

## UNITED STATES DEPARTMENT OF AGRICULTURE

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## NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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## INTERNATIONAL EQUIVALENCE

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## PLENARY SESSION

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August 27, 2008

8:30 a.m.

USDA South Building Cafeteria  
Washington, D.C.CHAIR: MR. ALFRED V. ALMANZA  
Administrator, FSISMODERATOR: MR. ROBERT TYNAN  
Deputy Assistant Administrator  
Office of Public Affairs and  
Consumer Education  
Food Safety and Inspection Service

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## GUEST SPEAKERS:

DR. DAVID ACHESON  
DR. JILL HOLLINGSWORTH  
MR. MICHAEL ROBACH  
MS. CAROLINE SMITH DeWAAL  
DR. MARK SCHIPP  
DR. RICHARD ARESENAULT  
DR. BILL JOLLY  
DR. WOLF MAIER

## ALSO PARTICIPATING:

MR. CHRISTIAN OUZTS  
DR. STEVE SUPPAN

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1 P-R-O-C-E-E-D-I-N-G-S

2 (8:30 a.m.)

3 MR. TYNAN: Good morning. Good morning.  
4 I'm going to ask you to take your seats so that we  
5 could begin our meeting this morning.

6 Good morning again, and welcome to our  
7 National Advisory Committee on Meat and Poultry  
8 Inspection. I'm Robert Tynan. I'm the Deputy  
9 Assistant Administrator for the Office of Public  
10 Affairs and Consumer Education, and I have the good  
11 fortune of moderating the meeting today.

12 We have a fairly ambitious agenda. There  
13 is quite a bit to do. So I'll save some of the  
14 preliminaries maybe for a few minutes after we get  
15 some of the welcoming remarks under way.

16 I do want to thank everyone for coming here  
17 today. I know everyone has a very busy schedule.  
18 So for you to take time out to be here with us today  
19 to talk about a very important topic for us on  
20 verifying international equivalence, I think that's  
21 to be commended, and we appreciate it very much.

22 Without further adieu, I'm going to get

1 into the agenda, and I'm going to ask Mr. Almanza to  
2 give us the opening remarks. I'm going to also have  
3 Mr. Almanza and Dr. Raymond when they do their  
4 remarks, perhaps stay at their place. We have a  
5 wall here that it seems to impede passing back and  
6 forth. So in the interest of just making it easier  
7 for everybody, we're going to let them stay at their  
8 seats. Mr. Almanza.

9 MR. ALMANZA: Thank you, Robert. Well,  
10 good morning to everybody. I want to thank  
11 everybody for being here and taking time out of your  
12 busy summer schedules. I know it's not easy to get  
13 in and out of this wonderful place this time of the  
14 year, but I do appreciate you all coming, and  
15 certainly I appreciate the members of NACMPI and  
16 your commitment to being at this meeting.

17 At this meeting, we're going to give NACMPI  
18 something that's pretty weighty, and that's the  
19 import equivalence. After coming back from  
20 Australia, I think that was an interesting trip for  
21 me in getting to see another country's inspection  
22 system, and all that to say is I believe that we

1 have a very good system in the United States. I  
2 believe that it is focused in the right areas as far  
3 as food safety, as far as being science based, and I  
4 believe that we can do a better job of performing  
5 our mission with your help.

6 But I think that with the issues that we're  
7 going to be discussing over the next couple of days,  
8 I think that it will be interesting to hear  
9 everybody's opinions and ideas on these issues.

10 Dr. James, Bill James will explain the FSIS  
11 system in greater detail, and how we carry out our  
12 import inspection system.

13 It's no small task to regulate imports and  
14 in the last five years, we've regulated imported  
15 meat and poultry products at about 4 billion pounds  
16 from about 29 of 34 eligible countries, 6 million  
17 pounds of eggs, egg products from Canada that were  
18 presented for reinspection.

19 So because of this huge amount of imported  
20 product, we've had an obligation as public servants  
21 to continue to look at new approaches, methods and  
22 also ideas to insure the safety of imported food

1 products.

2           So today's agenda will be filled with  
3 presenters who are experts on international  
4 equivalence and import safety. So you'll have a  
5 chance to hear from these presenters, and they've  
6 all, not all, but they've traveled a long way to be  
7 here. So I also want to make sure that everybody  
8 has equal chance to express their, their opinions  
9 and their ideas in this, and I certainly want to  
10 thank you for your help in this process.

11           With that, I'd like to introduce  
12 Dr. Raymond, our Under Secretary for Food Safety.

13           DR. RAYMOND: Thanks, Al, and good morning  
14 to everybody from me also. It's always good to see  
15 old friends and make new acquaintances at meetings  
16 like this, and I also thank you all for taking the  
17 time and also for some of you traveling, to come and  
18 help us with this subject today.

19           We actually, you know, we have some who  
20 have added to their frequent flyer miles  
21 tremendously. Bill Jolly and Mark Schipp are here  
22 from New Zealand and Australia, and there will be

1 other international presenters, too. So this takes  
2 on a little different flavor than some of our past  
3 meetings.

4 I think you all know me well enough to know  
5 I'm a strong proponent of holding public meetings  
6 for discussions like this. You sometimes do serve  
7 as our external conscience, and we need that. And I  
8 encourage you, although some of you I know don't  
9 need any encouragement, but to continue that and to  
10 keep the heat on us in the Agency to continue to  
11 look at ways to do Food Safety and Inspection  
12 Service better. And none of us will say we're as  
13 good as we need to be or that we can't get better.

14 This meeting, as you know, is going to be a  
15 little different. We're not going to debate or  
16 solicit public opinion on risk-based inspection.  
17 We'll do that again but not this particular meeting.  
18 This meeting will be focused on import safety for  
19 meat and poultry products. We'll also hear from the  
20 FDA about produce and the products that they  
21 regulate and what they're doing new and different to  
22 improve safety in that arena and then, of course,

1 we'll hear from some international experts on  
2 equivalence and the way they determine equivalence,  
3 and we'll hear their thoughts and ideas. And,  
4 hopefully, at your breakout sessions, you'll do some  
5 very serious brain storming based on what you've  
6 heard to see what you would advise us to do to do  
7 our issues better.

8           Equivalence is a complex and confusing  
9 topic. It sounds simple when we explain how we do  
10 it, and I've memorized our speeches very well. I  
11 can do it without notes, but other people do it  
12 differently and there are people on the Hill, there  
13 are consumer advocates, there are industry leaders  
14 who feel that the way we do it isn't necessarily the  
15 only way or the best way to do it, and so we hope to  
16 address subject de jour as it seems -- Mr. Tynan,  
17 your grandson is calling. (Laughter.)

18           I do need to stop since Mr. Tynan  
19 introduced me to the Grandfathers Hall of Fame. I  
20 do, Robert, need to let you know we have a new  
21 member with us today, and Kevin has some pictures he  
22 would like to show later during coffee break. Oh,

1 he's going to pass it around right now! (Laughter.)  
2 That's the only way you can get into the  
3 Grandfathers Hall of Fame is to, you know, be brass.

4 MR. TYNAN: Kevin has a PowerPoint that  
5 he's going to use.

6 DR. RAYMOND: So he's very happy to have  
7 joined you and me since the last meeting we had here  
8 I think or at least he's formally announced it.

9 This isn't a small task. We've something  
10 one way for a long time, and as you all know, change  
11 is painful and difficult, and I think we have to be  
12 willing to maybe bear some of that pain based on  
13 what you recommend to us and based on what you hear  
14 from these other experts today and tomorrow.

15 I would just encourage you to listen to  
16 these presentations with an open mind. I know you  
17 all have opinions, and your opinions need to be  
18 heard and vented, but I want you to hear other  
19 people's opinions with an open mind and perhaps  
20 allow yours to be molded a little bit based on what  
21 you hear, rather than based on what you came to the  
22 meeting with a foregone conclusion.

1           Our Office of International Affairs will  
2 explain to you very shortly how we do equivalence  
3 and how we do auditing and how we do reinspection.  
4 As I said, the FDA will visit with you about this as  
5 will our international experts, and hopefully you'll  
6 take home a better understanding of how we do import  
7 safety for meat and poultry products and a better  
8 idea of what the world is looking at as we go  
9 through this.

10           I think in a nutshell, the way to describe  
11 ours best, is when a country applies to export meat  
12 or poultry products to this country, we do a very  
13 intensive audit of their paper system. We make sure  
14 they have rules and regs and laws and policies in  
15 place that are at least equivalent to ours, and then  
16 we do an audit of the country and we not only go  
17 into the establishments but we go into the  
18 laboratories and we go into their headquarters to  
19 make sure they have the infrastructure that's  
20 necessary. In other words, what we do is we, we  
21 take a look at their process but other people like  
22 to take a look at the product.

1           It's called outcomes equivalency rather  
2 than process equivalency, and that's what I think we  
3 need to think about today. What is equivalency?  
4 How many inspectors are in the grinding plant? Or  
5 is it how much E. coli is on the product that's  
6 tested? Or is it a combination of both? Right now  
7 ours is pretty much focused on the process and we do  
8 the laboratory testing to confirm that the process  
9 works.

10           But it's the process that the country has  
11 that we use to determine equivalency, and I think we  
12 need to consider other measurements of equivalency  
13 that may be equally or even more important. That's  
14 one of the things you're going to hear about.

15           I just personally don't believe that the  
16 process should be the sole factor or even maybe the  
17 determining factor. It should be a factor. And we  
18 would like your thoughts on how we might expand this  
19 if you think we should expand this.

20           This can be a frank discussion, and this  
21 group has always had frank discussions. No one here  
22 is shy. So we do expect this to be healthy and

1 robust.

2           We do know, we read regularly that the  
3 amount of imported food products coming into this  
4 country and going around the world globally has  
5 changed dramatically in the last 5 to 10 years. The  
6 demand for fresh produce in the wintertime has  
7 increased the demand for these products I mean into  
8 this country but just so you all know, the imported  
9 meat and poultry products coming into this country  
10 has remained amazingly stable for the last 5 years,  
11 at just a little over 4 billion pounds. It just  
12 doesn't change much because we don't have the  
13 seasonal variations. So the product that we  
14 regulate, we're not having this meeting because of  
15 increased imports or decreased inspection. We're  
16 having this meeting because we think there may be  
17 other ways that we need to take a look at to make  
18 sure we are doing our best.

19           As said many times in public health, if  
20 you're just staying with the status quo and just  
21 maintaining a good system, but not moving forward,  
22 you really are going to be moving backwards because

1 things do evolve. And we need to constantly be  
2 evolving to make sure we're doing the best we can,  
3 and I can't find anybody in the Agency that  
4 remembers the last time we had a very serious  
5 discussion about how we do import safety and audits  
6 and equivalency. It's just been our routine for a  
7 long time, and I think we need to make sure that our  
8 routine is as good as could be or, if needed, we  
9 need to take a look at changing it.

10 When I was growing up, we always ate  
11 hamburger on Friday night. Friday afternoon was the  
12 day my mom went down to the grocery store and bought  
13 the groceries. She didn't have time to cook a big  
14 dinner. So she, you know, made up some hamburgers  
15 and we had six of us, six kids, and, you know, some  
16 are playing football and some were cheerleaders and  
17 some were in the band. So nobody could sit down for  
18 dinner on Friday night because that was football and  
19 basketball night. So she just kind of made the  
20 hamburgers whenever they came through, but I always  
21 knew that hamburger was probably made in the United  
22 States. Probably was ground in Nebraska. Probably

1 came from our local butcher shop, from the 4-H calf  
2 that my dad bought every year at the county fair.  
3 We didn't really worry about international trade  
4 with the hamburger or how many complements came from  
5 Australia or New Zealand or Uruguay or Mexico or  
6 Canada or wherever. It was probably from that calf.

7 Things have changed, but we're probably  
8 still doing import safety the same way we were back  
9 when I was growing up as a kid in Nebraska, and  
10 that's one of the reasons I think that with the  
11 global trade practices that are occurring now, the  
12 world has become so much smaller, that we need to  
13 take a serious look at this.

14 So it's going to be a neat two days, I  
15 think, to do something that we just have not delved  
16 into yet.

17 We have some good successes. We've also  
18 had some problems, but a lot of our successes are  
19 because of NACMPI and other external groups that  
20 help us take a look at our policies. And once  
21 again, I thank you all, both those at the table and  
22 those in the audience, for all the work that you

1 have done both past and present and hopefully into  
2 the future to help us continue to evolve as a public  
3 health agency.

4           Before I stop and let you get to work, I do  
5 need to point out for those of you who may not know  
6 that there was just a very recent audit done by the  
7 Office of the Inspector General. It has nothing to  
8 do with this meeting. We aren't smart enough to  
9 schedule a meeting on the day a report is released,  
10 but the report is either released today or will be  
11 released shortly.

12           MR. TYNAN: Will be released.

13           DR. RAYMOND: Shortly. Yes. Okay. So  
14 it's not released. I can't give it to you yet, but  
15 there will very shortly be a report from the Office  
16 of the Inspector General on the Food Safety and  
17 Inspection Service's controls over imported meat and  
18 poultry products. And I only mention that to let  
19 you know that it's there, but that's not the topic  
20 for today. Their audit looked at how we picked  
21 which samples to test, how we picked how frequent to  
22 audit countries, et cetera. It's the nuts and bolts

1 of the details of what we currently do.

2           That's not the discussion for the next two  
3 days. The discussion for the next two days is can  
4 we do better? And if so, how? Not by determining  
5 how many products to test as they come across the  
6 border, which products to test which is the OIG  
7 report, and if it happens to become available today,  
8 we'll get it all to you tomorrow so you can peruse  
9 it on the trips home, but I just want you to know  
10 it's out there but has nothing to do with this  
11 particular meeting.

12           So with that, I have no doubt that this is  
13 going to be a good two days. Once again, I thank  
14 you all for participating, and I'll let you get on  
15 with the agenda, Robert.

16           MR. TYNAN: Okay. Thank you, Dr. Raymond.  
17 Normally I go through the agenda first, but I'm  
18 going to through some logistical issues, sort of the  
19 rules for the Committee. The first one is if  
20 anybody has any cell phones on, could you put them  
21 on quiet? (Laughter.) I apologize for the  
22 interruption and the remarks. Even if it had been

1 my grandson, I apologize.

2           In terms of logistical issues, as we  
3 normally do in the meetings, as the discussion  
4 completes, there is a period, usually a short  
5 comment period, where we allow the Committee to ask  
6 a few clarifying questions on the presentations. As  
7 always, if you have a question, if you could stand  
8 your tent card up, and we'll find some way of  
9 acknowledging each person that has a question, so we  
10 keep it orderly.

11           We do have some time constraints. So if I  
12 can't get to all of the questions in order to stay  
13 on the time, it's not because I'm not interested in  
14 what you have to say but we do have to complete the  
15 agenda before 6:00. So again the tent cards up  
16 would be a good thing.

17           We also have hard copies of the  
18 presentations that you'll see today being made.  
19 They have not been completed yet or at least when we  
20 started they had not been delivered yet. So as soon  
21 as we have those, they'll be available for you and  
22 you can use those to go along with the meeting, and

1 I think that's primarily for the audience. For the  
2 Committee members, I think you may have some of  
3 those in your books already.

4 Men's room, we go out the door here, down  
5 to the left. Ladies' room, out the door and up to  
6 the right. So that's sort of our logistical issues.

7 In terms of meeting rules of order, I want  
8 to just remind you under Tab 2, in your notebooks,  
9 you have some rules and we go through these every  
10 time, but it's always worthwhile to just take a  
11 minute to go through them again.

12 The rules of order, the Chair, the FSIS  
13 Administrator conducts the meeting. He is the  
14 Chairperson, opens the meeting, recognizes those  
15 wanting to speak, imposes limits on time, number of  
16 speakers, and adjourns the meeting.

17 As always, to allow Mr. Almanza to pay  
18 attention to the comments, he normally delegates to  
19 me sort of the management of the meeting, and I  
20 assume Mr. Almanza will do that again today.

21 All the questions and requests to speak  
22 will be addressed by the Chair. People must be

1 recognized by the Chair before speaking and that, of  
2 course, as you can understand is to try and keep an  
3 orderly discussion going. This isn't McLaughlin and  
4 Company I guess.

5 Presentations of issues and briefing papers  
6 will be followed by a short question and answer  
7 period. In the interest of time, questions and  
8 comments should be limited in their length and those  
9 that are clarifying the presentation. The Chair  
10 will have to exercise some discretion on exactly how  
11 long that will go on.

12 Speeches, statements, longer type  
13 statements by the audience or even by the committee  
14 should be made during the Subcommittee discussions  
15 or perhaps during the time set aside for the public  
16 comments, and we'll go through the agenda very  
17 quickly in just a moment.

18 Committee members and the members of the  
19 public will be recognized by the Chair during that  
20 public comment period and requests to speak may be  
21 presented to the Chair in advance.

22 We may have a registration book outside for

1 those that would want to comment at the public  
2 comment period. So if you could sign up out there,  
3 and then we'll be sure to recognize you at the  
4 appropriate time.

5           Committee members are expected to attend  
6 the plenary session, as you're doing now, and the  
7 Subcommittee meetings that we have in your book, and  
8 I don't remember what tab it is, I don't have the  
9 book in front of me, but we do have the subcommittee  
10 assignments and you'll be expected to attend the  
11 Subcommittee session related to your particular  
12 group. The Committee members, if you don't attend  
13 that presentation of the issue, the Subcommittee  
14 participation, we're going to have to limit your  
15 conversation when we get back to the plenary session  
16 and the report outs. It seems fair that if we've  
17 assigned you to a group, that you should participate  
18 in that group if you're going to comment later on  
19 the final reports.

20           The Subcommittee Chair is designated by the  
21 Chair, by Mr. Almanza, and we have, Mr. Kowalczyk is  
22 going to take care of one for us, and Dr. Harris is

1 going to take care of the other Subcommittee.

2           Members of the public can attend those  
3 Subcommittee sessions. So when we do the break  
4 later on today for the Subcommittee deliberations,  
5 we'd invite the public to participate in that, but  
6 the amount of participation is going to be at the  
7 discretion of the Subcommittee Chairs. So that's  
8 not to limit you in any way, but they have a  
9 responsibility to provide us with recommendations  
10 that represent the Committee's thinking. So they  
11 have to move along. So to the extent they can, I  
12 think probably Dr. Harris and Mr. Kowalczyk will  
13 allow public comment but they will have discretion  
14 on that.

15           And then the rules of orders are always  
16 subject to review. So if the Committee has any  
17 issues with what we've talked about today and wants  
18 to change that for subsequent meetings, just let me  
19 know sometime during the session.

20           Now, real briefly, if I could take you to  
21 the agenda. It should be in the inside flap of your  
22 notebooks. It should be on the cover page. There's

1 a pocket on the left-hand side. But essentially the  
2 meeting today, we have two short briefings on topics  
3 that have come up at previous meetings. So Dr. Erin  
4 Dreyling is here and she's going to cover both of  
5 those topics. She's doing double duty today.  
6 Dr. Maczka was to be here with us. She's our  
7 Assistant Administrator for the Office of Food  
8 Defense and Emergency Response, and had an emergency  
9 herself that she needed to take care of. So Erin is  
10 kind enough to cover both of those topics for us.  
11 That will be a short presentation.

12 We'll have a few minutes for comments, but  
13 the substance of the meeting will be immediately  
14 after that. And as I mentioned earlier, the topic  
15 for today is verifying international equivalence,  
16 and it's a four-part session. I won't take you  
17 through each of the segments, but we have  
18 presentations on the U.S. Government perspective.  
19 That will be FSIS, and we also have Dr. Acheson from  
20 the Food and Drug Administration who will be  
21 presenting some of the issues from his Agency's  
22 perspective.

1           We also have an industry perspective. We  
2 have Mr. Mike Robach and Dr. Jill Hollingsworth will  
3 be here to talk a little bit about some of the  
4 global food safety initiative and some of the third-  
5 party audit systems that the industry is  
6 undertaking.

7           We will also have a consumer perspective.  
8 Caroline Smith DeWaal, I believe, will be the  
9 presenter for that, and she will be here and  
10 covering consumer issues.

11           And then last but not least, we have some  
12 international guests that will be participating, and  
13 they will bring about the fourth part of our session  
14 and kind of give their perspective on how verifying  
15 international equivalence should work.

16           So with those four major components, that  
17 will lead to a public comment period toward the end  
18 of the day and will then allow the Subcommittees to  
19 begin their deliberations on the questions that the  
20 Agency has posed for the subcommittees. So I think  
21 there will be about an hour later on this afternoon,  
22 an hour and a half maybe, for the Subcommittees to

1 begin their work. The majority of that work will  
2 occur tomorrow morning through lunchtime, and then  
3 after lunch, we'll have report outs from the  
4 Subcommittees.

5 And that's essentially how we're going to  
6 proceed with the two days.

7 Are there any questions from the Committee  
8 or from the audience in terms of how we're going to  
9 proceed?

10 Yes, Mr. Corbo.

11 MR. CORBO: Yeah, before we start, I just  
12 wanted to thank the Agency for permitting me to sit  
13 in the place of Carol Tucker Foreman, who is on  
14 another advisory committee here at USDA that's  
15 meeting also today, and so I want to thank you for  
16 making the accommodation to allow a second consumer  
17 representative to participate today, and I promise  
18 to be reasonably disruptive.

19 MR. TYNAN: I think the rule was you had to  
20 behave yourself, Tony. But since you bring it up,  
21 the last issue that I'm going to have is I'm going  
22 to ask perhaps to go around the Committee table so

1 that everyone knows who everyone is, including  
2 Mr. Corbo who is sitting in for Mrs. Foreman today,  
3 and I'll start.

4 I'm Robert Tynan, and again I'm the Deputy  
5 Assistant Administrator in the Office of Public  
6 Affairs and Consumer Education.

7 MR. KOWALCYK: I'm Michael Kowalcyk. I'm a  
8 food safety advocate with the Center for Foodborne  
9 Illness, Research and Prevention.

10 MR. ELFERING: I'm Kevin Elfering. I'm  
11 actually retired from a state agency and currently  
12 Adjunct Instructor for the University of Minnesota  
13 and New Mexico State University.

14 MR. TYNAN: And working on the Hall of Fame  
15 for Grandfather.

16 MR. ELFERING: I'm working on the  
17 Grandfathers Hall of Fame.

18 MR. TYNAN: Okay.

19 DR. RYBOLT: I'm Michael Rybolt with the  
20 National Turkey Federation.

21 DR. STROMBERG: I'm Stan Stromberg. I'm  
22 the Food Safety Director of the Oklahoma Department

1 of Agriculture.

2 DR. MURINDA: Shelton Murinda from Cal Poly  
3 Pomona. I'm a microbiologist and food safety  
4 specialist.

5 DR. NEGRON-BRAVO: Edna Negrón-Bravo from  
6 the University of Puerto Rico at Mayaguez, a food  
7 scientist and Food Safety Institute of the Americas,  
8 where we do some training in Spanish for the  
9 international group. Thank you.

10 MS. CONTI: Good morning. My name is Kibbe  
11 Conti. I'm coming from South Dakota where I'm a  
12 consultant dietitian and have my own consulting  
13 business, Northern Plains Nutrition Consulting.

14 MR. SCHAD: I'm Mark Schad, and I own and  
15 operate Schad Meats in Cincinnati, Ohio.

16 DR. HARRIS: Joe Harris with Southwest Meat  
17 Association.

18 MR. FINNEGAN: Mike Finnegan, from Montana  
19 State Meat and Poultry Inspection.

20 DR. HENRY: Craig Henry with Grocery  
21 Manufacturers Associations.

22 MS. JONES: Cheryl Jones, research

1 instructor, Master Public Health Program at  
2 Morehouse School of Medicine.

3 MR. CORBO: Tony Corbo, legislative  
4 representative for Food and Water Watch.

5 MR. COVINGTON: Brian Covington with  
6 Keystone Foods.

7 DR. DICKSON: Jim Dickson at Iowa State  
8 University.

9 MR. PAINTER: Stan Painter, National Joint  
10 Council Chairman.

11 MS. ANANDARAMAN: Neena Anandaraman,  
12 National Association of Federal Veterinarians.

13 MR. BUSCH: Frank Busch. I'm here  
14 representing the Association of Technical and  
15 Supervisory Professionals.

16 MR. QUICK: Good morning. I'm Bryce Quick  
17 with the Office of the Administrator.

18 MR. ALMANZA: I'm Al Almanza, the  
19 Administrator.

20 DR. RAYMOND: Doc Raymond.

21 DR. ENGELJOHN: Dan Engeljohn with the  
22 Office of Policy here at FSIS.

1           MR. SMART: Don Smart, Director of the  
2 International Audit Staff with the International  
3 Affairs.

4           MS. WHITE: Sally White with the  
5 International Equivalent Staff, Office of  
6 International Affairs.

7           MS. STANLEY: Mary Stanley, and I'm also  
8 with the Office of International Affairs.

9           DR. JAMES: Bill James, Office of  
10 International Affairs.

11           MR. TYNAN: Excellent. It's back to me.  
12 And I have the pleasure of introducing our first  
13 speaker, Dr. Erin Dreyling. She's our Deputy  
14 Director of the Data Analysis and Integration Group  
15 in the Office of Food Defense and Emergency Response  
16 at FSIS. And she has two topics that she's going to  
17 touch on, and at the end, we'll have about five  
18 minutes or so for any clarifying questions or  
19 comments that anyone would like to make. Erin.

20           DR. DREYLING: Great. Good morning. I'd  
21 like to welcome all of our National Advisory  
22 Committee members back to Washington. We're very

1 happy to have you here, and I'm very glad that we  
2 were given a few minutes on this morning's agenda to  
3 give you an update on the topics that we spent all  
4 of our February meeting discussing.

5           So this morning, I want to provide you an  
6 update on the improvements for processing and  
7 slaughter inspection that we discussed at our  
8 February meeting.

9           First I will give you an overview of what  
10 those improvements were that the Agency proposed at  
11 the February meeting, and then I would like to give  
12 you an update on the progress that we have made and  
13 will continue to make through refining our proposed  
14 improvements.

15           So if I could have my next slide.

16           At our February meeting, if you all  
17 remember, we discussed two improvements for our  
18 processing and slaughter inspection. And I want to  
19 just reiterate, as we did at the February meeting,  
20 that these improvements are intended to apply to all  
21 of our processing and slaughter establishments, and  
22 they all work within our existing regulatory

1 framework. So these improvements do not require any  
2 additional regulations, and they're not intended to  
3 add any additional burdens for industry.

4           So the first improvement that we did  
5 propose at our February meeting was a public health  
6 risk ranking algorithm. And this public health risk  
7 ranking algorithm has evolved from the work that we  
8 previously did on risk-based inspection but we are  
9 taking a much different approach to how we are using  
10 data to drive and inform our inspection activities.

11           So our public health risk ranking algorithm  
12 that we talked to you about at the February meeting  
13 had two purposes. The first was to prioritize our  
14 routine and our for cause FSAs. If you'll remember,  
15 we said we were going to place establishments into  
16 three levels of inspection based upon indicators of  
17 process control. So how well an establishment was  
18 controlling pathogens, based upon the NR rate in the  
19 establishment and other factors like that. So very  
20 discrete criteria about process control would place  
21 you into your level of inspection.

22           And we said establishments in our highest

1 level of inspection, where we were not sure they  
2 were maintaining process control, would have a FSA  
3 done. That would be a for cause FSA. And I want to  
4 point out, these reasons really are the reasons that  
5 we do FSAs for today. This is really formalizing  
6 the criteria we use to prioritize and identify when  
7 a for cause FSA needs to be done.

8           What we also said at the February meeting  
9 was that we would have Level 2 and Level 1  
10 establishments, and that those would be used to  
11 prioritize when we do routine FSAs, and the Agency  
12 has committed that we will do a FSA in all  
13 establishments every four years. So Level 2 and  
14 Level 1 will help us to prioritize when that FSA is  
15 done.

16           Okay. The second use for our public health  
17 risk ranking algorithm is to tell us when we do  
18 focused inspection activities, and let me just  
19 remind everyone what we said a focused inspection  
20 activity would be. We said a focused inspection  
21 activity would be really a new activity that the  
22 inspector does to comprehensively elevate the food

1 safety system, to make sure that the establishment  
2 is implementing its HACCP plan and carrying out all  
3 of the decisions that it made in its hazard  
4 analysis, that it's implementing its SOPs, its SSOPs  
5 and its GMPs. So all of your prerequisite programs.  
6 Inspectors would think comprehensively about the  
7 system. And we also said that they would consider  
8 or give most importance to vulnerable points within  
9 the process, the points within the process that we  
10 think are most important for controlling or  
11 preventing microbial growth or contamination.

12 So could I have my next slide.

13 So let me give you an idea of how we have  
14 progressed since the February meeting. First of  
15 all, we wanted to thank everyone, our NACMPI members  
16 and the public, all of our stakeholders for the  
17 comments that we received on the technical reports  
18 that were presented at the February meeting.

19 We have revised our reports in response to  
20 the NACMPI comments, our other stakeholder comments  
21 and also peer review comments. We did have peer  
22 review done on our reports. And, in April, we

1 posted revised reports and also a response to  
2 comment document that laid out exactly in response  
3 to every comment that we received, how the document  
4 was changed.

5 Can I have my next slide?

6 We are still continuing to refine our  
7 approach. The reports that we put out in September  
8 were revisioned, but they are no way the final  
9 version of our improvements for processing and  
10 slaughter inspection.

11 First of all, we continue to refine our  
12 focused inspection methodology. This summer, we  
13 have carried out three field visits, and this was a  
14 suggestion from one of our NACMPI members, that we  
15 actually go out into the field and we meet with our  
16 inspection personnel and that we go to establishment  
17 and we walk through the focused inspection  
18 methodology. And we have done that, and based upon  
19 that criteria, we are going to refine the  
20 methodology even further.

21 As you can see here, we did visit three  
22 districts. We went to Atlanta, DesMoines and

1 Raleigh, and in each district, we had a focus group  
2 with our field personnel, and then also we walked  
3 through the methodology in different establishments.  
4 We tried to hit establishments in all of our  
5 different HACCP categories so that we could see how  
6 this method works for different types of plants,  
7 different size plants and where they're making  
8 different products.

9 Can I have my next slide?

10 Our next plan is to further refine our  
11 focused inspection activities, our methodology and  
12 to come back to our NACMPI Committee in the fall.  
13 We would like to have a NACMPI table top evaluation  
14 for our focused inspection activities. And at this  
15 meeting we will present the refined method to you,  
16 and then we would like to play out scenarios with  
17 you to show you how we think this will help our  
18 inspectors to better evaluate food safety systems in  
19 establishments and to make sure that establishments  
20 are maintaining process control.

21 So I know that Robert is going to speak  
22 with all of our NACMPI members over the course of

1 the next few days to talk about some dates in the  
2 fall that we will have our meeting.

3 We also are conducting a historical data  
4 analysis. If you'll remember back to the February  
5 meeting, we said that focused inspection activities  
6 would be done in response to public health prompt,  
7 and what is a prompt? A prompt is a public health  
8 event in an establishment, so positive pathogen test  
9 results or an increasing number of HACCP or  
10 sanitation NRs in an establish.

11 And we are doing an analysis to identify  
12 what is an anomaly? When should a focused  
13 inspection activity be done? And it's my hope that  
14 for the fall meeting, we will also be able to  
15 present the results of that analysis to you. Okay.

16 Also, based upon comments that we did  
17 receive from our NACMPI members and from the public,  
18 we have decided to stand up a committee at the  
19 National Academy of Sciences to review the Agency's  
20 use of data to form its initiatives. And the first  
21 two questions that we will be taking to the Academy  
22 are, one, to review our proposed methodology for

1 attribution and to think about its intended use for  
2 a relative risk ranking of establishments as we  
3 propose to use in our public health risk ranking  
4 algorithm.

5           The second question we are going to ask the  
6 National Academy of Sciences is to evaluate our  
7 proposed indicators of process control that will be  
8 used in our public health risk ranking algorithm.  
9 So the committee is being studious, and we  
10 anticipate that they will begin their work this  
11 fall. So we look forward to their comments.

12           Okay. Can I have my next slide?

13           So that really is an update on our proposed  
14 improvements for processing and slaughter  
15 inspection, and at the end I can take some questions  
16 from the Committee, but I do want to move on to make  
17 sure I can cover all the material that we need to  
18 present to you this morning.

19           If you'll turn to your presentation now  
20 that is entitled FSIS Data Infrastructure  
21 Improvements. You will remember at the February  
22 meeting that we also talked to you about how FSIS is

1 strengthening its data infrastructure, and how we  
2 are making a strong effort to inform inspection and  
3 our auditing and our laboratory activities using the  
4 Agency's data. And in order to do that, we are  
5 redesigning our data infrastructure, and this is  
6 going to allow us to really strengthen our business  
7 process.

8           And what we talked to you about at the  
9 February meeting was the Public Health Information  
10 System. This is the Agency's new data  
11 infrastructure that is being designed now. I'd like  
12 to give you an overview of the functionality that's  
13 being put into that system and to really make clear  
14 for you how the Agency is trying to use data to  
15 drive its inspection activities and to improve its  
16 ability to protect public health.

