some states' focus on consumer protection, which is also called economic protection? And George mentioned this, in his introductory talk, as something that would be interesting to consider.

Also, people told us, as if we didn't know, that risk ranking would be difficult, time-consuming, expensive and hampered by insufficient data. Absolutely correct. It will be all those things. And the best way we can think of to make it work anyway is to make all the stages in that process visible to both the people at FDA and to the public, and so that way, we hope you will help us get the data we need to modify some of these assumptions we're gonna have to use.

Risk ranking will result in a requirement that feed manufacturers test for more contaminants, so I can actually say that we don't have any clue, at this point, whether that's gonna be true or not. Could be; could not be. We just aren't at that point.

And various comments differed about whether risk ranking should focus on human risk only or should focus on risk to humans and animals, and that's something we're going to have to address in a political, as well as a regulatory arena, when we get to the end of this, but at this point, we're committed to our focus on animals and human risk.

Do you like my chicken picture? That's the end, and -- Thank you.

DR. GRABER: Okay. We'll take one question or comment, or -- if anybody has one. We have one.

MR. SHERWOOD: I'm Greg Sherwood, again, with Aurora Cooperative. In the feed industry, the only thing -- or one of the things that we think we can be accountable for is that a feed that we produce goes to animal, if there's a disease and it can be expressed in the meat, and how does that get passed into the human food chain? And because of that, there's two samples you have under your biological: One of 'em is salmonella, and I believe that the cereal types found in the salmonella and animal feed are different than those that are found in the human, to cause a sickness in human, and, and the other one is E. coli. I don't believe there's any data out there that shows that E. coli in the feed will be expressed in the meat. It's more of a cleanliness issue of whether the hands of the handler were clean or whether it got ground inside the beef or whether it's on your lettuce

salad or, or -- And the issue of the largest E. coli outbreak in the United States was in a swimming pool in Atlanta, Georgia, not -- having nothing to do with feed. And because there is no scientific proof that it is expressed inside the meat, I guess I would ask that those two be taken off of the biological list, because it scares the heck out of the public --

DR. EKELMAN: Okay.

MR. SHERWOOD: -- and it may not be factual.

DR. EKELMAN: Okay. What I want to emphasize is the list of hazards is not a list of risks. The list of hazards is sitting down and saying to people -- experts in the field: What do you think might be in feed that you are concerned might cause a risk to animals and humans? When we develop our list to risk, we might conclude that some of those are highly unlikely to be in feed and, thus, highly unlikely to pose a problem, and they would naturally fall out of our assessment. That's No. 1. The second one is, we're aware of the fact that while there's -- there is difference

in salmonella that have been identified in animals, in feed and in humans -- and that data -- those data are very important, but we don't consider them conclusive at this point. You know, we could talk about it, but probably, this isn't the right forum. And E. coli 0157:H7 continues to be a problem. Even if it's present in animals at the time that they're slaughtered, that would be a potential for contamination in passing to humans.

So we hope to evaluate the risk of those with data available and assumptions and modify them as time goes on, but we want you to remember, we started with a list of -- a long list of hazards, and they may not all be on our list of risks when we're done.

DR. GRABER: Okay. Next on the program is Mr. Paul Bachman with the Center for Veterinary Medicine, Division of Compliance, and he'll be talking about process control for production of feed. Paul?

PROCESS CONTROL FOR THE PRODUCTION OF FEED

BY PAUL BACHMAN

MR. BACHMAN: Thank you, George. My name is not synonymous with process

control, although it seems to keep following me around. But I appreciate being here today, and now I know where I'm at. I'm in Omaha, something like that, and thank you, Dennis, for reminding me and that I have a responsibility this morning. Next slide, please.

We're just going to do a brief overview of the process control component, which you can find in your packet, as well as what's been published prior to this meeting, and the objective of the process control is to ensure the safe manufacture, packing, storage, distribution or use of all feed ingredients and mixed feed. The scope is -- As you can see, it applies to firms and individuals involved in the manufacturing, package, storage, distribution and use of feed ingredients in mixed feed, including on-farm operations. Next.

So somebody asked the question: Well, why process control, or what are we -- what are we trying to accomplish? And basically, what we're trying to accomplish, which is -- several other people have already mentioned this morning -- it's a preventative

measure to eliminate or reduce to an acceptable level risk to animals and humans that might occur during the processing of feed ingredients and mixed feed. What is process control? We're viewing it, at this time, as a systematic approach designed to ensure feed safety. Next.

And how are we proposing to go about that? And it's by identification and use of appropriate controls, within an established feed safety program, to prevent, eliminate or reduce to an acceptable level, again, risk to animals and humans and, by establishing procedures, to verify that the controls established within the feed safety program are effective. Next.

So the question is: How do we design this systematic approach? And when I mean "we" -- Or what I refer to as "we" is the public comments sought, and as Dr. McChesney indicated this morning, what Dr. Sundlof had indicated at the first public meeting, is that your input during the breakout sessions and following the breakout sessions, with written comments, is very critical to what we have defined to date and what direction the process may take in the

future. So it's very critical that you, you become active in your breakout groups today and tomorrow.

This is just a list of some of the approaches that FDA has used in the past or utilized in the past. As, as -- Some of you are quite familiar with the good -- current good manufacturing practice of Type A medicated articles and medicated feeds, and also, GMPs apply and low-acid canned food or hazard analysis and critical control point programs for seafood and juice, and, of course, seafood and juice also have some sanitary standard operating procedures involved.

But I do want to say, at this time, that we, meaning the Animal Feed Safety System Team, are not advocating any of these approaches for this issue. It -- Keep an open mind. Again, as Dan said this morning, try to keep an open mind. Think outside the box. And we are not in a position, as the previous slide indicated, to indicate any of those particular forms of approach.

Within process control, the team has identified only one gap at this time, and

that's, basically, that there's no current regulatory approach to govern controls used to address feed safety. Concerns associated with manufacturing, package, storage, distribution and use of nonmedicated feed, ingredients and mixed feed.

We have received several comments to the docket to this point. Some of these are rather recent comments, which were received after publication -- notice of publication of this public meeting. One comment indicated that the unidentified gap is not correct. The gap is focused solely on the medicated feed industry, and in no way was this our intent. Like I said on a previous slide, this goes beyond existing in our current medicated feed industry, and, you know, what we're trying to -- trying to work on here, the issue is much larger and beyond the scope of existing GMPs for medicated feed.

Another comment indicated it was very important for the agency to extend feed safety programs up and down the stream from commercial feed manufacturers, now, indicating this needs to apply to feed ingredient suppliers and

animal feeders. If we have not made that point clear prior, we apologize, but again, it is our intent -- and I think Shannon discussed this this morning in his presentation, as well as other people, that, again, this is a broad-scope-type approach. Next, please.

We've also had a comment indicating the identified gap contradicts the concept of flexibility embodied in one of the core concepts contained in FDA's draft definition of comprehensive. Next.

The comment went on to specify that the fourth component of the definition, as, as Shannon discussed this morning, the flexibility be process- or product-oriented, depending on the situation; okay? And as Shannon indicated, we need a little bit more discussion or comment as to: What do you really mean when you say a process control program should take the -- be oriented towards product control or vice versa?

And just put this in here for something to think about. You may want to discuss it in some of the appropriate groups -- of applicable groups. And then: What does process- or product-oriented mean to you within

the context of the identified gap for Component No. 3, process control? Okay. Next.

Also published in March of 2004 was the paper of basic elements of the Animal Feed Safety System process control. These elements are also in your packet. There's a -- I think, a single page or two pages on the elements. Again, these are some things for you to think about. Let's see if they're comprehensive enough, and we'll see what maybe should be added or, or make some comments about it. But basically, you know, the process -- The -- Basically, the elements group identified seven elements, with, as indicated, the subelements for -- a number of subelements for each one of these. I won't go down through the seven. I think you can see 'em, and they're also in your packets, so that should be sufficient to review. Next, please. Next. Back up one. I'm sorry. I forgot to cover something.

And just to point out that each of the saloma -- sal -- salamander, salamental (phonetic), salmonella -- seven elements -- The final subelement listed was indication for written SOPs; okay? Next, please.

Speaking of the master of senior moments, during the break, I went up to my room to get a copy of my presentation. Well, it was about 30 seconds before Dennis started speaking that I realized that I didn't have it, you know, so I don't know what I -- I'm not exactly sure what took place in my room or the trip up and back, but -- you know.

Some comments to the document -- Most of the comments were specific to each subelement of an element; however, there's one repeating comment specific to the indication for written SOPs. I think that it needs mentioned here for your further consideration. Next, please.

Written SOPs should be dependent upon type, size, complexity of the operation or number of personnel involved. Now, this is a comment we received, okay. The second -- Another one of the comments specific to the elements were that SOPs are advisable in most cases but may be inappropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for manufacturing or feeding of products. Next,

please.

Again, just something to think about, and you may want to comment on this, 'cause I think we're looking for additional information. In a risk-based approach for human and animal feed safety, how are risks dependent upon the type, size, complexity of the operation or number of personnel involved? And so if there can be a little more detailed explanation of how some people think that that -- You know, there's an implicit property in there somewhere that we're still not viewing. We could use that. And that's the end.

As you see, not everything is clearly focused. We're seeking input. There's a lot of variability, and -- This is a joke; okay? I have to say this is a joke, all right, because this came with a caption that said -- And this is sort of relative. "Relative" in the sense that the hen is related to the chick; okay? That type of relative, in a sense. The caption said, What happens when you feed Fruit Loops to chi -- to hens; okay? FDA is not saying this. It's not what happens, I don't think, you know. Maybe some of you poultry people know better,

but I've seen green eggs and brown eggs and white eggs in a previous life, but -- I don't know, you know.

Happy Easter -- belated Easter. Thank you.

DR. GRABER: We're really out of time, but we'll take one question, if someone has it.

Okay. All right. We -- Since Paul is having a senior moment, we're gonna -- we're gonna do Groundhog Day. The next speaker will be Paul Bachman to talk about -- No. See if he can get it right this time. Okay. Never mind.

Next on the program -- Before I forget, the -- For those of you who do not have the slides -- some of Barry Hooberman's slides and the definition of "risk-based," the one-pager that's supposed to have been in your book, they're now in the back of the room, so at the end of the day -- or at the end of the morning, you can pick them up. They're on the table at the back of the room.

Okay. Now for the fourth component, we have Dr. Steve Traylor with the University of Kentucky's Division of Regulatory Services.

I'm sorry, Steve, for the error in the -- in the agenda. It's Division of Regulatory Services. And he's gonna talk about regulatory oversight. Steve?

REGULATORY OVERSIGHT

BY STEVE TRAYLOR, Ph.D.

DR. TRAYLOR: Thank you, Dr. Graber. As a state representative on this committee, it is indeed my pleasure to present the next component of the Animal Feed Safety System entitled "Regulatory Oversight." Current regulatory oversight is present in levels commensurate with risk to the animals and humans through inspection enforcement activities. Thus, the objective of Component 4 is to develop a framework for the use of prioritizing and allocating inspection enforcement resources to minimize risk to animal and human health.

Although the Animal Feed Safety System is an umbrella program being developed by FDA, it is essential for us to consider the impact that this program will have on other regulatory agencies. This is especially true when one views the impact of such a program on

the relationship between FDA and the other regulatory agencies, including the states. With this in mind, the scope for this component was designed such that the process should apply to FDA's feed regulatory activities from the similar state acts as conducted using the FDA authority. Examples of this would include label review, education, inspections, enforcement and information sharing.

The next four slides will, will cover the subpart of Component 4, which is the inspection program, and the inspection program is utilized, thus far, by regulatory agencies to determine a firm's or product's degree of compliance with applicable regulations, include (sic) surveillance-based inspections or compliance-based inspections. Surveillance inspections are conducted to determine whether a firm is substantially in compliance with the regulations and are operating under control. In contrast, compliance-based inspections are conducted to evaluate a firm's compliance with the provisions of the regulations and to document the inspectional observations supporting possible enforcement action. An

example of this type of inspection would be a for-cause inspection, and one on the surveillance inspections would be a GMP- or BSE-based inspection.

In Dr. Graber's talk earlier this morning, he stated that one of the operating principles of the -- of this system includes a robust federal and state relationship covering all aspects of feed regulation. It is difficult to discuss inspection programs without noting the integral relationship and involvement and interaction between FDA and their state counterparts. This is because a large majority of the inspections are indeed conducted by FDA state counterparts. Therefore, a strong working relationship should be a significant component of the Animal Feed Safety System. Of particular interest to the states' regulatory agencies is that under the proposed regulation -- or the proposed Animal Feed Safety System Program, their role in inspection and enforcement, under their laws and regulations, should not change.

As an extension of what was discussed earlier today in Component 2, the regulatory

oversight component would utilize a risk-based approach to improve the agency's ability to prioritize and allocate inspection resources by targeting firms, facilities, products and processes that have been identified as posing the greatest risk to animal and human health.

Going into the second subpart of Component 4, which is enforcement, FDA has a variety of enforcement options that are indeed available to them. Regulatory enforcement often focuses on voluntary compliance with the law and regulations; however, when voluntary compliance and education are successful, the agency must use a variety of enforcement options that are at their discretion. These would include warning letters, untitled letters, criminal penalties, withdraw from distribution orders, et cetera.

Moving into the identified gap section, there were three gaps identified, with Gap 1 being establishing priorities, Gap 2 encompassed on-farm manufacturing in the transportation sector, and the third gap identified was inspector training. To discuss each one of those gaps in detail in the current

regulatory oversight program, the agencies have established priorities for inspections under BSE inspection program based on a combination of risks.

In -- Most of us are probably not aware of the next point, but CVM is currently developing a risk-based inspection approach for other feed-related inspections, and this is not expected to be completed until FY 2006. To discuss this just a little bit further, a committee within CVM was charged, in 2004, of developing a risk-based method for determining the feed products, processes and/or facilities that presented the greatest risk to animal and human health. In CDER, the Center for Disease (sic) Evaluation and Research, has just developed their risk-based model for prioritizing GMP drug inspections that occurred in September of 2004.

It's important to note that a member of the Animal Feed Safety System, Abraham Kamara (phonetic), is also one of the individuals working on CVM's risk-based inspection system, and he works to ensure that CVM's risk-based inspection approach for

inspector -- for inspections will be the same or similar to the Animal Feed Safety System risk-based approach.

For the eight major compliance programs that's gonna be encompassed in that system for CVM, it includes drug preapproval inspections; drug GMP inspections; drug post-approval inspections; the medicated CGMP inspections; the BIMO, or the bioengineered inspection and monitoring inspections; BSE feed contaminants; and residues for drugs, pesticides and tissues. I mean dioxin. Identified Gap No. 2, Subpart A, again, was the on-farm component.

As of today, regulatory oversight is focused principally on the commercial-medicated feed industry, even though there has been a major shift to on-farm production of feed. In fact, a lot of the on-farm integrated, if you will, operations produce a lot more feed in their facilities than do most commercial manufacturers.

The Animal Feed Safety System Team is developing a more comprehensive regulatory approach that will cover all aspects of the

animal-feeding industry, including transporters, mixer feeders and livestock producers. Next.

Subpart 2, where -- identified Gap 2, Part B, and -- is the transportation component. Part of the recent GAO report issued on the BSE identified the transportation sector as being a major area of concern. The Animal Feed Safety System Team would indeed like your thoughts and ideas on how to deal with this potential cross-contamination issue.

Recently -- it was in December of 2004 -- the Department of Transportation Act of 1990, there was a notice of proposed rule-making published, which dealt with the -- safeguarding food from contamination during transportation. Basically, just to summarize that, the Department of Transportation said that all transporters will need to comply with applicable regulations set forth by USDA and FDA, so basically, they passed the buck to you -- to FDA and USDA.

Our last identified gap was inspector training, and we are definitely seeking input from all stakeholders such that we have the

most knowledgeable and proficient inspection staff possible. The AFS (sic) should provide a program to ensure the competence and proficiency of all regulatory inspection staff, and this would include both FDA and state inspectors. Questions?

FEMALE VOICE: No questions?

(Inaudible.)

DR. GRABER: We'll take a question for Steve now that he's sat down. We got a few minutes. Hold on. Get -- Pass the mike up here, Sharon.

MR. BRIGHTSMAN: John Brightsman from Pennsylvania. I have a question for Steve, as far as -- You mentioned there are regulatory enforcement tools that FDA have (sic). Is that a gap? When you mentioned that, is that a gap, or is that something --

DR. TRAYLOR: That's not necessarily a gap. It's just how we implement those gaps on the enforcement side. We are -- We're trying to incorporate into this system an enforcement component, and those are the tools that they have available. Should we have other tools available to us from --

MR. BRIGHTSMAN: Well, is that something that should be discussed in the breakout?

DR. TRAYLOR: That's something that really should be discussed in the breakout groups.

MR. BRIGHTSMAN: Okay.

DR. TRAYLOR: Right. And there's some questions that you will get that will sort of lead you down that path.

MR. BRIGHTSMAN: Okay. Great.

BREAKOUT GROUP EXPLANATION AND INSTRUCTIONS

BY GLORIA DUNNAVAN

MS. DUNNAVAN: We're gonna hang on just a few more minutes. We want to give you some really important instructions before you leave today for a break and then lunch and our breakout groups.

I'm Gloria Dunnavan. I'm the Director of Compliance for FDA Center for Veterinary Medicine, and part of the fun thing with this meeting is I get to see so many of you that I actually know or we talk on the phone or we exchange e-mails. Thank you for indulging me. I'm not able to stand for any

length of time.

I just want to go over some instructions. This is a really important part of the morning, because you'll end up in the right place and get your questions if you follow all the instructions.

So basically, just listen carefully for a few minutes. Check your badge. Your breakout group is included on your badge. It's the little top line in your badge, so I hope you all have those. If you didn't check in and get a badge, you need to do that at the registration desk, 'cause it's critical to know your breakout group.

The location of the breakout group meeting are (sic) included in your packet. There's a map. I don't have, actually, a packet with me, but am I right? There is a map, and the breakout groups are listed. So it's a -- not a huge hotel. Oh, here we go. It'll look like this for those of you in the front. This is not a huge hotel, so I think you should be able to find it.

Lunch is gonna be served at noon, so you're gonna have some time, between now and

noon, to, you know, make those all-important phone calls, read your e-mail, do some discussion, take a smoke break, whatever you need to do before lunch. This is a working lunch, so your breakout groups are gonna be sitting together at lunch, so you need to look for your breakout group numbers on the lunch tables.

And just so you'll -- Just to help you out a little bit, breakout groups with the letter "A" -- When you go to the Regency Room, which is where we're having lunch, breakout groups with the letter "A" will be going to the right, and breakout groups with the letter "B" are gonna be going to the left, and the tables are marked, but this'll just help you get to the good stuff quicker.

Each breakout group is gonna have a facilitator. They stood up this morning, so you'll, you'll know they're the younger members of this meeting, and there'll be at least one Animal Feed Safety System Team member in your group. Some groups will have more than one, but there'll be at least one, and our, our goal in participating in the discussion is not to

twist your arm or sway you or influence you in any way, but if questions arise, the team member is there to help sort that out. And actually, I think all the committee members have a little red flag on their badge that says "committee member" or "team member."