17           Can I have my next slide?

18           So as I've already said, we are really  
19 actively strengthening our data infrastructure to  
20 improve our ability to protect food safety and also  
21 food defense. And many of the functionalities that  
22 are being built into the Public Health Information

1 System are based upon recommendations that came out  
2 of the December 2007 risk-based inspection audit  
3 from OIG. And, I am happy to say that FSIS has come  
4 to management decision on all 35 of the  
5 recommendations from OIG, and that it is the Public  
6 Health Information System that's going to help us  
7 meet many of those recommendations.

8 Next slide.

9 So I want to give you a very broad overview  
10 first of the functionality that PHIS will have, and  
11 how we think that the system will help us to improve  
12 our protection of public health.

13 First of all, the Public Health Information  
14 System is going to allow us to integrate a number of  
15 data streams. Currently, FSIS has many disparate  
16 data streams that cannot be linked together easily,  
17 that prohibits us from using that information in a  
18 real time capacity to inform our inspection  
19 activities or our sampling activities. And by  
20 developing the Public Health Information System,  
21 we're really coming up with a way where we can pull  
22 this data together easily and efficiently and to use

1 it to inform how we do business.

2           Second, as I've already said, we are taking  
3 a data driven approach to inspection to auditing and  
4 to laboratory scheduling, and I really want to point  
5 out, we are here to talk about international issues  
6 today.     We are doing this both for domestic  
7 establishments and also for our international work.  
8 So all of the functionality that I'm talking about  
9 today applies both domestically and internationally  
10 to our data.

11           And also we're going to have much greater  
12 information sharing in PHIS.   This is going to work  
13 through internal agencies to USDA.   So we will have  
14 much greater interaction and data sharing with APHIS  
15 and we are also working closing with FDA and CDC to  
16 be able to share data with them.   And in this  
17 presentation this morning, I'm going to give you an  
18 example of how we think that using a number of  
19 agencies' data together can really help us to refine  
20 and to better protect public health.

21           So I've already alluded to the fact that  
22 there is numerous functionalities throughout PHIS,

1 and I will give you an overview in this presentation  
2 of all those functionalities today. I'm going to  
3 spend most of my time talking about our predictive  
4 analytics functionality because this will really  
5 help you see how we're going to use data to drive  
6 our inspection activities and our laboratory  
7 activities.

8 I will also give you an overview of our  
9 domestic inspection functionalities and also our  
10 import and our export functionalities. Okay.

11 So predictive analytics. This is really  
12 going to allow the Agency to use data in a very  
13 novel way, in ways that we have not been able to do  
14 before, and this is really going to allow to much  
15 more efficiently and effectively use data to inform  
16 our policies and to identify research or outreach  
17 needs.

18 First of all, it's going to allow our  
19 analysts as I've already said to use multiple data  
20 streams, so to easily combine data streams and to  
21 analyze relationships in our data. And one example  
22 of the analyses that we have done to test this out

1 and to understand the value of integrating multiple  
2 data streams is work that we actually presented to  
3 the National Advisory Committee back in February.

4 We told you about our work where we looked  
5 at the relationship between public health based NRs  
6 and *Salmonella* test results, and to do that, we had  
7 to integrate multiple data systems and we had to  
8 really use sophisticated statistical techniques to  
9 do this.

10 We found for those of you who may not  
11 remember, that if you had an NR, a public health  
12 based NR two weeks prior to having your *Salmonella*  
13 test result, you were three times more likely to  
14 have a positive. Now, that's just one example of  
15 the kind of analyses we can do and the capability  
16 that we're building into predictive analytics, but  
17 that really helps us refine risk measures and to  
18 understand relationships that we may not be  
19 identifying right now because we can't link our data  
20 adequately.

21 Second, one of the functionalities we will  
22 have from predictive analytics is that we will be

1 able to monitor establishment data in real time, and  
2 we're building in alerts for anomalies. So we've  
3 already talked a little bit about focused inspection  
4 activities, and we have said that PHIS will be  
5 continuously monitoring in a real time capacity our  
6 inspection results and our laboratory results, and  
7 if we have certain public health events, focused  
8 inspection activities will be prompted.

9           But that's not the only anomaly detection  
10 or alert that we're building into PHIS through  
11 predictive analytics. We are also going to be  
12 monitoring for high rates of SRM noncompliance or  
13 high pathogen levels in an establishment. We're  
14 also looking at management controls such as if  
15 inspection activities are not being performed as if  
16 they should be. So there will be numerous alerts  
17 that occur for our inspection personnel and also at  
18 Headquarters or the district levels that we can make  
19 sure that establishments are maintaining process  
20 control and that inspectors are carrying out the  
21 activities that should be done in establishments.  
22 Okay.

1           We also are building a number of automated  
2 algorithms into predictive analytics. We've talked  
3 about the public health risk rank algorithm and its  
4 use for prioritizing FSAs. That will be built into  
5 predictive analytics. That will constantly be able  
6 to generate lists for when FSAs should be done and  
7 constantly tell us the regularity or the frequency  
8 of focused inspection activities. That will be  
9 built into the system.

10           We're also building into the system our  
11 risk-based sampling algorithms. Right now numerous  
12 people throughout the Agency have to run algorithms  
13 on a monthly basis. It can take a lot of their  
14 time, and this will give us the ability for those to  
15 be done automatically, and it will also insure that  
16 if positives occur, that follow up samples are  
17 scheduled immediately. So we'll have a real time  
18 response built into the system.

19           Also we have built into the system district  
20 activity reports. Our district analysts in all of  
21 our districts will be able to use PHIS to generate  
22 their reports on a regular basis. This will allow

1 for alerts to be built for the district, to identify  
2 what the district needs to pay attention to, and  
3 it'll make sure that there's consistent reports  
4 produced across all of our districts, for our  
5 district managers and our district analysts to  
6 review.

7           And finally, as I've said, this applies  
8 both to domestic and international activities. We  
9 will have our foreign establishment algorithm built  
10 into the Public Health Information System, and in  
11 addition will have our port of entry sampling built  
12 into the system. We're going to create a feedback  
13 loop so that those activities inform one another,  
14 and also explore maybe how we can use other data to  
15 figure out how we should carry out our international  
16 activities.

17           And finally, we have been working with  
18 Carnegie Mellon University to look at self-learning  
19 algorithms, algorithms that can constantly monitor  
20 data to look for relationships that we may not have  
21 observed. This is a new capacity that we're  
22 building in. And working with Carnegie Mellon,

1 we've really sought to see how can we novelly  
2 analyze our data, and what can we do? What is the  
3 power of combining our different data streams? And  
4 I want to give you a few examples of the work that  
5 we have done with Carnegie Mellon this morning.

6 Next slide.

7 So as we've worked with Carnegie Mellon  
8 University, what we're trying to do are to identify  
9 methods and tools that we need to program into PHIS.  
10 And so we have used our data to develop those  
11 methods, to make sure we cover all the functionality  
12 we think we should have as we capture requirements  
13 for our new information infrastructure.

14 And we also are using this to identify, you  
15 know, some interesting answers, some interesting  
16 questions that we have been wanting to answer for  
17 the Agency and to better understand public health risk in  
18 establishments.

19 So the three questions that we have asked  
20 ourselves as we have worked with Carnegie Mellon  
21 University are the following:

22 One, can we use our methods and our data

1 and our tools to identify establishments risk  
2 factors that we could use in our public health risk  
3 ranking algorithm? And I'm going to give you a few  
4 examples of that work in a second.

5 We're also asking ourselves, can we use our  
6 methods, data and tools to identify new patterns in  
7 our data that could indicate a problem?

8 And finally, can we use our methods and our  
9 tools to help us in investigations and trace back?  
10 Can we improve our effectiveness or efficiency  
11 really in recalls and investigations?

12 So if I could have my next slide.

13 All of the work that we've done so far with  
14 Carnegie Mellon University has focused on  
15 *Salmonella*, and I'm not going to go through all of  
16 the data sources that we've used in our analyses,  
17 but what I want to point out here and show you  
18 what's novel is we are pulling from multiple data  
19 streams in FSIS and multiple data streams from other  
20 agencies. So we are using data from CDC. We are  
21 using data from ARS and FSIS, and we're branching  
22 out. We will begin work now also with FDA and their

1 eLEXNET data.

2           So here's a few of the analyses that we  
3 carried out, just to look at how could we maybe  
4 develop better establishment risk factors. What are  
5 some ways that we could use our data to better  
6 understand risk in establishments and maybe come up  
7 with new variables that we would include in future  
8 iterations of our public health risk ranking  
9 algorithm.

10           So we did analysis which crossed over the  
11 FSIS/ARS data, our serotype data from our laboratory  
12 testing with the CDC PHLIS data which is serotype  
13 information from human illnesses, and we asked  
14 ourselves two questions. First, we wanted to know  
15 which serotypes in FSIS products are causing the  
16 greatest amount of human illness, and second, what  
17 percentage of *Salmonella* positives in FSIS regulated  
18 establishments are resistant to antibiotics.

19           So what we found is, and I don't think this  
20 is a surprise to anyone, that many of the serotypes  
21 that are causing human illnesses, *Salmonella*  
22 illnesses, are not due to FSIS products. And just

1 for your information, on the right is a list of the  
2 CDC top 10 serotypes causing human illness, and the  
3 ones in the boxes are also the ones that are the  
4 FSIS top 10 most common serotypes. You can see that  
5 not all of the serotypes causing human illness are  
6 the common FSIS serotypes.

7 And what we have on the right here are the  
8 serotypes that are not commonly causing human  
9 illness but are commonly found in FSIS products.

10 Now, what I want to point out about this  
11 is, this may not be new information to people but  
12 what is really novel here is that using our new  
13 statistical tools that will be in PHIS, we were able  
14 to do this analysis in a few seconds. That has not  
15 been able to be done before, and that is where the  
16 Agency is moving its data infrastructure. And we  
17 could use information like this down the road to  
18 further refine how we think about establishment  
19 risks and how we might rank establishments.

20 Can I have my next slide?

21 Secondly, I said that we looked at what  
22 percentage of *Salmonella* positives in FSIS

1 establishments were resistant to antibiotics. And  
2 we did this once again by crossing over our FSIS/ARS  
3 data along with our CDC data. And what we found was  
4 that establishments that had the greatest number of  
5 positives were not necessarily the establishments  
6 that had the greatest percentage of their isolates  
7 that were resistant to antibiotics. So we may want  
8 to think about this as a new way for thinking about  
9 establishment risks, and we have not included this  
10 in the public health risk ranking algorithm. This  
11 is just information that has been developed but it's  
12 our new way of thinking. How can we come up with  
13 more sophisticated indicators of establishment  
14 risks? So we will continue to take these methods  
15 and refine them and think about how can we better  
16 use our data to come up with establishment risk  
17 factors?

18 If I could have my next slide.

19 So just in summary, we were able to combine  
20 multiple datasets to answer this question very  
21 efficiently. Like I said, we have developed a tool  
22 that's able to take the CDC and the FSIS and the ARS

1 data, combine it and to produce analyses like this  
2 in a few seconds. It is really amazing, and it's a  
3 very exciting step forward for the Agency. And we  
4 will be continuing to refine methods like these as  
5 we move forward to develop predictive analytics to  
6 make sure that these capabilities are built into the  
7 system and to also use it to inform our business  
8 process, this kind of information.

9 I'm not going to go through the next two  
10 questions that we answered but just to give you an  
11 idea, we did look at, could we identify new patterns  
12 in our data? And what we've done is look at  
13 geographic and temporal relationships in *Salmonella*  
14 antibiotic resistance using the FSIS/ARS serotype  
15 data.

16 And then another question that we have  
17 undertaken is to see, how can we use our tools and  
18 this type of information to better assist us in  
19 trace backs and outbreak investigations? And we  
20 have been able to use the FSIS/ARS data and the CDC  
21 serotype data and pulse-type data to look at when  
22 were pulse types occurring in our establishments and

1 in human illness cases temporally and  
2 geographically, and this tool would allow us to much  
3 more efficiently carry out our outbreak  
4 investigations. Okay.

5 So that is really just a brief update and  
6 just touching the surface of our predictive  
7 analytics capabilities. But I hope that you  
8 understand that it is really going to allow the  
9 Agency to move its business process forward and to  
10 really take a data driven approach to all of our  
11 activities, our inspection, our scheduling, and our  
12 auditing, and it's going to apply both domestically  
13 and internationally.

14 Just to let you know where we are with  
15 PHIS, for all of the functionalities, we're  
16 currently in the design phase, and that we do  
17 anticipate that the system will be in full  
18 production readiness in fall of 2009.

19 Next slide.

20 I want to just spend a few minutes just  
21 giving you an idea of the functionality in our other  
22 modules. All of our modules will be informed by the

1 data analyses that are done in predictive analytics.

2           The domestic inspection module is going to  
3 replace our current PBIS system, and this is really  
4 going to give us the ability to capture a lot more  
5 information about our in-plant activities that our  
6 inspectors carry out on a daily basis, and then also  
7 to capture information that right now we don't  
8 capture in a format that we can analyze, and that's  
9 our information from our FSAs.

10           Also as I already mentioned, domestic  
11 inspection will have the capacity for automated  
12 laboratory sample scheduling and it will allow for  
13 secure data via the Internet. Okay.

14           On our import side, our import  
15 functionality is going to allow us the ability to  
16 receive electronic health certificates about  
17 incoming products and I'm going to leave it to my  
18 colleagues in OIA to talk to you much further about  
19 all of the capabilities that are being built into  
20 our import system for PHIS, but we are going to be  
21 integrating our system with the Customs and Border  
22 Protection and also we are going to have the ability

1 as I've already mentioned to schedule and inform  
2 when our audits are done in foreign countries and  
3 when our port-of-entry sampling is done, using our  
4 predictive analytic capabilities in PHIS.

5           Okay. And on the export side, I'll give  
6 you a brief overview of the functionality here.  
7 This is going to automate a lot of what is a manual  
8 process today, that we're really going from using  
9 printed and handwritten export forms to electronic  
10 forms. It's going to allow us to have automated  
11 checks to make sure that we are in compliance with  
12 foreign import requirements, and also the system is  
13 going to be designed with the capability for the  
14 ability for exporters to electronically pay fees.  
15 That capability will be there.

16           So with that, that is really an overview of  
17 the Agency's improvements for inspection and then  
18 our improvements for our data infrastructure. And I  
19 believe I have a few minutes, not too many, to take  
20 some questions from our Subcommittee members.

21           MR. TYNAN: If the Committee has any  
22 questions, if they could stand their tent card up

1 and we have maybe about four or five minutes to  
2 respond to some questions. Mr. Elfering.

3 MR. ELFERING: Yeah. You had mentioned on  
4 your predictive analytics that facilities that have  
5 had a recent noncompliance, that they're more likely  
6 to have a positive *Salmonella*. Do you have any kind  
7 of breakdown of what those noncompliances would be?  
8 For example, if you had a noncompliance for SRM  
9 removal, is that correlating to a higher prevalence  
10 of *Salmonella* positives?

11 DR. DREYLING: We do have a list of what  
12 are the W3, the public health based NRs, and I do  
13 believe they were identified by a group of our  
14 stakeholders. And, that was work that was done with  
15 our previous RBI work, and we can certainly make  
16 that list available. We did not individually break  
17 out our NRs. So we didn't look specifically at SRM  
18 noncompliance and *Salmonella* test results. We used  
19 all of the W3 NRs together so that we could have  
20 enough power to determine whether a relationship  
21 exists.

22 MR. ELFERING: Well, one of the questions I

1 would have is, is there any correlation between SRM  
2 removal and public health related to *Salmonella* --

3 DR. DREYLING: Right.

4 MR. ELFERING: -- and I know Dr. Raymond  
5 and I can probably have some fundamental differences  
6 on SRM removal, but honestly I don't know if it  
7 really fits into a risk-based inspection system,  
8 because I just don't think we can correlate the risk  
9 to the public health on *Salmonella*, *Listeria* and *E.*  
10 *coli* versus SRM removal.

11 DR. DREYLING: We are going to do some  
12 analyses where we further break down our  
13 understanding of our regulatory noncompliances with  
14 our pathogen results, and we can certainly make a  
15 list of all of our public health NRs to you.

16 MR. TYNAN: Other questions from the  
17 Committee? Mr. Corbo.

18 MR. CORBO: Tony Corbo from Food and Water  
19 Watch. I really appreciate all of the work that  
20 your group is doing, and I have a simple question.  
21 I didn't bring the OIG Report that the OIG  
22 identified the 35 areas for improvement, but there

1 was also a timeline. How close are you meeting the  
2 timeline that the OIG spelled out?

3 DR. DREYLING: We have been meeting I would  
4 say most of our dates for the OIG deadlines. The  
5 last few ones that I'm aware of, we had to carry out  
6 district analyst training and help our district  
7 analysts to produce consistent reports. That was  
8 due in June and we met that deadline. We were  
9 required to create a FSA prioritization plan, and  
10 that has been completed. We were required to put  
11 our reports out, our technical reports, and we had  
12 to do that by April 18th, and we did meet that  
13 deadline as well. So we have been meeting our OIG  
14 deadlines.

15 MR. TYNAN: Okay. Last call for questions?  
16 We'll let Dr. Dreyling off the hook.

17 (No response.)

18 MR. TYNAN: Okay. Thank you very much,  
19 Erin.

20 I think we're at the point in the agenda  
21 where we're going to get into the substance of  
22 today's meeting which is verifying international

1 equivalence. And the first speaker we have today is  
2 going to set the stage for us a little bit, talking  
3 about the Import Safety Working Group, and that's  
4 Ms. Mary Stanley, and she is the International  
5 Import Policy Advisor in the Office of International  
6 Affairs.

7 MS. STANLEY: Thank you. And the title of  
8 the slide is What the Import Safety Working Group  
9 Found, and trust me, in 15 or 20 minutes, there's no  
10 way that I could address all that the Interagency  
11 Working Group on Import Safety has approached. This  
12 session will be focused on FSIS activities that we  
13 have engaged in, in relationship to this Interagency  
14 Working Group.

15 First slide please.

16 It's hard to believe that it's been a year,  
17 just over a year, since the Executive Order was  
18 issued, and this Executive Order established the  
19 Interagency Working Group on Import Safety. And it  
20 was issued in order to insure that all appropriate  
21 steps were to be taken to promote the safety of  
22 imported products and was being driven by some

1 problems, significant problems on imported  
2 commodities. Melamine in the pet food and lead in  
3 toys and other major imported product breaches.

4 And so the mission of this Group is to  
5 identify the actions and appropriate steps that can  
6 be pursued with existing resources. And, I think  
7 the quote from Secretary Leavitt, the very end is,  
8 the purpose is not to just look at what we're doing  
9 today, but to anticipate tomorrow.

10 Next slide.

11 The Interagency Working Group was made up  
12 of 12 departments, agencies and we were represented  
13 by Dr. Richard Raymond, who was there for the  
14 Department of Agriculture, not just Food Safety and  
15 Inspection Service. And, there were three primary  
16 focuses of this Interagency Working Group. One was  
17 to review the current procedures that are in place.  
18 The other was to identify best practices that  
19 importers are already taking part in. That would be  
20 the selection of suppliers and perhaps inspections  
21 that they're doing in foreign countries from an  
22 industry viewpoint, and then the third charge was to

1 identify government best practices and to enhance  
2 the coordination between all agencies that are  
3 working on imported products.

4 Next slide.

5 The outcome of this Interagency Working  
6 Group, which we as an Agency, FSIS, dedicated full-  
7 time, we detailed full-time people over to HHS to  
8 work on this committee. Bob Tuverson worked very  
9 closely on the Strategic Framework for Continual  
10 Improvement, and then Karen Stuck was detailed to  
11 generate the action plan for import safety.

12 The Strategic Framework for Continual  
13 Improvement was issued on September 10th, and  
14 included in that were three organizing principles,  
15 six cross-cutting building blocks and four immediate  
16 actions that all of the agencies were charged with,  
17 and that was followed very closely with a  
18 complementary document that actually outlined the  
19 Action Plan for Import Safety, which was issued on  
20 November 6th, and that included 14 broad  
21 recommendations and 50 specific action steps.

22 Next slide.

1           For the Strategic Framework, the three  
2 organizing principles are prevention, if you prevent  
3 harm in the first place. The second one would be  
4 interventions, intervene when risks are identified,  
5 and the third is response, respond rapidly after the  
6 harm has occurred.

7           And the underpinning of these organizing  
8 principles are the six building blocks that are  
9 outlined here, advance the common mission, increase  
10 accountability, focus on risks of the life cycle of  
11 the imported product, build interoperable system,  
12 foster a culture of collaboration and promote  
13 technological innovation and new science.

14           During the discovery period for the  
15 strategic framework, it was communicated very  
16 effectively the FSIS statutory controls for imports.  
17 We're in a unique position from other departments  
18 and agencies in that we as an agency, and you'll be  
19 hearing this over and over throughout the day, do  
20 have a relationship with the foreign governments.  
21 We actually know the systems that they are producing  
22 the products that are being imported into the United

1 States. We've had a chance to evaluate those, deem  
2 them equivalent, and we also have an opportunity to  
3 have a presence on site during our audit and  
4 verification activities. And, we also have every  
5 shipment by statute is to be presented at port-of-  
6 entry for reinspection. That makes us very unique  
7 from some of the other agencies, particularly the  
8 Food and Drug Administration and others.

9 We also have an opportunity for direct  
10 government-to-government dialogue, and this is  
11 through the relationships built through the  
12 equivalence process, and it's carried through in  
13 regard to the certifications that are made on the  
14 products and information sharing which is a two-way  
15 information sharing. If we find problems on  
16 products, it's communicated back to the government  
17 for corrective actions and those corrective actions  
18 are communicated back and we exchange data,  
19 procedures, et cetera. So that's a very key point,  
20 the government-to-government dialogue that's already  
21 established.

22 Out of the four immediate actions, there

1 was one that really had significant impact on all  
2 government agencies and especially on the Department  
3 of Agriculture. For those of you that aren't close  
4 to the import process, the acronym, ACE/ITDS is the  
5 Automated Commercial Environment/International Trade  
6 Data System, and what this is, it's a long-term  
7 initiative under the Customs and Border Protection.  
8 It's been ongoing for many years, and it's the  
9 Government initiative to create a single window that  
10 will enable the collection, use and dissemination of  
11 all the international trade data. And so when the  
12 brokers are entering into the ACE system, the  
13 Automated Commercial Environment System with Customs  
14 and Border Protection, ACE/ITDS is going to enable  
15 the dissemination of these data to the appropriate  
16 regulatory agency and enable the communication  
17 mechanism so that we can communicate back to them in  
18 regards to the findings that we have and simply the  
19 process so that it will also speed the process  
20 through the entry through Customs.

21 So this immediate action, it was an OMB  
22 directive that was issued, and it required the

1 agencies to submit an implementation plan for  
2 completing ACE/ITDS, and it also charged this to all  
3 agencies involved in movement of product into the  
4 United States. So those agencies such as ourselves  
5 that are already actively involved, we had an action  
6 plan and implementation plan and it was a matter of  
7 packaging it into the format that was needed. Other  
8 agencies had a bigger challenge because they were  
9 not actively involved in the ACE/ITDS at that point.

10 And the implementation plan was to include  
11 the budgetary resources that were needed to support  
12 this, performance measures as well as your business  
13 and technical requirements.

14 Next slide.

15 So FSIS was well on its way. We had  
16 already completed or was nearing completion of all  
17 of these. We've been involved actively in the  
18 ACE/ITDS project since 2004, and so we had our  
19 Concepts of Operations. It had already gone through  
20 a clearance with Customs and Border Protection, and  
21 that includes our business processes for import  
22 port-of-entry and all the business scenarios that

1 define the IT system.

2           We have also already drafted a Memorandum  
3 of Understanding with DHS and that would support the  
4 ability for interface with our IT systems with the  
5 Customs system.

6           And also significant is last October, FSIS  
7 had just awarded the contract to develop the Public  
8 Health Information System, and that system is really  
9 going to provide the delivery of all these  
10 initiatives. It's the interface with our IT systems  
11 into the Customs and Border Protection, a very  
12 significant breakthrough there.

13           Out of the 14 recommendations and 50 action  
14 steps, there were very few that were really targeted  
15 towards initiatives that FSIS was going to be active  
16 in. Most of these were directed to the other  
17 agencies that had specific problems and so I've  
18 bolded on these slides the ones that FSIS does have  
19 an active role in. As an example, the good importer  
20 practices. Each of these recommendations, there was  
21 a lead agency that was identified, and when I say  
22 agency, that's OMB's term for departments. So

1 there's a lead department and in the case of good  
2 importer practices, that was HHS, and the Food and  
3 Drug Administration took the lead on this. But we  
4 had representation from all the other government  
5 agencies that participated in developing overarching  
6 good importer practices that would articulate what  
7 an importer should be doing, some guiding principles  
8 for them. And that's in the clearance stage and it  
9 may have been posted at this point.

10           Supplementing that, however, and this is  
11 the interaction that has been a benefit of working  
12 with all these agencies together, is that FSIS has  
13 undertaken development of good importer practices  
14 specific to FSIS commodities, and so this  
15 information will complement the overarching good  
16 importer practices but tailor it specifically to our  
17 commodities, and this will enable importers to  
18 actually know the rules, have it communicated,  
19 linking it up with what is expected. It is a very  
20 complicated process when you're trying to bring  
21 product into the country knowing, you know, the  
22 rules, the regulations, knowing the steps in regards

1 to who do you present to first and how you file  
2 entry and get the product successfully through the  
3 government maze and get your product to your  
4 consumer. So that's one example where we've been  
5 very active in a group.

6 In the interest of time, I've opted to  
7 focus on two of the recommendations that we have  
8 been -- if we want to switch to the next slide.  
9 This is just the rest of the 14 recommendations and  
10 action steps.

11 So if you go to the next slide, the most  
12 important, at least in FSIS' viewpoint, in regards  
13 to recommendations has been the common mission, and  
14 this recommendation working group is being led by  
15 the Customs and Border Protection. And, it's really  
16 just focusing on how can we as government agencies  
17 do a better job working together and so the action  
18 steps that the group has been charged with is to  
19 develop uniform inter-departmental procedures, where  
20 appropriate, to facilitate the clearing and  
21 controlling of shipments. And this is just  
22 springboarding some initiatives that FSIS already

1 had ongoing and particularly education and outreach.  
2 We had already staffed about 20 positions out in the  
3 field, import surveillance liaison officers that  
4 actually have that in their position description to  
5 do outreach, liaison and education. And so through  
6 this working group, we've actually opened more doors  
7 for them and for other opportunities for us to  
8 participate in training, ramping up the base  
9 knowledge particularly of legacy Customs and Border  
10 Protection officials of what FSIS laws, regulations,  
11 amenability, eligibility, so that we can stop that  
12 product that's not eligible at the port.

13 Another huge initiative under this  
14 workgroup is co-locating our officials with Customs  
15 and Border Protection particularly, and we've most  
16 recently staffed a position at the national  
17 targeting center which is going to be extremely  
18 significant in regard to our ability to form good  
19 relationships with Customs and Border Protection and  
20 keep FSIS in the forefront.

21 Next slide.

22 The other recommendation that we really

1 have focused on, which we think is where FSIS will  
2 benefit the greatest is through the  
3 interoperability. This is the ACE/ITDS project, and  
4 so again it's requiring all federal agencies by the  
5 end of 2009 to have the capability to exchange  
6 commercial data.

7           You heard Erin mention previously that the  
8 anticipated PHIS implementation is the end of 2009.  
9 So our IT development schedules are closely aligned  
10 at this point to enable this delivery. And in  
11 regard to the targeting system, FSIS has already  
12 developed rule sets. We did this a couple of years  
13 ago, and these rule sets are already firing in the  
14 targeting system. The limit there is we have  
15 limited access to that system. We only have a  
16 couple of users at this time. So through this  
17 initiative, we will expand that functionality.

18           And then as well, the last bullet point is  
19 the Standard Establishment Data Service which is  
20 called SEDS. This is an initiative to enable  
21 harmonized establishment identification, collecting  
22 information. You know, again FSIS is unique. We

1 have information on the establishments that are  
2 producing product and moving it into the United  
3 States, but not all the other commodities have that  
4 benefit, and so this will just help to close that  
5 chain of supply.

6           And then on the next slide, as an outcome  
7 of the work and the implementation of this action  
8 plan, we as a group decided it would be good to give  
9 an update. Before we were asked for the update, we  
10 generated it, and it's always better to be in that  
11 position. So at six months, which is was published  
12 July 2008, all of this information is available on  
13 the importsafety.gov website if you're interested in  
14 seeking more details. But it's a comprehensive  
15 summary of all the accomplishments as well as what  
16 agencies are doing to look ahead.

17           And so I just wanted to highlight a few of  
18 things that FSIS has done specifically. I mentioned  
19 the co-location of FSIS staff at the Customs and  
20 Border Protection National Targeting Center. That's  
21 a huge breakthrough for us.

22           FSIS has also developed and implemented an

1 Import Alert Tracking System, and this has enabled  
2 better coordination in enforcement. This was a  
3 brainchild of Office of International Affairs,  
4 Import Inspection Division, and it started out as  
5 just a database where we collected information.  
6 When our staff out in the field would find  
7 ineligible product, we would enter it in the  
8 database and through the work that we've done with  
9 OFDER and some of the other parts of the Agency, we  
10 were able to develop this tracking system which  
11 actually integrates with the Non-Routine Incident  
12 Management System. So if there is a breach, the  
13 information feeds the finding into the system, so we  
14 are able to keep the data and know what products are  
15 coming in and from what countries. We're also able  
16 to very rapidly notify our compliance officers so  
17 that they can do follow-up investigations, and we  
18 are also able, in the event of an emergency, this is  
19 linked into the Non-Routine Incident Management  
20 System and can activate the Emergency Management  
21 Council if necessary.

22 And so the data that reported, and this is

1 the timeframe from the implementation of the Action  
2 plan until July of 2008, there were 156 shipments of  
3 potentially ineligible shipments. This includes  
4 product that may be eligible and failed to present  
5 to FSIS, and so we were able to detect it based on  
6 the access to the data that we were given.

7           That's one thing that Customs and Border  
8 Protection has done for us, is given us access to  
9 summary data in their system. And so we now are  
10 better informed in regards to shipments that may  
11 have entered the country and we have better targeted  
12 surveillance and compliance activities, enforcement  
13 activities. So the amount of product, again this is  
14 product that we detected, and we took action, took  
15 control of the product. A lot of this product came  
16 into the inspected side of the equation and was  
17 presented and reinspected and moved on into commerce  
18 legally.

19           The ineligible product, that would be  
20 product that would be from foreign countries that  
21 aren't approved, has been destroyed.

22           The other major breakthrough in this is

1 that Customs and Border Protection is also  
2 sensitized to the eligibility requirements, and so  
3 they are now taking action and monitoring shipments  
4 coming in through the mail services and through  
5 Federal Express, the courier services, and they're  
6 actually taking action on our behalf, and then  
7 they'll report that. And so those data are also  
8 included in this system.

9           The next highlight is a significant  
10 breakthrough in April. We were able to connect with  
11 the New Zealand Food Safety Authority data system,  
12 and we're now trading data electronically,  
13 certification data. This is an interim step until  
14 the Public Health Information System is developed,  
15 and you'll hear more about that in a little bit but  
16 this is currently in a user acceptance test phase  
17 and so once we complete that testing phase, we are  
18 expecting to expand this to Australia who also has  
19 an electronic system, and that way we can exchange  
20 electronic data. The advantage on this is the fact  
21 that we will have advanced notice of what's coming  
22 into the country that's been certified by that

1 country.

2 DHS and FSIS participated in a G-8 exercise  
3 on food contamination. This is another significant  
4 accomplishment in that we're collaborating with the  
5 Department of Homeland Security and educating,  
6 including a process for sharing information if we  
7 have contaminations and events that occur.

8 Another significant highlight that we have  
9 had, the Office of Public Health and Science  
10 conducted or coordinated a public meeting earlier  
11 this year, and this is an outreach to collect  
12 information in regards to best practices and  
13 challenges for effective coordination. So this is  
14 just evidencing interagency cooperation,  
15 collaboration and leveraging the work that each  
16 agency is doing.

17 So all this work that's being done under  
18 the Action Plan, it's tasked, you know, beyond the  
19 current administration, we will continue to be  
20 working on it, and it really is simply just setting  
21 the stage that will accelerate the change that we're  
22 about to embark on discussing today. So I

1 appreciate the time and turn it back over to Bob.

2 MR. TYNAN: We're just a little bit ahead  
3 of time. So I'll allow a couple of questions, quick  
4 questions for Mary before we go onto the next  
5 speaker, and I'm going to start with Mr. Schad.

6 MR. SCHAD: Thanks, Robert. On the Import  
7 Alert Tracking System, this was data about shipments  
8 at the port-of-entry that was not being coordinated?  
9 I want to make sure I understand that correctly, and  
10 when was that implemented?

11 MS. STANLEY: We've had an Excel or an  
12 Access database in place for about four years but in  
13 April of this year, we implemented the Import Alert  
14 Tracking System that is more robust and it actually  
15 is part of our Non-Routine Incident Management  
16 System. So it moved it off a desktop and into our  
17 IT structure. The import surveillance liaison  
18 officers that I mentioned have access to the Customs  
19 and Border Protection through a portal access to  
20 their data. This is summary data. So the summary  
21 data means that that product is already entered and  
22 been released. It's about 10 to 15 days after

1 customs has released the product into commerce, but  
2 at this point, that's the only access that we can  
3 obtain. This requires a security level access.

4 MR. SCHAD: But in the PowerPoint, it said  
5 potentially ineligible shipments, but that was a  
6 problem at the port-of-entry, not prior to that. Is  
7 that correct?

8 MS. STANLEY: I'm sorry.

9 MR. SCHAD: The data was generated at the  
10 port-of-entry, not prior to that point?

11 MS. STANLEY: No, the data that I'm talking  
12 about in the Import Alert Tracking System is the  
13 findings that the -- will enter the shipment  
14 information, the country and all the information in  
15 regards to the importer, you know, where they found  
16 the product, the detention that they made, you know,  
17 the destruction, how they controlled the product.  
18 That's what we're talking about there is action.  
19 These are shipments that we've taken action on.

20 MR. SCHAD: Thank you.

21 MR. TYNAN: Dr. Henry.

22 DR. HENRY: Thank you, Robert. Craig

1 Henry, GMA. Based on Dr. Raymond's original opening  
2 statement where the equivalency program is focused,  
3 if you will, a little more so on processes as  
4 opposed to product outcome, or analysis, and looking  
5 at your slide 12 up there, bullet 2, in your  
6 consideration of the defining high-risk products as  
7 opposed to potentially high-risk processes, how does  
8 OIA today view the proposal that FDA is putting  
9 forth to use third party audits that is volunteered  
10 by the exporter, if you will, at the port-of-entry  
11 to deduce whether or not the process and/or product  
12 is high risk? Thank you.

13 MR. TYNAN: Is that an answer that we're  
14 going to be able to get done in a minute?

15 MS. STANLEY: No. One point I will make is  
16 this bullet here, the terminology, high target, high  
17 risk, this is through the Targeting System. So  
18 there was a vulnerability assessment done on risks  
19 associated with where product could come in  
20 illegally. So that term in that system there are  
21 for our food defense targeting, and then I think  
22 Bill James is getting ready to hit the --

1           MR. TYNAN:  If I can impose on you to hold  
2 that question because I think it's going to take a  
3 little bit too long and, Mr. Elfering, if I could  
4 ask you to hold onto your question as well.  We'll  
5 have another opportunity in just a minute to get  
6 some other questions in.  Thank you, Mary.

7           Our next speaker on the agenda is  
8 Dr. William James, and he's our Assistant  
9 Administrator in the Office of International  
10 Affairs.  And, he's going to give us a little bit of  
11 an overview on the triad system that we use.

12           DR. JAMES:  Good morning.  Much of what you  
13 will hear this morning is building on each other.  
14 Repetition is a good teacher, and so we'll be  
15 teaching you through the process of repetition.  
16 Each time this information is presented to you, it  
17 will be presented to you in a little bit greater  
18 level of detail.

19           So what I will be presenting to you this  
20 morning is an overview of the FSIS Import Triad of  
21 Protection.  Dr. Raymond alluded to this in his  
22 opening remarks.  Indeed, he has spoken on it at

1 great length a number of times over the last six  
2 months or so. What I will be presenting is also at  
3 a relatively high level but will include more  
4 detail. The presentations following mine will also  
5 get into additional details.

6 Next slide please.

7 The concerns that have been raised over the  
8 past year you are familiar with. As has been  
9 mentioned already, there were concerns about  
10 melamine in animal feed ingredients. There are  
11 concerns by the public regarding *E. coli* O517:H7 in  
12 beef trimmings. There are concerns by the public  
13 regarding avian influenza and it's potential  
14 introduction into this country through chicken  
15 products.

16 These concerns have foundation in that  
17 there are potential hazards associated with imports.  
18 Pathogens such as O157:H7 are real. We are  
19 concerned with residue such as veterinary drugs in  
20 imported product. There can be contaminants  
21 associated with imported products. Some things as  
22 simple as dirt. Condition of containers at port-of-

1 entry is important because it may provide for an  
2 entryway of contamination of products. So all of  
3 these hazards associated with imported products  
4 raise legitimate concerns by the public.

5           So how will we address these? Well, we  
6 have essentially what we would make reference to as  
7 international policy. The Agency has developed and  
8 is developing policies to address these hazards.  
9 Our Office of Policy and Program Development is the  
10 principal arm by which policy is developed and  
11 articulated. Our Office of Policy takes the lead in  
12 developing policy for both domestic inspection for  
13 the concept of equal to, which is applied to states,  
14 and the concept of equivalent, which you've already  
15 heard mentioned for the international arena. Those  
16 will be mentioned in a little bit more detail by  
17 Dr. Engeljohn, and so I will leave that to him.

18           Now, the objective that we want to  
19 accomplish through what we do for controlling import  
20 safety is to determine if a foreign inspection  
21 system has achieved and maintains equivalence, there  
22 is that word again, to the U.S. inspection system,

1 so that the U.S. appropriate level of protection is  
2 met. That appropriate level of protection a  
3 societal determination. It's a sovereign right of  
4 importing nations to determine what level of  
5 protection we want to establish, and therefore  
6 whatever system is developed in another country that  
7 wants to export to the U.S., it must be equivalent  
8 to ours, so that that level of protection can be  
9 met.

10 Now, this is a slide you will see again.  
11 These are the controls that are in place, our FSIS  
12 triad of protection. The three aspects of it, the  
13 three elements are equivalence, systems audits,  
14 port-of-entry reinspection. Again, my presentation  
15 is a broad overview. There are detailed  
16 presentations that will follow.

17 Now, this is a system that we believe over  
18 the years has served us well. It has been in place  
19 for a number of years as Dr. Raymond has mentioned.  
20 But there is an evolution that is going on in the  
21 area of import protections. We will hear later from  
22 FDA regarding ideas and plans that they are putting

1 in place. We will also be hearing from industry  
2 later in this meeting regarding concepts that they  
3 are pursuing. We will hear from foreign officials  
4 from countries such as Australia, New Zealand,  
5 Canada. We have a representative from the EU. We  
6 will hear their perspectives on this issue. These  
7 areas are evolving. The approaches that different  
8 entities take in response to this changing  
9 environment and the heightened concerns are  
10 important to us.

11           Although the system we have in place, we  
12 believe has served us well, we are interested in  
13 this Committee's ideas about where we ought to go  
14 from here. What parts of our basic approach are  
15 sound? What should we do to make changes so that we  
16 keep current with current concerns and challenges?

17           Let's talk for a moment about the basis for  
18 the import protections that we have. Currently for  
19 equivalence, we have two basic areas, two major  
20 areas. One is initial equivalence and the other is  
21 continuing equivalence.

22           For initial equivalence, that is as has

1 been described to you very briefly, a process  
2 whereby we determine whether or not a country should  
3 be eligible to export meat, poultry and egg products  
4 to the United States. Currently there are 34  
5 countries that are eligible to do so.

6           If we look at continuing equivalence,  
7 another way of describing this is an evaluation of  
8 changing SPS or sanitary, phytosanitary measures  
9 that are submitted to us by equivalent countries  
10 when they want to make changes to standards or  
11 procedures. These may be something relatively  
12 complicated in regard to antemortem or postmortem  
13 procedures that they want to change. It may be  
14 something a little more simple or objective to  
15 evaluate regarding changes in laboratory methods.

16           But in these continuing equivalence  
17 determinations, we are evaluating standards and  
18 procedures that the countries that submit them to us  
19 want us to evaluate and still be able to maintain  
20 their equivalence. So when we do that, we need to  
21 determine whether or not these proposed changes are  
22 likely to achieve the same objective as the

1 standards and procedures that we have in place here,  
2 the same measures. It is a segmented process that I  
3 just described to you.

4           So we have some questions to be considered  
5 regarding the future of this. Rather than use a  
6 segmented process as just described to you, should  
7 we be looking at objective outcomes of a system?  
8 How much of this, as Dr. Raymond described, should  
9 we be placing on process? How much on the outcomes?  
10 And what should these outcomes be that we look at to  
11 evaluate? Should they be based on hazard levels?  
12 Should they be based on risk levels that take into  
13 account foodborne illness if a country is able to  
14 demonstrate reliably what fraction of foodborne  
15 illness is related to the products that FSIS  
16 regulates?

17           These objective outcomes are of interest to  
18 us but we need to make decisions about what type of  
19 outcomes are most appropriate to evaluate.

20           Audits. Currently we have two aspects to  
21 our audit system. One is an in-country evaluation,  
22 and the other is an out-of-county evaluation.

1           Our in-country evaluations are periodic.  
2 We do in-country audits usually on an annual basis,  
3 and they cover areas such as government oversight of  
4 the inspection program and of the processes that  
5 plants have in place, laboratory support for their  
6 program and establishment performance.

7           Out-of-country evaluations take into  
8 account things such as types and amounts of product  
9 exported to the U.S. Reinspection results at port-  
10 of-entry influence what we do when we go on our in-  
11 country audits. We look at consumer complaints.  
12 All these things are evaluated here in the U.S.  
13 before we go and do in-country audits.

14           You'll get much more about the details of  
15 these audits in the presentation that Don Smart will  
16 be making.

17           In the future, however, we have questions  
18 about what type of information ought we be trying to  
19 accumulate during the year. These annual audits  
20 provide us important information but we are  
21 considering a concept that we are referring to  
22 informally as the 365-day audit. This is a concept

1 whereby inspection information or foodborne illness  
2 information or hazard information would be provided  
3 to us by countries that are equivalent and are  
4 allowed to export us. But the 365-day audit concept  
5 will need to be fleshed out with information or with  
6 concepts such as what type of information is most  
7 useful to us. Again, should it be foodborne illness  
8 data? Should it be hazard levels? Should it be  
9 supervisory reviews of establishment performance?  
10 Supervisory reviews of laboratory performance? What  
11 is the kind of information that would be most useful  
12 to us in conducting a 365-day audit?

13           And with this information, if it can be  
14 provided routinely, if it can be provided  
15 electronically, so that it arrives in a timely  
16 fashion, what effect should that have on things like  
17 the scope and the frequency of in-country audits?  
18 These are questions that we're going to be asking  
19 you to deal with. Is it acceptable? Is it useful  
20 for countries to perform self-assessments and to  
21 provide us with that data? Again, these are the  
22 types of concepts that we want you to wrestle with.

1           Let's move onto the third element of our  
2 triad of inspection, which is reinspection at port-  
3 of-entry.     Three basic aspects here, routine,  
4 directed and for cause.

5           Now, routine reinspection at port-of-entry  
6 examines things such as the eligibility of the  
7 shipment by product, plant and country.   As you've  
8 heard, a country has to be equivalent to export.  
9 That country certifies establishments for export to  
10 the U.S.   So we need to know that the product is  
11 coming from a certified establishment.   The product  
12 has to be eligible for entry into the U.S.   Is that  
13 country equivalent for export of meat and not  
14 poultry?   If so, we can take meat but not poultry.  
15 Does APHIS have restrictions on product that may  
16 come in due to animal disease concerns?   If so, we  
17 program that into our Automated Import Information  
18 System and that product is halted from entry into  
19 the U.S.

20           Directed looks at additional items.   It  
21 would consist of things such as product exams or  
22 laboratory samples that are collected as randomly

1 generated through our Automated Import Information  
2 System.

3           And then there are for cause audits. When  
4 we have concerns about shipments that may be coming  
5 in of particular products from particular plants,  
6 from particular countries, because of information we  
7 have received or generated through previous port-of-  
8 entry reinspections or concerns we have based on our  
9 audits or submissions for equivalence, we will  
10 target particular shipments for cause.

11           So these are the three basic areas of  
12 reinspection, routine, directed, for cause. You  
13 will hear more about this in detail from Mary  
14 Stanley.

15           In the future, we have questions about how  
16 best to perform directed reinspection. To what  
17 degree should it be influenced by equivalence  
18 determinations and audit information. Our triad of  
19 protection is very closely integrated and we think  
20 that is part of its strength.

21           So how can we better allocate the resources  
22 that we are dedicating to reinspection towards

1 countries that we have identified problems for?  
2 First of all, should we be doing that? Should we be  
3 treating all countries the same? We think and we  
4 are going to be talking about this more when the  
5 Subcommittees break out, that it makes sense to  
6 target directed reinspection based on country  
7 performance. We actually had started this for O157  
8 last year. Our *E. coli* O157:H7 sampling scheme  
9 takes into account things such as the prevalence of  
10 O157 in those countries, their history of control,  
11 and a couple of other aspects, but we believe that  
12 we need to move on and do this for other pathogens  
13 that we sample for, other hazards that are  
14 associated with these products.

15 PHIS, you've heard some introduction to  
16 from a couple of our speakers. I mention it again  
17 for the sake of consistency. Input of data we  
18 believe under the PHIS system is going to help us  
19 tremendously. It will become more efficient. The  
20 analysis of the data will be more timely and  
21 complete. Our connection as Mary just described to  
22 the ACE/ITDS system, will be through this PHIS

1 system that we are developing. It will enable us to  
2 respond more quickly. Our presence at the Targeting  
3 Center for Customs will make our response to  
4 findings more uniform and the actions that we take,  
5 the basis behind them will be more obvious.

6 So with all the tools that we have at our  
7 disposal, with the questions that you will be  
8 helping us to answer, it will improve the actions  
9 that we are able to take when there are problems.

10 Currently we have several tools in our  
11 toolbox, and based on findings at one or more  
12 elements of our triad, we do take action against  
13 specific product categories coming in from different  
14 countries. We do take action against specific  
15 establishments in countries, and we do on occasion  
16 take action against entire countries when we believe  
17 that their system equivalence is in question.

18 In conclusion, there are real concerns by  
19 the public. They're based upon the presence of real  
20 hazards, but we do believe that we have been  
21 providing real protection using our triad of  
22 protection, equivalence, audits and reinspection.

1 It has served us well in the past, but we need to  
2 know from you, is it still basically sound? How can  
3 it be improved? And, these are questions that we  
4 will be asking the Committee to wrestle with both  
5 today and tomorrow. So thank you.

6 MR. TYNAN: I think we're going to take  
7 Mr. Finnegan's question and that will be the only  
8 one at this particular point, because we're now a  
9 little bit behind. I don't know how that happened  
10 in just a few short minutes but, Mr. Finnegan, if  
11 you have a question.

12 MR. FINNEGAN: Yeah, Mike Finnegan from  
13 Montana. In the initial equivalence, do you take  
14 into consideration the ISO certification? The  
15 ISO9000 in foreign countries. Is that a part of  
16 equivalence or what do you think of that?

17 DR. JAMES: I'm not sure that I see the  
18 precise connection between the ISO9000 and what we  
19 do, but as Dr. Raymond mentioned in his introductory  
20 remarks, equivalence has two basic components. One  
21 is information that is provided to us through use of  
22 a questionnaire that we evaluate. If on paper, the

1 system is equivalent to the U.S. system, then we go  
2 in country, perform in-country audits to make sure  
3 that what is on the ground matches what is on paper.  
4 And I believe maybe the detail that you're looking  
5 for and more details will be apparent when Sally  
6 White makes her presentation and goes into more  
7 detail on equivalence.

8 MR. FINNEGAN: The reason I ask is that I  
9 had the opportunity to work with some meat plants in  
10 Armenia and that was three separate plants and that  
11 was their most prized possession, is that ISO  
12 certification.

13 DR. JAMES: Yeah, and it is something to be  
14 proud of. Our laboratories are ISO certified.  
15 They're very proud of that determination.

16 MR. TYNAN: Okay. We're going to move onto  
17 the next presentation, but I have to ask  
18 Mr. Finnegan, how Montana got lined up with Armenia?

19 MR. FINNEGAN: Through the USDA Bolca  
20 (ph.).

21 MR. TYNAN: Okay. Okay. I'm also going to  
22 suggest, the next speaker is Ms. Sally White, and

1 we're going to have her presentation, and I would  
2 make a suggestion, that unlike the way it's  
3 portrayed on the agenda right now, we take a break  
4 at the end of Ms. White's presentation. So that  
5 will be just about 10:30, if that's okay with  
6 everybody.

7           And with that, I'm going to introduce  
8 Ms. Sally White, and she's the Director of our  
9 International Equivalent Staff in the Office of  
10 International Affairs.

11           MS. WHITE: Good morning. I'd like to talk  
12 today about the first triad, the first part of the  
13 triad that's been introduced by Dr. Raymond and  
14 Dr. Bill James today. I'd like to give you a little  
15 more detail about equivalence.

16           Next slide. Next slide please. Next  
17 slide.

18           Okay. All right. We're going to talk a  
19 little bit about the background on equivalence, the  
20 concepts of equivalence, all those terms that have  
21 been used in previous presentations, and then we're  
22 going to get down to the practical aspects of how we

1 actually make those equivalence determinations in  
2 this Agency, both for countries that want to ship to  
3 the United States and who have never shipped, and  
4 for those countries that are currently shipping and  
5 would like to provide us with a new and improved  
6 either method or process for us to look at. And  
7 then, of course, we're going to touch on some of the  
8 questions we'd like for you, as the Committee, to  
9 review.

10 Imported meat and poultry products, and you  
11 will note that we also have jurisdiction over egg  
12 products and soon to be catfish, have to meet all of  
13 our requirements, and they can do that in several  
14 ways. They can either adopt our requirements which  
15 is the way they used to do it in the distant past,  
16 and sometimes now currently, or they can do  
17 something that is different that meets our current  
18 standards.

19 Okay. In other words, they can use  
20 equivalent methods but the methods have to provide  
21 the same level of protection, and that concept is  
22 what we call equivalence.

1           Now, before we go onto the next slide, I  
2 would like to make something, that I think will make  
3 it a little simpler. With equivalence, you can  
4 have, by doing the same thing you are doing, which  
5 sometimes is referred to in some countries as  
6 compliance, but the equivalence we're going to be  
7 talking about today is the other kind of equivalence  
8 in which we compare systems or methods and make sure  
9 that if a different method or system meets our level  
10 of protection and protects our consumers.

11           Okay. Now, where did this concept come  
12 from? It came from, as the slide indicates, the  
13 Agreement on the Application of Sanitary and  
14 Phytosanitary Measures, or because it's easier to  
15 say, the SPS Agreement, and that's what I will refer  
16 to it as today, and probably other speakers as well.

17           Now, it's an important concept to remember  
18 that it says Agreement, while it is a treaty and as  
19 such it is, in fact, law. Am I doing that?

20           COURT REPORTER: No, it's a PDA, a  
21 BlackBerry.

22           MS. WHITE: Okay. All right. Okay. In

1 any event, that's important to remember, that this  
2 has the force and effect of law and therefore we  
3 have to comply with the provisions of that treaty,  
4 and we have been doing so since the mid-nineties.

5           Now, countries that makes equivalence  
6 requests, one of the concepts that's in the treaty,  
7 is that they have to provide us with sufficient  
8 scientific evidence for us to make that equivalence  
9 determination. They can't simply just send us a  
10 letter and say we want to do X or Y. They have to  
11 provide us with the information or the evidence to  
12 review to make that determination. And, if they've  
13 met that threshold then, of course, if it is  
14 equivalent, we have to allow them to use that absent  
15 any other factors.

16           The concepts of equivalence, one of the  
17 ones I'd like to define a little bit more for you in  
18 this slide is what a sanitary measure is. Many  
19 times people focus on the word sanitary and think  
20 that that has to do with the sanitary conditions in  
21 the plant. That's one of the things that it covers  
22 but as you can see, it covers a lot of other things,

1 and for FSIS, what this treaty language means is  
2 that we will look at laboratory methods. That's a  
3 sanitary measure. We will look at proposals put  
4 forth for something different than our sanitation  
5 standard operating procedures or for HACCP or for a  
6 new postmortem inspection procedure or antemortem  
7 procedures. Any and all of those things are  
8 sanitary measures and sometimes they can be small  
9 things like a method or they can be larger systems  
10 like an antemortem to postmortem system that's  
11 different than ours.

12           Okay. But the sanitary measures, one of  
13 the other concepts a lot of people forget about  
14 because we look at what is sent to us, is that a  
15 sanitary measure or requirement that we impose upon  
16 a foreign country, it has to be based on scientific  
17 principles for us when, when we set forth a  
18 requirement and when we review another country's  
19 requirements, we can't impose a higher standard upon  
20 them than we would upon ourselves, and I think you  
21 can see the common sense reason for that.

22           Okay.           The           appropriate           level           of

1 protections, the other speakers have addressed this  
2 as well, or we refer to this as the ALOP, is a  
3 societal choice and an importing country can set any  
4 level of protection that they deem appropriate.

5 Next slide.

6 Okay. So those are some of the language we  
7 use when we will be talking today. The speakers  
8 have already been using them, and so I'm hoping that  
9 you can use the slides later on, in your  
10 deliberations, to go back for the definitions.

11 But now I'd like to get into how do we  
12 really do this? I mean how do you take this very  
13 thick language from this treaty and then apply it to  
14 a practical situation. And we have been doing this  
15 now since nineties, the mid-nineties. We were the  
16 first Government agency to have to do this because  
17 we had to implement in all the countries, the  
18 pathogen reduction HACCP requirements. And so it  
19 was at that point, that we started our process of  
20 making equivalence determinations. And one of the  
21 most important things that we would like you to  
22 remember is that in our system, which is indifferent

1 than say other agency systems, is that we work on a  
2 government-to-government basis. We work directly  
3 with the chief veterinary officer for the agency or  
4 entity in that country that has the authority to do  
5 inspection for the products that are to be shipped  
6 to the United States. We do not deal with the  
7 plants. If they come to us, we send them back to  
8 the government. We do not deal with the consumer  
9 groups in their country or the industry groups or  
10 trade associations. What we deal with is the  
11 country itself to make these determinations. And we  
12 don't put our inspectors in the countries to do the  
13 work the government should do. In other words, we  
14 leverage our resources so that the government is  
15 expected, if they want to ship to us, to have an  
16 equivalent inspection system overall. Inspection  
17 implementation, laboratories, everything. And  
18 that's a very important concept that we want you to  
19 know about.

20 Now, we make our determinations on  
21 equivalence for initial, the first time a country  
22 ships to the United States. All of our requirements

1 are set forth in the Code of Federal Regulations.  
2 And, if you look at them, you will see that a major  
3 part of those regulations, that the lawyers set out  
4 for us, talk about the concept of government, the  
5 chief veterinary officers, or the government's  
6 oversight of the whole system. They have to have  
7 control over that. The industry doesn't run the  
8 program. The government runs the program in those  
9 countries.

10           And it also lays out five areas that we're  
11 concerned about, and you'll see how important this  
12 is later on as the other speakers talk because  
13 they'll talk about five risk areas. It won't say in  
14 the Regulation these are the five risk areas, but if  
15 you read them, you can see how they're laid out.  
16 And this is what we do. We look at animal disease  
17 as it relates to public health. We look at  
18 sanitation controls, that's the second. We look at  
19 sanitation standard operating procedures within that  
20 sanitation controls. We look at slaughter and  
21 process controls. We look at residue controls, and  
22 we look at enforcement controls. How all those

1 things are implemented comes into enforcement  
2 controls. And those are the five general areas we  
3 look at and as we go through the process and as  
4 Mr. Smart goes through his process in audit, you'll  
5 see how that follows.

6           Okay.           We make two types of  
7 determinations, the initial equivalence which is  
8 what we're going to talk about in this presentation  
9 and then, of course, as Dr. James alluded to,  
10 individual sanitary measures, next slide, where a  
11 country that's already shipping to us wants to  
12 implement something new.

13           Okay. Next slide.

14           Okay. Any government can apply for  
15 eligibility to export meat, poultry and egg products  
16 to the United States. They do this normally by  
17 sending us a letter and saying we want to ship, what  
18 do we do? And from a practical standpoint,  
19 sometimes that comes in an e-mail. I mean, but  
20 that's how it's communicated, government to  
21 government.

22           At that point, we have a package of

1 information that we send out to the government. We  
2 sent out a list of those questionnaires concerning  
3 those five risk areas and questions concerning how  
4 they have oversight over those risk areas, and we  
5 send them all of our laws and regulations for their  
6 use. That all goes out to the government. That's  
7 the first step in the process. And, currently we  
8 have 44 countries in the queue at one level or  
9 another of this process that want to ship to the  
10 United States. Thirty-four of them have never  
11 shipped any products to the United States. The  
12 other 12 have one system or another approved  
13 already. For example, they may be able to ship meat  
14 but they can't ship poultry, and they'd like to.

15           So we're looking at 44 applications, 44  
16 countries that want us to look at their entire  
17 inspection system and approve it so that they can  
18 ship which is huge.

19           Next slide.

20           Okay. What essentially happens, some  
21 countries look at this big pile of paper, and they,  
22 you know, they don't contact us for a while, and

1 usually they haven't. Other countries hire  
2 consultants to work with them, to help them answer  
3 the various questionnaires. Many times we work with  
4 them on the phone or in person to answer the  
5 questions so that they understand what it is that we  
6 want because many of these countries, English is not  
7 their first language. So they're getting this all  
8 in English, and you can imagine taking the HACCP  
9 regs and translating it into Icelandic. I mean,  
10 there's going to be a disconnect through the  
11 translation process.

12 So once this all comes in, then we begin  
13 the document review process, and this is an  
14 extremely critical part of the process of initial  
15 equivalence. That is where our office facilitates  
16 teams of scientists in this Agency and maybe,  
17 depending on the issue, APHIS or FDA to look at  
18 those documents and make a determination as to  
19 whether their system on paper is equivalent, and  
20 when we do that, we document our meetings with  
21 minutes and eventually we document the entire review  
22 in a decision memorandum with all of the differences

1 laid out and whether they're equivalent or not. And  
2 it may sound simple, but it really isn't. We have a  
3 lot of back and forth with the governments to get  
4 additional information, and the key players in this,  
5 as I said, our office facilitates and documents and  
6 works on these. But the key players in the Agency  
7 would be the Office of Public Health and Science  
8 usually because of scientific methods and procedures  
9 but also more importantly, the Office of Policy and  
10 Program Development because we have to insure that  
11 our -- that the equivalence work that we're doing is  
12 consistent with the domestic requirements, and the  
13 way in which domestic policy is going.

14 Okay. We finish that, and that takes a  
15 long time, and once we finish that, we've made the  
16 determination that their system is equivalent on  
17 paper.

18 Then, okay, the next step is to audit, and  
19 our audits are a little different from the audits  
20 that Mr. Smart will talk about. Our audit is an  
21 initial equivalence audit. We put together a  
22 complete team of scientists so that we can look at

1 all the laboratories in depth, all the methods, make  
2 sure they're being done properly. Look at all of  
3 the various levels of inspection, interview all of  
4 the various people, and we want to make sure  
5 primarily that everything that that country said it  
6 was doing on paper, they're actually doing it on the  
7 ground, and currently, when we go out and we do  
8 this, one of these initial equivalence audits does  
9 not complete the process. Normally we find areas  
10 where the country needs to improve or add to the  
11 program, and so there may be a second audit that we  
12 conduct before we're completely satisfied that that  
13 country's system is equivalent to ours, and at that  
14 point, we then go through the rulemaking process  
15 with the proposed rule, to list them in the Code of  
16 Federal Regulations, to ship, and then finally after  
17 public comment period, then we have a final rule  
18 that comes out.

19           Okay. Next slide.

20           Once we've gone through the document  
21 review, the initial equivalence audit or audits, and  
22 then we go through the public rulemaking, we then

1 notify the country, hey, you're equivalent but  
2 there's a period of time there, as you all know from  
3 a practical standpoint, rulemaking just doesn't  
4 happen overnight normally. There's a period of time  
5 from when we were last there on the ground and when  
6 we send them the letter.

7           So some of the compensating controls that  
8 we have been putting in place after the foreign  
9 government submits to us a list of establishments  
10 they're certifying, all imported products are placed  
11 on a 100 percent port-of-entry reinspection for one  
12 year, and audit is immediately scheduled, as soon as  
13 possible, prior to the first shipment. And, how  
14 much we audit, the scope and the depth of that audit  
15 is determined by the length of time and other  
16 factors that we know about that particular country,  
17 from the time we were last there, time we were there  
18 last, and this date for them to ship.

19           Okay. Now, that's just in a nutshell what  
20 we do for initial equivalence. Now, what about all  
21 of those things that are sent to us from the  
22 countries that are shipping now? These are called

1 alternative sanitary measures, and we go through the  
2 same document review process. We look at the  
3 measure, we determine what the purpose of our  
4 requirement was and then we develop criteria, we  
5 apply the criteria to the facts that they've  
6 submitted to make a determination whether or not  
7 their measure is equivalent to ours and does it meet  
8 our purpose of our original requirement.

9 And those measures are also documents in  
10 detail. We have files on all of them by country and  
11 then we verify that, in fact, they're doing what  
12 they said they were doing on the next routine audit.

13 Now, currently in our office, in addition  
14 to the 44 countries that want to ship and their  
15 applications at various stages of document review or  
16 audit, we have 34 sanitary measures that we're  
17 working on today, as of this week, and they're from  
18 17 different countries.

19 Now, since '99, I mean since I think the  
20 big public meeting we held where we put forth our  
21 criteria for the pathogen reduction and HACCP  
22 decisions we made, we have made a total of around

1 350 equivalence determinations on sanitary measures,  
2 and of those, about 40 of them were not approved,  
3 and they were not approved either because the  
4 country put forth something where they didn't  
5 provide us with the sufficient scientific evidence  
6 or they couldn't meet the criteria that we devised  
7 to have an alternative sanitary measure or they just  
8 decided to withdraw it because they didn't want to  
9 do it anymore.

10 But then those that were approved all are  
11 documented, have criteria that's been approved and,  
12 and have been notified of that decision. So that's  
13 how we do the alternative sanitary measures.

14 Now, for the future. We're asking you  
15 today, Dr. James has raised this, Dr. Raymond also  
16 has raised it, we want to, instead of going through  
17 or in addition to or part of it I'm going through,  
18 this onerous document review process that we do, are  
19 there some other ways that we can look at a  
20 country's system and see if, it's equivalent?  
21 Can we look at objective outcomes? Can we look at  
22 hazard levels? For example, pathogens, can

1 we compare? And if so, how would we go about doing  
2 that? What about risk levels say for foodborne  
3 illness? Should we think about that when making our  
4 equivalence determinations either for the system as  
5 a whole or in terms of individual sanitary methods.

6 So what hazards or risks are appropriate?  
7 And those are the kinds of questions that we would  
8 like for you to consider today when you're in your  
9 deliberations so that you can give us some feedback.

10 This system has worked has worked very well  
11 for us. It's rigorous. It requires a great deal of  
12 time, not just by our staff, but by the whole Agency  
13 because all the people that are involved both in the  
14 document review and at the audit stage. We think  
15 that it's good. We think that it can be improved.  
16 We have requests for improvement, and we'd like to  
17 see your ideas on the subject. And thank you for  
18 listening.

19 MR. TYNAN: Because we're running a little  
20 bit behind schedule right now, I'm going to suggest  
21 that we don't take any questions at this particular  
22 point but, in fact, let's take a break so everybody

1 can kind of gather their thoughts again when we  
2 start up. I'd like to have everybody back at 10  
3 minutes to 11:00, using that clock up there. So  
4 I'll be ringing the bell in probably about 16  
5 minutes.

6 (Off the record.)

7 (On the record.)

8 MR. TYNAN: Mr. Corbo, am I on duty here?  
9 Hello. Could I ask everybody to begin taking their  
10 seats please?

11 (Pause.)

12 MR. TYNAN: How did I lose control?  
13 Where's my mic man? Could I ask everybody to take  
14 their seats please? If we could get, if we could  
15 get started please.

16 During the break I had a conversation with  
17 a person that I have a great deal of respect for,  
18 and we talked a little bit about the process that  
19 we're using here, and as you noticed, I mentioned  
20 earlier, that we were getting a little bit behind in  
21 our schedule, and so as a result, I was skipping  
22 some questions. So in the interest of quantity, I

1 think we were losing a little bit of quality. So  
2 what I'd like to do now before we go onto the next  
3 presentation, I want to give the Committee an  
4 opportunity if there are any questions for  
5 Dr. James, Ms. Stanley, Ms. White, that we have an  
6 opportunity to raise those questions at this  
7 particular point, answer a few of those. We can't  
8 take too many, and then we will move on to next set  
9 of presentations. So I apologize if we were  
10 speeding through. It was not my intent to eliminate  
11 questions, only to make sure that we got in the  
12 basic information that you need to have.

13 So with that, I'm going to start over here  
14 to my right and let Mr. Kowalcyk start off with a  
15 question.

16 MR. KOWALCYK: Thank you, Robert. My  
17 question is for Ms. White, about the initial  
18 evaluation of a food safety system at a potential  
19 importing country. One of our Subcommittee's  
20 charges is to look at the triad and identify areas  
21 where there's opportunity to either change, drop,  
22 increase certain levels of intensity among the three

1 parts. In your experience with the 40 countries  
2 that did not meet the requirements, where did, where  
3 did their process fall down? Did it fall down in  
4 the initial collection of the documentation or did  
5 it fail because of the initial audit that was  
6 conducted? And if so, what were the typical things  
7 found? Was there anything in common among those  
8 countries?