You are gonna receive a set of questions, from your group facilitator, at lunch, and you're gonna get all of the questions. You'll get your groups, as well as all the, the other groups. There are 12 groups -- 12 breakout groups. There's 1A, 1B, 2A, 2B. 1A and 1B will be dealing with the same question -- same set of questions. 2A and 2B will be dealing with the same set of questions. The only groups that are different are 6A and 6B, will be dealing with two separate sets of questions, just so you'll kind of understand it when you're looking at, at all of the questions.

And if you look on your agenda for tomorrow's discussion, you'll see the names of the different breakout groups, and they're pretty much covering what we talked about this morning, but let me just mention, there's a

breakout group on safe feed ingredients, breakout groups on limits for feed contaminants, one on risk and risk-ranking model, one on process control, one on regulatory oversight, and then the sixth group, which is the one that'll have two separate sets of questions, "How can AFSS help you?" So those are our basic groups, and just be sort of thinking about that.

Also, we like each group to cover as many of the questions as possible. If you don't get to all of 'em, it's okay. We like you to try to take these questions in order, but if you feel, as a group, that a particular question is important and you'd like to work on it, you know, out of the listed order, that's fine. This is not, you know, gestapo here. There's no wrong answers. You know, don't feel limited. Don't hesitate to ask questions. We're really seeking your input.

We are gonna have laptops available to record the information from your flip charts so they can be projected on the screen when the group reports. And I did -- Although, it was on my -- on my slide, I failed to tell you,

when you first get into that group, be sure you select a spokesperson and a recorder before you get started on the questions. That's a critical thing, and your facilitator is probably gonna emphasize that to you, also, but once you've recorded the gist of your discussions and your ideas for these questions, you'll have flip charts to work from. Then when you're finished, bring those flip charts to the registration information table, and then we're gonna have volunteers, this evening, type the flip chart information onto the laptop so we can project it on the screen.

I think that the size of this meeting and the number of participants and the -- and the room arrangement, it's really gonna be difficult for you to see flip charts, so we're hoping this will help.

And then tomorrow morning each group is gonna report the results of their discussion. Each group is gonna have 30 minutes, and when I say you have 30 minutes, remember, there are two groups. The 1A and 1B, for example, have the same set of questions, so those -- That 30 minutes will be for both

groups to report.

And your leader for the discussion tomorrow is Bob Wilson, and Bob will select, you know, how he's gonna do the "A" and the "B." I don't know how that will work out. The only difference here is that Group 6A and 6B will each have 20 minutes for their report rather than a, a total of 30.

These are pretty basic instructions. You heard some of 'em earlier this morning. We're just telling you again, just sort of remedial training, 'cause this is really important and will help get us moving and get to the heart of what we want at this meeting, and that's to hear from you.

With that -- I'm having to take any questions about the procedural things otherwise? George?

DR. GRABER: Any questions? Any comments? As Gloria mentioned, this morning we tried to -- we tried to give you enough background information so that the sessions this afternoon would be productive, and we certainly look forward to, to hearing the reports tomorrow, but I'll be walking around

this afternoon, going to some of the groups. I'm looking forward to hearing what you all have to say.

With that, we're a little bit early, but that's fine. We'll -- Again, we'll convene at, at noon for lunch, and the Regency Room is sort of back down towards the, the register for the hotel and then down the hall, back towards the -- out where the elevators are, and hang a right, I think, at the second bank of elevators, and the room is sort of by the pool, where the pool is. If someone knows a shorter dis -- a shorter way, fine. Otherwise, that's the way to go. Okay. We'll see you at noon. Thank you.

APRIL 6, 2005

ROBERT WILSON, MODERATOR

MR. WILSON: Start moving to their seats, and we'll try to get started here a little on time. Maybe a little early, even. I do have one announcement to make about the taxicab rides to the airport. It's my understanding that the taxicab ride is a flat rate, $25.05, one, two or three people, however many people go, so just for your information.

Good morning, I'm Bob Wilson. I'm the moderator for today's session, and what we're going to be doing is, is the presentations from our breakout groups yesterday. As you can see from the schedule, we've got a half hour scheduled for both Group A and B, except for group 6, which each have a half hour -- or they have 20 minutes each.

What we're going to do is, the first presenter for a group will have 20 minutes, the second presenter for the group will have 10 minutes to give their presentation, and hopefully, just cover the, the areas that are different or, you know, if they concur with an area, just so we don't have a lot of redundancy, move through it quickly. So it's gonna be kind of my decision who goes first and who gets 20 minutes and who gets 10.

So what we'd like to start with is Group 1, and the -- We'll start with Group A, and they'll have 20 minutes to present -- make their presentation, and it's my understanding the reporter for Group A is Bruce Arentson from Kent Feeds. Bruce, you have 20 minutes.

BRUCE ARENTSON, GROUP A

MR. ARENTSON: 20 minutes? Well, I can see the clock down there, so hopefully I won't go over 20 minutes.

My name is Bruce Arentson, and I work -- do work for Kent Feeds. Good morning, and we'll try to work through this this morning. First of all, I want to say my comments this morning are, are my comments, and even the comments I make doesn't mean that I or my company endorse this whole endeavor. I may -- I may bias what our committee decided, but I have the microphone and they don't, so . . . We'll build a foundation, hopefully, this morning, at least in my presentation, and then either we'll crumble today or others will build on it.

Well, we had a question -- or -- Group 1, and the first part of our presentation -- or questions had to deal with the definitions of "comprehensive," and as you remember, there are, I believe, if I have the -- eight points to the definition of what "comprehensive" means, and we were asked: What parts of the definition do we agree with? So

we decided to go down through, point by point, those eight different points, and determine whether we agree with these -- definition of "comprehensive."

The first one had to do with: Does it apply to the whole range of feed products, including all ingredients and finished feeds? And we typically agreed with that statement, that if we're gonna do comprehensive, it has to include all finished feed and ingredients.

No. 2, the use of ingredients approved and/or recognized by an established regulatory agency or entity whose members are charged with the responsibility of enforcing laws, regula -- regulating the production, labeling and distribution or sale of animal feeds, and we probably have up there, I believe, disagree with that at Point 1, if you just go down there, and we'll talk about more of that when we get down to the "disagree" section.

No. 3, cover -- had to do with cover the range and variety of facilities involved in animal feed over production, and there was really a lack of consensus on this particular

statement, and we'll cover that when we get down to "disagree."

No. 4, have the flexibility to be process- or product-oriented, depending on the situation. Again, there was probably some disagreement, and we'll talk more about that when it comes down to the disagree part.

No. 5, address feeds produced for food or nonfood animals, and we pretty much agreed with that as, as written, and if you're gonna have a comprehensive program, it had to be both food and nonfood animals.

No. 6, cover all known hazards and can be applicable to hazards not identified. We didn't have a lot of agreement on the way it was written there, and we won't cover a lot in this section on that, and I'm sure others have a lot more to say about that today.

Address both human and animal health issues. We agreed with that, that both human and health (sic) issues will have to be in part of the "comprehensive" definition.

And knowledge and coordinate regulatory authorities at all level (sic), including local, state, tribal and federal,

involved in safety. If it's gonna be comprehensive, all regulatory agencies are gonna have to be involved.

Then when it comes down to disagreement, what parts of the definition do we disagree with, we come to the first point, which had to do with the feed products and so on. We, we agreed with that. We didn't have any disagreements.

No. 2, the use of ingredients approved and/or recognized by established authority. I guess we had some difficulty in, in getting our handle on this part of the definition of who -- It's written, I guess, as a committee. It's written kind of broad, and we didn't all have agreement on this particular one.

And then No. 3 had to do with the complete range and variety of facilities involved in animal feed production. We had difficulty understanding what the range and variety of facilities are and what "animal feed production" means. We need to be more precise in that definition. That's our thinking as a company.

No. 4 had to do with the process- or product-oriented, and I guess we'll deal with that and address that later, and others, of course, will have a lot more to say about that.

No. 5 addresses feeds produced for food and non -- nonfood animals. No disagreements on that. We agreed with that.

No. 6 had to do with cover all known hazards. We need to define what "hazards" are. We really believe they need to be science-based. We talked about adding "all known hazards" and "reasonably likely to occur" as maybe some better wording to put in that question.

And No. 7 and 8, we both agreed with, so we'll go on to our third question, was to differentiate between process-oriented approach and product-oriented approach, and we didn't spend a lot of time on this. We were just asked to at least give our thinking on what a process approach would be, where testing is performed using GMPs, or good manufacturing practices, or SOPs performed, and that's all of the approach or all the talk that we had about that, and I'm sure others will address that

later today.

Product. Basically, we're looking at the final product and determining whether it meets the specs on the guarantee, whether labeling is correct and so on. So there is some differences, and we didn't go much further than that in our group.

No. 4 question was: Does the proposed definition for "comprehensive" contain any gaps? Is it too broad? You would -- If you would answer yes to either question, please explain why. And again, we kind of went through each point individually, and No. 1, we didn't see any gaps. No. 2, we used -- the word "entity" is used to refer to mem -- or whose members are charged with the responsibility of enforcing laws, regulating the production and so on, and again, we think that is too broad as a group. Our just -- Our group had difficulty understanding exactly what we were referring to. Would it mean that the foreign regulatory agencies wouldn't be involved, or is AAFCO excluded? And as a group, we had difficulty understanding this particular point, and that's the bottom line.

No. 3 refers to a complete range and variety of facilities involved in animal feed production. Again, the gap and the definition of "what is a facility" needs to be better defined about what animal feed production is, and would -- Does that mean that the crops in a field would be included? How do you define these firms? How do you incort transporta -- incorporate transportation? So we think it needs to -- It doesn't refer to any sort of transportation, so that needs to be involved, and just the little better definition of "animal feed production" probably needs to be involved in there. That's the consensus or some thinking in our group.

Process or product control in No. 4, who makes that decision of whether you use product or process control, and when it says "depends on the situation," what does that mean? Does the regulatory agency make that decision, or does the facility make that decision?

No. 5, we didn't see any gaps in that.

No. 6, it talks about all known hazards and applicable to hazards not yet

identified. Again, we, we disagreed with this. We think there needs to be some better understanding of what the hazards are. We think they should be science-based. All known hazards -- We, we just had trouble believing -- or understanding the "all known hazards yet to be identified" and including a huge, inclusive statement like that. I think that probably is what the committee was thinking when we talked about that.

Nos. 7 and 8, we really didn't see any gaps in that. I guess we just question -- We think that a big gap would be the, the ability for the regulatory agencies to, to have -- to regulate a comprehensive program or to implement and enforce a comprehensive program. We think that's a huge gap that needs to be determined or figured out or, or -- before we continue on and write a new program.

And then we go on to Question 5. We have identified one gap in Component 1, which is -- which refers to the ingredients, and our Question 1 is: Do you agree with the identified gap? And the gap in the Component 1 of the program has to do with AAFCOOP, a

nonfederal listing as a source of information on permitted ingredients and additives in animal feeds, and there is really nothing that pulls FDA and AAFCO federal listing together and holds 'em together and bind -- There's no binding statement.

So there is a thinking that there needs to be a compliance policy guide written such that there is a guide to FDA people saying that -- as I understand it, The -- We -- We're okaying the AAFCO listing. And we would agree to a policy guide and recommend a policy guide versus a regulation of some sort.

Getting back to the question: Do you agree with the identified gap? Yes. And why? From a regulatory standpoint, probably be a good idea.

Another gap that we see in Question 5 is that there needs to be availability of the OP to more people. That was brought up several times. There were several people that didn't have an OP and didn't know necessarily about the OP, so -- We just think that, that the availability, especially of ingredient listing, needs to be widely distributed.

There needs to be some transparency for new approvals of ingredients so that the public knows what's going on. There was some thinking that not everybody understands the process or realizes the process that's going on or knows that there's a new ingredient, and so there needs to be more publicity about that, maybe through Websites or, or mailings or something to that effect.

Going on to Question 6: Do you agree with the identified gap? Why? And then 7 and 8, during the last part of here -- our section here, what we have written up here, I think we kind of put everything into one, so it's a -- I'll just read the questions and then we'll go through what I have up here. What gaps have we missed, and what solutions do you recommend to fill those gaps, were our two remaining questions. And then we'll just talk about some of the things that we have written up here.

Again, getting some of the acceptability of the human food grass ingredients, there was some talk in our group that some of the ingredients used for humans are not accepted for the animal sector, and

even that process is not defined of how that can take place, and so there was some feeling that we should have a process that's kind of outlined and defined so that we -- people, companies, know how that takes place. One gap is, if you do get a new ingredient approved, there's no market protection for that feed ingredient. Others can market that same feed ingredient.

We need to have the regulations written, easily acceptable -- or accessible to everyone. Sometimes they're not especially -- if -- And I think -- Scroll down to the next one, and -- next page, and then I think we'll be done. Sometimes -- I think -- I got to think back to see what we were thinking about this, but one thing I think we brought up in our group was that if we're to have a new program, it needs to be accessible to any -- everyone and understandable by everyone.

Now, if -- Even if you look at the present written program, and there are a lot of -- lots of different informational pages, Websites, the CFR, the AAFCO, and for someone new or someone that doesn't work in this arena

every day, it's very confusing and very overwhelming. So if it's gonna be comprehensive and we're gonna include a lot of different people in the comprehensive regulatory program, it has to be simplified, has to be readily accessible to everyone, and they have to be able to understand what they need to do in their particular program.

With that, I think I'll quit and give the podium to Group 2A.

MR. WILSON: (Inaudible) B.

MR. ARENTSON: 2B?

MR. WILSON: 1B (inaudible).

MR. ARENTSON: 1B.

MR. WILSON: (Inaudible.) Just before 1B -- As they're making their way up, is there anyone in Group 1A that would like to add anything? We have the microphones available, if you would. It's very good on time, by the way. Excellent. Elwin (phonetic)? All right. The spokesperson for the re -- or reporter for Group 1A -- or 1B is Sara Blodgett?

MS. BLODGETT: Yes.

MR. WILSON: All right. I didn't ask you your name.

SARA BLODGETT, GROUP 1B

MS. BLODGETT: Good morning. I'm Sara Blodgett, and I am with Farmers Coop out of Farnhamville, Iowa, and I'm the reporter for 1B, and we had a lot of similar comments that 1A had. For Question No. 1, what do we agree with? We agreed with No. 1, 4, 5, 7 and 8 as written. We didn't have any changes or differences with those.

For Question No. 2, what parts did we disagree with? Items No. 2 and 3, we thought, were rather broad, and we needed to add the entities of storage, transportation and use on No. 2, and we needed to add storage, distribution, transportation and use to No. 3, because those entities are just as important as the ones that were mentioned and play an integral part, also.

The next one that we disagreed with was No. 6, and we thought that that was too broad, because it just says "all hazards and unidentified hazards," and we thought that it needed to say -- be further defined as hazards that are science-based and reasonably likely to occur.

For Question No. 3, we had a lot of discussion on this, and I don't know if we necessarily came to any specific conclusion as to how they should be defined, so what we decided was that each entity needs to have its own plan of how to get to a safe end product, and the key to the process-oriented and product-oriented was mainly that we have a safe end product at the end, and we didn't have any specific definition for each of those.

Question No. 4. The gaps, as I mentioned earlier, we referred back to Items No. 2 and 3, where we thought we needed to add the transportation, storage, distribution and use to those.

And too broad was Item No. 6, where we needed science-based and reasonably likely to occur so it wasn't so broad and open-ended.

Question No. 5, which was: Do you agree with the identified gaps and why? We did agree with the identified gap. We also disagreed, as you will see in the next question. The reason that we did agree was that the CPGs would formalize the understanding between FDA and AAFCO, which we felt was

important, and No. 6, why we disagreed, is that our group thought that we would prefer a CPG to a regulation. They felt that a regulation has the potential to be a significant regulatory burden, so they would prefer that we just stay with a CPG than set up specific regulations.

No. 7, what gaps have been missed? No. 1, we thought that, currently, there is no mechanism for evaluation and reviewing the grass substances to be used as feed ingredients, and secondly, we also believed that, currently, there is no rapid, validated, inexpensive test for certain hazards, so we need to get those created.

And No. 8, what solutions do we recommend to fill the gaps? Our group recommended that the grass notification proposal be implemented.

And that's all we have, unless somebody in my group has something to add.

MR. WILSON: Is there any questions of Group 1? No one has any questions of Group 1 or anything like that? Very good presentations, no questions. All right.

Continuing on Group 2, I'd like --

Let's switch and have 2B reporter be the primary reporter for this, this group, and that would be Michael Davidson, I believe, and then 2A -- He'll have 20 minutes, and then group 2A will have 10.

MICHAEL DAVIDSON, GROUP 2B

MR. DAVIDSON: Morning. I'm Mike Davidson. I'm with the Republic of California Department of Food and Agriculture. Our group was, was looking at the limits for animal feed contaminants, and the -- It was pretty much agreed upon in the group that this is gonna be a -- quite a daunting task to do risk assessments for all potential hazard contaminants, and basically, the, the first question: What gaps do you agree with? This is pretty much consensus throughout the group: As long as it was science-based -- And they felt that on the -- Oh, thanks. Hmm. They felt that it needed to complete the risk, risk assessments before attempting the second part, with developing methods for analyzing these things.

The, the other thing was that we felt that it -- there needs to be some clarification

on the third question, and basically, it was about -- A lot of this really -- The group felt that the key component was prevention through biosecurity, but that the AFSS system would be put in place after an exotic animal disease is diagnosed, and then the Feed Safety System could work on tracing back feed.

Then: What gaps do you disagree with? On -- There needs to be training. Levels need to be established, by a regulatory agency, on the, the hazardous contaminants, and then these standards need to be reviewed regularly, not just left in place forever. And then the standards need to be realistic. If you can't -- If the background levels are the same as the minimum standards, it's -- and you put the industry in a possible situation, they felt that that's just totally unrealistic, and based on science, again.

Then again, the, the third point, again, as -- I'm repeating myself -- that on a -- If there was exotic animal disease, the best medicine would be prevention in the form of biosecurity.

What, what gaps have we missed? On

the first point, the risk assessments must be species specific where appropriate, and that was identified, a couple of comments, yesterday.

And then the second point on, on the analysis of hazardous contaminants, that it felt like the -- all the laboratories that -- should be identified, they were capable of analyzing hazardous contaminants, and that these would be available for industry and producers so that if anybody had a problem on an on-farm mixer situation, they had a lab that they could go to, and then the, the limits that the lab was capable of doing should be identified, and also, have a listing of labs that had a specific matrix. In other words, if they can analyze liquid feed for a specific contaminant, for example.

Some of the solutions that we had to fill the gaps -- This is gonna be -- The risk assessments are gonna be, like I said, a very daunting task, and it should be a cooperative effort between federal, state, academia and industry groups, and also, because of the global economy, that we should consider

international standards, and then the laboratories need to be certified by type of analysis. Improper information or false reporting of a hazardous contaminant was felt to be highly destructive, and we wanted the results to be -- or the labs to be certified that they are capable of -- and they have the quality assurance steps in place. And then this was kind of a pipe dream, but unlimited research funding, and what the group said was, Well, if you don't ask for it, you know, you can't get it.