9 MS. WHITE: Okay. The numbers that I gave  
10 you, what I was trying to convey was that there are  
11 44 countries currently that are in the process, not  
12 that 44 failed, but I can answer your concern about  
13 the kinds of things that we would find that would  
14 delay the process of any of those countries or  
15 countries before them.

16 We haven't been in the situation where we  
17 have reached the point where we have said to a  
18 country, you're not equivalent, go away. What  
19 typically happens is we say, hey, you, you have to  
20 implement HACCP, all of HACCP, not just the seven  
21 principles or you need something equivalent. And so  
22 then what happens is the countries hires usually

1 consultants or works with their own training staff  
2 to further strengthen their system.

3 But the kinds of things that we normally  
4 find when we're looking at document review and we're  
5 looking at the initial equivalence audits,  
6 especially in some of the developing countries,  
7 would be the infrastructures, laboratories and  
8 perhaps how they implement methods, those kinds of  
9 things, and usually what they do is strengthen it by  
10 training. Does that help?

11 MR. KOWALCYK: That helps. Thanks.

12 MR. TYNAN: Mr. Elfering.

13 MR. ELFERING: Yes, Kevin Elfering. A  
14 question for Ms. White first, just a point of  
15 clarification. Did you say that you hold other  
16 countries more accountable than products that are  
17 produced here?

18 MS. WHITE: Can you repeat that? I'm  
19 sorry.

20 MR. ELFERING: You had said something, I  
21 wasn't sure. I believe it was in discussion.

22 MS. WHITE: Uh-huh.

1 MR. ELFERING: Did you say that countries  
2 are held more accountable for imported products than  
3 here?

4 MS. WHITE: No. What I was trying to say  
5 that according to the treaty, we have to make sure  
6 that we apply our standards to theirs. In other  
7 words, we can't require a country to do more than  
8 what we do.

9 MR. ELFERING: But there are some  
10 differences in standards, for example, for animal  
11 disease issues because --

12 MS. WHITE: Yes.

13 MR. ELFERING: -- that would be a different  
14 standard.

15 MS. WHITE: Yes, there would be different  
16 standards but in terms of us holding them to a  
17 different -- to a higher standard for product  
18 safety, that would not be allowed under the SBS.

19 MR. ELFERING: But wouldn't it be true that  
20 we would not allow products from a country that has  
21 a particular disease, that we would even have the  
22 same disease in the United States, that we wouldn't

1 allow that product to be imported even though that  
2 product would be freely sold within the United  
3 States? And I'll give you an example.

4 MS. WHITE: Okay. Thank you.

5 MR. ELFERING: Even certain age cattle, for  
6 example, coming in from a country, the restrictions  
7 on animals only of a certain age that would be  
8 allowed to come in. Older animals, for example,  
9 would not but yet we sell those same animals here.

10 MS. WHITE: Yes. I'm going to let  
11 Dr. James answer your question.

12 DR. JAMES: Yeah.

13 MS. WHITE: He wants to.

14 DR. JAMES: Our Animal, Plant and Health  
15 Inspection Service does set requirements for what  
16 animal end products can be imported to the U.S.  
17 based on the animal disease profile of various  
18 countries. That's a general statement, and we're  
19 not going to be able to get much more specific than  
20 that because it is an Animal, Plant and Health  
21 Inspection Service area, but the restrictions that  
22 they place on countries exporting to the U.S., we do

1 integrate those into our Automated Import  
2 Information System and enforce the requirements.

3 MR. ELFERING: Then one other quick one to  
4 Ms. Stanley. Enforcement actions, what are the  
5 enforcement actions and how do they differ from  
6 enforcement actions that we would take against the  
7 plant here in the United States?

8 MS. STANLEY: The enforcement actions that  
9 I spoke to in my presentation was on product that  
10 has entered the country. So the enforcement action  
11 at that point would be to gain control of the  
12 shipment, either retain it in a FSIS facility or  
13 detain it if it's in commerce and then do the trace  
14 back to verify whether or not it's eligible and what  
15 route it would take, but ultimately, if it's not  
16 eligible product, we would have that product  
17 destroyed.

18 MR. ELFERING: And then if there would be  
19 something that would be of significance, does that  
20 ever trigger like a FSA in another country?

21 MS. STANLEY: The product that I presented  
22 then was specific to ineligible product. So the

1 product would not be eligible to enter. There may  
2 be communication back to that government depending  
3 on the types of products. The action is turned over  
4 to Customs and Border Protection, and they act on  
5 the importer of record because that's the person  
6 that brought the product into the country illegally.

7 DR. JAMES: If I may, yes, Sally -- excuse  
8 me. Mary is going to speak more about reinspection  
9 following the questions here. Perhaps you'll get  
10 the information you're looking for then. If not,  
11 we'll go back to your question. But as Mary just  
12 mentioned, what she was referring to in her first  
13 presentation, was in regard to product that had  
14 entered the country either from a country that was  
15 not eligible to export at all or from a plant that  
16 wasn't eligible to export at all or the product  
17 wasn't eligible to come in. So I think it was a  
18 little bit different situation than what you're  
19 asking about right now.

20 MR. TYNAN: Dr. Negron, can I take a  
21 question from you?

22 DR. NEGRON-BRAVO: Well, I just want to

1 mention that some of the concern of those countries  
2 are that they feel sometimes that they are more  
3 stringent on their part than what they see they are  
4 applying here, and that's a general consensus every  
5 year that they sometime feel when they get the  
6 audits, they are a little bit more stringent than  
7 what they see applied in the United States.

8 MR. TYNAN: Okay. Thank you.  
9 Mr. Finnegan.

10 MR. FINNEGAN: Just one quick question. In  
11 one of your bullets, in your slide on 23, Ms. White,  
12 all inspected products are placed on 100 percent  
13 port-of-entry inspection for one year. Now, do the  
14 countries have to notify FSIS that they're shipping  
15 product or do we just try to catch them at the  
16 border? And then after the first year, then what?

17 MS. STANLEY: In the interest of time, I'll  
18 cover the sampling plans and the port-of-entry  
19 inspection. Perhaps that would be the appropriate  
20 place to make that clarification, if that's okay  
21 with you?

22 MR. FINNEGAN: Sure.

1           MR. TYNAN: Okay. We'll hold your question  
2 until the next round of presentations. Mr. Corbo.

3           MR. CORBO: Yeah, Tony Corbo, Food and  
4 Water Watch. In theory, I like the process that  
5 FSIS has laid out for these determinations. You do  
6 have a shot at, at commenting on establishing a  
7 trade relationship with the country. Where we, as  
8 far as our consumer group has always had a problem,  
9 is that there doesn't seem to be a system of  
10 progressive discipline, that once you're in the  
11 club, once you are in the Code of Federal  
12 Regulations, there's no way of removing a country  
13 even, even after periodic audits show that there are  
14 problems, and we have a couple of situations right  
15 now where your auditors have found systemic, I mean  
16 we're talking systemic problems with the country's  
17 food safety system, and we're not taking them off  
18 the list. And so that's an issue that, you know, I  
19 want someone to explore during one of the  
20 presentations here because it seems that once, once  
21 the regulatory process approves a country, there's  
22 no way of removing that country from the list.

1           Number two, while the initial equivalency  
2 audits are, the determinations are a public process,  
3 the equivalence determinations that occur after a  
4 country is found to be equivalent seems to be a  
5 black hole. Dr. Raymond, my first, my first FOIA  
6 that I ever filed with FSIS involved the initial  
7 equivalency determinations and Ms. White came up to  
8 me and said, you know, where have you been because I  
9 spent a summer of Fridays coming over here after we  
10 finally settled that FOIA, after a four-year  
11 process. I don't want to go through the FOIA  
12 process to look at these equivalency determinations  
13 that are made after a country has reached the  
14 initial equivalence stage. Is there any way that  
15 that information could be posted on a regular basis  
16 on the website? The only time that I ever see it  
17 publicly is when Congress asks for it as part of the  
18 annual appropriations hearings. It's a standard  
19 question, what equivalency determinations has the  
20 Agency conducted over the past year and a list is  
21 provided.

22           MR. TYNAN: Okay. I don't want to cut you

1 off, but again in the interest of time, you need to  
2 be a little more succinct with the question.

3 MR. CORBO: Well, the question is can  
4 those, can those equivalency determinations on  
5 antemortem, postmortem inspection procedures be  
6 posted on a regular basis on the FSIS website.

7 MR. TYNAN: Let me let Dr. James see if he  
8 can respond to either or both of those.

9 DR. JAMES: Yeah, the equivalency  
10 determinations are not a secret. Once the final  
11 determination has been made and the country is  
12 notified, that's a matter of public record. That  
13 information is readily available. The  
14 determinations I believe now are -- someone correct  
15 me if I'm wrong. Have we not started the process of  
16 putting them in directive on a quarterly basis? One  
17 moment please.

18 (Pause.)

19 DR. JAMES: So Sally just reminded me, we  
20 are in the process of trying to get something set up  
21 on the website so that those determinations are more  
22 readily available. It's not something we're trying

1 to hide. We think our system is a good one, and the  
2 determinations ought to be made readily available.

3 MR. TYNAN: Thank you, Tony. I'm sorry. I  
4 didn't mean to cut you off. It's not that we don't  
5 want your question. We just need to do it a little  
6 quicker. Stanley or Mr. Painter, do you have a  
7 question please?

8 MR. PAINTER: Yes. Stan Painter with the  
9 National Joint Council. I'm wondering about the on  
10 site audits, and I know if a plant wants to go under  
11 inspection here, you know, there's a lot of reviews,  
12 you know, the circuit supervisor or frontline  
13 supervisor, the name is used interchangeably, would  
14 go out to the facility to make sure they're up to  
15 snuff and when we're looking at a foreign plant  
16 coming under or a foreign country coming under the  
17 ability to export to the United States, is the same  
18 process used? Do we go the facilities in that  
19 country to make sure that the plants are meeting our  
20 guidelines or does one plant pretty much set the  
21 standard for the entire country?

22 DR. WILLIAMS: Okay. The bottom line

1 regarding certification of establishments in  
2 countries is that the country has undergone an  
3 equivalency review. The processes that are in place  
4 there for this aspect of their system should be  
5 equivalent to ours. Therefore, different countries  
6 have the authority to certify and decertify  
7 establishments for export to the U.S.

8 Now, what we do, of course, through our  
9 process of port-of-entry reinspection and in-country  
10 audits, we evaluate these establishments that have  
11 been certified to make sure that they are meeting  
12 the requirements of the U.S. So it's in locking  
13 measures.

14 DR. RAYMOND: Let me try to answer  
15 Stanley's question a little bit better though. I  
16 think Stanley is asking, do you go and look at one  
17 establishment and that serves as the standard for  
18 the country, and to answer that question, when we do  
19 our annual audit, if a country has 10 or fewer  
20 establishments, we go into all of them. If they  
21 have more than 10 establishments, then there's a  
22 ratio based on the number of establishments. The

1 more establishments they have, the more that we will  
2 go do an audit, but we do not do 100 percent audit  
3 because of the systems equivalency. I don't know if  
4 that helps but --

5 MR. PAINTER: Yes.

6 MR. TYNAN: Okay. Thank you. And with  
7 that, I'm going to close out the questions and,  
8 Tony, if you have another question can we save it  
9 for the next round of questions.

10 I'm going to introduce Mr. Don Smart. He  
11 is the Director of our International Audits Staff,  
12 and he's going to talk a little bit about the audit  
13 process and the audit system we use.

14 MR. SMART: Good morning, everyone. Can  
15 you hear me? I can't hear myself. So --

16 I have been told to expedite the process of  
17 delivery. So using my best southern drawl, let's go  
18 to the next slide.

19 As we've already said, any meat, poultry or  
20 egg product coming into the United States must  
21 achieve the same or appropriate level of protection  
22 as our U.S. products. Our regulations provide the

1 authority for us conducting the audits of the  
2 countries. The five risk areas that Sally mentioned  
3 earlier, for an inspection system controls, animal  
4 disease, sanitation, slaughter/processing, residue  
5 and then their government oversight and enforcement.

6 We achieve our regulatory requirement for  
7 these countries by conducting systems audits, and we  
8 work directly with each foreign country government  
9 on a government-to-government basis. And I don't  
10 want to take too long, but I want to describe  
11 quickly that we have come a long way since the  
12 seventies and eighties. Back in the late seventies  
13 and early eighties, we had people stationed in each  
14 country and essentially we were the certifying body  
15 for the establishments. We don't do that anymore.  
16 We've evolved through, you know, about six different  
17 types of covering foreign programs to the one that  
18 we've been using for the last approximately decade  
19 or so, and I've been in charge of audit for that  
20 decade. So I'm pleased with the advancements that  
21 we've made but we can still go forward.

22 Again, as Dr. James said, if we keep

1 telling you enough times what we're doing, you'll  
2 perhaps figure it out. Audit is one of the triad  
3 approach that we use, and I think we've used very  
4 successfully over the years.

5           Again talking about systems audits, we do  
6 this to verify that the country is maintaining their  
7 equivalence and the appropriate level of protection  
8 that the Act provides for.

9           As Dr. Raymond said earlier, I believe it  
10 was him, our audits are pretty much annual.  
11 Sometimes we go more frequently within that, and  
12 sometimes we go within physical years but we got 16,  
13 18 months before get back to a country. We have in-  
14 country evaluation and out-of-country evaluation.

15           On the in-country evaluation, we use a  
16 standardized approach of verifying the country's  
17 competent authority, implementation and oversight of  
18 the food safety system. We review establishments,  
19 laboratories. We do interviews with different  
20 levels of the government inspection program from  
21 headquarters down to the plant level to make sure  
22 that they share information adequately and provide

1 the oversight necessary to keep the program running.

2           In an attempt to assure that every country  
3 gets a fair shake and that we don't have auditors  
4 that get too familiar with a country, we do a  
5 rotation where an auditor will keep a country for  
6 two years and then hand it off to someone else. On  
7 larger countries, and I'll use Canada as an example,  
8 with about 460 approved establishments to ship to  
9 the U.S., we use more than 1 auditor. We figure  
10 it's too big of a workload for one to take care of.  
11 So in most circumstances, we use two, sometimes even  
12 more.

13           On the other end of the spectrum, we have  
14 many countries that have one, two, three plants, and  
15 so that's a one auditor approach and the audit  
16 doesn't last nearly as long.

17           The out-of-country evaluation seems a  
18 little backwards because we do this process before  
19 we go in-country to do the audit. We do all of our  
20 research. We look at all of our own audit results  
21 over the last three years to see what have we been  
22 finding.

1           We look at the types and the amounts of  
2 products that they have shipped to the United  
3 States.       We look at our own port-of-entry  
4 reinspection results to see if we can pick up any  
5 trends, any issues that we need to look into further  
6 when we do the audit.

7           Consumer complaints, we don't seem to be  
8 getting a whole lot of those on foreign product, but  
9 we do take those into account whenever we have  
10 those.

11           Third country audit results, and we would  
12 like to have more but right now we're somewhat  
13 limited on availability of other countries' audit  
14 results that have audited the same country that we  
15 have.   The European Union is an exception.   They  
16 publish, as we do, all of their audit results.   But  
17 they don't audit with the frequency that we do, and  
18 they do not cover the same areas all the time like  
19 we do.   So sometimes their audit results are useful  
20 and other times, it's just information.

21           And then any other relevant information  
22 pertaining to the country, economics, government

1 overthrows, hurricanes, anything that might impact  
2 on the delivery of the inspection program.

3           And all of this information we use to  
4 determine the scope of our upcoming audit. When we  
5 get ready to do an audit, we have a meeting in which  
6 we invite our scientists from OPHIS. We invite  
7 APHIS to cover animal disease, and we have our OIA  
8 representatives also to make sure that the auditor  
9 in preparation hasn't overlooked any important item.  
10 And then through all of that, we develop the number  
11 of establishments that we feel like need to be  
12 visited in order for us to be comfortable with the  
13 results and we look at all the other information  
14 pertaining to laboratories and government oversight  
15 that we collected over the years to see if we need  
16 to focus on micro lab processes or residue lab  
17 processes, or whether we've seen that they seem to  
18 be up to snuff on all of it and this is one year  
19 that perhaps we don't need to do a laboratory audit.

20           Okay. That's the way we do it now. As I  
21 said, I'm very proud of the way we do it now, and I  
22 think it served us well, but if you look at fiscal

1 year '99, 2000, 2001 all the way to today, no two  
2 years are alike. We've continually improved our  
3 process. Things continue to change. We just want  
4 some new ideas so we can figure out what's the best  
5 process to use to make sure that the American public  
6 is protected.

7           So our premise is that exporting countries  
8 do not need to be audited in the same manner and the  
9 same frequency to verify equivalence, and that's  
10 based on our history of what we've seen. We have  
11 some countries that traditionally we find very  
12 little, and we have other countries that give us  
13 problems. And, you know, it makes sense that we  
14 would put more resource into the countries that  
15 don't have a really good history than the ones that  
16 we go back to year after year and present us with a  
17 good program.

18           We refer in the slide to our level of  
19 confidence. We're looking at different ways to  
20 approach this. The 365-day audit's been mentioned  
21 before except for leap year. We would work that  
22 extra day. The desk audit is what that's referring

1 to, is to where we get a continuing flow of  
2 information from the country. We've been looking at  
3 that for a while now, and we have some difficulties  
4 because there's only 6 of our 34 countries that  
5 English is their language. And when we start asking  
6 for information from countries and they provide it  
7 to us in another language, we run into a great cost  
8 factor on translation. So we've been looking at how  
9 can we approach that and perhaps to the point of  
10 mandating a form, a chart, something where they're  
11 filling in numbers or things that don't have to be  
12 translated, so we don't have to rebut the time delay  
13 plus the cost associated.

14           For both types of audits, we're going to  
15 emphasize the system, not individual establishments  
16 or laboratories or whatever. It's the overall  
17 system and how well it functions.

18           Some countries, as I just said, have the  
19 ability to provide us with more information than  
20 others because of the data that they collect and the  
21 form in which they collect it. If we have access to  
22 that information, we can make better judgments on

1 how we develop audit protocols and how often we need  
2 to go.

3           We need to make sure, as Dr. James pointed  
4 out, that our activities are objective based. And  
5 one thing to me that is extremely important is that  
6 when we do on site audits, our main function is to  
7 verify what we've already seen on paper. Sometimes  
8 those match up perfectly and other times there's a  
9 great disconnect on what the country presents us in  
10 writing and what's actually occurring in the  
11 country.

12           The scope and timing of the verification  
13 audit for any country would consider the volume of  
14 product, you know, Canada, we're going to put a lot  
15 more emphasis on than the Czech Republic just  
16 because the volume of product, the types of product  
17 and associated risk, all available historical  
18 information, and we hope to be able to get even more  
19 when we start moving into the Public Health  
20 Information System area. We keep pretty good  
21 information now but there's other information out  
22 there that we can probably get a hold of. And then

1 just do more analysis of all the information that we  
2 have available.

3           So things that we're considering is what  
4 type of information should we ask a country to  
5 provide so we can do more effective analysis?

6           Should the length of time between audits be  
7 more than our annual target of today? I mean if  
8 they have a good history, should we go strictly with  
9 paper for a while and not do an audit or a few  
10 months longer?

11           Should the scope of audits vary by  
12 compliance history? In the past, Dr. Raymond  
13 described our establishment selection chart which  
14 says that we do all establishments if there's less  
15 than 10. Is that necessary? Does that provide us  
16 any more information than what we could get from  
17 date of submittal, date of analysis and history?

18           That's as fast as I can talk. (Laughter.)

19           MR. TYNAN: Okay. I'm going to hold the  
20 questions until our next speaker. Ms. Stanley I  
21 think is going to come back around and talk a little  
22 bit of reinspection. So I'm going to let her do her

1 presentation and then maybe we can ask questions of  
2 both Ms. Stanley and Mr. Smart at the same time.  
3 And I should warn you, while I have the microphone  
4 open, that our sound technician was kind enough to  
5 give me a new more powerful microphone. I have one  
6 that can cut off your microphone. So I just want  
7 you to know. (Laughter.) I have the power.

8 DR. RAYMOND: I'll take back over.

9 MS. STANLEY: That's good to know. Next  
10 slide.

11 The system of reinspection, I just wanted  
12 to run through real quickly some data so that you do  
13 have some context of what types of products were  
14 coming into the country. In calendar year, 2007, we  
15 had 3.8 billion pounds of meat and poultry. That's  
16 from 29 of the 34 eligible countries. So there are  
17 29 actively exporting foreign countries, and 84  
18 percent of that product is fresh red meat, and most  
19 of that is going into manufacturing, further  
20 manufacturing in FSIS domestic establishments which  
21 they are subjected to even more inspection.

22 Next slide.

1           Most of our product is from Canada, 45  
2 percent in calendar year 2005. The next country is  
3 Australia with about 22 percent, and New Zealand  
4 with 11 percent and Uruguay is with 8 percent, and  
5 all the other countries make up a total of 14  
6 percent of the product coming in.

7           Next slide.

8           And for egg products, we only have one  
9 eligible country, and Canada has shipped about 20.5  
10 million pounds of egg products into the U.S., and  
11 the breakdown is on this slide.

12          Next slide.

13          And you're familiar with this now. Port-  
14 of-entry is the third prong of the triad. So move  
15 onto the next one.

16          The entry process into the United States,  
17 the importer of record files entry with Customs and  
18 Border Protection. CBP is doing the animal health  
19 checks on these products. So if there is an animal  
20 health concern, they should detect it and hold the  
21 product at port-of-entry. So we should never see  
22 that product. Then CBP conditionally releases that

1 product to FSIS so that we can do our public health  
2 reinspection. Currently, we are totally reliant on  
3 that importer of record or broker to present that  
4 product to FSIS at the import establishment.

5 Next slide.

6 We currently have about 70 import  
7 inspectors that are stationed at approximately 140  
8 official import establishments, and these  
9 establishments are located in close proximity to  
10 major ports of entry. They are not located at major  
11 international airports. These are around the border  
12 of the country, along the border or ports, and they  
13 verify every shipment.

14 Currently the import inspectors have to  
15 manually enter this data into the Automated Import  
16 Information System, which is our current centralized  
17 computer data system, and this system generates the  
18 random and targeted inspection assignments that we  
19 generate at port-of-entry. It links all the ports-  
20 of-entry. So if you have a failure at one port,  
21 then that information is automatically into the  
22 system and so if another shipment arrives at another

1 port, they're placed on the intensified level of  
2 inspection.

3           The current system is programmed to confirm  
4 both animal and public health eligibility. We took  
5 this as a precautionary measure to back stop APHIS  
6 just in case some products get through from an  
7 animal health perspective. It also drives some of  
8 the types of inspections that we perform, and then  
9 it also maintains the compliance history that Don  
10 referenced in regard to the port-of-entry.

11           Routine reinspection is performed on every  
12 shipment. The system as well as the inspector are  
13 looking at the eligibility of that country and the  
14 establishment. There was a question on the break in  
15 regard to how the foreign establishments are  
16 certified, and the country has the systems  
17 equivalence, but it's up to that competent authority  
18 in that foreign country to certify establishments to  
19 us. Those get entered into the AIIS, and then the  
20 system would accept or reject the shipment according  
21 to that information and the status of that  
22 establishment. The system is programmed as well on

1 eligible product and the inspector is verifying this  
2 information, and then looks at the documentation  
3 that accompanies the shipment from the foreign  
4 country and also verifies any transportation damage  
5 making sure that damage is segregated and verifies  
6 the label, general condition and making sure that  
7 the box count of what's certified and what was  
8 presented is in agreement.

9           Dr. James           referenced           the           directed  
10 reinspection. These are random inspections that are  
11 performed on the shipments. We perform a product  
12 examination that's an organoleptic evaluation. The  
13 inspectors have appropriate sampling plans. They  
14 have defect criteria, accept/reject criteria for the  
15 types of products that are being presented, and they  
16 sample and take action appropriately.

17           And then for laboratory examinations, for  
18 micro contamination, residue contamination, food  
19 chemistry, species identification, pathology and  
20 then the biological threat agents are tested, but  
21 that's blind to the inspector. They have no  
22 knowledge of what is directed for that type of

1 testing.

2           Product examinations are assigned according  
3 to a statistical schedule, and this will address the  
4 question that was asked earlier. We have a table  
5 that's programmed into the system that runs on an  
6 algorithm, and the targeted numbers of lots is based  
7 on the imported lots from the previous year. And  
8 this is by country, by species and by process  
9 category. So if you have a new country that's  
10 coming in, you know, that's just been viewed as  
11 equivalent, it starts at the bottom of the table  
12 which is 100 percent reinspection and it's a sliding  
13 scale, that as, you know, the next year, as they  
14 ship more product, then they would move out of that  
15 100 percent up into the other categories based on  
16 how much they're shipping. And this sample size,  
17 this was all presented in a public meeting when we  
18 introduced the systems approach several years ago,  
19 and so it is based on the volume of product that's  
20 moving in. It's truly a benefit. These large  
21 volume countries that are shipping a lot of product,  
22 you know, they're basically subjected to about 600

1 product examinations over the course of the year.  
2 This is random. The system assigns it. The  
3 inspector, nor the industry, knows when it's going  
4 to hit. And then the laboratory samples are  
5 collected as a subset of those product examinations.

6 And important note of the current system is  
7 that we do have the ability to increase and decrease  
8 inspections, reinspections that are assigned to the  
9 products by either country or by establishment. So  
10 if we detect a problem, we can make an adjustment  
11 within the system. And then it also applies  
12 different frequencies for reinspection for the types  
13 of inspection that are performed. So you have the  
14 flexibility to change either the level of inspection  
15 that's applied to the country, the establishment or  
16 the type of inspection that we're looking at.

17 For cause inspection, we have two levels  
18 under this. This is when we suspect a problem and  
19 so there's either been an audit deficiency or some  
20 other intelligence that suggests that we should  
21 increase the level of inspection. It's a management  
22 decision, and it takes us out of that directed

1 reinspection that is random and is programmed into  
2 the system. We're able to increase that, and it can  
3 be applied again to specific types of inspection,  
4 type of product or the establishment or even the  
5 entire country.

6           For intensified level of inspection,  
7 however, that's an algorithm that automatically  
8 fires in the current AIIS system, and if you have a  
9 failure at port-of-entry, for whatever the type of  
10 inspection, then that would apply back to the types  
11 of product that are in that product classification.  
12 The organization of the products is based on the  
13 HACCP process, categories that are defined under the  
14 HACCP regulations. And that would be 15 consecutive  
15 lots for laboratory failures and 10 consecutive lots  
16 for product examinations.

17           And then if the reinspection process has  
18 been successful, they get a stamp, the Official Mark  
19 of Inspection, on the shipping containers, and that  
20 product is allowed into U.S. commerce. In the case  
21 of Canadian product, that product is not stamped.  
22 The stamp is applied actually to the health

1 certificate in lieu of the product. Keep in mind  
2 all product moving into the country, they have  
3 shipping marks applied to them. That mark on the  
4 carton links that product to the health certificate.  
5 So we have that trace back capability.

6           If there is a failure of meeting U.S.  
7 requirements, then at that point our refused entry  
8 process goes in. The product is rejected. That  
9 triggers the events of future shipments so that we  
10 do 100 percent reinspection for the next 15 or 10  
11 consecutive lots and then the product is controlled  
12 out of the country or destroyed or converted to  
13 animal food.

14           For the future, we're intending for port-  
15 of-entry reinspection to focus our inspection  
16 activities on the public health-based data. As part  
17 of the process with the Public Health Information  
18 System coming on line, we're in the process of  
19 converting our import manual procedures into FSIS  
20 directives, and through that process, we're  
21 reevaluating all of our inspection activities and  
22 techniques that we've applied over the years. And

1 so there will be some changes to how we perform the  
2 product examinations and some of those other  
3 elements, but it's all driven by public health-based  
4 data.

5 We're also enhancing the ability to use  
6 data at various levels. You heard this morning from  
7 Erin in regard to the power of predicted analytics,  
8 and it will be applied at import port-of-entry as  
9 well.

10 We're certainly intending to incorporate  
11 the data that we can import from the foreign  
12 countries, consider that information as well as the  
13 process controls that are in country that have been  
14 verified through the audit process, and then any  
15 results that we have from our own testing at port-  
16 of-entry.

17 The PHIS import functions, one of the  
18 enhancements will be that this system will include  
19 the ineligible countries. This is key because we  
20 will be receiving data from Customs and Border  
21 Protection that will eliminate the inspectors having  
22 to key in data, and so we will have both eligible as

1 well as ineligible country activities in the system.

2           We have defined requirements to expand the  
3 foreign establishment profiles, so information that  
4 the auditors are gathering, any additional  
5 information that we're gathering domestically, we  
6 will be asking the foreign countries to define that,  
7 so that we can have a better informed sampling  
8 program and direct our inspection verification  
9 activities at port-of-entry.

10           We will be integrating the codes/dates at  
11 port-of-entry enforcement actions. This links back  
12 to the way that we lot product at port-of-entry, and  
13 so there's a lot of discussion going on right now  
14 internally in regard to how codes/dates can be  
15 effectively used to reduce the risk. If you have a  
16 lot of product with a certain production date that  
17 has failed, you know, the test or the verification  
18 activity, does it apply to all the product in that  
19 lot or just to that specific production date and  
20 what controls are in place to get that? Currently  
21 we can't capture that information in our system.

22           And then as well, it will incorporate the

1 foreign audit results and it will automate. When  
2 there's a problem in the foreign countries, say an  
3 establishment has been de-listed, there will be an  
4 automatic feedback into the PHIS so that we can take  
5 the appropriate inspection activities for product  
6 that's in the pipeline that's either on the water or  
7 being presented at port-of-entry.

8           Electronic certification is another key  
9 element of enhancement for the Public Health  
10 Information System. This is going to enable the  
11 electronic transmission of all the data elements  
12 from certification, replacing the paper health  
13 certificate that is currently required, and the  
14 three countries that have been prioritized are  
15 Australia, New Zealand and Canada, which would  
16 account for about 85 percent of our products moving  
17 into the country. And this is going to expedite  
18 clearance, reduce errors, eliminate the computer  
19 time that the inspectors are spending, and it will  
20 also enable, you know, I've mentioned ACE/ITDS. The  
21 information will be flowing from the ACE/ITDS system  
22 as well, and we'll be getting it from the foreign

1 governments as well. So when they ask is that  
2 double entry, well, the CBP side is from the trade.  
3 Industry has entered that information. Our  
4 transaction is government to government from the  
5 competent authority to the Agency. We were the only  
6 participating government agency in ACE/ITDS that  
7 defined this requirement, and Customs and Border  
8 Protection pushed back at first but, you know, we  
9 argued our point. We have got to have that  
10 government-to-government transaction on  
11 certification of the products. And so the two will  
12 meet and the systems will verify and if a shipment  
13 that's been certified from the foreign country never  
14 comes through the trade side, that will be flagged  
15 in the system. So we will have enhanced controls.

16 Next slide.

17 The interface with Customs and Border  
18 Protection, the most powerful thing about this, we  
19 will have advanced notification that these shipments  
20 are coming into the country, and we'll be able to  
21 take the appropriate enforcement. This is aligning  
22 with the prior notice rule with Food and Drug

1 Administration. We have product classification  
2 initiatives going on that's going to ensure that  
3 these products are coming into the country, and then  
4 we will have enhanced communication between and  
5 among the federal agencies and with the foreign  
6 governments.

7 And most importantly, Customs and Border  
8 Protection will not release shipments under FSIS  
9 jurisdiction until they get our inspection results  
10 back. Thank you.

11 MR. TYNAN: Thank you, Mary. I'm going to  
12 make an adjustment, if you have no objection, to our  
13 agenda. I think next we were going to talk a little  
14 bit about international policy development, but we  
15 have a guest from the Food and Drug Administration  
16 and he has a scheduling issue. So we need to get a  
17 little bit back on track. We'll hold the questions  
18 for Ms. Stanley and for Mr. Smart until a little bit  
19 later after we have our presentation on  
20 international policy development, but right now I  
21 would like to introduce to you Dr. David Acheson.

22 Dr. Acheson is currently the Associate

1 Commissioner for Foods at the U.S. Food and Drug  
2 Administration. He graduated from the University of  
3 London Medical School in 1980, and following  
4 training in internal medicine and infection diseases  
5 in the United Kingdom, he moved to the New England  
6 Medical Center and Tufts University in Boston, which  
7 I really like. In September of 2002, Dr. Acheson  
8 became the Chief Medical Officer at FDA's Center for  
9 Food Safety and Applied Nutrition. In May of 2007,  
10 the Commissioner of Food and Drugs appointed  
11 Dr. Acheson the Assistant Commissioner for Food  
12 Protection to provide advice and counsel to the  
13 Commissioner on strategic and substantive food  
14 safety and food defense matters.

15 That bio does not, however, acknowledge the  
16 fact that Dr. Acheson is a former FSIS'er. So part  
17 of our team at one time. So we're very pleased and  
18 want to have a sincere and warm welcome to  
19 Dr. Acheson to talk a little bit about the FDA  
20 import system.

21 DR. ACHESON: What I wanted to do is to  
22 just sort of briefly take 15 or 20 minutes maybe max

1 to tell you why we're focusing on FDA's food  
2 protection plan. Some of the changes that we're  
3 having to address in relation to imports of FDA  
4 products, the shift fundamentally which is an  
5 important message to get over to you, that we're  
6 moving away from a port-of-entry approach to a  
7 production lifecycle approach, which essentially  
8 means that we need to be looking at what's going on  
9 in foreign manufacturers much more than we were  
10 previously.

11 And then I will talk a little bit about  
12 some of the major elements and the legislative  
13 proposals in the plan that address these issues.

14 Next.

15 I'm sure you're all familiar with this, but  
16 just to put this out in front, the FDA is  
17 responsible for protecting about 80 percent of the  
18 food supply, and essentially it's everything that  
19 the USDA doesn't cover. It includes food for humans  
20 and for animals. It includes dietary supplements  
21 and bottled water.

22 Next.

1           Some of the trends and changes that are  
2 driving this is the fact that consumers are  
3 expecting a lot of FDA regulated products to be  
4 available 24 hours a day, 7 days a week, year round.  
5 That is driving the global food supply, and we're  
6 currently at a state where about 15 percent of all  
7 FDA regulated foods is imported. It varies hugely  
8 with the type of food. Seafood is 75 to 80 percent.  
9 Fresh produce is 50 to 60 percent, depending on the  
10 type of produce and the time of year. Other things  
11 are a lot less because they're essentially produced  
12 domestically.

13           This slide is a graphic of the trend that  
14 I'm talking about in terms of the increase in global  
15 food supply. There's 10 years worth of data on  
16 here, from 1997 to 2007, closest to me. The food  
17 line is the bottom one. That's the red triangles,  
18 and effectively it's showing this increase in trends  
19 so that in 2007, we were up to a little over 9  
20 million lines which is essentially a shipment of  
21 food. By the end of this year, I think it's going  
22 to be well over 10 millions, and there's no signs

1 that this trend is diminishing.

2 Next.

3 Our universe is very different from USDA's  
4 universe. We're importing from over 150 countries.  
5 If you include territories and provinces, it gets  
6 over 200. We're importing through every port.  
7 There is no restriction for importation of FDA  
8 products. It can come through any port. So it's  
9 coming through over 300 ports.

10 There are about 200,000 foreign firms  
11 registered to import FDA products. They have to be  
12 registered to import as part of the Bioterrorism Act  
13 because they have to submit prior notice to come  
14 into the United States. So they have to be  
15 registered. We currently have about 200,000.

16 The key part about this registration is  
17 submitting prior notice is that people register, but  
18 then they don't update it, and they don't unregister  
19 when they go out of business. So that's part of the  
20 fix that we need to do.

21 Next.

22 The whole goal here is to move from being

1 reactive to being proactive. FDA has done pretty  
2 well with reacting to some bad situations in terms  
3 of foodborne illness around domestic and imported  
4 foods. What we're essentially trying to do with the  
5 food protection plan is to continue to react fast  
6 but to shift in a preventative proactive direction  
7 which you'll see hopefully as I continue.

8 Next slide.

9 So the food protection plan has got three  
10 elements in it. I'm not going to go into it in  
11 great department, but essentially it's prevention  
12 about building safety and up front. It's  
13 intervention, which is risk-based inspections and  
14 risk-based sampling, and response, which needs to be  
15 rapid, effective with good communication linked into  
16 it. It's an integration of food safety and food  
17 defense, so that we are essentially paying attention  
18 to the bioterrorism threat, and the other issues  
19 that constitute food defense, the deliberate attack  
20 of the food supply with the inherent risks  
21 associated with food safety.

22 Next.

1           Part of this plan focuses on specific  
2 Agency actions, things that we can do that do not  
3 require no authorities and some require new  
4 authorities. This slide summarizes the things that  
5 we're focused on in term of Agency actions.

6           Prevention is around promoting increased  
7 corporate responsibility. It's the role of the  
8 industry can play. It's the important role that  
9 they have in essentially assuring that they produce  
10 a safe product, whether it's domestic or foreign.  
11 Identifying the vulnerabilities and the areas of  
12 greatest risk, again looking at the spectrum of  
13 foods that we need to be concerned about. Where on  
14 the production lifecycle is that concern greatest?  
15 From the farm through the process of the  
16 transporter, the distributor, the warehouse or  
17 retail, or indeed consumers and balancing the  
18 messages accordingly.

19           Expanding our understanding of effective  
20 mitigation measures. This is key in terms of you  
21 understand the risks and what further mitigation  
22 strategies do we need to deal with those risks,

1 whether they are a shrimp manufacturer/producer in  
2 China or Indonesia or a tomato grower in Mexico.

3           The intervention piece is more what the  
4 regulator is going to do. That's, as I said, the  
5 risk-based inspection and sampling, and linked to  
6 that in the second sub-bullet here on improved  
7 detection is about what can we do to get ahead of  
8 the curve when things start to go wrong? Through  
9 adverse event reporting, consumer complaints,  
10 biosurveillance that we may be doing, inspection and  
11 sampling, so that we're getting ahead of the curve  
12 in terms of response.

13           And then finally when things go awry and  
14 there's illness, how to do it faster and to  
15 communicate more effectively.

16           Next.

17           The legislative proposals, which we have 10  
18 of them in the food protection plan, and I don't  
19 have them all on these slides, but these are three  
20 that are under the prevention element which I think  
21 are particularly relevant to imported foods.

22           One is preventative controls against

1 intentional contamination. This is focused on food  
2 defense issues. This is not something that I think  
3 we would seek authority to implement controls in  
4 foreign countries but foods, whether they be  
5 imported or domestic, once they're in the United  
6 States, if we know there are high-risk points, where  
7 we feel that preventative controls should be placed,  
8 then this is what this is about. For examples,  
9 requiring locks on tanker trucks is an example of a  
10 high vulnerability where I would see this rule if it  
11 gets enacted in the way we currently envision it  
12 could be used.

13           The preventative controls for high-risk  
14 foods is to give FDA explicit authority to require  
15 manufacturers, processors, to put preventative  
16 controls in place for high-risk foods. I'm sure  
17 many of you are aware that there's a lot of activity  
18 on the Hill in terms of new food safety authorities  
19 and many of those draft bills have taken this one  
20 further to require preventative controls for all FDA  
21 regulated foods. Our food protection plan is  
22 essentially focused on high-risk foods because we

1 think that's the place to start.

2           The registration renewal, this is a  
3 requirement for people to reregister every two  
4 years, so that if they don't reregister, that  
5 registration will lapse and they will essentially be  
6 able to be taken out of the system. That will help  
7 to clean it up somewhat and it will help to maintain  
8 its currency.

9           Next slide.

10           Under the intervention, all these are  
11 things that again relate to imports. The  
12 accreditation of third parties for food inspectors.  
13 This is a very emotive topic with many, and I think  
14 to illustrate the point here, I've already told you  
15 that we have 200,000 plus foreign manufacturers. We  
16 do not get to inspect those on anything like a  
17 regular basis. In 2007, we inspected just 95 of  
18 them. The point of this is how can we build and  
19 leverage off what industry is already doing through  
20 certification processes and accreditation systems to  
21 be able to use that data to inform our risk-based  
22 inspection process, setting standards, using

1 standards that meet Congressional and public  
2 approval within the United States that essentially  
3 match FDA standards and then use that information to  
4 help inform our risk-based inspection and sampling  
5 at the port-of-entry and overseas.

6           The second one is about requiring  
7 certificates for entry. Right now we don't have the  
8 authority to require a certificate even if we wanted  
9 to. This is a strategy that we're pursuing  
10 specifically with China. It's a government-to-  
11 government agreement. Without that, it constitutes  
12 trade issues. This would be an agreement at least  
13 as we currently envision it, would be focused on  
14 certain aquaculture products from China and certain  
15 ingredients from China, like wheat gluten where we  
16 had the problems with melamine. And it would  
17 require the product to be certified by a foreign  
18 entity. That certification process needs to reach  
19 again a standard that is acceptable, and if products  
20 are not certified, they would be refused entry. We  
21 do not have the authority to do that right now.  
22 Even if somebody chooses to certify, we can't act on

1 it.

2           The third one is simply to refuse entry of  
3 a product if when we approach a foreign firm, they  
4 refuse our inspectors. Right now that is not  
5 grounds for us to refuse the product, and this would  
6 give us the authority to say, if you don't let our  
7 inspectors in, then you can't import into the United  
8 States. This is essentially a gap that needs to be  
9 plugged.

10           Next slide.

11           Just to put this in the context of the action  
12 plan for import safety, which is I'm sure there is  
13 something that you're all familiar with, which is  
14 the broader Presidential approach to imports. It  
15 covers many, many products. In fact, it covers all  
16 imported products including foods, and I just want  
17 to really basically tell you that the food part of  
18 the import safety action plan is reflected in FDA's  
19 food protection plan. The food protection plan at  
20 FDA is imports and domestic. This is just imports,  
21 and the food part of this is really identical to  
22 what's in the food protection plan and both are

1 built under a prevention intervention and response  
2 type of structure.

3 Next slide.

4 Part of our major focus here in terms of  
5 where we're going with imports, we're doing a lot of  
6 other things, but I've tried to focus this down on  
7 that. A lot of outreach. We're meeting with a lot  
8 of states and locals. We've just come out of a 50-  
9 state meeting talking about how to integrate better  
10 and build partnerships to a greater extent with  
11 states and locals. A lot of interactions with  
12 foreign government and industry, focusing both on  
13 domestic and imported issues.

14 We are establishing an updated risk-based  
15 approach for inspection and sampling. It's called  
16 PREDICT and is essentially that we have run a pilot  
17 on with seafood, which was looking successful and  
18 we're looking at evaluating that pilot and  
19 determining whether we can extend this into other  
20 areas. It's essentially an artificial intelligence  
21 approach that continuously builds on risk-based  
22 information.

1           Voluntary certification programs, I talked  
2 a little bit about that. We are currently  
3 undertaking a shrimp pilot on this to determine its  
4 validity. Is it going to work? What are the  
5 problems? What are the pitfalls? The closing date  
6 for applications for that has just ended. It just  
7 closed I think within the last day or two. We will  
8 be reviewing the information that's been sent in and  
9 then we will be auditing these programs to see if  
10 they meet adequate standards, and then make a  
11 determination of whether we can actually make use of  
12 this. So this is essentially a pilot to explore its  
13 validity.

14           And important part that links back to my  
15 opening comments about shifting from port-of-entry  
16 to production lifecycle, is that we are establishing  
17 a presence in countries overseas, something that we  
18 have not done before. And in a subsequent slide,  
19 we'll get into that in just a bit more depth, and  
20 also pursuing these legislative proposals that I've  
21 talked about, working with Congress to try to move  
22 those forward.

1           Next slide.

2           In terms of FDA beyond our borders, this  
3 summarizes the current state of play with this. We  
4 have signed an agreement with China in 2007 which  
5 focuses on food and feed issues. There was a  
6 similar one signed that related to drugs and medical  
7 products. The food and feed one was signed in  
8 December, and we are planning to establish an office  
9 later this year in China where we're currently  
10 intending to put at least FTEs on that. There will  
11 be some Chinese nationals part of that, too, so that  
12 number will grow. Similarly, in India, we're  
13 looking to establish an office, and currently there  
14 are 11 FTEs that are slated to be there. South and  
15 Central America similarly with the presence there  
16 with estimate of seven people, and also in Europe  
17 and in the Middle East.

18           The purpose of having these people there is  
19 multiple. It's going to help build relationships,  
20 understand processes. It's going to be able to  
21 undertake inspections. It's going to enable us to  
22 act more quickly if something goes wrong because

1 we'll already have a presence in certain parts of  
2 the world. This is an exciting approach but it's  
3 necessary to be able to build the product lifecycle  
4 approach that we need as opposed to just focusing on  
5 when the product arrives in the United States.

6 Next slide.

7 So in summary, there are a lot of changes  
8 in the food supply. Obviously these changes are not  
9 reflective of the fact that we're seeing a dramatic  
10 increase in the number of foodborne illnesses or  
11 number of outbreaks, although we have had some very  
12 high profile outbreaks recently. We're all aware of  
13 that. It's more a reflection of the fact that from  
14 FDA's perspective around imports, is the global food  
15 supply is here to stay, and what we're trying to do  
16 here is to build a national system with partners,  
17 industry, states and local regulators and other  
18 federal partners that will address the global food  
19 supply as it relates to FDA products.

20 The plan that I've gone over very quickly  
21 is an integrated approach with a greater emphasis on  
22 prevention. That's key. We've got to build safety

1 and up front whether it's a domestic or a foreign  
2 product, linked with risk-based inspections and  
3 rapid response when things go wrong, and clearly a  
4 need for changed approach for imports, in terms of  
5 the way that we determine risk at the port-of-entry  
6 and sampling and inspection criteria, the FDA beyond  
7 our borders and looking very critically at this  
8 whole product lifecycle component as opposed to what  
9 our Secretary talks about of a snapshot of the port-  
10 of-entry. That's what we've got to get away from  
11 and look at the whole spectrum.

12           Next slide. I think that's it. Thank you  
13 for your attention.

14           MR. TYNAN: Can you take a few questions?

15           DR. ACHESON: I can take a few questions.  
16 Absolutely. Yeah.

17           MR. TYNAN: Mr. Elfering.

18           MR. ELFERING: Yes, this is Kevin Elfering.  
19 I guess one of the things I want to make is a little  
20 bit of a comment and especially on this action plan  
21 for import safety. I really think both Dr. Raymond  
22 and you, if you can really take this to heart is

1 start getting the state agencies more involved with  
2 these issues. I know it's listed as kind of a  
3 number 12 out of 14 points. It should be moved up,  
4 and I think especially working with state agencies,  
5 sharing information because they're the ones who are  
6 really doing a lot of these investigations when it  
7 comes to foodborne illness outbreaks. That's really  
8 where the rubber hits the road, and I think you're  
9 really making a mistake by not putting a higher  
10 priority on that.

11 One of the issues in here is that it's a  
12 long-term goal to work on sharing information, and I  
13 think that should be a very short-term goal to  
14 sharing information with state agencies.

15 DR. ACHESON: Let me just comment on that,  
16 and I want to assure you that as part of the food  
17 protection plan at FDA, that is a huge priority. We  
18 have just come out of at 250 person, 50-state  
19 meeting. We're sharing data, discussing how to  
20 integrate, build uniformity around training,  
21 standards, approaches is critical, the importance of  
22 the partnerships, of extending the contracts with

1 states, from FDA's perspective. No question at FDA,  
2 that is a priority and a short-term goal.

3 MR. ELFERING: And then I had one other  
4 question on this shrimp survey that you're doing  
5 with the voluntary certification. Is that with  
6 Department of Commerce, one of those? I notice  
7 there is some discussion in this also, in this  
8 report, of using the Department of Commerce. I  
9 believe though that that's more economic, and they  
10 always call it a flip and sniff inspection as a  
11 matter of fact, where it's more quality issues, not  
12 based on food safety. So is this shrimp survey, is  
13 that based on food safety issues or on quality  
14 issues?

15 DR. ACHESON: This pilot that I talked  
16 about is exclusively focused on food safety. It's a  
17 FDA program. It's not being done in conjunction  
18 with commerce, and essentially what we did was we  
19 put out a Federal Register notice inviting anybody  
20 who "inspects" seafood through using a  
21 certification, auditing process, that meets  
22 standards, submit those standards, submit the

1 process to us, and we'll look at it and see if we  
2 want to go and audit it, but this is something that  
3 is FDA standalone, and it's entirely food safety.

4 MR. TYNAN: And I'm going to move on so  
5 that we can have a couple of more questions, and  
6 that will be it. Mr. Corbo, you had a question.

7 MR. CORBO: Good morning, Dr. Acheson.

8 DR. ACHESON: Good morning.

9 MR. CORBO: This morning we've reviewed the  
10 way USDA handles imports, imported food safety. Why  
11 does the FDA reject that method of equivalence  
12 determination, reinspection or audits in-country and  
13 reinspection? And I ask that in light of  
14 information that I gleaned from some of the Office  
15 of Regulatory Affairs work plans that we did get  
16 some information on. In the 2007 work plan, there  
17 was this statement. "To the best of our knowledge,  
18 approximately half of the foods that have been  
19 associated with foodborne illness have been  
20 imported." It seems that a more rigorous approach  
21 to making sure that the imported food is safe needs  
22 to be taken, and I still feel very uneasy about the

1 food protection plan in terms of some of the  
2 elements. So can you explain why you're rejecting  
3 the way USDA does import food safety?

4 DR. ACHESON: We're not rejecting anything.  
5 We're looking at where we are and where we need to  
6 go as a first step. You're describing equivalence.  
7 If you think about equivalence in the context of  
8 close to 150 to 200 countries, with the myriad of  
9 standards, foods, types of foods, different size  
10 manufacturers that FDA regulates, putting  
11 equivalence in place and making it work in any short  
12 term solution I believe is beyond our current  
13 capabilities. I'm not ruling anything out but what  
14 I'm saying, what we're saying at FDA is we need to  
15 make change. We need to move forward, and this is a  
16 start in terms of looking at production lifecycle.  
17 And establishing a presence in the foreign  
18 countries, yes, you can criticize it and say, well,  
19 it's not gone far enough and, sure, it's not  
20 establishing an inspector in every one of those  
21 200,000 firms on a 24-hour-a-day basis, which is  
22 certainly an option, but it's not frankly a

1 pragmatic one.

2           So we are looking to move the ball forward,  
3 to improve food safety in the United States,  
4 recognize that the global food supply is a key part  
5 of that, and taking some first steps and they are  
6 first steps. It's not like we're here, we're going  
7 to go there and we'll be done.

8           MR. TYNAN: Thank you. Dr. Negrón, do you  
9 have a question?

10           DR. NEGRÓN-BRAVO: Yes, I have a question.  
11 We are moving from port-of-entry inspection to the  
12 production lifecycle. What percentage of your  
13 products were done on port-of-entry?

14           DR. ACHESON: In terms of inspections?

15           DR. NEGRÓN-BRAVO: Yes.

16           DR. ACHESON: The way it works through the  
17 prior notice enter and when a produce enters in the  
18 United States, if it's a FDA-regulated product,  
19 every shipment has to go through prior notice and is  
20 reviewed initially electronically in terms of is it  
21 a country of concern? Is it a product of concern?  
22 If it passes that test and about 25 percent do, it

1 then goes for a review by a FDA import inspector.  
2 That is still just looking at the paperwork. That  
3 is determining, looking in more depth, about do we  
4 have specific concerns around this, and if so, what  
5 are they and then they make a determination of  
6 whether this should be a physical inspection.

7           And at that point of a physical inspection,  
8 it is about 1 percent of those total shipments that  
9 get physically inspected, and it varies by product.  
10 Some products that we have had no problems with ever  
11 is much less than 1 percent. Other things like  
12 seafood, it's higher. It's more like 4 to 5  
13 percent, and then a portion of that, depending on  
14 the inspection will lead to samples to be taken.  
15 That's the current status.

16           MR. TYNAN: Dr. Acheson, I don't see any  
17 other questions for you.

18           DR. ACHESON: Very good.

19           MR. TYNAN: So I appreciate your coming --

20           DR. ACHESON: Thank you.

21           MR. TYNAN: -- and providing your  
22 perspective on FDA's program.

1 DR. ACHESON: A pleasure. Thanks for  
2 inviting me.

3 MR. TYNAN: Thank you very much. Dan read  
4 my mind. We're back on the agenda to talk a little  
5 bit about international policy development, and I  
6 think Dr. Engeljohn is our Deputy Assistant  
7 Administrator for Policy Develop.

8 DR. ENGELJOHN: Well, thank you and  
9 welcome, everyone, to the Committee and to the  
10 audience.

11 I do want to give you a give you a  
12 perspective about how we here at FSIS have a team  
13 effort in which we are looking at international  
14 issues and, in particular, the issue of equivalence,  
15 but it's not done in a vacuum of just equivalence  
16 alone. It's really done with the perspective of  
17 what we're doing overall in the domestic system.

18 On the next slide, I want to give a  
19 perspective about the role of the Office of Policy  
20 and Program Development here in the Agency. It is  
21 our responsibility to establish the intent behind  
22 policy decisions associated with meat, poultry and

1 processed egg products in terms of their safety and  
2 the labeling of those products.

3           That's not an easy task, and it's one since  
4 1995, the Agency has had a very concerted effort at  
5 modifying our prescriptive regulations that we have  
6 on the books and converting them into performance  
7 based standards. It's quite difficult to issue  
8 regulations, and I would say it's probably just as  
9 difficult to remove existing ones. And so the real  
10 intention that we have behind what we have is to  
11 really be sure about what the intent of the policy  
12 was so that we can actually determine whether or not  
13 the domestic system inspection requirements are  
14 actually addressing the issue, and then from that,  
15 are the state programs who are involved in an equal  
16 to decision meeting that through the process by  
17 which they implement their programs and then whether  
18 or not the imported products are, in fact, meeting  
19 the intent of the inspection system criteria that we  
20 have through the equivalence process.

21           We have become more active in terms of the  
22 roles between the Office of International Affairs

1 and the Office of Policy in terms of being engaged  
2 in making sure that we are, in fact, identifying  
3 what the intent of the policy is and that we do, in  
4 fact, agree that the way that we go about making  
5 that equivalent determination is, in fact, one for  
6 which we can say is, in fact, equivalent. I think  
7 that's an important concept in that other countries  
8 around the world do things differently than in the  
9 United States. I think Sally in her presentation  
10 identified that in the distant past anyway,  
11 countries would apply for equivalence in systems  
12 that were really compliant with the FSIS system in  
13 that they did things the way the FSIS program was  
14 but not necessarily the way that they do them in  
15 their domestic program. But today I think things  
16 are different, and things are certainly becoming  
17 more complex, and the issue about identifying intent  
18 is one that we need to take at heart and for us, as  
19 an inspection agency, make some determination as to  
20 whether or not we should change our system because  
21 it might be a better way of doing things. And so I  
22 think it's really important that the Policy Office

1 is involved in international program processes.

2           We do know that the process by which we  
3 deal with rules of practice are not really well  
4 articulated in terms of how we deal with  
5 international programs. And so we do have Section 9  
6 C.F.R. 500, which deals with the rules of practice  
7 for how we engage in enforcement actions and  
8 suspensions and other activities which give rights  
9 to establishments in terms of making appeals. We  
10 believe we can articulate that better and be more  
11 transparent about that. And so one of the projects  
12 that we're initiating is looking at this process and  
13 see how we incorporate the international activities  
14 into that process.

15           And then secondly, the Agency in terms of  
16 considering where do we need to go into the future,  
17 even though we need to insure that we don't apply  
18 criteria, that is different or more burdensome on  
19 the international program than we do on the domestic  
20 program, we do need to look to see if we are  
21 inheriting or importing problems into the country  
22 through the products that are coming in. And by

1 that, I mean that countries may, in fact, be meeting  
2 the domestic requirements but may have different  
3 pathogens or food safety hazards or may have them at  
4 different levels and may address them differently in  
5 their country than we do here, and we can't ignore  
6 that. So the issue becomes one, how do we address  
7 those issues in our system of policy to insure that  
8 we're on top of what issues might emerge as a  
9 consequence of imported products.

10 With that, then it does cause us to look at  
11 this and anticipate what it might be that we need to  
12 address.

13 I would also point out that in other  
14 countries, there may be adulterants in those  
15 countries that are not adulterants here. The law  
16 and the requirements that are set up are is that we  
17 cannot import adulterated products. So just because  
18 it's coming in from a foreign country and we don't  
19 have a requirement here that addresses that, we  
20 still wouldn't allow it to come into this country  
21 because it would be adulterated in that country.

22 Just a good example of that, just to put it

1 into a perspective would be that food additives is  
2 one area where countries differ in terms of those  
3 approvals, and that's an issue that we need to  
4 attend to in that there may be approvals for  
5 additives or drugs in one country that are not  
6 approved here, and that we have to address that in  
7 terms of can those products come into this country.

8           And then finally, we don't look at just the  
9 international program as a separate entity. We look  
10 at the international program and the import products  
11 as we do with the state programs, in that we look to  
12 see how those products and those processes and those  
13 systems impact the overall measures that we have in  
14 place in terms of meeting our food safety objectives  
15 that FSIS has defined.

16           So we have established performance goals  
17 that we have. Mainly they're addressed as pathogen  
18 product pairs right now, but the Agency's continuing  
19 to look at how we measure our inspection system  
20 performance, and we include the performance of the  
21 international programs as well as the state programs  
22 in making a determination about what impacts we have

1 and need to address.

2 Thank you very much, and I'm sure we're  
3 happy to answer any questions you might have.

4 MR. TYNAN: Okay. By changing the agenda,  
5 we cut short some questions you may have had for  
6 Mr. Smart and Ms. Stanley, and now with Dan's  
7 discussion. I want to reopen it if there are any  
8 questions from the Committee at this particular  
9 point. Mr. Corbo got up first.

10 MR. CORBO: Yeah, I have a question for  
11 Mr. Smart. As far as the audits that are conducted,  
12 you don't visit all of the plants that are certified  
13 in a particular country. You indicated that if  
14 Canada has approximately 460 plants that are  
15 certified, and you assign 2 auditors, but you don't  
16 visit all 460 on an annual basis.

17 MR. SMART: That's correct.

18 MR. CORBO: Okay. The other thing is have  
19 the number of plants that you visit been reduced  
20 over the years. Specifically, I know that we've had  
21 a Brazilian audit and a Mexican audit, and in both  
22 instances I hear only 11 plants were visited. Is

1 that true?

2 MR. SMART: That's correct.

3 MR. CORBO: And in those particular audits,  
4 what did you find in Brazil and in Mexico?

5 MR. SMART: Just to keep the answer simple  
6 and short, both audits demonstrated systemic  
7 problems in several areas, and so I think to get to  
8 the answer of your question, we believe that the  
9 sample size that was collected in each country  
10 revealed to us the information we needed to know.  
11 So it was adequate for the purpose.

12 MR. CORBO: And in Brazil's situation, are  
13 we still receiving product from Brazil?

14 MR. SMART: We are not receiving any  
15 product from Brazil, except that which was certified  
16 before the date of which Brazil suspended exports.

17 MR. CORBO: And in Mexico's case?

18 MR. SMART: In Mexico's case, we are still  
19 in discussions to determine what the appropriate  
20 action should be.

21 MR. TYNAN: Tony, can we keep the questions  
22 sort of toward the systemic kinds of things that

1 we're talking about.

2 MR. CORBO: Well, this is a systemic issue.

3 MR. TYNAN: Well, I understand but we're  
4 getting into the specifics of different countries.  
5 So if you can keep it maybe to a little bit higher  
6 level, that would probably help with the responses.  
7 I'll come back to you though, Tony. Mr. Elfering.

8 MR. ELFERING: Yes, Kevin Elfering. On  
9 your random sampling, there are some issues with  
10 food chemistry, species and pathology. In my  
11 experience, most times those are more economic  
12 issues. Do you prioritize food safety concerns  
13 versus economic issues for example?

14 MS. STANLEY: Yes. The laboratory sampling  
15 is an annual plan, and that's under consultation  
16 with the Office of Public Health and Science,  
17 Policy, Food Defense and OIA, and we establish a  
18 sampling plan. The other consumer protection type  
19 testing, we do a very small percentage of these  
20 types of testing, economic testing which you're  
21 mentioning. This is a verification activity because  
22 we are not in-country, on site, and domestically

1 these are types of activities that are generally  
2 verified through observation by the inspection  
3 force. So there is definitely a reduction of those  
4 types of testing so that we can ramp up more testing  
5 on the pathogens, microbiological type testing,  
6 residue.

7 MR. ELFERING: And the other thing is that  
8 I'm still not quite clear, and I think Dan brought  
9 up an issue, too, with the rules of practice and all  
10 of these different things. If we have a plant in  
11 the United States, for example, that has multiple  
12 violations, multiple recalls for a particular  
13 pathogen, you start going then to a system where you  
14 have an enforcement action. What happens to a  
15 country that would have the same thing? If you have  
16 a country that all of a sudden we've got 3 out of 10  
17 shipments were positive for *E. coli*, what are the  
18 enforcement actions then for that particular  
19 country?

20 DR. JAMES: I touched on that briefly in my  
21 presentation, and I'll touch on it briefly again.  
22 If there is a certain product category from a

1 country that we're finding multiple violations with,  
2 we have and can prevent or stop the export of that  
3 product category to the U.S. If there are multiple  
4 problems with a particular establishment, exporting  
5 to the U.S., we will ask the exporting country to  
6 decertify that establishment until they have  
7 identified what the cause of the problem is and can  
8 verify for us that corrective actions have been put  
9 in place and that the plant should be able to start  
10 exporting again. And then on occasions, sometimes  
11 an entire country will suspend exports to the U.S.  
12 based on various findings.

13 DR. RAYMOND: I want to add just a little  
14 bit to what Dr. James said, too, Kevin, just so you  
15 know. We can also immediately implement a hold and  
16 test on all product coming from that country, and  
17 from an economic standpoint, that's very hard on  
18 industry, you know, to have that product held while  
19 we spend a week or two, but we also have recently  
20 sent teams into a country. When we find a problem,  
21 we don't wait for an annual audit if we feel that we  
22 need to go up there and audit those plants, and we

1 have done that in the last year or two also as an  
2 enforcement, not as suspending of inspection but we  
3 get into the country to see what's happening in  
4 those plants to find out why we're seeing what's  
5 happening at the border.

6 MR. TYNAN: Mr. Kowalcyk, I know you had  
7 your card up and you're back down. Are you okay?

8 MR. KOWALCYK: Yes.

9 MR. TYNAN: Okay. All right. I'd like to  
10 move then into perhaps -- oh, I'm sorry. Brian.  
11 Mr. Covington, did you have a question?

12 MR. COVINGTON: Yeah, more of a systemic  
13 question. We've heard a lot this morning about PHIS  
14 and the rollout and the role that PHIS will have in  
15 streamlining the entire process, kind of a two-part  
16 question. Is the expected rollout of PHIS to  
17 incorporate both the domestic function and the  
18 import/export function all at once? And then how  
19 long will the duplicate manual system that we have  
20 in place coincide with PHIS' rollout?

21 MS. STANLEY: It is the Agency's intention  
22 to have all the functionality of the system come up

1 at the same time, and that would be domestic modules  
2 or functions, the import/export as well as the  
3 predictive analytics. And it's currently on the  
4 schedule as Erin communicated this morning. And  
5 your second question, I'm sorry.

6 MR. COVINGTON: How long will the paper  
7 system that we have in place now? Will it be a  
8 duplicate effort?

9 MS. STANLEY: The paper system in regard to  
10 the import process, the expectation is that for the  
11 countries that can trade electronically, we will do  
12 so. Those that can't, we will have to continue to  
13 provide a paper certificate for verification. So  
14 it's really contingent on the capabilities in that  
15 foreign country.

16 MR. TYNAN: Okay. We are going to move  
17 onto the next segment of our presentations which has  
18 to do with an industry perspective.  
19 Dr. Hollingsworth was suggesting that she would be  
20 willing to wait until after lunch. Mr. Robach, what  
21 is your schedule?

22 MR. ROBACH: (Off mic.)

1           MR. TYNAN: Michael is hungry along with  
2 all the rest of us. If no one has any objection,  
3 then what I would suggest we do now is take a break  
4 for lunch, and we'll come back at 1:15 promptly  
5 please and thank you.

6           (Whereupon, at 12:30 p.m., a lunch break  
7 was taken.)

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1 pesticides, evaluation and authorization. In 2002  
2 Wolf Maier became responsible for food imports from  
3 the Asia-Pacific region in the International Food  
4 Safety Unit of DG Health and Consumer Protection.  
5 Dr. Maier is a graduate as an agronomist at  
6 University of Kassel. Did I pronounce that  
7 correctly, Dr. Maier?

8 DR. MAIER: Yes.

9 MR. TYNAN: Okay. In 1981, as a  
10 veterinarian at Freie University, correct?

11 DR. MAIER: Yes.

12 MR. TYNAN: Good. I have done good. In  
13 Germany in 1987, and in 1989, he received a Ph.D.  
14 from the same university based on research in  
15 molecular genetics. And with that, I am going to  
16 ask Dr. Maier to come on up and talk a little bit  
17 about his perspective on equivalence.

18 DR. MAIER: Thank you very much, and thanks  
19 very much for the invitation. I'm really honored  
20 and pleased to have the opportunity to speak here.  
21 I must admit that probably some of my thoughts may  
22 be a bit provocative for you but still I would like

1 to share them because we have a perspective on  
2 equivalence obviously, and we have a stake in this  
3 discussion as Europeans, and so I'm quite pleased to  
4 just bring forward our views and I'm looking forward  
5 to your questions and discussion thereafter. Next  
6 slide, first slide.