Anyway, the -- On the -- Question 5, did we explain clearly enough? There was a lot of discussion, but the consensus was no, and what was confusing, there was -- it was never established at what level -- where risk is regulated, and the -- One of the things that they felt would be helpful is an example of how -- something that's currently regulated, how that risk was established and what the steps were, and just a couple of examples for people to understand what to expect from this risk-based assessment of hazardous contaminants. So if we could have gone through

and better explained how this whole process was -- is likely to work in the future based on the things that FDA has done in the past.

Question 6: Do you think AFSS should use risk-based? And the answer was yes. What other approaches should we consider? There, there was considerable discussion on record-keeping and complaint files, recalls and whatnot, but based upon our part of the program, the limits, we didn't have any other recommendations.

Is the new risk-based definition more understandable? Yes. The only -- We felt that the second definition on that single page was much more clear and that -- It -- It's this single page in your packet, "Definition of Risk-based." The only thing that we added was -- On the bold portion in the middle of the paragraph, where it says "animal and human," we added "animal and/or human exposure."

And that was -- that was pretty much it. Does anybody from 2B have anything to add? Thank you very much.

FEMALE VOICE: (Inaudible) question.

MR. DAVIDSON: Yeah.

FEMALE VOICE: What do you mean by "prevention" (inaudible)?

MR. DAVIDSON: "Prevention through biosecurity"? Well, they were just -- The question is: What do we mean by "prevention through biosecurity"? Well, the, the Point 3 was about how AFSS could assist in the event of an exotic animal disease, and we felt that there should be -- On the on-farm mixing and many feed-manufacturing locations, the accessibility to these locations by unidentified people was a very common practice, and so whether it was intentional or somebody bringing pathogens from one location to the other, that the prevention of something like that is the key and that, really, you're not gonna be able to test for exotic animal diseases in feed, on a regular basis, that you would respond after it was diagnosed. Does that answer your question?

FEMALE VOICE: Yes.

MR. DAVIDSON: Okay. Do you want a microphone?

FEMALE VOICE: I think with the

experience -- with the experience that you've had in California with some of the exotic animal diseases, you probably have a little more sensitivity than, than, maybe, some of your counterparts, but what I'm understanding is that, that when you mention prevention in the form of biosecurity, you're talking about limited access --

MR. DAVIDSON: Cor --

FEMALE VOICE: -- as one factor?

MR. DAVIDSON: That's correct. And, you know, the -- Any, any vehicles or people that are exposed to where livestock are, that they be sanitized before they go from one location to the other.

MR. WILSON: Do we have any other questions? Okay.

And the presenter for Group 2A, Amy Wesley.

AMY WESLEY, GROUP 2A

MS. WESLEY: Good morning. I'm Amy Wesley, and I'm with Murphy-Brown's out of Algona, Iowa.

Our group took a different approach on answering these questions. We've lumped

Question 1 and 2 together if we agree or disagree on the gaps that were presented in the framework. As discussion started, Greg did a good job of, of paraphrasing everything, and we didn't say yes, we agree or disagree. These are the comments that came out, questions. We were all, I think, trying to grasp how the model was gonna work, how the components were gonna be put together, and so these are the comments and opinions and questions that we had as a group.

Do we agree or disagree with Gap 1? And I -- You can refer back to the framework document for Gap 1. We thought we needed to be cautious when using the word "potential" and "potential" hazards, biological, chemical and physical contaminants. What is really meant by the word "potential"? We wanted to be sure we rely on science-based data when making the regulation or decisions.

Must be con -- be a consensus about the methodology used when measuring and qui -- quantifying risks. Be careful about using risk models for which there is not significant scientific consensus.

One firm had linked the factors of HACCP program. HACCP was passed back and forth in our group discussion yesterday. When adding animal risks and human risks, we had to be really careful on what control points need to be looked at.

Will the risk ranking for animals and humans be separate? These are questions that came out that we wanted to understand how this was all put together. If combined, the agency needs to develop a consensus about weighing human and animal risks. How much is a human death worth compared to an animal death?

Is -- The risk-ranking model, should it be able to be used and tested by the industry, as well?

And where this next comment came from -- I don't remember it being written down. If it looks like HACCP, smells like HACCP and sounds like HACCP, it is HACCP. And if there's questions, we can refer that back to the rest of the group.

FDA does not appear to be focused on HACCP for this risk-assessment model.

Can information or approaches be

used -- in the Harvard BSE Risk Assessment, be useful for the AFSS risk model? Is there other risk models out there that need to be looked at to, to bring back and help put this model together?

Gap 2, these are the comments that we -- they agree/disagree, the comments that came out of that: Availability of effective, inexpensive and reliable testing methods is crucial. Industry may need to help develop some of these methods. And will the FDA will be likely (sic) -- not be able to develop all of the methods that, that are needed for this testing?

Gap 3: Historically, FDA has played a limited role in these matters. How does this fit the "F" -- Gap 3: How does this fit into the "F" -- the AFSS? How do agroterrorism risks compare to the usual feed contaminant risks? What contaminants' agents' hazards has the FDA identified for agroterrorism? If FDA uses something other than exposure to rank these risks as agroterrorism agents, what will it use? What are the facilities, processes or product risk factors associated with the

vulnerability of agroterrorism risks? How will these risks from products produced in other countries be evaluated for agroterrorism risks, particularly if the FDA relies on process control model and doesn't have access to the plants in other countries? So we went outside the realm of what we do here, but how can we control what's coming into the country, as well?

How will the risks from products produced -- Whoop, got that one already. Sorry.

Question 3: What gaps have, have we missed? We thought there needed to be more emphasis and explanation, and perhaps in the models, in how it's gonna handle imports.

Even when science-based decisions are made about feed safety, we -- can we have the WT -- what problems can we have with the WTO on science-based decisions? Process-based controls are more difficult to enforce for imports. Risk systems must look at entire supply food chain, chain for feed and not focus on only the segments of the feed industry. It also should be more explicitly defined in terms

of processing steps.

What can be modified, the original risk scores, for ingredient hazard pairs? So we kind of wanted to get away from more focused, and some of the statements was focusing on feed aspects, but we need to incorporate the whole chain of transportation ingredients and the whole process in how things are worded so it includes the whole realm.

Will regulations be applicable to farms? Will risk assessment consider some risks are industry-segment-specified or species-specified?

To what extent does the AFSS consider or address the issues of ingredient traceability? International sources of ingredients may pose particular problems with reg -- with regard to traceability.

How does the AFSS consider the response time needed to prevent an emergency situation from becoming a crisis? Do we need to take 10 days before we realize there's a problem, and by that time, there's product halfway across the world, or what's that time frame that needs to be established?

We need a clear information on limits. For example, if there's a dioxin limit of 10 parts per million, what will the agency do if a sample tests 15, a hundred or even a thousand? What does the agency expect the industry to do in each of these situations? We kind of want a specified outline of: If we're over the limit that may be set, what do we need to do?

FDA needs to link risk ranking/risk assessment with regulatory actions. How will FDA approach working with on-farm transportation and other parts of the food supply -- the food supply and FDA does not -- that they don't regulate now? Will guidance levels or action levels be set for some limits? Will the risk-assessment method -- What will the risk-assessment method be when setting such limits? Will it differ from the method that's used to rank these for the AFSS?

Question 4: What solutions do we recommend to fill these gaps? Go out and utilize trade association, universities and private industry feed safety programs that can be used to help set up these models and

resource for the agency. FDA should attempt to secure funding to develop testing for methology -- for methodology, and that will be a long shot, as was mentioned earlier. Very expensive to develop those tests. FDA will be able to develop validation guidelines for the industry to set up methodology processing. FDA should search globally for technological innovations that may influence risk, and will the FDA become more efficient through implementation of the AFSS? are questions that were posed.

Question 5: Did they explain clearly enough how we plan to use the risk information? We wanted to see an example of how that risk model is gonna work before it either, "A," goes into regulation or becomes a suggestion.

Show what happens to the risk ranking when some changes -- when you change some of the assumptions to the risk model. Make sure clear definitions for each category of the sources, ingredients and processes are provided. Will expectations about resources change if the AFSS is implemented? And how will the AFSS affect the current feed ingredient approval process?

Question 6 was -- It's not listed on my paper. How would you -- That's not even our question. Sorry. Turn it over. Do you think the AFF -- or the AFSS should use risk-based approach to determine which feed contaminant needs to be reduced, eliminated or controlled in the feed and feed ingredients? Any scientifics-based (sic) approach include risk assessment and should be okay, is the group consensus on that one.

Programs should keep in mind potential media usefulness and reaction and develop, and any approach used is effective.

Information guidance to provide any agency may be useful, but if the guidance is a requirement in sheep's clothing. Now, I don't remember this one coming up either, but -- It's good as it's given in guidance, but once it becomes a regulation, everyone thinks on it differently.

How will the AFSS be modified as we move forward? Will there be other opportunities for public comment? Will the model and the AFSS system be designed to permit easy modification as environments and risks

change? Will FDA continue to evaluate data affecting safety and risk? Will periodic review of the data used in the model be built into the AFSS?

The last question, which didn't make this: We have modified the definition of "risk-based." Is the new definition more understandable? I believe our group agreed that it was more understandable. One comment that, that I can remember is that it needs to include and state both feed and feed ingredients to kind of cover the whole realm.

These are the comments and questions that we had when we discussed these questions, and anybody that has comments about this component, feel free to fill out one of those comment cards in the back.

MR. WILSON: Then we continue on. I think we're up to Group 3A, and the reporter is Blaine Hull.

BLAINE HULL, GROUP 3A

MR. HULL: My name is Blaine Hull, and I am a reluctant spokesperson for our group. My thanks go to Heidi for recording all this information down and the nameless

volunteer that typed it up on our sheet last night.

We centered most of our efforts on the gap for Component No. 3, and I'll read that just -- I'm sure most of you have it memorized -- this is exciting reading -- but for those of you that don't, follow along. Currently, the FDA has regulations that govern the controls used in the manufacturing, packaging, storage and use of medicated animal feed; however, to have a comprehensive Animal Feed Safety System, a broader regulatory approach may be required to address feed safety concerns associated with the manufacture, packaging, storage, distribution or use of nonmedicated feed ingredients in mixed feed. The AFSS team intends to consider the information gleaned from the public meetings and from responses to the materials placed in the AFSS docket in its development in -- of process-control approaches.

We had eight questions, and I haven't seen this, so I'm gonna go just off what I remember us discussing, and then those of you who feel that's not a true representation of

what we talked about can stand up in a second.

Questions 1 and 2 were problematic for us because of -- Do you agree with the identified gap? Yes, we agreed that there was, in fact, a gap. Do, do you agree with the identify -- Do you disagree with the identified gap? Yes, we do, and the exception that we took was to the second -- the second line, which states: However, to have a comprehensive Animal Feed Safety System, a broader regulatory approach may be required to address feed safety concerns. We had -- We had a difficult time with the regulatory part of that concern.

We, we recognize that there is a gap, of course, between some facilities. Those of us who are highly regulated would like the rest of you to share in that joy, I think was the consensus, really. Either that, or those of us who are currently feeling the joy would like to stop that, depending on, on, on that. That's good.

The FDA currently doesn't have the authority to demand process control by industry, and, and that's not entirely true, as was brought up -- There is a system in place

that will take care of these sort of concerns now in just the FD&C Act itself, and so what solutions do we recommend to fill the gaps? We had written on our sheet, in great big, giant, bold print, "no additional regulation," and there wasn't a "please" there, but we'll say "please" just the same, because it was felt that there is current -- currently in place, a way to take care of that problem.

No. 6: Would it be appropriate to recommend that firms develop written standard operating procedures for the entire feed production process? Alternatively, would it be sufficient to recommend that firms develop written SOPs for only those process steps that directly impact the safety of the feed? Correct me if I'm wrong, but I believe our consensus was that a minimum amount of required SOPs would be sufficient and not the entire process.

Now, we -- In, in saying that, we wanted to make sure that any, any requirements that -- Isn't this fun, trying to figure out where I'm talking from? I don't know where they are, but -- Just ignore that. Okay. Hang

on right there for a second. I'll get there.

Just requiring the limited amount and making sure that if it becomes a compliance and regulated thing, that our requirements are clear. There was a question of whether or not they should be gen -- broad generalizations as to the -- as to what our responsibilities would be, and our response to that question was: No, they need to be very specific to ensure that there is no interpretation of different inspectors, that we know very clearly what we -- our responsibilities are and can, therefore, fulfill them completely.

With limited regulatory resource, we should focus on hazards instead of -- Yeah, okay. That's pretty clear.

How should the process-control component incorporate feed-safety-related transportation concerns for both incoming materials and the outgoing products? That's Question No. 7. Basically, doing what we can to secure our facilities, secured drop pits, covered trucks, locks on train cars, those kind of things, were what -- basically, what we came up with.

No. 8: As envisioned, the Animal Feed Safety System addresses the labeling, production, distribution and use of all feed ingredients and mixed feed regardless whether these products are produced at commercial operations or on farm. How should the process-control component of the AFSS address the use, feeding or feed ingredients and mixed feed on the farm? What type of on-farm controls should apply to animal feeding? That was a very difficult question to answer because we recognize that, in fact, the agency has very limited funds, very limited resources, and to expand the scope of, of their responsibility from, from the, the medicated facilities that they have responsibility over now to every single solitary manufacturing facility, large or small, and farms, we, we couldn't come up with a way to make that work.

And so, again, with the FDNC that's already in place, should there be a -- should there be a challenge? We determined that perhaps it would be better not to start something else, to expand regulation, where it really can't be done effectively.

Okay. Scan through those now, and let's see if I've missed anything. Oh, hang on a second. The problem is the reaction versus proactive. We felt that, in fact, FDA's current method to deal with these is more reactive than proactive by just necessity, not necessarily by choice. That was just how it has to be. And we would like very much for there to be educational components to the industry so they can tell us exactly what we're supposed to do, because that will help us comply.

Okay. Let's see. There -- First visit with education in mind. That's right. That's right. It was suggested that, in fact, we get a freebee. First time we're not gonna lock you up if we come over and find that you guys are not doing it, but that that would be our -- a way for us, as an industry -- especially if there are new guidelines in place, for us to understand what our responsibilities are.

Okay. Agroterrorism concerns. Really, that was just common-sense stuff again, just locking up our facilities, 'cause it's

kind of hard to prepare for a problem that there isn't really any set -- You know, if we -- If they just give us an itinerary of how it was gonna work, then we could plan better for it; okay?

Okay. That -- Okay. All right. I believe that's all our group discussed. We discussed many things. Sometimes the discussion was pointed, but it was good.

From that group, now, are there any things that I missed?

MR. COSTIGAN: Tim Costigan with Prince Agroproducts. We got a little bit into the discussion about being proactive or reactive, and out of necessity, we feel that most of the regulatory agencies are reactive. They find a problem either in feed or they find a problem in a food site, and they investigate that back, try to identify a source, and that's very helpful.

The responsible industry and responsible individuals involved in the industry tend to be more proactive, and that's really their role in this whole scheme. If they can take a look at their process, evaluate

where risks come in and take care of that, then that certainly makes the entire feed system a little bit safer.

There's kind of that third group there, and that's the group that's really of concern. They're inactive. They really don't do much of anything to prevent safety concerns. They're not overly concerned about 'em. Part of it is due to ignorance or, or, you know, not understanding what they need to do, but I think there are individuals who just aren't interested in that part of it. They're there to make a buck. They want to move on.

So the real question with the Animal Feed Safety System isn't how do you put more regulation on industries that are willing to comply, but how do you bring the rest of them into the fold? And that's something that this system needs to address.

MR. HULL: Any others? Okay. Thank you.

MR. WILSON: All right. Now, we have one question here. We'll --

MS. DUNNAVAN: I, I want to ask the group a question.

MR. WILSON: Okay. Just wait for the microphone.

MS. DUNNAVAN: Well, I (inaudible) -- Ferris, can you go back to the very beginning of their -- I just wanted to ask this -- the group, 'cause I don't quite understand -- In your comment here, regulation should be based on end result, some agreed with this only with respect to the regulated industry segment, which is medicated feed. In this respect, the term "process control" is wrong. Can you explain that? I -- I'm not sure that I quite understand what you mean by "process control is wrong."

MR. HULL: Honestly, I can't explain that paragraph, because I don't remember it being one of our conclusions, so -- Is there anybody in the group that can address that?

MALE VOICE: Is this on? We felt there is a lack of understanding, Gloria, to what "process control" means, that there is a need for upstream and downstream controls from the feed mill and that the term "process control" implies controlling a particular

process -- i.e., feed manufacturing -- and that, therefore, we need to incorporate some other terminology in order to address those types of systems they use.

MS. DUNNAVAN: Thanks, (inaudible).

MR. HULL: To expand on that just a little bit, when we were talking about process evaluations, you know, I think that's maybe a little bit clearer term for people, but looking at the process control, there's two aspects, and I spoke about that a little bit earlier. When you have no process to control, you're handling a material produced by someone else and you cannot get to their process, whether it's overseas or someone that you really don't have access to, then you need to revert to the product control. And just referring to process control, it left it awfully wide open. It was not easily understood, and it's a term that's better understood in many other industries to mean other things.

MS. DUNNAVAN: Thank you all.

MR. WILSON: Okay, Lee

(phonetic). Any more questions I -- Oh, we have a --

MS. PETERSEN: No, I -- Just a comment. Process control -- This is Marlene Petersen with Milk Specialties. Process control is generally considered to be a quality program, not a hazard or risk-based program, so in the industry, if you use the, the name "process control," you're generally talking about quality programs which are not necessarily applicable to what we're talking about here.

MR. WILSON: Any additional comments? Okay.

We'd move on to Group 3B. Randy Sample is the spokesperson -- the reporter for this group.

RANDY SAMPLE, GROUP 3B

MR. SAMPLE: Good morning. We had many of the questions that the previous group worked on. I'm Randy Sample with ADM, Alliance Nutrition and Animal Health Nutrition. I'm affectionately known by our marketing department as Director of Sales Prevention, so . . .

We looked at: Do you agree with identified gap? And this area worked -- The objective was to develop a framework for the use in prioritizing and allocating inspection enforcement resources to minimize a risk of animal and human health, and the gap that was, basically, identified in here dealt with the hazards of the Bioterrorism Act and controlling livestock diseases and bringing in the transportation issue. I said, Do you --

We did it a little bit differently than the other people reported. We kind of broke it down into the industry's concern, the state concerns and the FDA concerns, so we felt like, in many cases, they were a little bit different. We wanted to get those down and -- that we could discuss.

I said, Do you agree with the identified gap? I think we all said -- industry said yes. We agreed that the gap -- We feel that on-farm operations or nonmedicated feed mills are the missing link that's not being looked at previously. FDA says they have the authority to go on farm now and the FDA authority to inspect unlicensed plants, but

they don't routinely do this. That falls under the state purview, and the state side of it said some states may not -- don't have the authority to go on farm, and some may not want the authority to go on farm, unless they've got the governor of California to go in with 'em as a backup.