7           Just very briefly, I'm not intending to  
8 speak about our food safety system and how it's set  
9 up, and all the rest of it. This might take the  
10 whole day, but I still have to do some introductory  
11 remarks about it, but I will mainly focus on the  
12 principle of equivalence and how it's implemented in  
13 Europe by the Commission.

14           One fundamental difference which we have to  
15 keep in mind is that in Europe after the BSE crisis  
16 and the reorganization of the whole food law, we  
17 have assigned entire responsibility for enter food  
18 chain to one administrative body which is Director  
19 General of Health and Consumer Protection, which I  
20 represent here in Washington.

21           And so we have responsibility for animal  
22 feed throughout the farm hygiene through processing

1 of foods, harvesting of the primary produce and to  
2 the supermarkets, restaurants, it's all under one  
3 roof of responsibility and under one set of food  
4 laws, and this is a major difference I must say  
5 because basically we cover what USDA does and what  
6 FDA does and what -- does in terms of food safety.

7           A major distinction because we don't have  
8 the distinction between the agencies, obviously we  
9 have a distinction between food of animal origin and  
10 food of non-animal origin which is driven by the  
11 inherent risk of these categories. It's very  
12 similar to the notion of the -- what is it? High-  
13 risk foods in the food protection plan which is  
14 defined by FDA for example. So you could roughly  
15 correlate food of animal origin, processes and laws,  
16 to the high-risk foods basically from the food  
17 protection plan but also with foods under the  
18 auspices of FSIS.

19           Next slide please.

20           As I said, we have one legal basis from  
21 farm to fork. This is just very briefly an outline  
22 of the major, major -- which is continued to the

1 next slide. The main thing here is Article 11 of  
2 the General Food Law which is just to say that the  
3 principle of equivalence is embedded into our  
4 Primary Legal Act. So we have in the Primary Legal  
5 Act an explicit authorization to recognize  
6 equivalence and also to enter into specific  
7 agreements with authorities of other countries which  
8 we have, for example, in our equivalence agreement  
9 with U.S. but also with New Zealand and other  
10 countries. So the intention of the slide is only to  
11 show you that this is a concept which is embedded  
12 into our law at the fundamental level.

13 Next slide.

14 Again as I said, the domestic production is  
15 governed by the distinction of food of animal and  
16 non-animal origin. Basically very briefly to say  
17 food of animal origin can only be produced after the  
18 approval of the operator. And this is true for  
19 pizza restaurant, just the same as for a butcher  
20 shop or for a slaughterhouse or for a processor who  
21 processes -- makes soup from ingredients which are  
22 of animal origin. This has to do with products,

1 fish, egg, milk, meat products. You need an  
2 authorization to operate, and in order to get an  
3 authorization, you have to be inspected. So that's  
4 the fundamental principle. Every business has  
5 HACCP-based health controls and every business is  
6 under regular inspection based on risk.

7 Food of non-animal origin is different.  
8 It's a notification process. So if you're importing  
9 food and vegetables, you have to notify the  
10 authorities but they don't have to authorize you.  
11 If you just say here I'm in business, that's what  
12 I'm doing, and I open my doors for you to inspect me  
13 and I also have to have HACCP-based health controls  
14 in place, but it's not an authorization. It's a  
15 notification process. And you're going to be open  
16 for inspection on a risk basis.

17 Next slide please.

18 Basically then what we do, we have  
19 different principles for inspection and control. We  
20 have 27 member states. They're not doing the same  
21 things necessarily exactly the same way but we have  
22 uniform principles on inspection and controls. In

1 some respects, you may even say the single market of  
2 the EU27 works on the basis of an equivalence  
3 exercise because the member states do not exactly  
4 the same things. In some member states, the  
5 inspection of milk, farms, may be designated to this  
6 agency and -- to that, and so there may be slight  
7 differences but there are uniform principles on how  
8 these agencies and how these inspection bodies have  
9 to perform in terms of freedom of conflicts of  
10 interest, of training, of all the things,  
11 accreditation of laboratories, testing standards.  
12 So that's all harmonized.

13 But an important element for the single  
14 market to function is that member state authorities  
15 are audited by the Commission. So the Commission  
16 level makes sure that these goals of food law is  
17 implemented by the authorities of the member states  
18 credibly and vigorously but the Commission does not  
19 inspect the establishment itself. So the member  
20 states inspect. The Commission audits the member  
21 states. That's the system.

22 With respect to the first slide, and other

1 elements here is also important that the member  
2 states have to submit control plans, what are they  
3 going to control next year, which manpower is  
4 assigned to different parts of the food chain,  
5 because as I said controls are risk based, which  
6 sounds good, but then how do you implement it. It's  
7 how we implement it that member states have to  
8 submit a control plan, annual control plan every  
9 year, what they are going to inspect. We will spend  
10 three weeks in feed establishments and I don't know  
11 what, to make sure that the entire food chain is  
12 covered, and then these control plans are subject to  
13 peer pressure. They are audited by the Food --  
14 Office, by the Commission, but they're also open for  
15 comment by the 26 others, and that's basically a  
16 very important element to ensure that controls and  
17 to verification activities of the member states are  
18 working. Because Sweden has no reason to believe  
19 the Italians, just because they have so nice -- ice.  
20 They believe in the Italian food safety system and  
21 the Italian inspection control system because it is  
22 audited, and they have an opportunity to comment on

1 it and to influence, and that's basically why the  
2 single market is working. It's not based on trust.  
3 It's based on permanent peer pressure and controls.

4 So next slide please.

5 Everything we do, we have similar things in  
6 the import. We also distinguish between foods of  
7 animal origin and non-animal origin, -- to the  
8 authorization of businesses within Europe, food of  
9 animal origin has to come from a positive listed  
10 country and positive listed businesses. Country  
11 listing may be based on the compliance or  
12 equivalence, if they have comply with our standards  
13 or they have equivalent standards, and needs an  
14 audit similar to an inspection of a business,  
15 country has to be audited before it can be listed  
16 and it will be reinspected on the risk basis, not  
17 necessarily on a fixed scheduled basis. We need  
18 official certification of foods of animal origin.  
19 It can enter only via designated border, inspection  
20 posts similar to products under FSIS authority.

21 In contrast, food of non-animal origin, you  
22 have no country listing. You make importers liable

1 for the safety under the General Food Law. So they  
2 have to have a system in place to ensure quality.  
3 We check occasionally market surveillance and the  
4 food can be imported without certification via any  
5 port-of-entry similar to FDA regulated products  
6 basically. But we have the opportunity, the  
7 possibility like, for example, peanuts are foods,  
8 high-risk foods of plant origin. They can basically  
9 be put into this category based on the inherent risk  
10 or based on repeated findings, for example,  
11 pistachios from Iran or Turkey after repeated  
12 findings of aflatoxins. We have now required  
13 certification, pre-export checks and they enter via  
14 a designated border inspection posts. So there is a  
15 bit of a possibility to escalate the level of  
16 control for these products.

17 Next slide.

18 Country listing, the conditions, competent  
19 veterinary authority have to have a system in place  
20 to credibly verify the quality, animal health. I  
21 mean it's the criteria which you have to meet. So  
22 the level of protection is quite similar to the U.S.

1 in Europe. A monitoring system for residuals,  
2 inspection of FEI, FEO, certification and then what  
3 we have, also it's not only our discretion. At the  
4 Commission, we need the approval of the member  
5 states in Standing Committee. So it's sort of a  
6 shared decision of the Commission. The Commission  
7 makes a proposal. The member states agree to it,  
8 and then the country is listed. Basically that's  
9 how it works.

10 Next slide.

11 A big difference is now then establishment  
12 listing because we say, basically the philosophy is  
13 if we have audited the country and we have audited  
14 the inspection system of a country, and we are  
15 confident that they can meet our criteria, and it  
16 can meet our expectations, then the authority of the  
17 country gets the power to list establishments. So  
18 the authorities of the country basically lists  
19 establishments for export according to our criteria  
20 and then they get to become eligible for export  
21 unless there is a reason to deny that but the  
22 principles before is that the country proposed, the

1 establishment and then after four weeks, it will be  
2 listed.

3 Next slide.

4 So now equivalence, the word, equus valere  
5 means different measures may have the same value or  
6 lead to the same result. It's also embedded into  
7 the world trade system. As you know, it's embedded  
8 in the SPS Agreement that member states shall accept  
9 measures as equivalent even if they are different  
10 from their own and also member states shall enter  
11 into consultations, but it's not so easy to  
12 implement obviously.

13 Next slide.

14 It's a multilateral system, eight years, to  
15 come up with some guidance on how it's supposed to  
16 be done. I mean the SPS Agreement was completed in  
17 January 1995, and only 2003, the multilateral  
18 standards heading bodies finally came up with some  
19 sort of a guideline on how you do that, and another  
20 appendix to this guideline was agreed now in this  
21 year's CODEX Committee I think, 10 years, more than  
22 10 years after the concept had been agreed.

1           What the guideline says now, right now, in  
2 the multilateral system, they have sliced the food  
3 safety system into many, many slices, measure by  
4 measure and they compare measure by measure which  
5 basically is the idea. This has advantages because  
6 you can just target to exercise to certain parts.  
7 You can say I want you to agree that my methods of  
8 my microbial testing are equivalent to yours or you  
9 can say I want you to agree that our antemortem  
10 system is equivalent to yours, and you don't look at  
11 the rest, which makes the task of an equivalence  
12 exercise manageable which is important. And then  
13 also it makes the assessment a little bit more  
14 robust because if you have an equivalence exercise  
15 based on methods of analysis, for example, you  
16 wouldn't necessarily look at the inspection system  
17 in these steps and also if you would have a problem  
18 now, for example, which the inspection of the  
19 establishments, then this shortcoming would not  
20 necessarily put into question all the other elements  
21 of the equivalence exercise because I mean the  
22 laboratory method, the antemortem inspection which

1 will be in place, would still be written to the  
2 equivalence, and you would have only a minor issue  
3 with the verification for example.

4           However, the isolated assessments of  
5 individual measures does not necessarily consider  
6 the performance of the entire system.

7           So in my opinion, this CODEX guidance is  
8 very valuable because it provides a systematic  
9 framework and a concept on how you get started. But  
10 I think it's not good enough to stop there.

11           Next slide please.

12           We have in Europe more an outcome-oriented  
13 approach. So we do, similar to the CODEX concept,  
14 this tabletop exercise to compare objectives,  
15 measures, legal basis, to infrastructure. We put a  
16 lot of emphasis in our assessment on the  
17 verification process, on the control process because  
18 we think that the control system must reliably  
19 guarantee compliance with the rules of the exporting  
20 country. So that's a key element of our equivalent  
21 exercise, and that's why I had before mentioned this  
22 point because actually if you have an outcome-based

1 approach, the reliable performance of the control  
2 system is the key element. It's the hook where the  
3 whole assessment hangs on.

4           As I said, after we have done this measure  
5 by measure, that's why I think this CODEX approach  
6 stops too early. We would have a weight of evidence  
7 assessment of the overall performance, the level of  
8 protection sort of, so that you can compensate one  
9 measure against another. A country may not have  
10 this and this measure for example, but they may  
11 achieve the same goal with something different which  
12 is in place somewhere else but if you have a  
13 measure-by-measure comparison, you would say here,  
14 there's a shortcoming. So there is a non-  
15 equivalence. So I think that you have to go one  
16 step further and look at the overall performance to  
17 see whether different measures may not compensate  
18 against each other or whether -- measures may be  
19 necessary, all given the circumstances in the  
20 country of origin and these sort of deliberations  
21 which have to come into the picture.

22           And then finally we do a verification.

1 Again we have a major focus, emphasis on the control  
2 authority, on the inspection control system, on the  
3 verification system which is we believe key. Again,  
4 we do a joint decision with member states. It's not  
5 only us. It's with our peers we decide, and again I  
6 say if you do this outcome-based thing, as I said,  
7 this control system is the hook where the whole  
8 validity of the overall assessment hangs on because  
9 you have to be really sure that, if you say this  
10 domestic production, even though it's different,  
11 delivers an equivalence product, in terms of safety  
12 or hygiene, and you would import it on the basis of  
13 compliance with the exporter's domestic rules, if  
14 these domestic rules are not reliably enforced, the  
15 whole equivalence exercise is basically smoke, and  
16 that's why the verification issues are very, very  
17 important if you have an outcome-based assessment of  
18 equivalence.

19 Next slide please.

20 Our experience, we have equivalence  
21 agreements with several countries, New Zealand,  
22 Switzerland, USA, Canada, just to mention some.

1 They're all different in scope and ambition. They  
2 can deliver. New Zealand and Switzerland are the  
3 best examples. I mean you have a massive, massive  
4 simplification of trade with New Zealand. We trade  
5 about 80 percent of our imports on the basis of full  
6 equivalence and New Zealand basically certifies with  
7 one sentence, this product complies with our  
8 domestic legislation food -- and that's it. Imagine  
9 what this means for businesses. This is so much  
10 easier. So there is a huge incentive to get it done  
11 and to achieve this status because it simplifies the  
12 trade so massively that it's really worthwhile  
13 doing. It's not easy. Switzerland went even one  
14 step further, even we don't have any border controls  
15 anymore at all. It is part of the single market now  
16 even though they're not part of the Union because we  
17 went through this equivalence. It's a bit different  
18 case because Switzerland has by and large adopted  
19 the entire European Food Law, but still it's based  
20 on the equivalent exercise.

21           It's clear, I mean the equivalence  
22 agreement doesn't make your life easier as a

1 regulator. We have to look at these different  
2 agreements. We have to deal with them. We have to  
3 keep them alive. We have to evaluate them and so  
4 you have not only one piece of legislation which you  
5 apply, but you have then one piece of legislation  
6 which applies to so, so many countries but then you  
7 have a different piece which applies U.S. -- under  
8 the equivalence rules which are different, different  
9 certification forms, different procedures, different  
10 inspection frequencies. And so it becomes more  
11 complex but it's worth it.

12 But to overcome this workload and to  
13 overcome this sort of mountain of work which is  
14 ahead of you, and it's good to start small because  
15 then you can write some good news and you go further  
16 and you create a positive -- as a result of these --  
17 we have. I mean with New Zealand we start with  
18 fresh meat I guess and then we expand it to seafood  
19 and to byproducts and as I said, you have generated  
20 a success story there, and just me personally when  
21 we back in Brussels years ago.

22 Next slide.

1           Then it doesn't really stop there. You  
2 have to maintain equivalence. What we do is, if  
3 there are changes in the legislation, of course, the  
4 import and export may affect equivalence but it's  
5 not necessarily lost. So the concept is that each  
6 side evaluates the impact of its own legislation,  
7 on, if you will, situation. So if we would have to  
8 enhance our level of protection for poultry or for  
9 fish, and we would have doubts about equivalence of  
10 products from New Zealand, we would inform the New  
11 Zealanders about it, and they would have time to  
12 react to it and then come to a solution. But it's  
13 basically the side which changes the law who first  
14 assesses the impact on the equivalence, and then  
15 informs the other side to comment and then we see  
16 how we get from there.

17           Reciprocity of equivalence is certainly  
18 advantageous to build support and good faith but  
19 it's not automatic it's clear. I mean if my level  
20 of protection is higher than yours, I may be  
21 equivalent to you but you may not be equivalent to  
22 me. So reciprocity is not automatic, but it

1 certainly helps convince the people to do the work  
2 because as an incentive.

3 Next slide please.

4 I think there is no way around that finally  
5 equivalence remains a judgment. Equivalent is not  
6 identical, that much is clear, but what is it?  
7 Different measures may have similar results. For  
8 example, which I like to use is *Listeria* for  
9 example. You have a *Listeria* tolerance of 0, we  
10 have in Europe a *Listeria* tolerance of 100 coliform  
11 units per 25 grams of product, in products which do  
12 not allow the further growth, like salami use salt  
13 and drying, whatever. So the properties of the  
14 product wouldn't allow the further provocation. In  
15 this situation we allow a certain amount of *Listeria*  
16 to be present, not as a process control in the  
17 business but on the shelf in the supermarket.

18 And still even though the tolerances are  
19 different, you have a 0 tolerance, we have 100 CFU,  
20 the incidence of *Listeria* in the population is  
21 exactly the same. So both measures, even though  
22 they are not identical, have exactly the same result

1 because the risk of Listeriosis is not driven by  
2 compliance with the tolerance, whether it's 0 or  
3 100. The risk of Listeriosis is driven by the risk  
4 that the noncompliance sample escapes the controls.  
5 Of course, the samples which make you sick are the  
6 ones that have 10,000 CFUs. So they wouldn't comply  
7 with either standard, either tolerance. And again  
8 this is an example that the different measures may  
9 have similar results and that the enforcement of the  
10 measure is frequently the point which determines the  
11 risk because if you enforce it to the 100 CFU or if  
12 you enforce the 0 tolerance, you end up with the  
13 same incidence. And if you don't enforce either of  
14 them, the tolerance doesn't help you. You have  
15 Listeriosis. So the control system is the main  
16 determinate of the risk frequently. And sometimes  
17 criteria data are different to generate or difficult  
18 to compare. I'll have some other examples later.

19 I think that to agree on equivalence some  
20 goodwill is always necessary because you always have  
21 to make a judgment in order to have goodwill or to  
22 generate goodwill and to have that courage or the

1 political support to make a judgment, you have to  
2 have a bit of a broader view. You also have to look  
3 at other aspects. I mean I don't want to be trivial  
4 but one aspect is if I have my children here, I mean  
5 they eat whatever. I have no difficulty having them  
6 eating American meat or fruit. I hope you do the  
7 same Europe. So this is also some reality check  
8 about the equivalent of the food safety system. Do  
9 you hesitate to eat there?

10           The history of collaboration is important.  
11 Information is exchanged between the authorities.  
12 The history is important to build the trust and to  
13 build goodwill. And you can do miracles because as  
14 I said, there is always some element of judgment,  
15 some element of goodwill. If this goodwill is not  
16 there, it's a political -- you have lost, you have  
17 to agree that there are certain limitations how far  
18 you can go. I mean, one example is the longstanding  
19 issues we have on hormones, for example, or where we  
20 have a different political paradigm and so we cannot  
21 just forget about this or eliminate it with an  
22 equivalent exercise. So there remains things which

1 have to be resolved on another level.

2 Next slide please.

3 Just an example of what I mean with this  
4 equivalence and different measures. Example is  
5 *Salmonella* in hogs. You have just published your  
6 results with 3 to 4 percent *Salmonella*. We have  
7 made a baseline study recently and end up with  
8 having 8.6 or so incidence of *Salmonella* in the  
9 lymph nodes at slaughter. You may say this is not  
10 equivalent. You can also easily compare these  
11 figures or the skin swabs, a lymph node assay, but  
12 if you look at the legal limits which we have set in  
13 Europe and in the U.S., they are basically  
14 identical. We have a tolerance in the  
15 slaughterhouse for skin swabs, carcass swabs, of 5  
16 in 50 or 6 in 55, and we both are concerned, FSIS as  
17 well as in Europe about *Salmonella*. We want to  
18 bring these figures down. We have put programs in  
19 place to bring these figures down. They are  
20 different. We're looking at the farms. We want to  
21 get the incidence prevalence down at the farm level.  
22 We look at the processes, but we both have programs

1 in place, and we both have the power and the vigor  
2 and the determination to implement and enforce these  
3 programs. And so I think if we collaborate, you can  
4 consider this an equivalent situation.

5 Next slide.

6 Similar in poultry. You have a performance  
7 standard of 20 percent positive samples based on  
8 carcass wash sampling. We have 7 out of 50 positive  
9 based on skin neck sampling. This is not the same.  
10 This is not equivalent or is it?

11 Most of our businesses perform much better,  
12 but still those agencies, FSIS and the Europeans,  
13 are committed to bringing these figures further  
14 down. You categorize your businesses, name and  
15 chain basically. We have the food chain oriented  
16 strategy implemented now in Europe to get the farms  
17 free of *Salmonella* and to implement at a certain  
18 point, market restrictions will be implemented for  
19 poultry coming from positive establishments from  
20 positive farms. They can only then be cooked and so  
21 cooked, but no longer fresh but it's coming into  
22 force in a sequential way. But still, I mean these

1 strategies are different. The methods are different  
2 but we have the same goals, we have very similar  
3 situations as it is now and we have similar vigorous  
4 determination to improve the situation. So I think  
5 this can be equivalent if there is a close  
6 collaboration, if there is a close dialogue on how  
7 do you make progress and how the situation is.

8 Next slide please.

9 Finally, the bottom line, if you look at  
10 the data, what's public health, what do we deliver  
11 in terms of public health, the U.S. is much better  
12 in terms of *Salmonella* and *Campylobacter* because the  
13 incidence is reported per 100,000 population based  
14 on diagnosed and reported cases. This is one  
15 example where you have data, but it's not so easy to  
16 compare them because if I speak to experts at CDC  
17 and at the European Center for Disease Control,  
18 basically they all say because European system of  
19 health insurance is different, there may be a  
20 smaller gap between real and reported cases, because  
21 if you have diarrhea, you go to the doctor, you get  
22 your diagnosis, you don't pay a penny, and you don't

1 lose your pay because you spent a day at the doctor  
2 and that's it; whereas in the U.S., workers may not  
3 be paid if they don't show up, and they may have to  
4 pay for the diagnosis themselves. So it may be a  
5 stronger bias towards underreporting of these cases  
6 because the more severe the disease gets, the more  
7 severe numbers get. If you have Listeriosis which  
8 brings you to the hospital, you have exactly the  
9 same figures. If you have *E. coli*, severe  
10 infections, you have the same figures.

11 So in my perspective, even though it's  
12 difficult to really get hard data on these things  
13 and to really prove it, on a level which can be just  
14 accepted by anybody, I have the strong impression  
15 that our food safety systems deliver exactly the  
16 same level of protection, not only based on this one  
17 figure but on several other parameters but it's not  
18 so easy to really quantify it line by line by line  
19 by line, that anybody can -- it remains a judgment  
20 to some extent. And that's what I wanted to say.  
21 Thank you.

22 MR. TYNAN: Dr. Maier, thank you very much.

1 Do we have any questions before we move onto the  
2 next speaker?

3 (No response.)

4 MR. TYNAN: No questions for Dr. Maier.  
5 Thank you very much.

6 We're going to try and get back onto the  
7 agenda proper. I say that very flexibly and with  
8 all due intent at this particular point.

9 I think when we broke for lunch, we were  
10 going to present an industry perspective on third  
11 party audit system and our global food safety  
12 initiative, and I think Dr. Jill Hollingsworth was  
13 going to be the first presenter up.

14 DR. HOLLINGSWORTH: Well, first thank you  
15 for the opportunity to be here today and spending  
16 the entire day with you especially as a former  
17 member of this Committee and also as a person who  
18 spent a good chunk of their career working at FSIS,  
19 it's always a pleasure to come back and address this  
20 group.

21 One of the things that I've been asked to  
22 do is to talk about accredited third party

1 certification from an industry perspective, and what  
2 I really want to do is spend some time just trying  
3 to clarify what this really is. There's a lot of  
4 misunderstanding on what this system is, what the  
5 terminology means and how the industry is  
6 approaching it. And so I'm going to try to cover  
7 all of that. It's a little bit complicated  
8 sometimes with all the use of the terminology, and  
9 I'm going to have to go through it kind of quickly  
10 to try to get the schedule back on. So bear with  
11 me. I'm going to race through this, but hopefully I  
12 can answer any questions if you don't understand  
13 when I'm finished.

14           First of all, I just wanted to let you know  
15 who I am, what industry I represent. Basically the  
16 Food Marketing Institute represents grocery stores.  
17 We have 1500 members and they represent over 75  
18 percent of all the retail food store sales in the  
19 country. So it's coming from the retail or grocery  
20 store perspective.

21           Do I have a clicker or -- okay. Next  
22 slide. That's all right.

1           What I want to do real quick is just cover  
2 what is this new model that we're talking about for  
3 assuring food safety compliance of suppliers. Also  
4 what is an accredited third-party certification  
5 system? What is the global food safety initiative  
6 which is something you may have heard in association  
7 with accredited third-party certifiers, and also how  
8 we want to use this system to develop trust. And  
9 that's a twofold thing for us as the industry. We  
10 want the government to trust that we're doing the  
11 right thing as an industry and we also want to help  
12 build and restore consumer confidence.

13           Next.

14           So essentially this is the very simple  
15 version of what the old audit system, and in some  
16 cases, the current audit system, looks like. There  
17 are third-part auditing companies. They can use any  
18 standard audit checklist really that they choose to  
19 use or that they've been asked to use by their  
20 customers and they go out and they visit suppliers  
21 and they do these audits. And that's about all  
22 there is to it. I mean there aren't systems of

1 checks and balances. There aren't licenses. There  
2 aren't registrations. It's really kind of a willy-  
3 nilly type of system that's unfortunately been out  
4 there for too long.

5           What that system, though, really results in  
6 is if you'll look here, you'll see that there's all  
7 these different standards, and then there's  
8 customers asking for different standards to be used  
9 by different audit companies. Go ahead, click on  
10 this again. One more time. This is what we end up  
11 with. You have company suppliers who are getting  
12 audited by anything from an audit company's own  
13 personal audit that they use. They may be asked to  
14 do multiple retail audits. For example, they may  
15 have a Kroger audit or a Safeway Audit or a Publix  
16 audit, and a lot of those audits are redundant.  
17 Basically the system we have now is really resulting  
18 in a lack of confidence and more so it's costly and  
19 repetitive and not assuring us that the food is any  
20 safer. We also recognize with the suppliers that  
21 this kind of system just isn't sustainable. There  
22 must be something better, something more practical.

1           Next.

2           And that's the system that we've been  
3 trying to build. It is a system that is going to  
4 require four key components. That's the standard,  
5 the auditing component, the certification piece and  
6 the accreditation piece. And so the question then  
7 is, so how can we coordinate all of this into a  
8 single approach that everybody can buy into and  
9 understand.

10           Well, what the retailers did was they came  
11 up with something called the Global Food Safety  
12 Initiative. This started out as a group of about 30  
13 international retailers. It has now grown to a very  
14 large group of retailers, suppliers, audit companies,  
15 all the stakeholders who were involved in it. But  
16 what they said was we need to have continuous  
17 improvement. We want to have a system where we can  
18 set standards that everyone agrees to and we need to  
19 have a strategy for how to implement that. And that  
20 is what the GFSI was all about.

21           It started back in 2000, and now today it's  
22 a very large and strong organization that's looking

1 at what is accredited third-party certification and  
2 how do we do it together as an industry.

3 But I want to make it clear that the Global  
4 Food Safety Initiative, the GFSI, does not own a  
5 standard in and of itself, nor do they do any  
6 audits. What they did was developed a guidance  
7 document. That guidance document has two main  
8 parts. The first is the standard itself, and to be  
9 honest with you, the standard was the easiest part  
10 to develop because food safety is food safety. Most  
11 of us, even on an international basis, can agree on  
12 what are the best practices? What are GAPS and  
13 GMPs? We know what food safety management systems  
14 are. We all recognize HACCP-based programs.

15 We've organized our standard around CODEX,  
16 HACCP, ISO requirements and felt that the standard  
17 was something that everybody could buy into, but  
18 again let me point out it is not a specific detailed  
19 standard in and of itself. It is really a document  
20 against which standards can be benchmarked or  
21 measured for accuracy and completeness.

22 The tough part with this was the second

1 piece, and that was, how do you implement it? Once  
2 you had the standard, how do you have a system that  
3 you can build to assure that when a supplier is  
4 recognized as having met the standard, that everyone  
5 agrees and has confidence in that result or the  
6 outcome. And that was the new part that we really  
7 had to develop and it also is the more challenging  
8 piece. But this is what became known as accredited  
9 third-party certification.

10           Accredited third-party certification is  
11 actually a very well known and proven concept. It  
12 is used in other industry. It's been used in some  
13 industries for a long time. It has been used in the  
14 food industry but not really in North America at  
15 all. It's very common in Europe. They understand  
16 the terminology. They've been using this, doing it,  
17 and so our mission has been to try to get everybody  
18 on a global basis to take the same approach.

19           One of the things about accredited third-party  
20 certification though is it does have a lot of checks  
21 and balances, and that was something we felt the  
22 process needed. It's strongly based on verifying

1 that suppliers do, in fact, conform to the standard.  
2 And we also wanted to point out that we're not  
3 looking to be inspectors. What this is, is an  
4 assessment of a company's ability to manage their  
5 own food safety programs. We don't want to be  
6 replacing the government. We only want to know that  
7 a company can ensure how they're making sure that  
8 their products are safe.

9 So let's start with the terminology of  
10 accredited third-party certification.

11 First is there's an organization called the  
12 International Accreditation Forum. It's an  
13 organization that's based in Switzerland and what  
14 they do is identify and recognize all of the  
15 accreditation bodies around the world. In most  
16 cases, there is one recognized accreditation body in  
17 each country. The primary one in this country is  
18 ANSI, and other examples would be UK as in the  
19 United Kingdom, JAS-ANZ in Australia and New  
20 Zealand, but those accreditation bodies have a peer  
21 review system, and each year, one organization  
22 reviews the other. And the reason they do this peer

1 review is to make sure that everyone is adhering to  
2 the same quality, the same guidelines, meeting the  
3 same ISO protocols. So that system is in place so  
4 that we have confidence in the accreditation body's  
5 work.

6           Now, what do the accreditation bodies do?  
7 Their function is to accredit or verify that a  
8 certification body is doing its job properly. The  
9 certification body is basically an audit company,  
10 but it's an audit company that has to meet a higher  
11 level of standard. The certification bodies are the  
12 companies that actually send the auditors out to do  
13 the audits, but the certification bodies, in order  
14 to be a part of an accredited third-party  
15 certification system, have to be accredited by one  
16 of these recognized accreditation bodies. So you've  
17 got these multiple tiers, accreditation,  
18 certification, auditing.

19           Some of the features that make a  
20 certification body more than just an audit company  
21 are these types of things we have here. They must  
22 be able to demonstrate their infrastructure and how

1 they operate. They have to be willing to show  
2 financial statements, their legal requirements, how  
3 they're organized, how they operate. They have to  
4 have written procedures and practices in place that  
5 they follow.

6 They have to meet international standards  
7 if, in fact, particularly if they want to audit  
8 outside the U.S. For example, one of the  
9 requirements is that an auditor has to be able to  
10 speak the language of the company in which he is  
11 auditing.

12 We also want them to be licensed by the  
13 standard owner. The certification bodies cannot be  
14 the owners of the standard. The standard is owned  
15 independently. The certification bodies are  
16 licensed to use the standard when they go out and do  
17 their audits. That's another way we try to avoid  
18 any conflict of interest. Also they have to be  
19 impartial and as I mentioned, we're very focused on  
20 no conflicts of interest.

21 One of the things that is very different  
22 from what has happened in this country in the past,

1 for example, is a certification body that does  
2 audits can also not consult for the same company.  
3 There's been a real long history here where  
4 consultants would go out, help a company get up to  
5 speed, to prepare them to meet the audit, and then  
6 they would actually conduct the audit. Well,  
7 needless to say, if you've consulted with them to  
8 pass the audit, you're going to be sure that they  
9 pass it. That's considered a conflict of interest  
10 under this system, and it's no longer allowed.

11 Next.

12 Some of the other things that we expect of  
13 our certification bodies, of course, the assessments  
14 have to be clear and measurable. They have to be  
15 based on checklists that anyone can read and  
16 understand.

17 The auditors have to be qualified, and I'm  
18 going to come back and address auditor qualification  
19 in just a minute.

20 The certification bodies have to be able to  
21 determine what the status is. In other words, the  
22 auditor themselves, when they go out, he or she

1 completes the audit, they do not make an on-the-  
2 scene decision as to whether a company complies or  
3 not. Their audit results are then given over to a  
4 panel, part of the certification body function. The  
5 certification body assesses the results of the  
6 audit. There's both desk audit and on-site audit,  
7 and the certification body takes the legal  
8 responsibility for making the decision whether or  
9 not the company does or does not comply.

10           There's also a competitive review process  
11 of the auditors and the certification body by the  
12 accreditation companies. Remember, these  
13 accreditation bodies are going to be held  
14 accountable to make sure the certification bodies  
15 are doing their jobs properly. And the  
16 certification body gets audited themselves every  
17 year by the accreditation body.

18           This has a whole series of bullets. You  
19 can put them up now if it's easier.

20           I mentioned that we wanted to talk a little  
21 bit about auditor competency. One of the ways we do  
22 this is that the accreditation body, as part of

1 their requirements for the certifications, they  
2 require that the auditors actually be calibrated.  
3 And the certification body has to be able to  
4 demonstrate what systems they have in place to make  
5 sure that their auditors, when they go out and  
6 perform audits, are being consistent, reasonable and  
7 also detailed. The accreditation body also conducts  
8 shadow audits, and this is something pretty new, a  
9 first in this country, where there is actually an  
10 audit of the auditor. The shadow audits make sure  
11 that the auditors are doing their jobs properly,  
12 that they've properly been trained, and that they  
13 are, in fact, calibrated so that no matter who the  
14 auditor is, you should expect to get the same  
15 result.