And yes, we do -- did agree with the gap. The -- Question 2 says: Do you disagree with the gap? We said no. What gaps have we missed? We had a lot of discussion on the transportation issue, how it was dealt with within the framework. I think you also -- We thought that the local farmer transporters needed to be dealt with because they were also a possibility or a risk area that could cause contamination.

And then, again, we brought up the age-old comments about the railroads. How do we get the railroads to buy into this process without just having us -- We won't give you a car to load your feed.

So those are things, I think, we all are dealing with. We need a standardization form, that accompanies shipments, showing

compliance with AFSS procedures. We sort of answered this again in Question 4. And also, we need to look at the mixing at the farm level, but there's also manpower issues to implement on the industry side and on the regulator side, and again, a lot of discussion was held on equal enforcement. As a gentleman earlier talked about, you know, we all are into this inspection mode, and sometimes it's, Get all the inspections we really don't need. With all the BSE and other issues, I wonder if -- sometimes, that, you know, they should kind of be combined.

And also, it comes down -- They felt like the cost of the farmer was going to be an issue, and it comes down, it's gonna be forcing more of the prac -- to go the route of integration that the poultry industry and the swine industry is going to very quickly.

What solutions do you recommend to fill the gap? We felt like the industry was -- need to catch up other groups -- i.e., the transporters and on-farm processes -- before putting more regulations on the feed industry in general. We thought that a standardized

form for compliance with AFSS was needed to cover the farmer transporters.

And for gap on dealing with farmers, we need to make it appealing to the farmer to be interested in the process and in the products that are in compliance, and possibly would go through -- via the different, like, pork board associations to get this word out to these different farm groups. I saw the certificate -- certification of buying, selling appeal -- certification received due to going through training, and the training sessions need to be held through all processes -- all steps of the process.

I also felt like that a national animal I.D. system would be needed. States felt like, currently, the I.D. system is for disease traceback. Therefore, information may not be available to do all that we want to do or provide.

For dealing with the on-farm mixers, we like the certification of training, and the industry felt like we'll need deadlines for training or you're-out-of-business-type process. Joint meeting with pursuit --

producers and farmers and tell them to bring their books to show that they are complying with that.

And FDA felt like the recertification, after a required number of hours of training, pretty much like some -- where the pesticide industry has gone. And for manpower on how to do this, we don't know. You know, we couldn't come up with some real issues with -- there.

As far as dealing with enforcement, felt like that there isn't equal enforcement now, through that lower part of the pyramid, to the on-farm, to the small producers.

How do (sic) the process-control component incorporate agroterrorism concerns? We felt like we needed to show or get complete compliance with the Bioterrorism Act, and it is impossible to check every contaminant. We could, but no one could afford our fee.

Facility security, we talked about that, how the small operations can make their systems more secure, and felt like we also needed to know our vendors who we're getting product from.

Educating. The states felt like educating parties need to be involved in what they're affecting. Assess the risk within your facility or process, the vulnerable points, and the impact that agroterrorism may have on those points. We also felt like we needed to be able to reference lists of who to call if a situation occurs. Like if you know a contamination happened in your plant or in your operation, who do you call first, or how do the contacts need to be made? Reactionary plan for: If something happens, what do you do? Mock recalls, mock inspections should be the norm.

We also felt like training employees to look for things that are odd. I think one of the people in our group had some background in the enforcement area and felt like we need to train people how to look -- if something is out of place or just doesn't look right.

Question 6: Would it be appropriate to recommend that the firms develop written SOPs for the entire industry production process? I think the industry side of it said they like SOPs, and farmers have a difficult --

difficulty passing the cost of keeping SOPs to someone else. A lot of discussion was on, we can -- As an industry, or ingredient-wise or production-wise, we can pass these costs off to the farmer, but the farmer doesn't have that same opportunity to pass his costs off to who he sells his product to. And who is going to do the SOPs for the farmers and the mom-and-pop mills? That question was brought up. Should we provide them assistance in doing this? We like the idea, but it's hard to implement at the farm level.

And Question 6 is: Alternatively would (sic) be sufficient to recommend that firms develop written SOPs for those process steps that directly impact the safety of feed? It says -- The industry said, Difficult to separate what does affect the safety of feed, because it all does to some point.

Must be careful when writing SOPs. If you write a garbage SOP, you will have a garbage product. And we went through the whole issue about -- We have people out there that want low-cost products, so the industry has a blast with that. Might consider making SOPs

for known hazards. Of course, we felt like that was difficult to test for everything. In the FDA, some parts could be pulled out, exemp -- SOPs if it does not affect the safety but only affects the quality: the size, the crumble, the fines in the feed and those areas that doesn't really affect the animal. States felt like they needed generalized SOPs, not specific ones. How do we do this? We don't know. We like the idea. We don't know how to implement and enforce these.

Question 7, we kind of went back to Question 3, where we talked about the transportation issue and what needs to be done in that area to the truckers and the railroad companies.

Question 8: How should the process-control component of AFSS address the use of feed ingredients and mixed on -- feed on the farm? I -- The industry felt like we have, have met -- (Inaudible).

(Inaudible.)

MR. SAMPLE: Okay. I didn't -- -- packers mandate -- put pressure on the farmers, the farmers follow the process --

procedure. So that was probably one area that -- And you see a lot of this coming from Japan and the foreign market, where they're demanding certain things be done.

The states also felt like that there's a niche market people out there more difficult to bring into compliance. People who are selling organic products or unnatural products or specialty products would be hard to reach with this process.

And we had one comment I think you hear about at any meeting: We need to teach farmers how to read the labels, 'cause many times, that's not done. FDA said they had jurisdiction over the animals, maybe also under USD -- USDA control.

And the Question A -- Part B, what type of on-farm control should apply to feeding -- to animal feeding? A farmer should not have to pay for this. Consumers want it; they should pay for it. Comes back to: Have we seen a groundswell movement asking for these specialty deals?

Farmers have obligations to produce safe feed and safe product, which I truly

believe they all work within that guideline, 'cause they know if they don't have that, they won't be in business much longer. Should the production of safer food be at any cost? And that was raised.

It was interesting, as we went through all of these, one of -- the facilitator, the young girl that was there after it was over, we asked her, would she now go out and eat meat after hearing all the different topics? But yes, she said she would.

(Inaudible.)

MR. SAMPLE: No, I think the discussion went real well. We had a lot of participation around the area, and -- Any questions?

MS. DUNNAVAN: I, I have a question. Randy, earlier in your discussion, you talked about a standardized form. Can you talk about that a little bit? Is that just -- Is that just for the transportation piece, or is this something that the industry would have to check off, I've done this, I've done this, I've done this, or it --

MR. SAMPLE: I think what they

were -- we were discussing -- and some of the other ones that are in our group, correct me if I didn't portray this right -- was an SOP standard form that a farmer or a small operation could take and utilize.

MS. DUNNAVAN: Oh. Sort of a fill-in-the-blank kind of --

MR. SAMPLE: Right, fill in the, kind of, blank.

MS. DUNNAVAN: Oh, okay.

MR. SAMPLE: Because it's gonna be difficult to get that segment of the industry to follow this without giving 'em some help to do it.

MS. DUNNAVAN: Okay. Thanks.

MALE VOICE: Yeah. Randy, also, I think we were looking at more in the transportation side of things, where, right now, when we call a supplier of ingredients and say, Hey, you know, can you tell us what was in that car, you know, something looked suspic -- we, we get very little paperwork oftentimes showing previous loads and all that type of thing. If there was a standard form, you know, within the industry that would automatically

accompany invoices, bill of ladings, whatever, and that everyone would demand it and expect it from any type of carrier, I think it would help a lot.

MR. SAMPLE: Any others? One more back (inaudible) --

MR. WOODWORTH: Yeah. Rich Woodworth, Food Animal Concerns Trust. We're a consumer group, and we like niche markets, and I'd like to hear why it is you feel niche markets would be hard to regulate or involve in this program.

MR. SAMPLE: Finding those niche markets, where they're produced, sometimes is difficult. Does anyone else have any comments? I think we felt like that they weren't well known by the regulators or the states, how these niche markets move in and out. And also, the e-mail -- the Internet, how does that affect? Someone else?

FEMALE VOICE: Yeah. Okay. I just wanted to make the comment in, in response to, to your comment over there. AFIA's Ingredient Suppliers Council has developed a transportation form that ingredient suppliers

are to use for -- or to make sure for restricted products, as well as other ingredients. It's not just to those products. And that form requires them and the transportation company to identify what was in that -- in that truck, or whatever, prior to that shipment, and they have to sign off on it. So if -- You know, if ever you --

MALE VOICE: (Inaudible)?

FEMALE VOICE: And if the --

MALE VOICE: In other words, if --

FEMALE VOICE: Well --

MALE VOICE: -- (inaudible) doesn't supply (inaudible)?

FEMALE VOICE: Hopefully, they're not gonna use 'em, but I'm not naive either. But on the -- It is a little more controllable on the truckers, I think, than the rail.

MALE VOICE: I mean, we, we can put things in place ourselves --

FEMALE VOICE: Right.

MALE VOICE: -- but there's still that one (inaudible) where if there's no

(inaudible), I mean, there's nothing to encourage them (inaudible).

FEMALE VOICE: Right. I know some of the ingredient companies have reported back to me that they -- And I know this is just some, but they reported back that they absolutely will not use that truck unless those people sign off on it, so . . .

MALE VOICE: The trucks (inaudible).

FEMALE VOICE: Yeah, exactly.

MALE VOICE: We addressed that same issue in our group, 3A, and most of the feed mills today have a requirement that truckers, when they come in, they sign off that the truck has been cleaned and so forth, but I think we went along with that same point, the problem being that a lot of 'em will say anything to keep their job. In fact, we had an example within the group where one recently just lost a job that refused to do that, told the truth. So that you need a regulation to back it up, to put some teeth into it, and unless you have that, we continue to have an exercise that really doesn't really guarantee

safety.

Also, in the area of SOPs, 3A addressed that, and one of the things that we got into on that was that SOPs would be needed for the safety issues, and the point being that, well, maybe you don't need 'em for the nonsafe issues, but all in all, when you end up with it, you end up with a total written package, because it's -- you can't really differentiate.

MR. SAMPLE: To answer the gentleman's question about the niche markets, I think the group felt like there was just lack of knowledge, what those products were and how they were used, so . . .

Any other questions?

MR. BRIGHTSMAN: Yeah, Randy. John Brightsman.

MR. SAMPLE: I didn't do it, John. Wasn't me.

MR. BRIGHTSMAN: I got a question for both, both groups, as far as the -- I heard about the SOPs and whether there was any discussion about AAFCO's checklist --

MR. SAMPLE: No.

MR. BRIGHTSMAN: -- whether anybody is using that --

MR. SAMPLE: It wasn't brought up at our group.

MR. BRIGHTSMAN: -- whether -- You know, that would be a good starting point, 'cause that was -- excuse me -- that was a voluntary program that AAFCO had worked on with the industry to come up with something that would provide guidance and so forth.

MR. SAMPLE: Well, again, I think we'd look at it as far -- It'd be an education process. Has that gotten out to the farm level or to the small production area, that this is available? It's almost felt like it's just, basically, an education process. There are forms out there they can utilize. People just don't know where they're at, how to use 'em. Okay.

MR. BRIGHTSMAN: Thank you.

MR. SAMPLE: And I guess I got my immunity stick; right, Bruce? Did you negotiate that, too, for our next inspection? We can get an immunity stick? Okay. I can see we're all together. Whap. No.

MR. WILSON: Okay. We're a little bit ahead of schedule, which is great, because then we can make sure we have plenty of time for questions and answers at the end. I think now we're gonna go ahead and take our 30-minute break. I've got about -- a little past 9:15, and so about a quarter 'til 10, we'll get back and get started. They have set up for us, I think, just the -- As you go out the door to your right. So 30 minutes.

(A break was taken from 9:15 a.m. to 9:45 a.m.)

MR. WILSON: -- a little bit out of order on the way -- the 1, 2, 3, 4, 5 scenarios and jump straight to 5, which is risk and risk-ranking method. If we could, I'd like the reporter for Group 5A, which is Judy Thompson, to come down and take the podium.

JUDY THOMPSON, GROUP 5A

MS. THOMPSON: Thank you. I'm Judy Thompson from the Canadian Food Inspection Agency, and it's a little bit -- I was a reluctant reporter, as well, I must say. I tried a new tact. I kept my mouth shut for five minutes, and I got nominated instead, so

that didn't work.

I want to put on my other hat just for a quick second. I'm the president-elect for AAFCO, and I wanted to thank the FDA, on behalf of that organization, for inviting all the states to participate in this very exciting meeting about an, an initiative that we're all very interested in participating in, so thank you very much for putting on this meeting. It was great.

So the group I was in was very -- What's the right word? We were very quick in getting our work done, so we had some extra time and put together a PowerPoint that sort of summarizes our discussion. So our first question -- And I thank Dr. Hooberman for his help, 'cause if he wasn't in the room, I'm quite sure that we'd still be there talking about the risk-ranking method, 'cause we had a lot of questions, and he was very, very helpful in, in helping us all see the light. So I think if you could send him around to a variety of places and he could describe it all to people, that you would be very well served by that spending of that money, as well.

And so the first question was, was our explanation of the risk-based -- ranking method understood, and how can we improve its clarity? And the answer is on the next slide. I think the answer to that first question is pretty obvious, that -- We, we spent about 40 minutes talking about things before we actually got to answer the question, so I think the answer was, kind of, no. We more or less understood what was going on with the process, but we didn't really know what other things might be considered besides science. Was politics in there? Was there economic impacts? Were we concerned about the environment? How was that all gonna impact on the final ranking? So there was a lot of, I guess, uncertainty about what that actually meant. And I think the thing that we all sort of felt that would have helped is if we had a couple of examples of, of common feed ingredients and known risks and had put them through the process, and we could look at their relative scoring, that we would have an understanding of sort of how something that was pretty uncommon, that had a big impact, or whatever, would look and what

that number would be, and so we did sort of evaluate whether or not it made sense, so . . . That would be our suggestion.

And we actually talked about, maybe, corn and aflatoxin as being a good example, 'cause you look at, sort of, maybe, either high-risk years or high-risk situations versus kind of a normal situation and give a comparative rating, and that would give people, I guess, more of an understanding of what was going on and some comfort with the whole process.

So the first -- The second question was: Do you agree with the risk-ranking method? And our answer was yes. It looks like it was conceptually sound, and again, just felt we needed to see that in action to make a final determination, but it looked like it was the right way to go.

Third question was: Do you agree how -- with how we plan to use the risk-ranking method? And yes, we did agree with that, and we felt that -- again, that the use of the system needed to be based on science, not on politics.

The fourth question: Are there other methods other than risk ranking that should be considered for prioritizing these hazards, how they should be addressed, and what are those messages -- methods, and what are their advantages over risk ranking? That was a bit more difficult. We kind of went through a process, and luckily, we had a break right then, and we had asked Dr. Hooberman to think about some ideas of things, and then he came back and told us he wasn't allowed to talk to us anymore, and we told him that that wasn't really -- wasn't really very helpful, so -- 'Cause he had been informed that he was supposed to be a listener and not a participator, and we said that he wasn't, sort of, taking over the group, so it was all right if he talked, and so we had a bit of a chat.

And then somebody brought up the fact -- We had talked about -- Most people could probably come up with what they thought were the five biggest risks based on their experience or based on things that they -- suppositions or whatever, and we thought it might be a good idea to go out to the various

state regulatory officials, the stakeholders' industry groups, the farmers, and just ask them what they thought the top five were, kind of look for some common elements there, and we felt there was also a lot of information out there. People are testing for things and looking at things, and they're most likely looking for the things that they think are problems so they'd have a lot more information on their top five than other things. And if there was a way to collect all that information, maybe have an on-line database on the FDA Website, where people could just go and enter their data sort of anonymously, and then it could all be there as a -- sort of a hazard database or a risk database that we could use long term. There was some -- We're not, I guess, all naive enough to think that everybody is gonna go there and dump all their information onto this Website, but there was thoughts that if it could be anonymous, that that might be an option.

And then the last question was: We have modified the definition of "risk-based." Is the new definition more understandable?

And, I guess, given the fact that there's four bullets there, the answer to that question, again, is no. We felt that you need to keep it simple, and you shouldn't define another thing in the -- in the definition for something else. If you're gonna define "risk," you can have two separate definitions. Define "risk," then define "risk-based," so don't put them two -- the two things mushed together in one definition. And we also thought that having the third sentence, which talked about how are we gonna use the risk-based, was really unnecessary in the definition, because a definition is just that. It's supposed to define what it is, not necessarily how it's gonna be used.

So that was our thing in a nutshell. Sorry it didn't take 20 minutes. But we really had a good discussion, and if anyone else in the group thinks that we missed anything in our synthesis of all the spreadsheets and flip charts, please speak now. That's it. Thanks.

MR. WILSON: Are there any other questions for (inaudible) at this time? Okay. Then let's move on to --

MALE VOICE: (Inaudible.)

MR. WILSON: Oh, we have a question.

MALE VOICE: Well, it's not a question, just a further comment. In the group, we also spent some time discussing the, the dynamic that who defines the risk often will determine the level of the risk and the nature of the risk, and we talked about, you know, the industry or consumers or public health participation, and out of that, some of us were encouraging that the process do include risk setting involving all those segments, particularly public health.

MR. WILSON: Thank you. And now the next presenter is Mr. Charles Breen from our Seattle District Office.

CHARLES BREEN, GROUP 5B

MR. BREEN: Good morning, and thank you. First of all, in our group, as you can tell from the very beginning, more no than yes, yes, it's clear. We didn't ever really come to a consensus. We had to use diplomatic speak, a full, frank and vigorous discussion of the questions and issues. And I'm going to

refer any difficult questions to legal counsel, whom I have just spotted in the group here.

For the first question: Was the explanation of risk ranking understood? Well, some of us thought we did; others disagreed. The majority opinion was no, it's not well understood yet, and as mentioned in the earlier 5A group, some examples would help.

I won't just be reading all of this because you can do that as well as anyone, and I know that farmers do read. They just may not want to pay attention to what they are reading.

The, the question of risk-ranking method really was a difficult one to come to any consensus among us, because the vigorous discussion was -- Well, there were too many unknowns yet: the way it was going to be used, how it would apply to specifics, in how much detail would it be applied. These kinds of things are issues that, I think, the Center for Veterinary Medicine would be well advised to explore and provide more information to the stakeholders on how to -- or how it is intended to be used.

The second question of, Do you agree

with the risk-ranking method? Well, it got tied up with the first question and the third question, also. From the industry representatives, the answer is pretty much no, but a lot more data is needed. The idea of, you know, assigning each ingredient an impaired risk ranking, that becomes an enormous task when you have to cover the whole gamut of potentials that -- Other variables, would they be considered? The comment was made, and it appeared to be one that was broadly accepted, that, in many cases, feed is not the problem. The control mechanism should not be applied in feed when it might be applied much more economically and effectively at some other point in the process, between farm to fork.