16           The auditor must also demonstrate that they  
17 individually have the knowledge of food safety,  
18 HACCP and regulatory requirements. One of the  
19 things we also require is that when a company is  
20 audited, they have to be able to demonstrate that  
21 they not only meet the regulatory requirements of  
22 the country where they're operating, but if they

1 know they export to other countries, they have to be  
2 able to demonstrate to the auditor that they are  
3 aware of what those other requirements are and they,  
4 in fact, can comply with them.

5           One of the other things that we've  
6 instituted in accredited third-party certification  
7 is that the auditors have to identify what category  
8 sector they're competent in. One of the programs,  
9 one of these programs that FMI administers, called  
10 Safe Quality Food, for example, we have 30  
11 categories, and what we're trying to avoid here is  
12 if a person has a long history and experience, for  
13 example, working in meat processing, we don't feel  
14 that they should be able to go into a dairy and  
15 assess a pasteurization system. They may know  
16 nothing about proper procedures for canning, and so  
17 each individual auditor has to prove the knowledge  
18 and expertise that they have in each food sector  
19 category and they are only allowed and licensed to  
20 do audits in those categories.

21           Next.

22           So quickly a summary of what we saw as the

1 advantages and why we built an accredited third-  
2 party certification system was that we wanted a  
3 system that was well defined, and it used HACCP,  
4 ISO, CODEX standards, that everybody could accept  
5 and be familiar with.

6           It also helped us level the playing field.  
7 We wanted to be sure that there was a competent  
8 application of food management systems. We're not  
9 looking just to do the walls, floors, ceiling kind  
10 of inspection or review, but we really want to know  
11 that the company has a handle on how to manage food  
12 safety.

13           We wanted to require compliance with  
14 regulatory requirements, as I mentioned, both for  
15 the country you operate in and the countries to  
16 which you export.

17           Of course, this system, as I mentioned, has  
18 a series of checks and balances throughout the  
19 entire process.

20           There are risk classifications. In other  
21 words, during an audit, everything is assessed as  
22 either being incompliant, a minor, major or critical

1 deficiency. And those terms are clearly defined as  
2 part of the audit process.

3           We also have a very strong corrective  
4 action plan, and the corrective action system is  
5 managed by the certification body. If a company has  
6 deficiencies, there must be a specific written plan  
7 for how they're going to address every deficiency  
8 and if they don't properly address them in the time  
9 allowed, they will not be certified and if they have  
10 been previously certified, they will lose that  
11 certification. And although everyone thinks that  
12 never happens, trust me it does. We have removed  
13 certifications from some companies.

14           The certification is ongoing. Every  
15 company must be audited every year and if they have  
16 what we consider an unacceptable performance or a  
17 marginal performance, then we may require additional  
18 audits throughout the years.

19           As I mentioned, we feel we have a good  
20 system in place for auditor competency and we feel  
21 that we can build stakeholder support for the system  
22 because it is open and transparent to everyone.

1           Again, remember this quick slide I showed  
2 you about what the old system looked like. Well,  
3 here's what the new system looks like. Go ahead and  
4 just click all of these, too.

5           Basically what we have here is a system  
6 where the International Accreditation Forum, makes  
7 sure that the accreditation bodies are doing their  
8 job. The accreditation bodies oversee what the  
9 certification bodies are doing. The certification  
10 bodies are responsible for the auditors who go out  
11 and do the audits, and everyone is using the same  
12 set of standards. In this case, those standards  
13 that have been recognized by the GFSI.

14           Next please.

15           So I quickly wanted to go back to the GFSI  
16 recognition portion of that because there does seem  
17 to be some confusion about GFSI is. And again all  
18 the GFSI is, is a benchmarking process. Anyone can  
19 submit their standard and their protocol and  
20 actually this is what the Europeans call a scheme.  
21 It's the standard and the implementation, the  
22 certification and auditing component. That can be

1 submitted to the GFSI. They have a panel that  
2 reviews them, and what they will do is anyone who  
3 can meet all of the requirements in their guidance  
4 document, can be recognized by the GFSI as  
5 equivalent. And basically it means that these are  
6 the programs that retailers will accept because they  
7 feel that they are consistent, reliable and levels  
8 the playing field for everyone.

9           However, it's not easy to do. There have  
10 been many, many programs submitted to the GFSI and  
11 to date, only these four have ever been able to meet  
12 the full requirements of GFSI. It's a rigorous  
13 process. Safety Quality Food, SQF, is one such  
14 program that's actually administered by the Food  
15 Marketing Institute. Our retail members wanted us  
16 to have one of these programs to be available to  
17 them, and so this is the one that we actually own  
18 the standard and administer the program. There's  
19 also one called the International Food Standard  
20 Program, the IFS, primarily used in Germany and  
21 France. The BRC, primarily used in the United  
22 Kingdom, and the Dutch HACCP, which is almost

1 exclusively used in the Netherlands.

2           So when we look at where we are with  
3 accredited third-party certification, we believe  
4 that right now we have achieved our goal, and that  
5 is to have more and more retailers require suppliers  
6 to be certified to one of the GFSI standards,  
7 willing to accept these results and drop all of  
8 those other standards and programs that you saw in  
9 that slide that was just a big mish mash of arrows.

10           The other thing that we're very pleased is  
11 just last year or just this year, in fact, the food  
12 service industry and restaurants have also agreed to  
13 come together with us and support those companies  
14 that are meeting GFSI requirements.

15           Currently we have over 30,000 certificates  
16 issued to suppliers around the world who have met a  
17 GFSI standard and are now certified to one of the  
18 four GFSI programs.

19           The retailers and suppliers are using these  
20 accredited certifications to demonstrate that they,  
21 in fact, have integrity and confidence in the  
22 system, and that they can now demonstrate to their

1 consumers that they have corporate responsibility  
2 when they select a supplier.

3 But the one thing we want to be sure that  
4 we're clear on is that we do not want to be a  
5 replacement or a substitute for the government. We  
6 don't see ourselves at all in that mode.

7 What we see ourselves doing is filling a  
8 gap that needs to be done and also being able to  
9 demonstrate corporate responsibility that as an  
10 industry, we are stepping up to the plate to make  
11 sure only the safest foods are sold to our  
12 consumers. Thank you.

13 MR. TYNAN: Thank you, Dr. Hollingsworth.  
14 If I could ask you to stay at the podium for just a  
15 minute and see if the Committee has any questions  
16 regarding GFSI. Dr. Harris.

17 DR. HARRIS: Just one real quick question.  
18 The scheme that you laid out is somewhat complex to  
19 say the least. I mean there's a lot of layers to it  
20 and a lot of moving parts if you will. How is that  
21 whole process funded?

22 DR. HOLLINGSWORTH: Well, there's a number

1 of different ways that revenue is generated in order  
2 to fund the program. First of all, the suppliers  
3 themselves pay for their audits. That money goes to  
4 the certification companies directly. In other  
5 words, they're paying a company to do an audit for  
6 them like they do today. The certification  
7 companies actually pay the standard owners to be  
8 licensed and to operate or to use their standard.  
9 There are other additional fees. Some of the  
10 standards, and the different programs do it  
11 differently. Some of them actually charge a fee for  
12 their standard. Some of them actually charge a fee,  
13 for example, to use their database. So there's  
14 different ways of collecting fees, but primarily  
15 it's the standard owner is charging the  
16 certification bodies. The certification bodies then  
17 charge the suppliers who get the audit.

18 MR. TYNAN: Other questions for  
19 Dr. Hollingsworth? Mr. Painter.

20 MR. PAINTER: Stan Painter with the  
21 National Joint Council. Five slides prior to the  
22 last one, you mentioned major, minor and critical.

1 We had a process a number of years ago using a  
2 decision tree. Can you tell me what would qualify  
3 someone under each category? In other words, what  
4 would it take to receive a major, minor or critical?

5 DR. HOLLINGSWORTH: Well, actually the way,  
6 and I can only speak for SQF directly. The way our  
7 standard is set up, on the audit form, for every  
8 item, line item, and our audit forms are set up  
9 basically like a CODEX form is, where there's all of  
10 the different items that are being assessed. For  
11 every item, there is what is the conformity level,  
12 and then there's actually a drop-down screen that  
13 will tell you if this piece of it is missing, it's  
14 minor. If this is missing, it's major. And it  
15 varies for every item. In some cases, for example,  
16 if you have a document that is expired, yet you can  
17 show that you've been having testing done or water  
18 quality tests done, for example, then there will be  
19 a drop-down box that will actually say this  
20 qualifies as major, minor, critical.

21 The reason we do that is so that it's not a  
22 subjective decision by the auditor, but rather when

1 the auditor rates something major, minor, critical,  
2 there will actually be a definition of why it was  
3 rated that way.

4 In general, this is not different or the  
5 way we rank them is not different than what would  
6 happen on most other types of assessments. Anything  
7 that could result in a public health hazard, for  
8 example, will be a critical. A minor is often  
9 something that can be corrected without even having  
10 to come back and redo the audit. There are some  
11 issues, major issues that would require the auditor  
12 to return and verify that they've been done.

13 MR. TYNAN: Last call for  
14 Dr. Hollingsworth, and we're going to let her sit  
15 back down.

16 (No response.)

17 DR. HOLLINGSWORTH: Thank you.

18 MR. TYNAN: Thank you, Jill, very much.

19 Our next presenter is Mr. Mike Robach, and  
20 he's the Vice President of Corporate Food Safety and  
21 Regulatory Affairs for Cargill, Incorporated, and  
22 he's responsible for the company's food protection

1 quality assurance, animal health and regulatory  
2 programs. He wanted me to tell you that he's also a  
3 graduate of Michigan State University and Virginia  
4 Tech. So he has some local ties here as well.

5 From 1995 to 2000, he was also a member of  
6 our sister committee, the NACMCF, Microbiological  
7 Criteria for Foods, and with that, I'm going to turn  
8 it over to Mr. Robach.

9 MR. ROBACH: Thank you, Robert. I  
10 appreciate that, and thank you for the invitation to  
11 come and speak with the Committee today. I  
12 appreciate it very much.

13 I'm going to be talking about third-party  
14 audits and certifications in a similar vein as Jill  
15 just did but with a slightly different perspective.  
16 I'm associated with an organization, Cargill, which  
17 operates in 66 countries around the world, and we  
18 produce product that starts out in which we would  
19 call origination, grain, oil seeds, basic  
20 commodities, all the way through finished, consumer-  
21 ready products. So we really see the global supply  
22 chain and I think to answer Jill's question earlier,

1 we're the ones that pay for it. So just to make  
2 that clear.

3 So next slide please.

4 And I'm going to talk a bit about CODEX,  
5 and I'm going to take more of a global perspective.  
6 I think we've heard a lot this morning about imports  
7 and how do we assure the safety of imports.  
8 Dr. Acheson talked about what FDA's approach is.  
9 We've heard what USDA's approach is.

10 And, I can tell you want Cargill's approach  
11 is because we operate in this world every single  
12 day, and we have a standard. We have a corporate  
13 standard, a corporate policy that's followed by all  
14 1,000 plus of our units around the world that have  
15 anything to do with processing food, whether it's  
16 food ingredients, whether it's grain, oil seeds,  
17 sweeteners, texturizers or whether it's meat and  
18 poultry.

19 So we try to keep it very simple and very  
20 straightforward, and as you can see, we have out  
21 there a food code. We have CODEX Alimentarius that  
22 exists today. It's been referenced several times

1 today. Is it the perfect system? No, it's not the  
2 perfect system, but it brings into play a number of  
3 elements that take into account all the stakeholders  
4 in the process, in terms of establishing the  
5 criteria and the standards that we believe are  
6 necessary for the production and distribution of  
7 safe food.

8 Next slide.

9 So the law on food safety is our reference  
10 point. So it's the best tool we think to compare  
11 and commoditize audits. It's a way that we can all  
12 unite and speak the same language as it relates to  
13 food safety, and it's a way that we can resist, as  
14 Jill pointed out, the audit proliferation that's  
15 gone on. I have plants that get audited upwards of  
16 30 times a year against the same criteria by  
17 different people. It's redundant. It's a waste of  
18 time. We spend money on things that don't add value  
19 where we could be spending that time and money on  
20 things that do make a value and continually  
21 improving our processes.

22 Next slide.

1           So really to break this into components, we  
2 also have to understand that we're talking about  
3 three major components in terms of the way we look  
4 at it.     We have our food safety components,  
5 regulatory components and quality components.

6           Next -- there you go.

7           So here you've got food safety clearly, and  
8 I'm going to show you a slide in just a minute, that  
9 kind of breaks down the various schemes that exist  
10 today, and we have looked at that as it relates to  
11 standards around CODEX, and there's a high degree of  
12 agreement among these schemes out there today.   So  
13 we have very little audit differentiation around  
14 food safety using CODEX as our base.   We know what  
15 the country laws are.   So from a regulatory  
16 standpoint, we can be very clear on what's expected.

17           Most of the audit differentiation that you  
18 see out there today are really around quality  
19 systems, and looking at what's expected in the  
20 marketplace.   What does a customer expect?   What did  
21 they want to see?   And those are negotiable things  
22 as opposed to the absolutes around food safety and

1 regulatory compliance.

2 Next slide.

3 So this is an analysis that we did. I  
4 don't expect you to read that. If anybody is  
5 interested in seeing that spreadsheet, let me know.  
6 I can make a copy available to you. So it's out  
7 there but it really lays out the differences between  
8 the various schemes that exist today and the basis  
9 of CODEX.

10 Next slide.

11 So here's a little summary, just to make it  
12 simple. AS you can see, around the 37 criteria of  
13 CODEX, if you look at all these audits and the GFSI  
14 benchmark audits that Jill mentioned, you've got 99  
15 percent agreement. And if you look at other non-  
16 GFSI benchmark audits, although some of them I think  
17 are in the benchmarking process, Jill, is that  
18 correct? You've got 97 percent. So you've got  
19 about 98 percent agreement on these criteria. So  
20 we're not far off. I think when Jill said the food  
21 safety standard piece was the easy piece, she was  
22 absolutely right. We just have to get down to where

1 we agree upon a standard and move forward, and if  
2 you look at some of the other criteria that relate  
3 to quality management, you fall off a bit. You're  
4 about 91 percent.

5           So again, we have I think a good basis for  
6 moving forward in terms of agreement on what those  
7 standards ought to be around the world.

8           Next slide.

9           So right now I think, as Jill mentioned,  
10 you know, you've got a policy out there with CODEX  
11 which is in the public domain, and then we've got  
12 all these different, uniqueness, differentiation,  
13 competition, around whose audit system is best, and  
14 we've just got this mishmash and, you know, these  
15 people will show up at my door, you know, once a  
16 week wanting to do an audit and take three or four  
17 days of my food safety quality manager's time to  
18 take them around the plant.

19           Next slide.

20           So the way we look at this, we need to kind  
21 of take a step backwards and say, look, we've got a  
22 policy out there. We've got a public domain in

1 CODEX. It's stakeholder driven. You've got  
2 governments working within input from the private  
3 sector, from the civil society. So you've got the  
4 people who have stakes in the ground in the area of  
5 food safety working together, and we've got a system  
6 now in place as standards may change, as science may  
7 evolve, we have the ability to make those changes in  
8 the standard.

9           Albeit, I'll admit, CODEX is a little slow.  
10 You know, we probably could look for a way to make  
11 that a little faster, but we have a base system in  
12 place that I think we can leverage and use around  
13 the world.

14           Go back for just a second. Thanks.

15           And we've got our global supply chain and,  
16 you know, we work on that every day. Most of, I  
17 think, Jill's big members do the same thing. We  
18 match up with them very well. Our footprint is  
19 global, Wal-Mart, McDonald's, some of the other  
20 folks, we all match up and we all look at food  
21 safety the same way. It's consistency around what  
22 the elements are for our systems and we've got the

1 consistency across the globe.

2           So then we look at the opportunity to take  
3 auditors and let auditors go through the process  
4 that Jill was talking about in terms of a  
5 accreditation and certification, to be in the  
6 position to audit against those criteria that have  
7 been agreed upon by all the stakeholders.

8           Next slide.

9           And one of the problems we have right now  
10 is that we, you know, talk about transparency but  
11 we've got a lot of confusion when we look at these  
12 different schemes because although you saw there is  
13 99 percent, 98 percent homology in the criteria, the  
14 way we number things and the way we try to  
15 differentiate them gets a little confusing. And we  
16 could really clean that up I believe and make it a  
17 lot simpler, so that we could become transparent to  
18 CODEX and use that as the basis for what we need in  
19 our global supply chain moving forward.

20           Next slide.

21           So when I look at audit equivalency, when I  
22 think about it, I think about promoting that

1 equivalency based upon agreed upon global supply  
2 chain guidance document. So let's put the criteria  
3 together and let's put the guidance together so it's  
4 available to everybody out there to implement as  
5 part of their systems. And then that equivalency  
6 should reduce redundancy, it should reduce costs,  
7 and it would give suppliers a choice of equivalent  
8 audits to choose from, not necessarily a mandate  
9 like you have to use this one. As long as you've  
10 got accredited auditors out there, and you've got a  
11 system of criteria, an audit that everybody has  
12 agreed upon, it really simplifies that entire  
13 process.

14           So we really need a process and a place for  
15 the global supply chain and all the stakeholders to  
16 agree upon that.

17           Next slide.

18           So CODEX-based criteria, you know, in the  
19 meetings that I've been in, the discussions that  
20 we've had, there's general consensus around that  
21 point, that this is a good place for us to start and  
22 from a trade issue, it makes a lot of sense.

1           We've done work with OIE, the world  
2 organization for animal health, on animal health  
3 standards around the world, and there's movement  
4 very nicely in that direction. We've been talking  
5 with FAO and CODEX about the same sort of thing, and  
6 they're in agreement that, yeah, we have an  
7 opportunity to do something like that.

8           So we need all the stakeholders represented  
9 in this process. Industry, and when I talk about  
10 industry, the private sector, talking about  
11 originators, processors, retailers, food service  
12 people, distributors, anybody who is involved in  
13 that global supply chain, need to have a seat at the  
14 table.

15           Government I believe needs to have a seat  
16 at the table. The system that GFSI set up is  
17 evolving very nicely within the industry and there's  
18 great opportunities. But in order to make this  
19 information more powerful and really provide more  
20 value, we need to have the input from government and  
21 from consumers and from inter-governmental agencies.  
22 Because we've got to work on this together. We

1 spend an awful lot of time, spending a lot of money,  
2 doing the same thing over and over.

3           And this is a system that's based on  
4 putting a food safety system in place that addresses  
5 the key criteria. It is an audit, but it's also  
6 verifying that a system is in place. It's not about  
7 inspection, and I think we've all been through this  
8 before. You can't inspect safety into a product.  
9 You can't take enough samples to get where you want  
10 to go. This is really the implementation of a  
11 science-based HACCP system where you take the  
12 principles of good hygiene and a HACCP system and  
13 you make sure that it's in place and that it's been  
14 verified and validated. And that data that then  
15 comes out of that process becomes very transparent.  
16 It becomes available. It holds the importer in this  
17 country responsible for knowing their supply chain  
18 and make sure that they've got their systems in  
19 place that make the products they bring into this  
20 country safe and suitable for consumption.

21           And the way we look at Cargill, it's very  
22 simple. It's wherever we produce it, it's got to be

1 safe for wherever it might be consumed. And with  
2 our supply chains going across countries and  
3 geographies, it's absolutely essential that we have  
4 those kinds of systems in place. It's very, very  
5 difficult now when we're producing product in Brazil  
6 that's being, you know, exported to 27 different  
7 countries, you know, trying to meet all those  
8 requirements and have that altogether. If we had a  
9 system in place, that focused on food safety, and  
10 countries took CODEX and used it as the basis of  
11 their food safety systems and their regulatory  
12 oversight, we would all be in a much better place  
13 from a safety and a consistency standpoint.

14 So international standards and policies  
15 based on sound science. I mean we've heard this  
16 time and time again. We have an opportunity to do  
17 something about it, and to work collectively and  
18 collaboratively on this. We have to have these  
19 strategies in place to insure our supply chain  
20 continuity. We're more and more reliant on food  
21 coming out of other parts of the world into the U.S.  
22 and the U.S., our economy is getting even more

1   reliant on our ability to export product. And so we  
2   always have to remember that whenever we're  
3   considering anything like this. It's a two-way  
4   street, and we can invoke OIE and CODEX when it  
5   meets our domestic needs because sooner or later  
6   we're going to get slapped across the head or even  
7   worse, when we're trying to export product out of  
8   this country. So we have to keep that in mind.

9           It also then gives us opportunities to  
10   share risk management options by having this  
11   transparent system in place and people working  
12   together and sharing information. We can  
13   collectively share best practices and drive change  
14   through the system and get the right criteria and  
15   the right standards in place, and that will give us  
16   some more robust food protection system across the  
17   globe. And above all, it's the opportunity for  
18   transparency, to open up the debate and have the  
19   discussion making sure that we understand what we're  
20   after, and this is all about the safety of the food  
21   supply chain and it's all about public health  
22   outcomes.

1           So     outcome-based     system     orientation,  
2 working collaboratively together so that we can  
3 share this information. Government has to have a  
4 seat at the table. They have to cover the oversight.  
5 We all understand that. But let's not set up two  
6 parallel systems. Let's work together and put the  
7 right system in place around the world. Thank you.

8           MR. TYNAN: Thank you, Mr. Robach. If I  
9 could ask you to stay there at the podium for just a  
10 moment. Let's see if the Committee has any  
11 questions for Mr. Robach. Mr. Elfering.

12           MR. ELFERING: Yes, this is Kevin Elfering.  
13 In my experience, there's a lot of these auditing  
14 groups, and some of them are really good at some  
15 aspects of an audit and some, you know, I just  
16 remember one that focused almost strictly on  
17 warehousing and really didn't look at all at the  
18 process itself, look how the product was stored  
19 after it was manufactured. I've also dealt a lot  
20 with some of these real small auditing groups, like  
21 for organic certification, and there are some that  
22 are very credible but there are some that are quite

1 frankly in it to make money. How do you as a  
2 company, how do you sort through all of these things  
3 to actually determine whether or not an auditing  
4 organization is really meeting all of the criteria  
5 especially related to food safety?

6 MR. ROBACH: Well, you know, for us and  
7 we're probably a little unique in this, in that we  
8 have our own internal policy and procedures set up  
9 that's based on CODEX. So we do our ongoing audits  
10 against those criteria. So to have a GFSI audit  
11 come into one of my facilities, you know, I don't  
12 really care because I know that I'm going to meet  
13 the standard because that's what we do day in and  
14 day out. Now, you talked about special  
15 certifications like Halal or kosher or organic. You  
16 know, there, you know, we have to work with our end  
17 customer in determining who they believe is the  
18 right person to do that job. So I separate that  
19 from food safety. So there, you know, that to me,  
20 that's more one of those quality issues that I  
21 talked about. So that is something that is, you  
22 know, the customer says, gee, I really want this,

1 and this is the people that buy my product, this is  
2 what they want to see. Well, okay, fine then. You  
3 know, we'll go through that process.

4 But for food safety, I have a different  
5 viewpoint in terms of, you know, knowing what are  
6 the right criteria. That is something that I think  
7 we need to do collaboratively. I don't want  
8 processors saying what that is. I don't want  
9 retailers saying what that is. I don't want  
10 Caroline saying what that is. You know, I think  
11 that's something that we need to do together.

12 MR. TYNAN: I have to remember to turn my  
13 own microphone one. Mr. Corbo.

14 MR. CORBO: Tony Corbo, Food and Water  
15 Watch. What's the role of the government, of the  
16 government inspection program in this? You know,  
17 how frequent would there be verification processes?  
18 Is it a paper review? Is it an on site?

19 Our organization has a philosophical  
20 problem with turning over food safety functions to a  
21 private entity. Can you explain exactly what role  
22 the government will play in this?

1 MR. ROBACH: Sure.

2 MR. CORBO: And then as a follow up, I  
3 wanted to talk about a recent case here locally with  
4 one of these organic certifiers who really fell down  
5 on the job. So if you can answer the first  
6 question.

7 MR. ROBACH: Yeah, I mean, you know, my  
8 feeling about government is government has an  
9 oversight role to play here. And I think this is  
10 something that we have to do collaboratively, not  
11 just with the United States Government but with  
12 other national governments. They have to be on  
13 board with this. I mean they send representatives  
14 to CODEX.

15 So there has to be a role the government  
16 plays as part of this overall certification process.  
17 I'm not saying that the government needs to certify  
18 but they need to be involved and comfortable with  
19 the system in place, and they always have that  
20 oversight responsibility and the authority that if  
21 they don't feel comfortable with something, they can  
22 go in and take a look at it.

1           But I don't think it's responsible to think  
2 that the FDA and the USDA are going to set up  
3 inspection forces in the countries that import food  
4 into this country, nor would I like to see the  
5 Japanese or the Europeans or the South Americans, or  
6 anybody else, do the same thing in this country.  
7 And we have to be careful that we -- if we can focus  
8 on the standards and the criteria and the systems  
9 collectively, I think we're in a much better place  
10 than if we're trying to rely on government  
11 inspectors to do the actual inspection because we're  
12 going to get into this tit for tat and we're going  
13 to continue to have the escalating trade issues that  
14 we've had that have nothing to do with the safety of  
15 the food and have everything to do with politics.  
16 So --

17           MR. CORBO: Yeah, the example I wanted to  
18 bring up local, it involved Whole Foods again. They  
19 were importing ginger from China. A local  
20 television station here did their own testing of the  
21 ginger. Not only were there pesticides on the  
22 ginger, it was an illegal pesticide to begin with to

1 use on ginger, and so here's a fairly reputable, you  
2 know, company that was relying on a third-party  
3 certification process and they got nailed.

4 MR. ROBACH: Sure. And I think that gets  
5 back to the idea of the accreditation and the  
6 certification, and you've got to have transparent  
7 standards and processes in place to assure that.  
8 And there is a role for government, no doubt about  
9 it.

10 MR. TYNAN: Last call for questions for  
11 Mr. Robach.

12 (No response.)

13 MR. TYNAN: Thank you, Michael, very much.

14 I'm going to introduce the next speaker  
15 that's going to talk a little bit about a consumer  
16 perspective, and Ms. Caroline Smith DeWaal. She's  
17 the Director of the Food Safety Program for the  
18 Center for Science in the Public Interest, and she's  
19 a co-author of the book, Is Our Food Safe?, a  
20 consumer guide to protecting your health and the  
21 evaluation. She represents CSPI in Congress and in  
22 the regulatory arena on a broad range of food safety

1 issues, including meat and poultry safety, seafood  
2 safety, food additives, pesticides and sustainable  
3 agriculture and animal drug. That's quite a  
4 portfolio.

5 So I'm going to let Ms. DeWaal do her  
6 presentation. Thank you.

7 MS. SMITH DeWAAL: Thank you very much, and  
8 good afternoon, everyone.

9 First, I really do want to thank you, FDA  
10 and FSIS, for getting us all together to talk on  
11 this important topic. A lot is happening on the  
12 issue of imports, and we'll go through that. A lot  
13 of it's happening actually with FDA-regulated  
14 product. But it really is impacting where consumers  
15 sit on this issue.

16 I do just want to note that they gave me  
17 the topic, insuring safe food in a global  
18 marketplace, and some day I really want to talk on  
19 that topic, but today I'm going to give you guys a  
20 little bit of a reality check.

21 MR. TYNAN: We'll bring you back.

22 MS. SMITH DeWAAL: We're going to do a

1 little bit of a reality check here because I've  
2 heard Mike's presentation and Jill's presentation  
3 which were both excellent and very forward thinking.  
4 I know we're going to hear from Australia, New  
5 Zealand and we've heard from the EU and probably  
6 from Canada, also with very forward thinking ideas.

7 Well, we represent over 900,000 consumers  
8 in both the U.S. and Canada, and they're not happy  
9 with the safety of their food right now.

10 You can go ahead. I'm going to skip  
11 through a -- this slide I'll stay with, no, go  
12 ahead.

13 Bottom line for U.S. consumers is we eat a  
14 lot of imported food. We have seen huge increases  
15 in agricultural and seafood imports in the last 10  
16 years. We do appreciate that there are two separate  
17 regulatory systems operating, and the one at USDA,  
18 we've actually highlighted in testimony to Congress  
19 as being much better than the one that's operating  
20 at FDA. You can go ahead and go ahead.

21 Okay. So here are a list of some of the  
22 reasons why consumers are a little nervous right

1 now. I'm going to show you in a minute some opinion  
2 polling we did back in July, but the bottom line is  
3 the consumer confidence in imported product is very  
4 low right now and it's because they are hearing that  
5 they have to worry about products they've actually  
6 sometimes already purchased.

7           We have had outbreaks or public warnings on  
8 jalapeno peppers, serrano peppers, tomatoes.  
9 Mexican green onions was the big one but also  
10 cantaloupe this year has caused another outbreak as  
11 well. The pet food outbreak, I can tell you that  
12 people lived through the spinach outbreak and recall  
13 back in 2006 quite successfully, but when it came to  
14 melamine showing up in pet food, I started to hear  
15 about it from people on the street, you know, people  
16 would approach me and say what are you doing about  
17 the food supply? I mean it really impacted people  
18 that an ingredient showed up in pet food that was  
19 causing illness, and I think it really ticked a  
20 nerve in a way and made people aware that we're  
21 getting so many ingredients from other countries and  
22 the controls are not there within our national

1 regulatory system.

2 Fish, there have been long term problems  
3 with seafood, but last year, of course, a bunch of  
4 them were put on import alerts.

5 You can go ahead.

6 Okay. So the survey I'm about to show you  
7 was given to 6,000 consumers. It's an Internet  
8 survey and if we decide we're interested enough,  
9 we'll go ahead and do it as a standardized telephone  
10 survey, but what we did find is we got about a 10  
11 percent response rate which is actually quite good.

12 So what did the consumers tell us? They  
13 said that their concern is very high, and I'm going  
14 to show you in a minute these actual results, but I  
15 do want to focus for a minute on what they said were  
16 their top concerns which always surprises me, was  
17 unsafe pesticides with pathogens and bacteria coming  
18 in as a second level concern.

19 One of the things to look at is the last  
20 number in this column which is what they ranked  
21 least. Antibiotics and animal drugs also actually  
22 showed up as something of concern, and this concept

1 of unsanitary conditions.

2           So the bottom line is that consumers have a  
3 generalized concern. They don't always know what  
4 the biggest risk is to them because I would not rank  
5 unsafe pesticides as the top risk coming in on  
6 imported product, but at the same time, they have a  
7 lot of generalized concerns which are pretty high.

8           You can go ahead.

9           Okay. So here is the actual survey results  
10 and the top question deals with domestically  
11 produced food. And we had, you know, either a very  
12 concerned or somewhat concerned response among about  
13 95 percent of the respondents, with 51 percent  
14 indicating that for domestic food, they are very  
15 concerned.

16           When we shift down to imports, the very  
17 concerned number goes up almost 30 percent. And the  
18 not at all concerned number is less than 1 percent.

19           So again people are indicating very strong  
20 levels of concern here.

21           You can go ahead.

22           So what are they concerned about? Well,

1 produce, of course, tops the charts. Now, this  
2 survey was done right at the time when we had a  
3 several month outbreak going on from *Salmonella*  
4 Saintpaul. We do hope it's stopping now, but it's  
5 been going on for a long time and it took FDA a long  
6 time to identify the product. The products were  
7 ultimately imported, or at least from what we can  
8 tell right now, they appear to have been imported.

9           But meat and poultry also is showing about  
10 a 21 percent ranking, and overall the rankings over  
11 on this side, try to give us some gradation of where  
12 their concern level is. Bottom line is red meat and  
13 poultry and seafood are all pretty much the same.  
14 There are high levels of concern but not at the  
15 level of produce.

16           Okay. Here are the countries that we  
17 tested. Of course, China shows the highest levels.  
18 Mexico is second but significantly lower, and then  
19 our principal trading partners, Australia and Canada  
20 have even lower levels and again our rating averages  
21 are shown in that column there but pretty much, you  
22 know, we would -- these are findings that we would

1 expect to find and, in fact, our testing, other  
2 surveys that have been done as well, I'll show them  
3 in a minute.

4           Okay. And what did people say in the  
5 survey? Because we always give them the opportunity  
6 to tell us what they're thinking. People expressed  
7 the fact that there need to be more food inspectors  
8 at all levels of government, and their principal  
9 concerns were on food imported from China,  
10 bioterrorism, safe handling in markets, restaurants  
11 and homes, which is another issue of concern to  
12 CSPI, and the conditions of where food is  
13 manufactured.

14           So how does this fit into other surveys  
15 also that we're looking at? The leafy green  
16 marketing survey which is really testing the issue  
17 of how to improve the safety of produce which has  
18 been a major food safety problem in our country for  
19 a number of years now, in that survey they found  
20 that 89 percent of consumers favor a mandatory food  
21 safety program featuring government inspections, and  
22 that 60 percent believe food safety should employ

1 government oversight and mandatory government  
2 inspections, rather than private auditing companies.