The industry acknowledges that a lot more scientific data is needed, a lot more public scientific information. There is a great deal of scientific information that is held by industry but is not shared with FDA because we, FDA, cannot keep that information private. There is the Freedom of Information Act and, also, the public records. The data that is held by industry is used by industry in

its quality assurance programs, and I'll touch on that a little more later.

The third question: Do you agree with how FDA intends to use risk-ranking method? Well, no. Whether it was top to bottom would be preferred to bottom up, as long as there's significant data to assess the risk. A broad-based -- A broad-based research and comprehensive data set is needed to provide information necessary to provide a good, solid, risk-based system.

We also acknowledge that there are other factors outside of scientifically available data that drive FDA's risk-based decision-making process. For instance, right now, in this country, BSE is a very low-risk problem, but it is a high priority for the Food and Drug Administration. There are nonscientific drivers that make it a high priority for the Food and Drug Administration.

So how is this risk-based process going to accommodate these nonscientific drivers? They can be considered -- called politics. They can be called consumer perception. Whatever it is, there are issues

that are outside of the probability and the consequence matrix that are used for risk determination. Risk ranking is just not enough.

The fourth question: Are there other methods for risk ranking that should be considered? What and why are they better? Well, again, we talked about risk in the context of all three of the previous questions, and some advice was suggested about focusing on current programs to identify weaknesses that do exist, a test pilot, you know, just to see how it works, to say, Using this kind of ingredient that would be used in this fashion, how would this method apply?

There was a suggestion that the AFSS survey the industry to see what programs there are out there, and the programs that are out there may provide those industry members who used them with a competitive advantage, and because of that, those industry members are reluctant to share them because they could not be kept confidential, and why tell your competitor what you're doing to make your product better when what you want to do is make

your product better so that it sells better than your competitor?

The second part of that question: No, no alternative methods currently.

And the last question: Is the new "risk" definition more understandable? Well, yes. It's as clear as the first one. There wasn't much discussion in our group as to whether one was any better than the other.

There were some other currents during this discussion, this full, frank and vigorous discussion that we had -- that we had, that I'd just like to mention, that will affect how we, FDA, deal with the question. One is that industry is rapidly consolidating. From a regulator's perspective, which is what I have, to me, that sounds like a moving target, and the government bureaucracy always has a hard time hitting a moving target.

Likewise, there are industry practices that are rapidly changing -- not necessarily improving, but changing in response to market demands. Pull-through, I think, was the term that was used, where a big customer says, I want you to . . . Whether or not it

makes sense, if you want to keep that big customer, you will do whatever that is the customer asks for. Although the big customer was not named, I know that Wal-Mart does a lot of that. They don't buy that much animal feed, but the same kind of practice, where they say, you know, Do this for us so that we can say whatever to our customers.

And not only individual pull-through for the market, but other governments. For the export industry, some countries have what amount to -- well, I hesitate to call it nontariff trade barriers, 'cause they apply to everybody, but they're certainly trade barriers.

And there is also, at times, a competitive advantage to having a quality system that's better than the other guy's. As I mentioned just a little bit before, one of the reasons why industry -- some industries are reluctant to share with the government what it is they're doing to assure quality is, when you've built a system that's working and you have a brand-name product in the market, you don't want your competitor to be able to

piggyback on the benefit of that experience, and that this is not just a competitive advantage, it is at a competitive disadvantage to be publicizing those details.

Now, are there any questions that I need to refer to counsel?

MS. DUNNAVAN: (Inaudible.)

MR. BREEN: Gloria?

MS. DUNNAVAN: (Inaudible.) I don't know if you need to refer this question to counsel or not, but I just -- Could you give me a little more explanation? At the -- sort of at the beginning of your discussion, you talked about that maybe something would be -- Let's say I'm a finished-feed manufacturer, and there's an issue that I'm concerned about, but I may not be the one that has to deal with that. It may be somewhere else in the --

MR. BREEN: Yes. Let me get to an example --

MS. DUNNAVAN: -- farm-to-table continuum.

MR. BREEN: -- that was discussed. Microbiological quality of animal feed. What data is there to suggest that the

microbiological quality of animal feed contributes to food-borne illness in humans? Salmonella in chickens. Well, if you cook the chicken, that kills the salmonella, and that if there is salmonella in chicken but it wasn't in the feed, how did it get there? It could well have been feeding practices at the animal producer. It could have been flies that land on the manure and then onto the feed. If there are other control steps, other than feed-control steps, that might control that hazard better and more effectively than just providing a pasteurized feed product to an animal producer.

MS. DUNNAVAN: So under that sort of scenario, then, I would -- If I -- If I'm thinking it's better control somewhere else, than I just -- I wouldn't deal with it (inaudible)?

MR. BREEN: That --

MS. DUNNAVAN: I'm just trying to make sure I'm understanding the concept.

MR. BREEN: Well, the -- Please, any of the group pitch in, as well.

MS. DUNNAVAN: Sorry. I'm not picking on you, Charles.

MR. BREEN: The way it was being presented -- The way it was being presented is that for that particular scenario, the cheapest way to control human illness is to educate consumers to cook the chicken well and use separate cutting boards, or whatever, and not cross-contaminate it in the kitchen with the chicken and the raw vegetables on the same cutting board, that sort of thing, that that works and is cheaper and more effective than whatever we might want to spend on feed controls.

MS. DUNNAVAN: Okay. Thank you.

MR. BREEN: Anyone else? Thank you very much.

MR. WILSON: All right. Now that we've finished with Group 5, let's jump back to Group 4. Would the spokesperson for Group 4B, Dan Danielson, please come up. Group 4B -- or Group 4 is brief -- is discussing regulatory oversight.

DAN DANIELSON, GROUP 4B

MR. DANIELSON: Or better known as cart way before the horse. I think once this comes into focus, we could be better

served to make recommendations on an enforcement strategy.

We had a good group, as well, very diverse, very participative, except for the point when they chose to elect a spokesman, and then the patterns in the walls and the carpet and everything got real interesting, so I guess I was anointed as being from the Volunteer State and should keep up with that tradition.

As far as the identified gaps for the regulatory oversight, the first one we had a little trouble with only because we think that's the gap and the solution all in one, I guess. Currently developing a risk-based inspectional approach, that's a gap, and I guess the development of such is the solution.

No. 2, I think we had a spirited debate about, as was said. Not quite the same words the last speaker used, but there's a couple things we wanted to take exception to. First of all, the statement that we focused principally on commercial medicated feed industry is true to an extent, but particularly in my state, we have focused on feed manufacturers. Our, our FDA-licensed mills in

Tennessee keep dwindling. We -- We're down to about eight or nine, something like that. We have about 150 manufacturers, so we've been looking at manufacturers in general.

Secondly, the, the statement about some on-farm operations are making more feed than most commercial feed companies, well, I don't know. I guess that could be true somewhere. Certainly not in Tennessee. Some of our integrated outfits may make more feed than some of our smallest mills, but I'll guarantee you they do not make more than some of our biggest manufacturers. So that may be true in some states, not, not particularly in all.

Let's see. Going to 3 -- Oh, just to say, we basically agreed with all the gaps in some fashion or another. The third gap of insurance competency and proficiency with state and field inspectors, that's very admirable. We want to do that. We want to do that in all of our programs to make sure our inspectors know what they're doing, they're capable, they understand the, the industry and what we're doing. It asks for traditional novel

approaches providing training. Well, maybe we'll want to take a step back, and maybe my bias is dealing a lot with EPA programs. We do a lot of hands-on training, a lot of regional training for inspectors via EPA. I think we like that better than these computer modules. I don't know how it works for your field staff. I have field staff. They're very proficient in working through computer modules. I have others that it's extremely painful for, and I don't know what they really get out of it. So again, I think some face-to-face, hands-on regional training by FDA for state inspectors would be great, and again, prefer that over computerized modules.

I think the gap that, that we identified in No. 3 was, Well, what about the industry? How are we gonna get the word out to industry? And I think big industry, the, the larger players, the more responsible industry are in this room. They get it, or they want to get it, or they want to fight it, whatever, but they're in the game. It's Billy and Bubba out in Podunk, Tennessee, that we worry about. How are we gonna get the word out to them? They

probably do not belong to AFIA. They may not belong to any trade association. Perhaps extension would be a way to get to some of those folks, but we think that's a gap. How are we gonna get the word out to industry and especially the smaller mom-and-pops or Billy and Bubba out there running a little bit of a mill in a Quonset hut?

And also, as part of my agreeing to be the spokesman, I was assured that I would be backed up -- it remains to be seen how far back -- by my -- by my group as far as if I miss some salient point here.

I think one of the gaps, as far as the Inspection No. 2, is this whole issue of what states have on-farm authority, to what extent do we have on-farm authority. FDA claims to have on-farm authority. Do they have the authority if none of these products are shipped interstate? So I guess the solution for that is, is, we'd like to see AAFCO come up with some language in a model bill for on-farm authority. The other choice that some states have done is go out there on that limb by themselves, but I think we're better served to

have a model bill, have some framework and have something that we can go to our local legislators and administration, say, Yeah, this is the thing to do. We have a model. Everybody else is doing it, so we need to do it, as well.

One additional gap, I think, that we identified on this whole manufacturing process is we cannot keep our -- we can't lose sight -- take our eye off the ball or the finished product. You know, quality is, is an important thing. Quality is really the genesis of a lot of our feed regulatory programs. As we know, these feed regulatory programs go way back in states, and again, foundation is consumer protection. While process for safety, we feel, is very important -- I don't think we can forget that, and within that, we still have the issues of imported feeds. You know, that was mentioned in one of the other presentations. There may be firms, we can't get to their process, so we have to rely on looking at their finished product. Frankly, it's easy for us to look at finished product for quality, look for some contaminants and things of that nature.

There's this whole Internet thing. We're not gonna be able to get to processes there, so again, that's a place where we need to focus on the -- on the end product and not just the process.

This is a little disjointed. It's no fault of our recorder, Andy Gray (phonetic). He did a -- He did a -- He put a good effort into it, but our, our discussions were so freewheeling that I think it -- we had a little, little trouble keeping on, on target.

We think there's a component here for self-inspection programs. I, I hesitate to use voluntary self-inspection programs. I think there should be self-inspection programs with a regulatory oversight. Not "I," "we" think. There should be self-inspection programs with some sort of regulatory oversight component.

Back to the, the gap on record-keeping of, of transportation. We talked about trucks and rails. Nobody has mentioned barges. I think barges come through. And again, I think -- we think that there's the potential for some sort of self-inspection program with regulatory oversight.

Now, to get to the, the, the other questions, how, how may the AFSS affect federal/state relationships? Well, it depends. On one hand, you could see it as an unfunded federal mandate. Here I am with my pesticide bias. In other words, if we're asked to go out there and do a whole bunch of firms that we don't normally do -- I mean, again, we focus on manufacturers -- commercial feed manufacturers. If we start going on farm, we start going to dairies, the integrators that are not FDA licensed, well, we've just opened up a whole new clientele for us, and that's not necessarily a bad thing, but again, from the state that's probably doing about all we can do with what we got, what's going to give -- something's got to give.

We -- You know, of course, there is always the money issue. You know, I think it's only fair to bring it up. You know, what, what level of funding are we gonna see -- increase of funding for doing increased number of inspections? Perhaps FDA ought to look at the EPA model and look at performance partnerships, grants with states, instead of paying by

inspection or these partnership agreements, whatever they are. Doesn't amount to a whole lot. If we're gonna get into this, then, to a much larger way, I think it's something that must be addressed.

Question 5: Should regulatory programs focus solely on risk? Well, no. Again, back to what I said, we can't take our eye off the ball on finished product. And again, maybe it's just from me coming from a production background, but if you buy 36-percent protein feed, I would think that you pretty much expect somewhat close to that. I think the consumer protection part of it is, is still vital and still real, and I don't think that the safety -- although it's an important component, we don't want it to overshadow the quality assurance and the quality-of-the-product issues.

If process controls are established for on-farm manufacturing, what would regulatory oversight, such a program, look like? Well, one of the wags (phonetic) in our group said platypus. That's probably what it's gonna look like. In reality, I think the only

way it's going to work is we're gonna have to have a defined implementation schedule, put this in place over time. An example might be the first year would be completely outreach and education; second year, you might go to some compliance assistance, actually visiting these firms, looking at what they're doing; and then lastly, going to a compliance program. But again, there's got to be some time and some effort spent on putting this in place before we go into enforcement. And again, as it says up there, lots of outreach.

And then it was suggested that the risk-based system -- And I think that was mentioned in some of the earlier ones. There's some risk-based systems already out there, and perhaps we want to model, model, model this after that.

But basically, assistive controls must include economic protections to fulfill state statutory mandates and provide consumer protection, as well as feed safety. I don't think we can forget about that.

Okay. What'd I miss, y'all? Is there any questions? All right. Thank you.

MR. WILSON: All right. Next, next on the program would be the presenter from Group 4A, which is -- I'm sorry, your name, ma'am? Oh, no. This is Marlene, Marlene Petersen.

MARLENE PETERSEN, GROUP 4A

MS. PETERSEN: I wanted to thank the FDA for the opportunity to participate in this process, and since there is a lawyer in the room, add my legal disclaimer that in no way should my comments be construed as an endorsement.

And for our group, we essentially agreed on the gaps, and we spent some time talking about them from the standpoint of, of, you know, what we agreed -- We got kind of mixed up between the agreement -- where we -- the gaps and where we thought there were some misses. In essence, if there is gonna be an inspection program, we did agree that it should be a risk-based system, but there was some concern over the BSE inspection process, the guidance, because the risks are different in BSE, and -- You know, whether or not that was a good example or not -- You know, it's probably

the only one out there, but . . . We felt you need to develop a separate risk base for feeds and foods and that the risk-based model was definitely the way to go.

We did agree that the -- you know, the predom -- preponderance of the inspections, the regulatory focus in the past, have been on medicated feed and, to some extent, feed manufacturers, and that there is a component that really needs to be brought in. Transportation was discussed extensively. There are -- I don't think there's anybody who -- in the industry who doesn't feel that transportation is a problem for us, and if you're gonna have a comprehensive program, you've got to deal with the transportation aspect and also the on-farm aspect.

It was also brought up to not overlook mobile mixers. Apparently, there are, in some parts of the country, people who get, I guess, old cement trucks and drive from farm to farm mixing, and I'm pretty certain those mixers have been validated, so I wouldn't be concerned about it.

There was a lot of discussion about

the size and scale of the term "on farm," because "on farm" can go from a huge integrated operation to, you know, a very, very small hobby farm, which may have one or two animals on it, and we felt that the term "on farm" needed to be, I guess, broken out to have more definition to it, because if you're gonna set up a regulatory oversight program and you have a category for "on farm," you can't really deal with integrators the same way you're gonna deal with, with hobby farmers, so there needs to be more classifications, more definition within that.

There, there was a lot of discussion on the FDA industry education materials. There's gonna be a component here that is going to require a huge amount of education. There is -- There are people already, you know, in the regulated industry who still need more education, and as you break into the on-farm component, the transporters, the ingredient suppliers, there just needs to be a huge amount of education that goes on.

And then lastly, it's the gaps, and this is the one that I really struggle with,

is: How is the FDA ever going to identify the inventory of facilities? farmers? truckers? railcars? I don't know how -- How, how is that list of places for inspection gonna be developed? I mean, where are you gonna get that information from?

Our Gap No. 3 was, you know, that that training was needed for proficiency and -- of inspections, and we feel added to that should be uniformity. When an inspector comes in the door -- And I realize there's gonna be some variation in how an inspector -- or an investigator inspects, but when an inspector comes in the door, there should be a standard to which that investigation or that inspection is done. There shouldn't be a huge amount of variance, you know, from one part of the country to another, from -- whether it's a state or federal, federal inspection, if it's being done under the federal contract. There shouldn't be that kind of variation.

And solutions. One of the things that we discussed from the ingredient side -- or from the -- I'm sorry -- receiving side is that industry could require metal seals on all

receiving vehicles, whether it be railcars or trucks. We talked about needing more educational materials. Currently, they're broad-based, but we need some very specific educational materials. One of the things that was commented on was the, the BSE video for the trucking industry. You know, we'd like to see that available. You know, from an industry standpoint, we would be very open to having the video, you know, in our facilities and playing it for truckers while they're unloading or loading, as the case may be.

Regulatory oversight and field presence. Some of the, the, the issues with, you know, varying training and varying levels within inspectors or investigators could be helped with some regulatory oversight and field presence, and I believe the FDA said they're already starting an auditing process to try and provide feedback to their investigators in order to, you know, try and even out that inspection process.

Consider third-party certification program and or self-inspection programs with some level of regulatory oversight. The fact

is, if you expand what is being done, you know, to include a larger scope, resources are an issue, and one way of redirecting the FDA and state resources might be regulatory oversight and acceptance of some type of third-party certification program and/or inspection program. And we need more education through land-grant colleges, extension agents, producer groups for programs, to all program areas -- the farmer, the hauler -- and working through state groups and allied industry associations.

Question No. 4 dealt with the relationship between state and federal if AFSS becomes a federal regulation, and from -- There was a lot of discussion, you know, particularly with regard to the state component, and they felt pretty strongly that if AFSS becomes a federal regulation, then money would be needed to fund state activities and to really try and get information of what -- you know, how the states are gonna react to this and what they're gonna do. We felt it was important that individual state regulatory officials, you know, provide input to the FDA as to -- 'cause states vary, the level of funding, what they

do, what's important to them. And there's also some difference in regional parts of the country as to what the issues are in that part of the country. Mycotoxins, aflatoxin may not be an issue in the Northeast, but, you know, they're a problem in Texas in any particular year.

And the big one was communication, open communication between -- from the FDA back to the states, from the states back to the FDA. There needed to be more, broader, open communication on, on regulatory oversight and more uniform compliance with FMD145 from district to district, and this had to do specifically with contact -- contract inspection reports and/or checklists. A facility is supposed to get some type of report back after an inspection has occurred, and, and it appears that, in some areas, that's not occurring.

Question 5 was related to, you know, should a regulatory oversight program be based solely on risk, and the answer came back, from the state standpoint, that in a number of states, that consumer protection component is

extremely important to the consumers and their state and that it was essentially an impossible sale, that they would not be able to discontinue that component of what -- the services that they're currently providing, so that it was gonna be necessary to have both a consumer protection component in those states and also an animal feed safety component. So the recommendation was that, essentially, AFSS should remain silent on, on that topic and allow the states to make that decision as to what their program needed to look like and what they needed to provide to the consumers in their state.

The last question was a fairly difficult one, you know: What would an on-farm inspection program look like? And this one, until you know what it is, you know, specifically you're looking at wanting to do, this is really difficult to, to answer. The idea was, with a definition of "on farm" that's a little more expanded, could be devised for the various types of entities. You know, for instance, you know, a hobby farm feeder would be a different type of classification for an

inspection as opposed to an integrated operation. And there's just -- You know, you've got on-farm mixers, sale barns. You've got, you know, dairies. You've got mobile mixers, integrated operations, cattle feedlots, et cetera.

We really didn't spend too much time addressing this from the standpoint of -- We didn't happen to have anyone who represented the on-farm component in our group and didn't, didn't and don't really understand what it is that is expected to be done, and you have to know what you want to do before you can do a regulatory oversight program for it. So we, we talked about this one but really couldn't come up with anything specific.

MR. WILSON: Are there any questions of this group, or (inaudible) in the group like to add anything? Gloria has a question.

MS. DUNNAVAN: (Inaudible.) Can you just give me a little clarification on the, the discussion about the states not buying in on, on some of this? I mean, was there some discussion that, that the state legis -- that

they'd have to go to the state legislature, for this -- for this kind of system, or?

MS. PETERSEN: I think they felt that -- You know, and please correct me, 'cause I'm, you know, obviously, not a state regulator, but they felt that their customer base, their consumer groups, their farmers, their, you know, producers, want and need that consumer protection part of it, and for them to change or delete or get rid of that component in their program was gonna meet some significant resistance within their legislatures. Now, whether it's because they're wanting to get something through the legislature -- I mean, these programs are somewhat funded through that mechanism.

MS. DUNNAVAN: And was the thinking that they would potentially have to do that if -- for an Animal Feed Safety System to re -- would replace that, or?

MALE VOICE: (Inaudible.)

MS. PETERSEN: Okay.

MS. DUNNAVAN: I'm just trying to make sure I'm understanding the state concern.

MALE VOICE: While they're looking, Glo, let me chime in. I think, in our state, our statute addresses commercial feeds that are in channels of trade. Once it gets on farm, and especially once it gets dumped in a trough, I'm not sure what our authority is. And again, I think our solution was, perhaps, work through it through AAFCO and the model bill, and it potentially may require a statutory change, at least in my state, to ensure that we have clear authority and clear -- what would you say? -- remedy, for violations on farm, because this feed is not in channels of trade, and we cannot use our traditional hammer of stop-saling. You gonna stop-sale it? It's in the trough. Big deal. Okay. Can a state vet maybe quarantine some animals and stuff? Well, maybe, but this is all things that need to be fleshed out, and I think that's where at least our group is coming from.

MS. PETERSEN: Glo, the question specifically was: Should regulatory programs focus solely on risk, and how would a risk-based approach affect economic protection

activities? So from the state's standpoint, there is a component of the state programs now which is based on consumer protection, and in some states, they felt it would not be salable. It wouldn't -- You couldn't sell the concept in their state as it's currently formulated.

MALE VOICE: Another aspect of this, Glo, is that we're venturing into an area, as Dan's already alluded to, that -- We -- We've traditionally done the feed mills. We've not had authority to go on farm, and some people don't feel very highly about going on the farms, not to even consider the volume of farmers out there. You know, farmers are very protective, and, and to get people coming onto, onto their farm, we, as regulators, are gonna have to sell this, not only to our superiors but to the legislators, too, and I think this is an issue that we would have to face on the state level.

MS. DUNNAVAN: Thank you.

MS. PETERSEN: One more.

MR. SMITH: I have a question. I'm Kevin Smith of Division of Federal and State Relations. I want -- I was wondering if

the other Group 4 brought up this issue, and one thing we failed to mention in this group, 4B -- or 4A, rather, was the question of: As this -- As AFSS gets rolled out and we seek input and feedback from the states, what would be the most effective way of doing that? And we asked -- We kind of debated the question of using AAFCO as a primary tool for sharing information, and their -- and the point was made that it's probably best to get feedback directly from the states -- individual states in the form of telephone calls, e-mails, draft surveys, and make sure that it goes on an individual basis. I'm just wondering if the other Group 4 discussed anything along those lines.

MALE VOICE: Not really. Not really.

(Inaudible.)

MS. PETERSEN: I -- Do we have someone from 4B who can answer that question?

MALE VOICE: (Inaudible) come up in our (inaudible) were either via AAFCO for input or individual states. I guess just me thinking personally, either one would be fine,

I guess. I think when you go to individual states, you're gonna have some, some -- oh, I don't know -- vagaries to work through. You know, we, we all may be saying the same thing in a different way, I guess is what I'm saying.

Teresa, any of the rest of our group have any thoughts on this?

MR. WILSON: Okay. Thank you. Moving on. I think we're -- If I've kept count right, we're ready for Group 6, and we go ahead and with Groups 6 -- 6 has 6A and 6B, but they're actually 6 and 7 because they have different questions, so 6A can -- could go ahead, and then we'll have -- They'll have the -- Each of them will have the full 20 minutes, so . . . Thank you.

RANDY GORDON, GROUP 6A

MR. GORDON: Well, we had such a cerebral group that it's gonna take two of us to present our findings today. I'm Randy Gordon with National Grain and Feed Association, and Liz Wagstrom with the National Pork Board will be presenting the second half of our report.

Our questions -- Actually, our

presentation kind of divides naturally, because our questions were kind of grouped into two different sections. One was kind of asking our group what we thought of the overall framework itself and the components -- the four different components of the framework, and were there parts we agreed or disagreed with or any gaps or omissions from the components themselves that we might recommend be included. So that's the portion I'm gonna touch on, and then Liz is gonna respond to our thinking, within the group, of some of the elements that relate to the specific elements of what AFSS might be able to do for, for different sectors of industry.

I'd like to thank Roger Osborne (phonetic) for being our, our very good recorder. I'm gonna kind of synthesize the comments you're gonna see on the screen a little bit here in interest of time and maybe to bring some concepts together a little more.

I think, within our group, there generally was an agreement that FDA -- that this is a useful exercise and that FDA does need to take a more comprehensive and science-

and risk-based approach to feed safety that is more inclusive of all different sectors of industry, including ingredients and transporters. Those two came up in our discussion.

Likewise, there is general agreement with the broad outlines of each of the four components that are in the framework from within our group, although we did have some specific areas with which we would recommend some changes, and I'll touch on these as we go through each of the components.

Consistent with the bottom-up risk evaluation we heard about yesterday, we're gonna start with Component 4, which has to do with addressing the regulatory oversight issue, and within our group, there was a, a strong support for government-based inspections and oversight, including those performed by the states. There was a belief that the government-based inspections do provide -- and oversight of self-inspections do provide an objectivity and a credibility that's needed by the marketplace, as well as by consumers, to maintain consumer confidence; a belief that

this provides some uniformity and consistency across states and regions, given proper training; that it provides some consistency between the approaches that inspectors take, both federal and state.

There was this issue discussed within our group about: How do we get more uniform training of the inspection work force so there is more consistent application of the -- of the standards and interpretation? There was a belief that we can adopt a more risk-based approach to inspections and fo -- the focus now being, primarily, on medicated feed, but we need to take the cost-benefit-based approach to this, too, that costs are not a nonissue as we look to establishing a -- establishing a risk-based inspection program.

Concerning Component 3, which dealt with the process-control issue for production of feed and feed ingredients and mixed feed, there was general agreement, I think, within our group, with the importance of addressing hazards that are shown through science- and risk-based analysis to be important in preserving human and animal health, but there

was a concern about the use of the term "process control," and Marlene touched on this a little bit from the audience earlier today, that that term carries with it a quality control or, in some international circles, a HACCP connotation that we don't think is what FDA is really intending here, and that kind of belies the flexibility that FDA is trying to provide within this particular component of the framework that would recognize other kinds of quality assurance techniques like CGMPs, ISO, standard operating procedures that companies have and other quality assurance approaches that may be more appropriate for different sectors of the industry. That -- And that we do believe that these approaches should be appropriate for the type and size of firms and establishments that are involved in a comprehensive approach, when you're running the full range and gamut of different entities, and that, that we, we think that this component might better be titled SOPs for safe production and -- of feed and fee -- ingredients in mixed feed, so -- to get away from that, that connotation of process control.

There also was a concern that this component might be too broad to be realistically implemented, and there was quite a bit of discussion in our group, particularly in the on-farm situation, in that there is a need, maybe, in, in those sorts of situations, to enter into a more collaborative approach, where we look at guidance and other kinds of approaches to accomplish this objective.

On Component 2, which dealt with the limits for animal feed contamination, there was concern about -- registered within our group about the use of the term "contaminant," given the legal liability that this term conveys regardless of what the risk ranking of, of the, the -- that a contaminant might be. We discussed a lot of different possible replacement terms, didn't really come to a consensus on, on anything, but we were toying around with things like "foreign substances" or "unwanted substances." You see a term "toxic residues level," and there was some dissension on that particular term within our group, but we do think that this word "contaminant" does need to be discussed more, as this framework

moves forward, as to whether there might be a better term used.

On Component 1, focusing on the ingredients and the approval process, there was a belief that the current AAFCO feed ingredient definition process is, is a good one that needs to be formalized and expedited so that there is a more timely review of, of feed ingredients through the, the IDC process within AAFCO, the ingredient definition process, but that once those definitions are replaced, they also need to be enforced and that the enforcement component on unapproved feed ingredients is kind of a missing element right now that needs to be addressed.

Finally, in response to Question 3, are there major components or elements within the framework components that might have been missed? We came up with three that might need to be looked at. One, we felt, within our group, there might not be an adequate recognition in the framework document currently of the existing private sector quality assurance initiatives, both in the commercial setting, as well as on farm, with different

species groups that currently exist, and that goes back to this comment about whether we look at guidance or regulatory approaches as the appropriate vehicle in the future.

A second potential area in the framework that might need to have more focus, we're not sure -- and you've heard this discussed by some of the other reporters already today -- that there is an adequate homework done in this document yet about the authority that FDA and the states might already have, under existing federal and state laws, to conduct on-farm inspections, particularly for cause. I think -- We didn't have a real thorough discussion of the kind of inspections that we might be looking at on farm, but I think the general -- within our group, there was a belief that a for-cause inspection might be an appropriate thing, but to have broad, regular GMP-type inspections on farms is really overreaching in this area. But that factual piece needs to kind of be filled in, we think, to the framework as to what the existing authorities are.

And third, before I turn it over to

Liz, we felt there was a need for more collaboration between -- within all sectors, and that includes between different federal agencies, a good example being the DOT's recent final rule issued on the Safe Food Transportation Act, where they call for MOUs to be established between FDA, USDA and DOT on, on enforcing the existing standards that USDA and FDA have in place on transportation between federal and state governments, through different kinds of MOUs, and between federal and state and the private sector, and that can range from -- the gamut of all the kinds of areas that we're looking at addressing here, from ingredients to commercial-manufactured feed to specie and on-farm mixer-feeder-type groups, as well as the transportation sector. And we have in place some models that we might be able to use in that regard, best-man -- best-management-practice-type collaborative agreements that have been worked on between industry and FDA in the past, that might serve as a vehicle to look toward as we move forward in the future on that.

And to discuss the rest of our

report, I'm gonna turn it over to Liz. Thanks.

MR. WILSON: (Inaudible) ask any question -- have any questions for Randy in this first section or anything? Very good.

LIZ WAGSTROM, GROUP 6A

MS. WAGSTROM: Thanks, Randy. I work for the National Pork Board. My name is Liz Wagstrom, and as the regulated feed manufacturers here that may not have a good understanding of, of what we do on farm and things like that, I just wanted to say, coming from the pork producers, we know, as producers, that we have a responsibility to provide a safe and wholesome product, and that includes feeding our animals in a way that does not impact their health or the health of the people who eat the product we -- that we produce.

We definitely need to know and need to be involved and need to correct anything we do, via feeding our animals, that may impact the safety and the wholesomeness of our product, so we want to be at the table, we want to understand where you're going with an AFSS, and we want to make sure that we are able to continue to produce that safe and wholesome

product in a way that is economically viable for the industry.

Now, as I get to the rest of the questions, our group had a ver -- It was very diverse. We had lots of ideas, and we put lots of them just under questions that, maybe, they didn't really fit, but we had opinions, and we wanted them to be heard, so I'm hoping that they actually make sense when you see our, our answers.

We talked about how the Animal Feed Safety System could help you maintain and create a level playing field, and it's interesting, because whichever segment of the industry you're at, you always think that you've got it worse than the guy either upstream or downstream from you, but we did say there are areas of the industry that, that would be held to similar standards as the rest of the industry, including from the very, very beginning, whether it's the ingredient manufacturer, all the way down to the end, whether it's the producer that has a responsibility and is responsible for the safety of the product that they produce.

We also thought that you could help level the playing field with a correctly designed system by having clearly defined roles and responsibilities among agencies so that there was this -- not an overlap or a reluctance to step in when there is a problem because nobody is sure who's got the authority.

We definitely thought that we could -- that it could help by assisting to develop educational information, whether it was sample SOPs or, you know, other information on a, a feed safety system that could then be distributed through the producer groups and through the industry groups and become part of their volunteer quality assurance programs to really build kind of a, a culture of feed safety as part of an operating practice. And, you know, as an example, for many of you who aren't familiar with the pork industry, in 1985, we had issues with, with violative residues in our pork. As a result, Pork Quality Assurance Program was developed. We now have almost 80,000 producers that are, are on -- certified under Pork Quality Assurance, and our violative drug residues are almost

nonexistent. They're very, very low. They're well within the acceptable ranges. And there are consequences, obviously, for the producers who have violative residue. So that's just an example of how a quality assurance program can help address problems.

We definitely need -- felt there was a need for these agreements -- along with defining roles, the agreements between regulatory agencies, and then also, the regulated industry, as Randy mentioned with the GMPs. Best done through collaboration and, and planning rather than, perhaps, necessarily increased regulation.

And then, finally, we all agreed that each segment of the industry needs to assume responsibility for the safety of their product.

Under Question 5, how can the Animal Feed Safety System help you address risks to human and animal health, one of the things we thought is we, we are missing data, and the development of risk systems and the whole prioritization may help provide information to feed segments about not only segments that haven't had much attention, but also help them

identify where the risks enter their system, where they're best addressed. Really help us decide what risks are truly risks versus perceived risks, what's real versus theoretical.

And also, we really talked a lot -- We had a -- We got into a dioxin talk. It sounds like a few other groups got talked dioxin (sic), and help us understand: What's a limit that, that really creates a risk, you know? And do we have the data that says, you know, If you have a foreign substance -- which we decided was better than "contaminant" -- at what level does it present a risk, and at what level is it background? And, and that was something that we felt was really missing. There are now firms, if you test for something and you find it at any level, then what do you do? Is it a risk? Isn't it a risk? What do I do with the product? How -- Do I have to report this to somebody? So that was something we hoped could come out of the whole setting the risk ranking.

By understanding what the risks are, you're gonna able (sic) to prioritize where you

need to intervene. Is there a need for intervention? Is there a need to protect -- Will this intervention protect public health? So we thought the risk-assessment portion of the project, although it's gonna be the most difficult, it's gonna be the most rigorous, will probably create a lot of value, and it's -- The value it may create, to begin with, is just identifying knowledge gaps and allowing us to understand where we need to fill in those knowledge gaps, and it's gonna afford a more uniform approach to problem solving. If you set up a hazard as a model and this is how you -- how you address it through the system, then, as another hazard may be identified, you have a model for a way to look at addressing it.

We also thought that by having a pro -- you know, looking at the process control, it may make manufacturers more aware of their process, and it increases the awareness of the issues. And, and then, definitely, we talked a lot about the need for collaboration to determine levels of concern. Work with all the areas of the industry, get a

collaborative effort, get an agreement that there is a concern, work through how to address that concern, and that's probably a way to get by and -- rather than just adding on a lot of regulation.

And again, this bottom one is kind of a reiteration of our dioxin talk. We need to understand what levels of risk exist when you find something and, you know, have the data to say, Here is an acceptable level or an unacceptable level.

Then we got to talking about trade, and started out, we divided it between domestic and international trade, and under domestic trade, we actually got to talking about something that may not -- that, that came kind of out of the -- you know, the blue -- and I don't know that it's been addressed with the AFSS -- was that perhaps that AFSS would allow a regionalized approach to risk, and we had examples, like, in areas. Blister beetle may be a regional concern, but it's not in other regions, so how does AFSS address, even within domestic trades, the difference between geographic regions in the United States?

We also talked about that by preventing any health incidences that may, you know, theoretically, come through animal feed or possibly come through animal feed, we -- Our consumers assume we provide them safe food. We want to maintain that assumption, and we want to, you know, not have an incident that may shake consumer confidence.

With international trade, we wanted to make sure that with the new Codex animal-feeding document, that we don't have any sanitary and fido sanitary issues in exporting meat if the AFSS is not in line with the Codex document. And I'll put in a plug for our poor quality assurance program. We're in the process of rewriting it this year, and one of the things we are making sure is that our PQA program is going to be in line with that Codex document so that we can document that we are in line with that Codex document.

We also, though, when we talked about international standards, wanted to make sure that those were standards, that we tried to meet, that were based on science, that were achievable standards, not -- We got into

discussion over who, who -- certain countries that say, This is what we do, but do they really do it? And so we wanted to make sure that we had standards that were scientifically based and that were achievable and, and not just a lofty goal that would be nice to meet. And so that's where we went on international trade.

We talked a lot about economic -- Well, actually, we talked more about costs. Economic benefits. We talked -- did talk a lot about: What is the cost -- the risk versus cost benefit, and is, is the money that you might spend -- and we'll get into this more in the next question -- to implement and comply with such a program going to provide benefit? And we felt very strongly that there had -- at least most -- some of us in the group, felt strongly that if you -- you had to show a benefit. You had to be able to say that if we're going to go this extra mile, there is a benefit to either animal health or public health.

Again, we talked about maintaining consumer confidence that is equal to

maintaining trade. Obviously, we don't want our names in the newspapers, we, we don't want our names on the -- 60 Minutes, and, you know, we have to provide a safe product.

We did think that by having a system -- an integrated system that had -- was risk-based and scientifically based, that if something went wrong and you went back and you said, Here's a set of -- whether it's good practices or whatever, and went back and reviewed that product and how it was, was produced and that it had been produced following these good product -- or good practices, but it did provide a defensible position, that you said, Here are the things we did to assure safety, something went wrong, we'll, you know, make -- try to correct it, make sure it doesn't go wrong again, but it's sure a lot better to say, We had a set of practices that we were able to show we followed, instead of just saying, Well, we threw a bunch of stuff in, and, well, something went wrong. So that, that was the idea that, you know, did provide a, a ruler to be judged against, perhaps.

When we got to cost concerns, we got pretty passionate, even though it's toward the end of the discussion. There was no doubt among the group that if you have additional inspections, sampling, testing, record-keeping, retention of samples, whatever, it will add additional cost, and it'll add additional cost in every segment of the industry. And so --

And then our -- The regu -- The inspectors and regulators in our group started talking about their additional costs, including equipment they might need as -- in -- disinfectant equipment, if they go on farm. Do they need bigger cars or bigger vehicles to carry the equipment? What are their safety concerns on farm, including biosecurity? Once you have been on a farm, do you end up having to have downtime to shower, disinfect? You know, you can't necessarily go from farm to farm, or there's -- At least most producers aren't gonna like it if you go from one farm to the next. So what is that -- What is the time -- downtime you're gonna have? So there were costs throughout the system, on all ends, whether it came from regulatory or from

producers or from manufacturers.

It'd be nice to think you can take those increased costs and pass them on to consumers. That's usually not reality in agriculture, and if it is -- would become reality here, what does that do for the consumers? We do know that anytime the price of meat increases, that consumption does go down in some -- in most cases.

We also talked about the impact not only to small producers, which is where I came from, but also to, perhaps, the small feed manufacturers. If there is increased costs, increased need for -- whether it's, you know, specialized weighing or mixing machines or whatever, it is likely to cause producers and small manufactures to exit the industry. We're consolidating rapidly, and this may increase the, the rate of consolidation.

We definitely looked at: What are your up-front costs for somebody? And I think we talked more from a manufacturing point of view, but it could be from a producer point of view, too, for staff costs to train them on sampling, on record-keeping, on doing

microbiological assays, et cetera. So we looked at education and training. It may -- After you've gone through the process, that, over time, you may recoup those costs, but it's definitely looked at as an up-front cost of education and training.

And then finally, if this becomes truly regulatory based with a fine and enforcement potential, there is the cost -- potential cost down the road of financial penalties, and that was probably the -- That is on the bottom of the list, 'cause that wasn't our top-of-mind concern of cost but definitely needed to be considered as a potential cost of the program.

And the final question on how AFSS could help us in other ways, we got back again to where we really talked about: Will there be improved safety? Does this improve safety? If it improves safety, it improves safety at what cost? And we really thought there needed to be some risk benefit or cost benefit -- or cost/risk benefit assessment of what, what you would gain in increased safety versus the cost of implementing a system like this.

We did have -- think there was a potential to -- Because this is a systems approach and, and it would be throughout the entire system, there may be a chance for improved overall compliance, and especially if it -- you know, with the increased education and putting it into quality assurance programs and having, you know, a systems approach, not from -- just from FDA but from the manufacturers and the producers. You know, with their quality assurance program, there may be an improvement in overall compliance, although nobody could tell us that we had a big compliance problem at this point in time. It wasn't that we thought there was a big compliance problem.

We thought that, perhaps, industry segments that didn't currently have quality assurance programs, if we worked with the Animal Feed Safety System as part of a quality assurance program, maybe, enticed to develop quality assurance programs for their industries or their segments of the industry. We definitely thought that we, again, wanted to stress that, you know, you needed to clarify

the responsibilities of all parties involved and that perhaps defining the system would help clarify those responsibilities.

And then we talked about, finally, that there needed to be collaborative development to improve communication among the sectors and that we felt, in a -- some way, that collaboration was gonna be the only way to really get buy-in to any kind of a feed safety system that -- You know, if all the people aren't at the table, if they're not looking at the impacts and the benefits to their portion of the -- of the feed chain, that it was going to be tough to get, get, you know, a good industry -- or good -- total buy-in, and we felt that that way, you could look at -- as you worked with each segment, addressing risks in the way that's most appropriate to that segment.

And as a closing, I'm just gonna give you -- tell you a little story of the Danish pork industry, and I, I am very fortunate that I get to go to Denmark, probably -- at least once a year since I started with the pork industry, and many of you may know that Denmark

has got a -- started out with an incredible on-farm food safety program, and they've spent -- They spend -- still spend about 60 cents a pig on on-farm salmonella control, and they've got salmonella feed controls and things like that.

And over the years, they've very much stressed a stable-to-table approach, as we do farm-to-fork approach, and when we were over there this last year and they started really looking at the benefits of that approach, the pork industry there said, Well, we're starting to call it a table-to-stable approach now, and I said, Well, that makes me feel kind of -- a little nervous, because that means everything at the table is a problem at the stable? And they said, No. What it means is we start at the problems with the stable, and we go just as -- or at the table, and we go just as far back in the system as we need to go to correct the problem to make it safe at the table. We're not assuming we have to go all the way back to the stable.

So I think that as you looked at that risk-based approach with an animal feed safety

system, as you look at that end product or the end risk and go as far back as you need to fix it. That's, that's my pers -- That wasn't from my group. That's my, my personal story about the Danish pork industry, but I think we can learn a lot from that.

I'd be glad to take any questions. Okay. Short. People must want to go home.

MALE VOICE: On this idea of a risk-based system, you know, it occurs to me there needs to be a baseline established to determine what the risk is, and I'm -- It might have been Dr. Grabers (sic) or one of the earlier presentations, it was up there that something happened in '68, and something happened in '74, and then something happened in '83 --

MS. WAGSTROM: Uh-huh.

MALE VOICE: -- of national importance. Well, to me, that doesn't connotate (sic) a tremendous amount of risk, and kind of makes you wonder.

MS. WAGSTROM: Right.

MALE VOICE: And lastly, just quickly, I wanted to thank Randy for bringing

up this whole idea of the unapproved ingredients. Seems to me also that as long as we're allowing unapproved ingredients in feeds, that's a little bit contradictory to an overall feed safety system, and -- Anyway, just a comment. Thank you.

MS. WAGSTROM: That's one of the things we thought with the whole risk-based and risk assessment, is you're going to help, really, identify what truly is a risk and also identify your knowledge gap, so that, that was one of the things we really thought was important.

MR. WILSON: All right. For -- Our last group is Group 6B, and if you'll notice, when we're going through here, that, that Questions 1 through 4 on Group 6A and 6B are basically the same, but 5 through 8 are different. So 6B, if I understand, is Bill Grande?

MR. GRANDE: That's fine.

MR. WILSON: "Grand" (phonetic)?

MR. GRANDE: "Grandy" is fine.

MR. WILSON: "Grande"? "Grandy"? Okay.

MR. GRANDE: Yeah. Thank you.
MR. WILSON: Grandy/Grande --
MR. GRANDE: Grande, yeah.
MR. WILSON: -- tomatoe/tomato.
MR. GRANDE: There you go.
MR. WILSON: Very good.

BILL GRANDE, GROUP 6B

MR. GRANDE: I don't do very well behind a podium, so I'm gonna be out front. And these groups and sessions that are put on by the FDA are certainly appreciated, and I appreciate being here. While we do participate in these, we all have jobs, and I was, unfortunately, delayed in getting here, so I don't have any notes, so I'm gonna have to work off the PowerPoint.

Our group, as everyone before me has stated, was very involved in our topics of discussion, very insightful, folks from different parts of the industry, regarding the components and what we agree with. The -- You know, how can you decide on oversight before deciding risk, was one of the issues, and we've heard it before. You know, being the last up, there's gonna be some repetition, and I

apologize for that, but, you know, how can you decide on oversight before you really understand what risks you're facing and the degrees of risk and the hazards that those risks might, might pose?

And then thinking about tolerances and -- Once you decide what risk factors there are, the hazards that they may present, what are the tolerance levels? And it was felt by our group that we needed more data, more information before we could really decide on that.

And then focusing on significant risks and, and the significance of those risks. Again, different parts of the industry, different processes involved all bear on, on what levels might be acceptable and, and the ranking of those, and with all that, you know, flexibility, and we've heard a lot in previous discussions. This type of, of a feed safety system needs to have flexibility. It needs to be adaptable to the various components within the, the manufacturing of feed. We, too, like others, had a real problem with the term "contaminant" or "contamination." The

liability issue, real or perceived, was of great concern, so our group, as well, was trying to figure out what we could use as a synonym to replace "contaminant."

The bottom-up approach was interesting for us in how you could begin to develop the risk and the ranking.

Transportation, really interesting for us. As others had stated: How do you deal with all of the various modes of transportation for feed and the different aspects of hazard and risk that they bring, and then how do you address those? Let's see. Certain farm (inaudible). Yeah. And then again, different segments where farms -- they have different components. They receive, maybe, ingredients, or they have complete mix, and so how do those folks deal with the various issues?

What else, Tim? I'm stuck.

NANCY: The question was whether (inaudible) produced feeding (inaudible), and the question was: The animal (inaudible).

MR. GRANDE: Yeah. Thank you, Nancy.

NANCY: In this particular

question, there was a discussion about what our -- on-farm processes would be controlled. It said, The farm doesn't produce feed; it produces animals. Question was whether or not those animals are, are regulatable until they become food.

MR. GRANDE: Yeah, exactly. Thank you, Nancy. I appreciate that.

MALE VOICE: (Inaudible.)

MALE VOICE: Animals intended for food use, such as beef, et cetera, et cetera, are, by jurisdiction, food, walking food, so . . . Under FDC Act. All right. Thank you.

MS. DUNNAVAN: But that's -- But that's why we had our -- that second --

MALE VOICE: Second question, wasn't it?

MS. DUNNAVAN: That's what led to that second point here about health for sale. If you're having feed produced on farm to give to the animals and your real product are the animals, where is our jurisdiction on the feed? And that's why we have the health for sale. So we consider that feed health for

sale if it's going to, to animals that are gonna be marketed, so food animals. So those two, sort of, points kind of go together.

MR. GRANDE: Okay. Thank you, Glo. You can -- There you go. Okay. And then -- (inaudible). Yeah, and as we've -- as we've touched on, recognize that the different components with -- within feed need to be treated differently, because they can -- they can contribute -- There are, potentially, different risks and levels of hazard, so you have to treat them differently, and how, how might that -- how might that be addressed?

FDA recognizes differences, looking to incorporate similarities and commonalities, so, as we've said, you know, how might those differences be, be addressed? Training SOPs, control variabilities, you know, what are the hazards that these types of things might look to? How do you control different hazards across the continuum or across the feed-manufacturing program? You know, how -- Training, and we heard about training in the past. How do you train to meet controls that are set? If there's a problem, is it likely --

(Inaudible) off-the-screen producer. I don't -- What was that, Nancy? I don't know what that -- I'm sorry.

NANCY: I'll just hold on to this for a minute. If there is a problem, the comment was it was likely to be an off-the-screen producer. In other words, one of those folks that you don't see very often. Could be one of those, those portable mixers. It could be one of those, those folks that's buying something that most of us wouldn't think about. And the comment was -- to that that the additional cost of running these programs to reputable dealers or reputable folks would not affect the, the bad actor again.

MR. GRANDE: Yeah. What -- With this program, how might we be able to strengthen existing rules, AAFCO, and, and we've heard about other potential models, other potential quality system methodologies that could be used, so how might this umbrella -- we, we looked at that as a term -- how might this umbrella strengthen those?

When we look at ingredients, key elements, background tests for hazards, what

might those be beyond what is currently considered industry practice? The -- Work upstream from the product, so maybe the, the table-to-stable, as we heard just a moment ago, working back might be a way.

Product expectation. You know, the customer has an expectation for the product that he or she is receiving, so if the -- if, if we look at a product spec, that's our target, and then internal to the operation would be the processes that you control to deliver on that product expectation. Regulatory component to that product absolute -- for that product. So specific to the product that you're making, there could very well be different levels of process control given on -- given the product that you're making. It will probably vary based on that end product and, and the, the spec that you're trying to hit. Processes begin where -- Yeah. Where, where might that process begin? Where, where would the first point be that you would need to incorporate some type of process control?

We talked some about the economics

and, and customer expectations. Again, if, if you're trying to figure out what level of risk avoidance or what types of hazards are important, it might be looking at the customer's product spec and the expectation that the customer has, and that could be some of the framework that you would look to to go back into your process and develop control points. Is that -- Is that a fair representation? Yeah.

And with that, again, flexibility and naming hazards. I think this relates to, again, product-specific or, or process-specific components within an individual feed-manufacturing system. And then specifications. Again, we talked a lot about, about the, the end -- the end product, the finished product, and how the specs that you're trying to hit should dictate what types of the products -- what product specs would dictate to processes within your manufacturing operation. What exists on the book? What was that, Nancy?

NANCY: That refers again to what rules, what regulations, what statutes.

MR. GRANDE: Oh. Current,

current rules and regulations, and do we really need more, given what we already have? And then maybe marrying those with AAFCO or other quality-assisted methodologies, could we strengthen what we currently have and, and achieve the end result? And then problem-oriented fixes. Again, trying to be proactive.

Question 3, missing components. Traceability. We didn't -- We didn't really see anything about traceability, and that brought up some real interesting questions for -- What exactly is traceability? How, how far back or how far forward do you go, and then how do you do it?

Education was a big one -- and we've heard that before -- for training, not only for folks that might be on the regulatory side, but, but in the feed-manufacturing facilities, as well. How do you create awareness for folks that need to abide by whatever regulatory issues may present themselves? Point of origin. What was that, Nancy? I, I don't --

NANCY: That was a question, again, of keeping track of where your

ingredients -- where your products came from.

MR. GRANDE: Oh. So the trace -- more traceability and tracking within the program. Record-keeping nightmares. Again, if -- depending on how far forward you might have to go, knowing where your feed is. I think that was one, one question related to a particular feed that was sold at the last, last point of retail. Having to know where that -- where that feed actually wound up, how would you do that?

Mandatory system. They have IP issues. This was intellectual property, so if, if I have a particular system or process for manufacturing feed that's proprietary and I have to now share it through inspection or some other vehicle, I would lose that intellectual property right, and that was a -- that was a concern. And then voluntary self-inspection, we talked some about how we could -- how we could utilize that as a tool to, to create better compliance.

And then again, our -- the components, all part of an umbrella, and again, we were looking at -- and thinking about how

this Animal Feed Safety System could be an umbrella over all of the existing regulatory pieces and other quality system methodologies and food safety programs and, and kind of marry all those, but yet still have flexibility so that you could address the various feed-manufacturing components that go into the finished -- making the finished product. Process control, certainly one. I'm not sure what the "who chooses" --

NANCY: The "who chooses" refers to: Are you using a process control? Are you using a product control? And who, who decides?

MR. GRANDE: Yeah. And who decides, yeah. And I -- And I -- Yeah, who decides. And, and there was a lot of discussion that we're not there yet. We just don't know. More information is needed.

Industry-developed systems are acceptable. Again, there are several, so again, under that umbrella, how best do they fit given where you might be in the -- in the feed-manufacturing program? How can we help you build your system? So I think that was speaking to this, this whole effort. How could

we -- How could we build a better feed safety system? Utilize (inaudible) as part of the educational team (inaudible) --

NANCY: That was "trade associations," for whoever typed that.

MR. GRANDE: There you go. Meet uniform minimum standard. Yeah, we were talking about having a baseline, leveling the playing field for all the folks within the -- within the feed industry, and then how you'd want it to build on top of that is entirely up to -- up to you, for, for where you are in the business.

Without defining standards, how can you document improvement? Yeah, that's, you know, baseline. We've heard a lot about baseline. There certainly should be a baseline coming from FDA, but within an individual operation, you're gonna create your own baselines. I mean, that's -- Within quality systems work, you have to start somewhere, so you, you start building baseline data, and that's from where you measure improvement. So there could be an argument about having, actually, a minimum baseline, and then industry

or individual people could build off of that and, and relate that to their internal baseline data.

Medicated CGMPs are a shining example that works, and I think we've -- we heard that, again, earlier today, about how that could be -- how something similar could be applied across, across the remaining feed-manufacturing components.

Transportation, and, and it's broken on the slide, but we, too -- We had "mission impossible" in quotes, because, as we heard, earlier, how do you do it with rail and barge and truck and Ready Mix trucks running around manufacturing feed? We, we talked a lot about, particularly with rail and truck, the diminishing numbers of railcars and trucks, and, you know, it was -- Many of us are at the mercy of the railroads for, for wanting either dedicated cars or clean cars or knowing that, that what was in the car previous to your load doesn't present a problem. How do you do all that? So that's why we framed it as "mission impossible." And then some of the examples, just the age of equipment and how they're

treated out there, verification of clean-out. There's been a big effort on trucks, with, probably, a pretty good degree of success, but again, if you go back to rail or barge, it's a much more daunting task.

Backhauls. We talked about the price of fuel and how folks aren't gonna be deadheading. I mean, they're gonna be pull -- They're gonna be want to having (sic) loads coming back, and you don't necessarily know what they're backhauling.

Product disposal. This was -- This was the issue with --

NANCY: It was a damaged load --

MR. GRANDE: Damaged load.

NANCY: -- and the trucker, under DOT regulations, has complete authority to get rid of that load wherever he wants.

MR. GRANDE: Right. And, and --

NANCY: It doesn't belong to you anymore.

MR. GRANDE: Right. And, in fact -- Yeah. He could sell it, and, and, and it's your stuff, and it could create a problem somewhere, and so that -- I think that's a,

a -- We talked about needing to get with DOT and, and revisit some of those regulations that were how old? Some --

NANCY: Well, they were supposed to write regulations starting in 1990.

MR. GRANDE: Yeah. Yeah. There you go.

NANCY: Some of you have kids, you know, that are in the middle of high school now.

MR. GRANDE: Yeah. Yeah. Yeah. So, you know, with all that, the regional differences, as well. We talked about unit trains and 108 -- you know, the railcars, and there's more, more folks that are -- that are having dedicated railcars, and with that, there's better control, but, you know, if you have individual cars or smaller, smaller groups of cars, the control becomes less and less.

Ruminant meat and bonemeal. That was the situation where you would have to have -- either owning or leasing cars to know that you -- that you aren't winding up with some kind of a cross-contamination issue.

Increased regs can increase risk.

I'm not sure what that one was.

NANCY: That was a question regarding: If you put folks at risk for losing their, their transportation, then they'll use anybody who'll haul what they need.

MR. GRANDE: That's right. Yeah. Exactly. Yeah, yeah. And that related back to the diminishing numbers of folks hauling stuff.

Approved suppliers, we talked a little bit about that. How, how do you go about developing a, a supplier program, an evaluation program, and then making sure that what the supplier is delivering to you is what you've asked for?

On-farm safety issues, again, we spent some time thinking about, you know, what -- what's the scope of that, and how do you -- how do you level that playing field with -- against some of the commercial feed manufacturers? And that's been discussed, I think, enough.

Feeding food, producing animals, customer satisfac -- Yeah, again --

NANCY: Customer -- Yeah, the

customer satisfaction issue there is: Can you sign that certificate that says that cow hasn't eaten any ruminant material? Can you -- Can you make sure that you're part of that Pork Quality group?

MR. GRANDE: Right. Do you really know? Yeah. Do you really know? Yeah.

Again, education. Very broad topic, starting with the consumer and going back or starting with, with folks in the -- in the feed-manufacturing program and going forward. It really doesn't matter. Just everyone needs to understand what -- you know, what the feed safety program is all about and where they play and what their contribution needs to be.

I.D. the risks, spot 'em up. That was -- Yeah.

Finding and inspecting ruminant feeders. What is the risk and perceived risk? What was the emphasis on that, Nancy? I --

NANCY: Well, the emphasis there was particularly regarding the next statement that says, Some risks, such as that for BSE, are decreasing because of increased compliance with the rules and the changes to the rules,

but, as we heard earlier today, the perception of that risk is still very, very high.

MR. GRANDE: Right. Yeah. And then: What is the risk of unapproved ingredients? We heard -- We heard some of those comments, the -- today. It's an unknown. What is the risk?

State regulatory programs are more effective. The funding issue, we've heard. You know, as the scope grows and with budgetary constraints, you know, how do you do more with less?

Reinforce issue and compliance with AAFCO definitions. Again, the umbrella issue, looking at current programs out there married with quality systems methodology, and define risks and hazards, focus on bad actors, so if, if you've got folks that are doing what needs to be done, doing a good job, can you turn your attention to, to areas that, that might be more important in risk and hazard control?

Voluntary process control. I think that relates to the inspection -- the self-inspection program. Having capable and trained personnel. So again, how do you

effectively train and make sure that your folks understand their roles and responsibilities?

What other -- What other issues might AFSS help us with? Well, getting industry-involved, and that's certainly evident today -- over the last two days, and then having representatives of those folks as part of the -- part of the development of this -- of this program.

And I think that's it. Sorry for it being so disjointed.

MALE VOICE: We have a couple over here.

FEMALE VOICE: I'm so sorry, everybody. I was part of this group, and I just wanted to comment. We did have quite a bit of discussion about -- The, the Food and Drug Administration is sort of talking here about risk and hazards and -- but our group did have a -- just a lot of discussion about the fact that there are other things to think about when you're -- when you're looking at these systems and customer satisfaction, and, and being able to talk about your quality product to your customers is a real advantage and a --

something that our group talked about, even though FDA is kind of focused on, on the risk and the bad stuff. So I think that was an important point that we spent quite a bit of time on.

MR. WILSON: Do we have any other questions of this group? Ladies and gentlemen, I want to thank you very much.

MR. HERMAN: Yeah, I'd like to make a comment.

MR. WILSON: This has been a -- Whoa. Never mind.

MR. HERMAN: Yeah. Yeah. Tim Herman, Office of the State Chemist. That is Texas State Chemist.

MR. WILSON: Republic of?

MR. HERMAN: If, if there was only -- No. You're gonna have a little bit of fun with that.

I think that maybe -- And we have one other folk -- person from Wyoming, who was there, who could answer No. 7, and I think Question 7, what make -- what state regulatory programs -- or excuse me -- make state regulatory programs more effective, and I think

maybe we were the only ones who had that question, so I just wanted to reinforce on those components that, certainly, when I look at it, Component 1 and 2, felt real good about; Component 4, I think we all agree, you know, show us the money; and Component 3, I don't believe that there was an entire consensus, but perhaps voluntary is the way to go, the way everybody believed that process control would be part of this overall universal concept of what should be part of an animal feed safety system, but how that would actually fit within a regulatory scheme and -- or at a state level was something that -- Well, maybe the emphasis should be on voluntary, but clearly, Component 1 and 2, we thought you guys were really right on track and wanted to give you a kudos in terms of how that can help us at a state level.

MR. WILSON: Once again, any more questions, please? Okay. Going once.

Again, ladies and gentlemen, thank you for the -- for your open-discussion stuff on these -- on these last, you know, very important -- we've -- we, as FDA, feel are very

important issues. And we're not concluded yet, because at this point, now, Ms. Gloria Dunnavan, our --

MS. DUNNAVAN: Really open discussion.

MR. WILSON: -- is going to have a truly open discussion, which I'm sure she has plenty of material to lead into to stimulate the open discussion. Glo, take it away.

OPEN DISCUSSION MODERATED

BY GLORIA DUNNAVAN

MS. DUNNAVAN: Well, no, I'm -- This is just your one last wonderful opportunity -- and I'm gonna go up front and sit down -- to, to, to ask and get answers to questions, to comment on issues that did not come up in our discussion today that you would like to comment on. We've got about a half an hour, and I'd like to just open it up to, to that kind of discussion, just give you a last chance to, to comment, to question. You got a captive audience here. The Animal Feed Safety System Team is all present. It's a good opportunity to -- I'm not gonna get any takers, am I?

One of the things I want to comment on -- and maybe, maybe you can address that a little bit -- in listening today, there were some common themes that I picked up on: science-based, need more clarification; transportation, who's really covered; need cost-effective tests; imported products and the, the complexities of dealing with that; and education. And those were just some things that I heard in multiple presentations, and I don't know if I missed -- if there's some others that you think are, are common themes that we really need to think about and focus on some more. Let me hear from you. Have any comments? Yes?

MR. BURKHOLDER: Dave Burkholder from here in Nebraska. There is some uneasiness out here among the group, I have kind of detected and felt myself, that FDA and this whole risk-assessment process is, is going to, to have the resources to, to draw up some scary-looking material and, and put it in -- out in the public domain for, for the enemies of animal agriculture to, to jump on without really having the resources to implement the

program anyway, and therefore, you know, nothing really constructive is gonna get done, and a lot of not-constructive stuff is likely to happen. Would you address that, please?

MS. DUNNAVAN: Well, I'll be happy to address that. I'll first see if there's any members of the team that want to address that. I, I just, from my -- Oh, okay. Go ahead, Karen.

DR. EKELMAN: Well, Glo, I was gonna wait 'til you were done. I was just going to say that if you do have a risk-based approach, first, remember that we're not estimating absolute risk, so you won't be able to say, You ought to take care of this one, because even though it's eighth down on your list, it's 1 times 10 to the -9th animal is going to die from this. You won't get that information.

Secondly, if you have a risk-based program, no matter what the resources are you have to devote to it, you at least can know that you're dealing with your most significant risk, so if you have a lot of resources, you can go further down that list. If you have

fewer resources, you don't get so far down that list. But one thing you can do is use that list to ask for more resources and ensure that they're going to be used in a risk-based-appropriate manner.

So it isn't really expected that we're gonna have a lot more resources. It's expected that we're gonna focus those resources a little differently, and I'll let Glo -- Since we don't have an animal safety system yet, we often have different points of view, and we're working on it. Thank you.

MS. DUNNAVAN: Karen and I particularly have, sometimes, different points of, of view.

Let me just make two comments. One of the things that I -- that I certainly heard in my group, and I think I'm sort of hearing today, and I think this is, in part, your comment, is that FDA is gonna come up with this complicated, scary, new thing that, you know, you're gonna have to scrap everything you're doing now, and it'll be this new thing, and I really don't think that's our intent. There's a lot of good stuff out there going on, and I

suspect, for many of you in this room, if you're an industry representative, that the concepts we're talking about here, you may already be doing a lot of that, and it may just be focusing it in a particular way or tweaking it or making -- helping to make sure that some of your suppliers and customers are part of the loop. So I'm not sure that -- for many of you, that it's a brand-new, scary, different thing. It's a more focused approach to a lot of what's already going on.

I, I -- In my personal view, the train is moving out of this station. Instead of focusing on doing stuff, making a product, and then at the end, you sort of look and make sure, Do I -- Is my product okay, and if it's not, you're missing -- you've just thrown away a huge bunch of work and effort, so that the sort of trend, as I see it, is to make sure that you have processes in place so you don't have to get to the end and test your product and throw it away, but you can fix the problem early, or you have assurances in place, you know you don't have a problem at the end. So, I mean, that's one issue.

The other one is that -- the issue you bring up about resources. As the Director of Compliance, you know, I'm kind of the enforcer here, and one of the things in my position is, is the emergency coordinator for, for CVM. I can't tell you just how many resources we end up spending when there is one of these emergency situations, one of these animals dying or feed contaminated, and we need to get control of it. You spend an awful lot of resources, and the states spend a lot of their regulatory resources in ways that we can't plan 'cause it happens today. You got to deal with it today. And that takes many more resources to deal with that kind of situation than if we could have a program where we plan inspections, we plan some sampling, we plan our outreach efforts. And we can -- We can plan that during the year so that we can use our resources most effectively.

So one of the -- One of the problems I see -- and I don't know if, if my state counterparts want to comment on that -- I think having a good program in place, that sort of covers the waterfront, makes it much easier, as

an -- as a regulatory agency, to plan and deal with these issues rather than, than being in crisis mode all the time, and you got to deal with Situation X, and then some of these other things don't get done, and at the end of the year, you're suddenly forced to sort of scramble and get something else done, and you're always in catch-up mode.

So I think this will be helpful from a resource -- actually, helpful from a resource perspective when resources are not likely to, to be increasing in the near future. Probably not in the distant future either.

Dennis?

DR. McCURDY: Dennis McCurdy, CVM. In response to what you're talking about, there was a paper -- it's on the Web, and it was forwarded to CVM -- that appeared in Journal of Animal Science. The paper misses a lot of things, and I'm responding to that officially for CVM. There was a meeting held at Fort Detrick in Frederick, Maryland, about that paper, and the authors were at Fort Detrick and principally focused on biosecurity and, and things that can happen in feed, but

the thrust of the article was -- is, we're not doing enough to protect the consumer. That's a large order and -- of accusations in that -- in that -- accusation in that paper, and I am responding to it, because it's not -- it's not true in the complete sense. But there are scientists and people who think they can get some government money by selling the proposition that we aren't doing enough, so . . . Is perception everything?

MALE VOICE: This isn't on that subject, but a year and a half ago, when we were in Virginia and had this meeting, we counted in -- There was only 10 percent of the people from west of the Mississippi, and I counted 'em up again today, and I realized we don't have as many people here as we had back in Virginia when we had that meeting, but close to 45 percent of the people are from west of the Mississippi today, so I think you got a lot broader spectrum by meet -- bringing your meeting out here -- out of the industry, and really appreciate your willingness to come out here to work with us, so . . . Thank you.

MS. DUNNAVAN: Thank you very

much for that. That's very insightful for us, and if you walk away with nothing else from this meeting, one of the things that I want you to walk away with is, all of the comments that we've heard today and in the discussions yesterday are extremely valuable for us. That's why we have these meetings. We, we need the input. There were some -- I mean, it's, it's very interesting to me to sit around -- We talk about this, and we work on this, and we think about it, and it's just crystal clear, the vision, where we're going and what we're gonna being doing and why we're doing it, and it's very clear to me today. It's -- The vision is clear to me, but it's not so clear to all of you, and it's really, really important for us to hear that, so I -- I'm -- I particularly appreciate the fact that we've got different types of, of representatives here from different parts of the country than we've had before and perhaps haven't had a lot of discussion before about this, and so it's new for them, and we get new and different eyes looking at this and commenting on it. It's extremely helpful for us.

So again, this is -- this is a great opportunity for you if you have something you'd like to say, a question, a comment, something you want us to consider.

MALE VOICE: One of the things that I find missing, which my company is dealing with, and that is, you know, we hear of a few animals here dying or a few animals there dying, and we look overseas, and even in our own country now, where we have these millions of animals being destroyed because of a major disease outbreak, and it seems like, to me, it would be very proactive and would actually complement what we're doing here if we started understanding what role we would play or not play in feeds as far as a major outbreak, what we could do to mitigate, what we -- where are our risks, that we could actually either break an animal disease outbreak, make sure that it didn't get transmitted through feeds, or, or whatever, or where our risks really are in that whole incident, if and when it may occur.

MS. DUNNAVAN: Actually, that's a really good comment and one that I, I didn't -- I didn't comment that I'd heard it,

but I've heard that from a couple of groups, that role of, of animal disease and animal feed related to animal disease and where we fit in, and that's certainly, certainly a risk, and I'm not sure we've had a lot of talk about that. I know the risk group is sort of focused more on the, sort of, known pathogens and the chemical-contaminant-type things. So I think that's a very valuable comment that we need to go back and talk about, and, and I guess the risk group -- the group -- the subgroup that's working on that is hearing that and, I know, will be taking that back to talk about and try to factor in.

MR. LATNENBURG (phonetic): Yeah, my name is Matt Latnenbrog -- burg (phonetic), by the way, and yes, I'll identify myself. I'm with APC, Incorporated. But --

MS. DUNNAVAN: Thank you.

MR. LATNENBURG: -- basically, we are looking into, well, many incidences, such as what in -- as specific disease, is a thermal destructive force, and what would USDA or FDA accept to get us back into operations, for an example, and -- you know, so we don't

have to wait until this crisis occurs to start understanding, as a feed group, what feeds are in danger, what can we do in our feed operations to render the product safe, where a government agency would allow us to again start productions and the like, and I think these are things that certainly I'm working with some universities at present, and we're just seeing how much traction we can get to, to support such an activity.

MS. DUNNAVAN: Do we have any other comments? questions? concerns? issues?

MR. ROACH: Yeah. Hello. I'm Steve Roach with Food Animal Concerns Trust. We're a consumer group. I just wanted a little clarification on part of the program, 'cause there seemed to be two things, and I just wanted to get this clear in my mind. I wasn't clear. So you -- You're doing two -- several different things. You would be doing risk assessments to define which things you see as the highest risk, and that's one type of assessment, but then related to that is setting the contaminant levels. So that's semiqualitative, but then when you would set a

contaminant level, that would need to be quantitative, and those would be two separate processes, or maybe one would come after the other? I'm just -- Because there are two sort of similar things: setting the risk of something, and then another thing is to set the contamination. And is that correct, my understanding?

MS. DUNNAVAN: I think you're right, and I'm hoping that the, the risk group will comment for me some more on that.

DR. EKELMAN: I think you both have it --

MS. DUNNAVAN: Thank you, Karen.

DR. EKELMAN: -- exactly correct. We're using a relative risk-ranking method for our risk ranking, and we will use that to, to inform us about whether or not we need to develop limits for contaminants -- I'm going to use that word now, I understand everybody wants me to think of a different word -- or the government to think of a different one -- and then we will use a very quantitative, our usual analytic method, reviewing data, coming up with what we consider

to be a safe level, considering background contamination rates and things like that.

So you're right, the first is semiquantitative, and the second one is a very quantitative effort that we have done for things like fumonisin.

DR. GRABER: I might add, the risk-ranking procedure, the method, is something we are doing as -- under the Animal Feed Safety System Team, but any work, probably coming out of additional limits for additional adulterants, contaminants, whatever the right word is, is work that we're gonna do as we do -- as we've done for any other contaminant. That -- There's processes -- There's groups that are established to do that work, and there are processes in place to do that work.

So that's -- You know, if tomorrow, Compound X needed to be -- we, we decided we were gonna go out and establish some sort of limit for, say, dioxins, we would be -- we would have -- we have processes in place to do that, and we would do that using the people and, and organization that we've had for many years.

MALE VOICE: Just to follow that right up, in other words, we can get rid of Delaney (phonetic) because you're going to have established what the real risks are, so we don't need that?

DR. GRABER: Delaney and I are not on speaking terms.

MS. DUNNAVAN: Okay. Do we still have some burning issues we want to bring up? This is one last chance. If we don't have any more comments or questions, I do want to just comment that Toni Wooten, Regulatory Information Specialist in my division, is responsible for the hotel and the amenities that we've had at the hotel, and as usual, she has done an excellent job, and our Animal Feed Safety System Team did a lot of work in -- behind-the-scenes work in, in getting ready for this meeting and having it run smoothly, and I want to thank them all.

CLOSING REMARKS

BY GEORGE GRABER, Ph.D.

DR. GRABER: Okay. We're down to the end. I just got a few remarks that I'd like to make, and first of all, I really want

to thank everyone for coming to this meeting, them taking the time from your (sic) really busy schedules to be with us. I don't really want to name any people, but I probably will thank some people for being here, especially the, the states and the FDA personnel, district personnel, for taking time out to be here and to participate.

Again, the industry, we -- I don't know. Sometimes we take it for granted that they'll be there, and we look down at the attendance at this meeting, we had, at least in terms of yesterday -- As of yesterday morning, we had 203 people registered for the meeting and that actually showed, so that's -- that was very good, and I think we ended up having -- Of the people who originally said they'd be here, I think there were, like, maybe 10 to 12 people who couldn't make it for whatever reason. So we're really, really pleased with the turnout.

I want to thank the reporters for volunteering to, to come up here in front of the group and report the work of the breakout groups, and, and Glo has already thanked the members of the Animal Feed Safety Team.

Probably be remiss if I didn't thank (inaudible) for all the work she's done behind the scenes for, for making sure this, this program went off smoothly and all the others, so I'm sorry if I don't mention anyone's name.

There are the comments -- The comment cards are still -- if you still have a comment card, if you had some comment that you didn't feel appropriate to make in the group and still want us to know about it, please fill out the comment cards and put 'em in the box in the back. Same thing -- We'd like for you to fill out the evaluation form, as well, and put that in the box before you leave today.

We will be -- As -- We're transcribing yesterday's session and today's -- yesterday morning's session and today's session, and that information should go to the docket fairly soon, and -- probably a month or so, but we're gonna try to put things up on the CVM Website sooner than that, so -- The PowerPoint presentations from yesterday and the Word reports that you saw up here today will go up on the CVM Website, maybe in a week or so, so look, look, look for them.

One thing I did -- You know, I wrote my down -- wrote myself some notes here, and, of course, I forgot to mention something when I was thanking people. I -- One of the individuals just mentioned something about the fact that we had a lot more people west of the Mississippi come to the meeting we were out here -- by meeting out here as opposed to Virginia, and there is a comment in the docket already arguing that the reason that we -- the reason we're out here is because we're in bed with the -- with the industry, and we should have had it back in Washington because then we can get all the trade associations. So, you know, you can't win from losing, so . . .

But I really do appreciate the fact that we do have some producers and producer organizations here. It was something -- We had a few at the meeting, but having actual producers show up at this meeting was, was extremely gratifying and, and very helpful for, for the -- for the group to hear.

The -- In breaking -- In putting -- assigning people to the breakout groups, the idea was to try to get a cross-section of

people within each breakout group, and somebody mentioned something about the fact that some groups didn't have any producer groups in 'em, and they should have. There were some producer groups that didn't, didn't show, and we probably didn't move them -- some things around at the last minute and try to make sure we had producer groups and -- producer groups represented in all the breakout groups. So hopefully, next time we have a meeting, if there is a next time, that we'll have more producer groups in attendance so we can ensure that their voice is heard with all the breakout groups.

Next steps. Well, obviously, there was a lot of information presented here, and the Animal Feed Safety System Team will review, digest, discuss. We'll have the -- what was Charles Breen's comments? -- the full, frank and vigorous discussion about some of these issues, and, and I'll tell you that we do have such discussions.

And so one thing we'll do, obviously, is, is make some decisions about what our -- what we consider to be the next steps for this

particular group. We're gonna decide -- or at least develop the options that we'll present to the senior management team within the Center of Veterinary Medicine as to what products we're gonna work on and then get their blessing on that, and that'll, hopefully, get us to the year 2007 or sooner.

There are some items that will come out of this group, and I've mentioned already, that probably will not be necessary for the Animal Feed Safety Team to work on, but there are some good ideas here that perhaps the Center for Veterinary Medicine could be the Office of Surveillance and Compliance. It could be the Office of Research within CVM, or it could be the Office of Regulatory Affairs. Some, some good ideas have come out of this meeting that won't fall exactly under the, the premise of the Animal Feed Safety System. That, perhaps, people should be working on. They could be compliance policy guides. They could be revisions to programs. They could be additional educational efforts. But we're gonna try to capture all that information and ensure that it gets full deliberation.

So with that, unless anybody has any further comments, I want to wish you all a safe trip, and -- no matter where your travels take you, and thank you for participating in this very important meeting. Thank you.