3           Again, this is the reality check on what  
4 we're talking about because I mean most of my job  
5 frankly is in the area of risk communication, and so  
6 when it comes to translating what these concepts are  
7 into the public, we need to know what the public is  
8 thinking right now.

9           And this is further evidence back from 2007  
10 of the level of concern both about food safety  
11 generally and also about imported foods. The China  
12 and Mexico results show up also in the USA Today  
13 survey done in 2007.

14           Okay. I want to shift over to one of my  
15 favorite topics of the moment which is the issue of  
16 traceability. Our survey, this is back to the CSPI  
17 survey showed that 93 percent of consumers supported  
18 COOL or country of origin labeling. COOL was  
19 adopted first probably five years ago or more. It  
20 was then delayed except for seafood products but  
21 finally the country of origin labeling requirements  
22 are going into place for most food products next

1 month in September.

2           And 80 percent, this is where my real  
3 interest is because I don't see COOL as a food  
4 safety measure, but 80 percent support more detailed  
5 labeling that would actually show the region,  
6 country, state and farm of origin. Now, this is  
7 forward thinking as well, but it's actually being  
8 done in a lot of companies. I bet Cargill knows  
9 where most of its ingredients come from. I've been  
10 to a veal packing plant in the Netherlands, a year  
11 ago, where they showed me, I mean you could pick the  
12 cow off the floor of the plant and they would go  
13 back and show me where the cow was raised, that that  
14 particular label that was attached to the meat,  
15 where the animal was raised, but more importantly,  
16 they could also show me that for products, they can  
17 trace them forward as well to the actual retailers.  
18 So we know that companies today can develop tracing  
19 systems that are very extensive and in some places  
20 they're using them because they need them to protect  
21 their own reputation.

22           And we have been calling on the federal

1 agencies to implement tracing systems starting with  
2 animal identification programs that we've seen  
3 functioning in New Zealand quite effectively and yet  
4 are not in use here at all.

5           So I'm going to shift over to the second  
6 hurdle. The first hurdle that I outlined in my  
7 presentation is the one of consumer confidence, and  
8 how do we communicate with the public about imports  
9 and about the safety of imports when they have a  
10 very high degree of trust in the government programs  
11 over any other types of programs.

12           The second hurdle for FSIS making any  
13 changes, if you were even thinking of making  
14 changes, has to do with our own statutory  
15 requirements.

16           Now, our Meat Inspection Act was drafted in  
17 1906, and I'm sure they have very good lawyers back  
18 then but would they require first of all the  
19 postmortem examination and inspection of all  
20 carcasses, I mean in all these requirements, they're  
21 very clear that all the requirements need to apply  
22 both to our domestic products but also to our

1 imports. So all is a very important word, and we  
2 have to remember that as we think about -- I was  
3 interested to hear the presentations by USDA  
4 focusing on the SPS Agreement because the SPS  
5 Agreement is important but the controlling authority  
6 for this Agency is this law right here.

7           You can go to the next one, which is the  
8 other controlling authority which is the Poultry  
9 Products Inspection Act. While the language is a  
10 little, and I don't have the best language under the  
11 Import section, the language is a little more modern  
12 because the law was passed in the 1950s. The bottom  
13 line is that all the regulations that apply to the  
14 domestic poultry industry have to apply to imports,  
15 and if you go to the next slide.

16           This slide is another cautionary note where  
17 USDA has attempted to implement a system where USDA  
18 inspectors did not look at every single chicken.  
19 They were on the line but then occasionally the USDA  
20 inspectors would leave the line to go do some  
21 sampling of poultry products. This program was  
22 challenged by a labor union and the Courts came back

1 and said both statutes clearly contemplate that when  
2 inspections are done, it will be federal inspectors  
3 rather than private employees, who will make the  
4 critical determination whether a product is  
5 adulterated or unadulterated. Delegating the task  
6 of inspecting carcasses to plant employees violates  
7 the clear mandates of the Federal Meat Inspection  
8 Act and the Poultry Products Inspection Act.

9           So again, just a cautionary note that the  
10 controlling authority here is quite clear, and  
11 whether we agree with it, whether we don't agree  
12 with it, whether we think that the law should be  
13 modernized which is something I've spent a lot of  
14 time on, it doesn't matter because this is what FSIS  
15 is responsible for today.

16           So I also just want to bring to your  
17 attention, and I think Tony's raised this before,  
18 but CSPI did a series of reviews of USDA audits, and  
19 we found that there are a number of countries that  
20 had failed USDA audits but no action was taken. So  
21 the audits are important but they also need to be  
22 enforced.

1           And we raised questions at the time, and  
2 this work was done probably in the early 2000s, but  
3 we raised questions about whether USDA really is  
4 challenged by the two hats that the Secretary of  
5 Agriculture clearly wears here, where the Secretary  
6 is responsible for promoting our products and we've  
7 seen a lot of that under a few of the Secretaries  
8 lately, traveling all over the world to promote our  
9 meat products and come buy our meat products when,  
10 in fact, they also have the responsibility for  
11 insuring the safety. And sometimes it may get in  
12 the way, this job of promoting our agricultural  
13 products and also insuring the safety both of  
14 domestic and imported products. But Dr. Raymond  
15 might disagree with me on that I suspect.

16           DR. RAYMOND: You guessed right.

17           MS. SMITH DeWAAL: I thought so. We've  
18 debated this a number of times over the last few  
19 years.

20           So I want to get to some general  
21 observations because I think I've given you, I told  
22 Tony this was going to be my kitchen sink

1 presentation. I've given you a lot of food for  
2 thought, and really outlined what I consider the key  
3 hurdles to a modernized system, but a few  
4 observations I want to make is simply that the U.S.  
5 laws are antiquated, they're out of date. They're  
6 not serving consumers well. And we have examples, I  
7 mean there are many studies and this is just the  
8 latest showing that the U.S. is truly falling behind  
9 other countries in implementing food safety systems  
10 that are credible and that have support. So that's  
11 one point.

12           You can go to the next slide.

13           The second point is that we're also buying  
14 products in many cases from countries and regions of  
15 the world that may have food safety systems that  
16 are, in fact, not as trustworthy as ours. And this,  
17 this really applies very much to FDA regulated  
18 product. I think you USDA's system is much better  
19 in terms of ensuring that the countries that ship  
20 meat or poultry products to the U.S. do meet the  
21 standards that are expected by our consumers. But  
22 we really have to look, as we're embracing this

1 global marketplace. What does equivalence mean?  
2 And when we're talking about equivalence, are we, in  
3 fact, speaking the same language? When we use the  
4 word audit, how exactly does that translate?

5           And really can we rely on these global  
6 supply chains in the absence of adequate government  
7 oversight? And it's both, in the U.S. where we have  
8 many examples of the absence of effective government  
9 oversight but also in the countries of origin. So  
10 CSPI has been some work with NGOs, non-governmental  
11 organizations, in developing countries because we  
12 want to bootstrap up the systems in those countries  
13 because it's critically important for our consumers  
14 who are often buying and eating products from those  
15 regions.

16           So I spend a lot of time talking about a  
17 modernized food system, but I want to leave you with  
18 two thoughts, and one is that as we're looking  
19 across what it's going to take to really modernize  
20 food safety, one of the key issues is traceability.  
21 We have a wonderful new system, not exactly new, but  
22 the PulseNet system is just creating scads of fun

1 for our epidemiologists because it's actually  
2 matching up incidents of illness with products, but  
3 it far exceeds our ability to actually trace those  
4 products back to the source, and we saw an extremely  
5 good example of that this summer with the tomato,  
6 then serrano pepper recalls and outbreaks and public  
7 warnings, and you name it, it became very hard to  
8 actually get consumers to listen to what we were  
9 saying because of the messages and the lack of  
10 traceability caused so many problems.

11 But the second thing is the effective audit  
12 systems. I am actually a believer that I would like  
13 someone looking over the shoulder of whoever is  
14 inspecting the food. And I want someone looking  
15 over the shoulder of our government officials. So I  
16 think these layers and I think Jill had a very good  
17 slide on, you know, the consistency of peer review  
18 at the top levels, but then allowing these levels of  
19 audit and checking to proceed. I think those could  
20 be effective but I think the government needs to be  
21 very actively involved in these systems. The  
22 standards need to be much more uniform than they are

1 today and we need to be able to trust. We need  
2 credibility in these systems that we don't have  
3 today. Thank you.

4 MR. TYNAN: I think Dr. Raymond wants to  
5 speak first.

6 DR. RAYMOND: Caroline, as always, we agree  
7 on a lot more things than we disagree on, but as  
8 always, we do disagree, and I'm not going to be  
9 lengthy at all because the Committee is more  
10 important than I today, but we do have media in the  
11 room. So there's a couple of points I would like to  
12 make.

13 In my opening comments, I tried to, you  
14 know, separate the USDA product from the FDA product  
15 and a lot of your talk as you readily admitted went  
16 to FDA product. So I'm hoping that people won't  
17 confuse those two as we try to look at the  
18 equivalency for the USDA's method of inspection.

19 I have a question, on the countries, the  
20 levels of concern, the five countries, including the  
21 EU as a country, that your people you polled, were  
22 those the five countries offered to them or were

1 they just asked to respond to what countries were of  
2 greatest concern?

3 MS. SMITH DeWAAL: They were offered.

4 DR. RAYMOND: The five were offered?

5 MS. SMITH DeWAAL: Yes.

6 DR. RAYMOND: The point I want to make on  
7 that then is that Canada and Australia combined  
8 account for 67 percent of our meat and poultry  
9 imports into this country, and 4 people out of your  
10 pool of over 600 said they were concerned about  
11 Canada and Australia. New Zealand, if you add New  
12 Zealand, you're up to 78 percent and you didn't even  
13 put that as one of your countries of concern because  
14 evidently you have 0 concern. So China had 75  
15 percent of the pollees, the people that were polled,  
16 75 percent said China's a great concern and just so  
17 the media knows, we don't import any meat or poultry  
18 from China. So that's why I point this out, to  
19 emphasize that the countries that we are importing  
20 from, the people you polled, really don't have a  
21 great level of concern about the product coming in,  
22 and I think that's borne out by the facts that in

1 the three and a half years I've been here, we've  
2 only had one incident that I can think of where we  
3 had an outbreak linked to an imported meat or  
4 poultry product into this country, and I think  
5 that's partly because of the system we use.

6           The second thing, and you knew because this  
7 is when you said Raymond won't necessarily agree  
8 with me, the slide says does USDA put foreign trade  
9 ahead of public health? I adamantly say no, not  
10 since I've been here. In the little over three and  
11 a half years, we have had three countries that have  
12 stopped exporting meat or poultry products. That's  
13 3 out of 29. That's 10 percent have been told you  
14 cannot export meat or poultry products to this  
15 country until you clean your act up, and I would say  
16 that's putting public health above trade. Thank  
17 you.

18           MS. SMITH DeWAAL: Thank you, Dr. Raymond.  
19 If I could just remind you of at least a proposal  
20 from USDA that we ship chickens, I never quite  
21 understood this, we were shipping chickens from the  
22 U.S. to China, processing them in China, and sending

1 them back, which I think one of your favorite  
2 members of Congress actually --

3 DR. RAYMOND: No, we weren't. We passed a  
4 rule that would allow it but not one chicken ever  
5 went from the United States to China to be further  
6 processed and back. So there is a rule on the books  
7 that would allow it. There's also a law that will  
8 not allow us to move forward with importing cooked  
9 chicken from China, and 100,000 people in Korea  
10 protested beef going to South Korea. I mean I'm  
11 thinking that sometimes laws, rules and protests are  
12 not based on science and common sense.

13 MS. SMITH DeWAAL: I just -- did that rule  
14 make sense to you because it certainly didn't make  
15 sense to us, and I might question whether there  
16 might have been a political motivation for even  
17 having a rule like that on the books.

18 DR. RAYMOND: From a food safety  
19 standpoint, it made great sense to raise that  
20 chicken in the United States, slaughter it here  
21 under federal inspection, ship it over to China to  
22 be cooked and further processed and back here, but

1 from an economical standpoint, no, but from a public  
2 health standpoint, yeah.

3 MR. TYNAN: I'm going to expand the  
4 dialogue now, and allow some of our other Committee  
5 members to perhaps weigh in. Are there any  
6 questions for Caroline at this point? Mr. Corbo.

7 MR. CORBO: Tony Corbo, Food and Water  
8 Watch. I'm not going to get into the Chinese  
9 chicken issue. That's one of my favorite ones but,  
10 Caroline, you've done an awful lot of work on the  
11 issue of traceability and, you know, we've attempted  
12 to have a national animal ID system. It's got  
13 bolloxed up over here. I know early on one of the  
14 controversies was as to who was going to control the  
15 data. Have you given any thought in terms of at  
16 least the FDA side of the equation, how a  
17 traceability system should be implemented, who would  
18 control the data?

19 MS. SMITH DeWAAL: First of all, with  
20 respect to traceability, the animal ID systems here,  
21 I think it's absolutely inexcusable that such a  
22 modern country and one that relies on exports and

1 wants to promote its exports can't seem to implement  
2 animal identification in this country. It's a  
3 critical issue.

4           The issue of FDA regulated products, the  
5 fruit and vegetable people told us it couldn't be  
6 done. There are individual apples. How could you  
7 label them all? But we went shopping and we  
8 actually went to the National Press Club with our  
9 bags of groceries and showed them what we found.  
10 Hundreds and hundreds of different fruits and  
11 vegetables already carry little stickers. I mean,  
12 you know, the ones you have to peel off, and they're  
13 really irritating. Well, in fact, those stickers  
14 are big enough to actually carry computer sized IDs.  
15 The way to do an ID would be a standardized number.  
16 I've heard that you could have a 19 digit number or  
17 20 digit number that might be necessary to get the  
18 level of detail you need. But, in fact, those  
19 numbers can be put on very small, just tags. I mean  
20 they're computer read tags, and it's quite doable  
21 today.

22           We're not talking about RFID requirements

1 on your product or even on your cattle for that  
2 matter, but the technology exists using computerized  
3 systems to do this tracking, and it can exist in the  
4 U.S.

5           The animal ID system in part fell apart  
6 here because there was this issue. The National  
7 Cattlemen's Beef Association was going to somehow  
8 manage all the information, and I mean the  
9 government needs to play a critical role because at  
10 the end of the day, the government's access to this  
11 information is what's going to count when we're  
12 having an outbreak.

13           With FDA, I believe that FDA could develop  
14 a system through their registration system of ID  
15 numbers and requiring those ID numbers to carry  
16 using some computerized technology to do that. And  
17 so it really doesn't actually require a lot more  
18 than what we have in place today, but it does  
19 require smart use of that registration system.

20           Stan, I answered all your questions?

21           MR. PAINTER: Stan Painter with the  
22 National Joint Council. I thought when Tony had

1 touched on the traceability issue, and I noticed the  
2 Agency bragged a number of years ago that, you know,  
3 we have everything at our fingertips, meaning, you  
4 know, the computer and then it took them eight  
5 months to figure out where things when we got into a  
6 SRM issue. Either it was one of the two things.  
7 The Agency didn't have what they thought they had or  
8 if they had it, they couldn't find it. And I'm of  
9 the opinion, Dr. Raymond touched on something about,  
10 you know, Chinese and what have you and, you know,  
11 when you see them on TV and they're pouring yellow  
12 paint to make medication that's coming to the United  
13 States and when you can't even feed your dog, you  
14 know, that's certainly something that we should be  
15 concerned about. I'm of the opinion the United  
16 States should start a FPAK, and we would be food  
17 producing and exporting countries and trade a loaf  
18 of bread for a barrel of oil.

19 MS. SMITH DeWAAL: Thanks.

20 MR. TYNAN: Thank you, Mr. Painter. If we  
21 have no other questions for Caroline, while we're at  
22 sit down, I'm also going to suggest in the interest

1 of our posteriors, that we take maybe a short break,  
2 10 minutes. I think the cafeteria will still allow  
3 for some drinks and things of that nature, but if  
4 you could be back by 25 after, so that we can finish  
5 up our presentations.

6 (Off the record.)

7 (On the record.)

8 MR. TYNAN: Can I ask everybody to take  
9 their seats please. I'm going to ask Dr. Raymond to  
10 issue me a cattle prod later on.

11 Welcome back, and I appreciate all of your  
12 patience and your flexibility to work with us as far  
13 as the agenda is concerned. We've kind of made some  
14 detours but I think we're still tracking well  
15 together. I think the last portion of the agenda  
16 before we get into the Subcommittee session is  
17 addressing international issues, and Dr. Maier  
18 presented the EU presentation a little bit earlier.  
19 So what I'd like to do is come back to the  
20 international issue and introduce to you Dr. Mark  
21 Schipp.

22 Dr. Schipp has been the General Manager of

1 the Animal Products Market Access Branch for the  
2 last year. Prior to this, he was Australia's  
3 agriculture representative in Beijing, and I guess  
4 in Seoul, Korea, between 2000 and 2006. He's a  
5 veterinarian and has worked in the field as a field  
6 veterinary officer for the Western Australian  
7 Government for a number of years before joining the  
8 Australian Quarantine and Inspection Service where  
9 he worked as an on plant veterinary officer at  
10 export meat establishments in Western Australia,  
11 Victoria and Tasmania.

12 And so with that, I'm going to ask  
13 Dr. Schipp to come on up and talk a little bit about  
14 the Australian program and the Australian  
15 perspective.

16 DR. SCHIPP: Thank you very much. I admire  
17 the stamina of the Committee. It's quite admirable.  
18 How are we going for time here? What's the --

19 MR. TYNAN: We have a half an hour set  
20 aside for you.

21 DR. SCHIPP: I'll try not to take that  
22 long. It's just after half past 5:00 tomorrow

1 morning for me. So I invite the Chair to cut me off  
2 if I'm rambling or incoherent. Firstly, apologies  
3 for my Executive Manager, Mr. Greg Reed. He very  
4 much wanted to be here but he had some surgery and  
5 is unable to join us as Chair of the CCFICS  
6 Committee. Greg has enormous experience and  
7 interest in this issue, and particularly the future  
8 direction of the application of the concept of  
9 equivalence and so he regrets not being with you  
10 today. Thank you.

11 In this presentation, I've been asked to  
12 reflect on Australia's international experience with  
13 equivalence. I would like to put to you that our  
14 experience in our respective domestic sectors must  
15 color and inform our consideration of equivalence.

16 In preparation for this presentation, I  
17 read the Interagency Working Group papers on import  
18 safety and they were very informative. And as a  
19 consequence, I'd like to relate to you our approach  
20 on import food safety and then to share some  
21 thoughts on the future directions in equivalence.

22 So then the question for me is how does our

1 experience and your experience shape the way that we  
2 approach equivalence and imported food safety?

3           We have experience at a number of levels  
4 but perhaps what we have experienced is not  
5 equivalence at all. What is equivalence? Perhaps  
6 it is nothing more than achieving great outcomes by  
7 different methods, and we've heard a few definitions  
8 today. And if indeed this is a rough definition,  
9 that is acceptable, then really it is an everyday  
10 concept and not something that is new or foreign.  
11 But the difficulty and the challenge is agreeing on  
12 an outcome and being able to measure it.

13           My next slide if we can. My mistake.  
14 Thank you.

15           I'd like to provide some quick examples  
16 that might serve to illustrate our experience in  
17 Australia. Anyone regulating food establishments  
18 will quickly recognize that no two establishments  
19 want to do things the same way. Indeed the same  
20 establishment will try and do things different every  
21 single day and there's no guarantee that you'll see  
22 the same operation done the same way ever again.

1 But does this mean that we need to carry out an  
2 equivalence determination on a daily basis? Of  
3 course, it does not.

4 An example for us, in Australia, is that of  
5 water. Water has become a major constraint in  
6 Australia. As a consequence, many establishments  
7 have been asked to conserve water, to meet new  
8 targets or to go out of business. New water  
9 conservation technologies and methods need an  
10 equivalence determination, a formal approval  
11 process. Sometimes they do but what about other  
12 technologies? What about different dressing  
13 techniques? Usually we don't go through a formal  
14 equivalence process for those but for laboratory  
15 techniques we do. If we wanted to use water at less  
16 than 82 degrees Celsius, I'm not sure about the  
17 Fahrenheit translation of that, but again we would  
18 probably have to go through an approval or an  
19 equivalence process and demonstrate that we can meet  
20 an equivalent outcome.

21 So a fundamental question is at what point  
22 is an approval or an equivalence determination

1 needed?

2           Another example for our experience is that  
3 in Australia we operate a dairy system to a set of  
4 agreed national outcomes but we in AQIS do not  
5 directly regulate that system. It's done by 6  
6 states and thankfully only 6, not having to deal  
7 with 50 states.

8           But how do we determine that the outcomes  
9 met by those six individuals states are to the same  
10 standard? Well, naturally we have a committee that  
11 ensures that there is a nationally consistent  
12 implementation, and I have to say it is a challenge.  
13 In every state, there are different agencies and  
14 different structures, different legislation and  
15 different priorities, but the outcome is important.

16           It matters both for exports and  
17 domestically. For imports, for example, some of our  
18 states would like to use third-party auditors to  
19 carry out that work, but such an outcome would not  
20 be acceptable to a number of importing countries,  
21 notably the EU. And it matters also for imports,  
22 you know, the state that has the poorest

1 implementation of those standards would become the  
2 benchmark for our imports. Under the SPS Agreement,  
3 you cannot impose a higher standard on imports than  
4 domestically, and it would also become the baseline  
5 for exports.

6 Any country willing to accept produce to  
7 the national standard would look at the poorest  
8 performing state and make that the basis of the  
9 decision.

10 At the same time, we would dearly love to  
11 have our national or our domestic standard accepted  
12 as the basis for exports. We export to over 130  
13 countries, and running separate programs for dozens  
14 of countries is expensive, exhausting, and I would  
15 argue restrictive.

16 The concept of equivalence should determine  
17 or should deliver that recognition but the reality  
18 is that it does not. Wolf Maier from the EU spoke  
19 about some of those constraints. And our experience  
20 is that preparing and arguing submissions for every  
21 procedure, every laboratory technique, every  
22 sanitary measure is unproductive.

1 I'm back at slide 7, sorry. There we are.

2 I would like to speak briefly about the  
3 Australian Imported Food Inspection Scheme, and ask  
4 the question, do we need equivalence? The  
5 Australian Imported Food Inspection Scheme does not  
6 require or use equivalence as an entry criteria.  
7 Provided a food meets the quarantine requirements,  
8 it can be imported and at the border will be  
9 inspected against the Food Standards Code.

10 Slide 8. And the way that we conduct that  
11 inspection is that food is inspected according to  
12 risk. Risk assessment and risk management are  
13 separated. The risk is determined by the Food  
14 Standards Authority, and risk foods receive 100  
15 percent referral for inspection and then a step down  
16 to 25 percent after 5 passes, down to 5 percent  
17 after 20 passes, and any failure pushes them back to  
18 100 percent referral. All other foods are referred  
19 at a rate of 5 percent and are deemed to be random  
20 foods.

21 Last year we conducted about 23,000 tests.  
22 About half of those, 48 percent, were for microbial

1 hazards, 27 percent chemical tests, 23 percent for  
2 contaminants and additives are about 2 percent. Any  
3 analytical failure, that is failure against those  
4 products that are mentioned, is recorded against the  
5 manufacturer and the country and the food. So the  
6 combination of manufacturer, country and food is  
7 combined and are recorded against that combination,  
8 whereas the labeling failure, and most of the  
9 failures are indeed label failures, are applied to  
10 the Australian importer and can be corrected at the  
11 border.

12           It is also interesting to note that our  
13 imported food program is 100 percent cost recovered,  
14 and all the costs, including laboratory costs, are  
15 met by the importer.

16           There has been quite a deal of talk about  
17 the CODEX standards, and the current CODEX standards  
18 provide for equivalence of measures but we are  
19 convinced that there is a need to move beyond  
20 equivalence of measures to assess the outcomes of  
21 systems and to consider equivalence of systems. But  
22 there is difficulty attached to that. It's very

1 difficult to measure and to understand what a  
2 systems outcome looks like.

3           If we look at equivalence of systems, and  
4 I'm talking about inspection and certification  
5 systems here, equivalence at that level will  
6 ultimately provide the most useful tool in  
7 progressing trade between countries.

8           AQIS sees this progressing through  
9 development of an international standard. There  
10 would need to be an agreement on how to objectively  
11 measure such a system and its performance, and we  
12 think it would be most productive to move the focus  
13 from prescription and detail to a set of agreed  
14 outcomes.

15           In Australia, we've commenced a trial of  
16 objective performance measurement across 19 meat  
17 processors, and this allows tracking of performance  
18 and ranking of establishments. Collectively, these  
19 indicators may be taken to define the performance of  
20 the inspection and certification system as a whole.

21           The trial is only in its early stages and  
22 once validated, we plan to roll it out across all of

1 our meat establishments. We will also be seeking to  
2 apply it to our dairy industry. Indeed they have  
3 come to us asking to participate in the trial.

4           But what are the benefits of the model?  
5 Firstly, we can use the tool to manage plant  
6 performance. We can allocate inspection resources  
7 according to risk and performance so that inspectors  
8 could be moved to poor performing establishments  
9 from those where we are frankly superfluous. We can  
10 also use this tool to measure the performance of our  
11 system as a whole, and this gives us our link into  
12 equivalency.

13           If Australia were to run this system across  
14 all of the plants that are registered to export to  
15 the U.S., and we have about 50 of those, and  
16 compared those trial outcomes with a sample of  
17 plants here in the U.S., then possibly we'd be in a  
18 position to assess the relative performance of those  
19 two systems and to confirm that we are indeed  
20 performing at a level which is consistent with U.S.  
21 expectations.

22           Ideally then, we would seek, if in the

1 future we decided that we needed to change some  
2 elements of our system, instead of seeking  
3 individual equivalence approval for each of those  
4 methods or small changes, we would only need to  
5 validate the change at the macro level to  
6 demonstrate that the performance of the system has  
7 not changed or has been improved, and this would be  
8 the validation required, the argument being that if  
9 any change does not impact on performance or if it  
10 only improves performance, then it should be  
11 acceptable.

12           The second benefit of such an approach is  
13 that you get real time and valid data. The data  
14 from the establishments is generated in real time  
15 electronically by the company itself. It's  
16 generated in a consistent format which facilitates  
17 exchange and comparison. The same criteria are used  
18 across all establishments, and so we're able to rank  
19 and compare establishments and the data is valid  
20 because it is getting AQIS verification on a daily  
21 basis.

22           In the initial stages of the trial, we did

1 see quite a large gap between the company and the  
2 AQIS data, but at the time, they became very closely  
3 aligned and we now have a very strong degree of  
4 confidence in the information that's being provided  
5 to us through these company data systems.

6           A third benefit is the ability to be able  
7 to conduct remote audits and that could be an audit  
8 conducted by AQIS or an audit conducted by an  
9 importing country authority. This allows us to  
10 focus our physical audit in the place where it is  
11 most needed. If you have assessed the performance  
12 of the establishment on a 365-day basis. You can  
13 quickly identify the areas where there are risks and  
14 where a physical audit is needed and should be  
15 focused.

16           Likewise, the U.S., an importing country,  
17 could conduct its audit here on the desk and then  
18 come out and conduct a verification audit which is  
19 quite focused and immediately returns the highest  
20 return on the effort and experience.

21           So we would propose that if there is an  
22 international interest in such an approach, that we

1 would need to develop a discussion paper for CODEX,  
2 and we think that this could indeed be the most  
3 significant standard that CODEX and CCFICS has  
4 developed for sometime, and then undertake a trial  
5 and share data with like-minded countries. We would  
6 be particularly interested and we think it would be  
7 particularly useful to compare results with a group  
8 of U.S. establishments to determine how transferable  
9 the data and the information is on the performance  
10 model in the real world situation.

11 So thank you very much for the opportunity  
12 to address the Committee, and if there are questions  
13 afterwards, I'll be happy to address those.

14 MR. TYNAN: Before Dr. Schipp sits down, do  
15 we have any questions from the Committee for him at  
16 this particular point? Mr. Elfering, you have a  
17 question.

18 MR. ELFERING: Yes, just a couple of real  
19 quick questions. Now, not based on product that's  
20 being exported, just on your inspection system,  
21 you're doing antemortem, postmortem inspection,  
22 carcass-by-carcass inspection?

1 DR. SCHIPP: AQIS is only responsible for  
2 export establishments. Our domestic system is  
3 operated at a different arrangement. So there's not  
4 -- it doesn't have veterinary ante and postmortem  
5 inspection in the domestic sector.

6 MR. TYNAN: Dr. Harris.

7 DR. HARRIS: Yes, Joe Harris. Dr. Schipp,  
8 in one of your slides you talked about the food  
9 hazard combination concerning risk, and what you  
10 termed risk foods get 100 percent inspection. Could  
11 you give an example of some different or at least  
12 some idea of what is considered -- what is -- how  
13 does that determination get made?

14 DR. SCHIPP: Sure. The food hazard  
15 combination results in about a bit over 20 risk  
16 foods in Australia, and so the *Salmonella* or  
17 *Listeria* in prepared meats, some antibiotics in  
18 prepared seafood, aflatoxins in peanuts. They're  
19 the types of risk hazard combinations. There are no  
20 raw foods, that is raw meats considered to be risk  
21 foods in Australia at the border.

22 MR. TYNAN: Do you have a follow up, Joe?

1 DR. HARRIS: No.

2 MR. TYNAN: Dr. Henry.

3 DR. HENRY: Thank you. Craig Henry, GMA.  
4 Dr. Schipp, just referring back to one of your  
5 slides, I want to make sure I understand which  
6 system we're talking about. In your trial of  
7 objective performance measurement across 19 meat  
8 processors, you know, most of the day we've been  
9 talking about equivalency of inspection systems, if  
10 you will, and then if you want to apply the term  
11 certification.

12 When I look at this and we're talking about  
13 ranking of establishments, I'm getting a little  
14 confused because if we look at the performance of an  
15 establishment, you know, various companies have  
16 different interventions and methods for minimizing  
17 exposure to pathogens, et cetera. That's one, one  
18 area which I could see ranking establishments but if  
19 we're really looking for equivalency in the  
20 inspection system between Australia and the United  
21 States, that's more of an evaluation of technically  
22 the inspection system, how uniformly you are

1 applying inspection and taking enforcement action  
2 against specific plants. And so could you clarify  
3 just a little bit on that because I'm not real sure  
4 which one we're talking about, or maybe we're  
5 talking about both, but I'm a little confused.  
6 Thank you.

7 DR. SCHIPP: Sure. When we come into this,  
8 what we're looking for was a set of objective  
9 criteria whereby we could go and put a number  
10 against an establishment and the basis for that was  
11 that we recognize that there are a couple hundred  
12 establishments that we're responsible for and they  
13 all do not deserve the same level of attention. And  
14 so we're looking at what we can measure objectively  
15 and then assign inspection results accordingly.

16 Our argument flowing out of that is that  
17 that must translate into a food safety outcome and  
18 if the food safety outcome is driving equivalence  
19 discussion, then perhaps it is a useful measure also  
20 to compare equivalence of systems at a macro level.  
21 But I agree with your point. There are, however, a  
22 number of non-objective, subjective elements that

1 are quite difficult to define and, you know, we  
2 heard some of that this morning in the initial  
3 equivalence assessment. And there's some slides  
4 there about a documentary assessment and then an in-  
5 country assessment, but it's pretty much a black  
6 box. You've got no understanding of how that  
7 assessment is done. You put all the data in and  
8 then the assessment comes out the other end, but  
9 it's not a very transparent process, and what we're  
10 trying to do is make this as transparent as  
11 possible.

12 DR. HENRY: I fully concur with you and  
13 that's where we're trying to go here with risk-based  
14 inspection, but you are tying the two together.  
15 This is truly risk-based inspection for allocation  
16 of your resources and ultimately to see the output  
17 of that or the outcome to be a direct impact on  
18 foodborne illness, however you're measuring it in  
19 Australia and how we're measuring it here. So I  
20 think that that clarifies it. Thank you.

21 MR. TYNAN: Other questions for Dr. Schipp?

22 (No response.)

1           MR. TYNAN: Thank you. The next speaker on  
2 our agenda is Dr. Richard Aresenault.  
3 Dr. Aresenault is the Acting Director of the Meat  
4 Programs Division for the Canadian Food Inspection  
5 Agency. Dr. Aresenault received his DVM from the  
6 Faculty of Veterinary Medicine at the University of  
7 Montreal in 1987. He joined the Canadian Federal  
8 Meat Inspection Program in 1989 and has worked as a  
9 frontline meat inspector, national program  
10 supervisor, program auditor, and other various  
11 positions in the program for over the last 19 years.  
12 And with that, I'm going to turn it over to  
13 Dr. Aresenault to talk about the Canadian system.

14           DR. ARESENAULT: Good afternoon. I just  
15 want to express my thanks for the opportunity to  
16 come meet with the Committee. I know it's a little  
17 late in the afternoon. So I'll try and get through  
18 this as painlessly as possible for your benefit, and  
19 all Dr. Jolly to close off the day for us.

20           So I'll just speak very briefly about what  
21 the mandate is at CFI and how it sort of differs  
22 from what USDA has in Food Safety and Inspection

1 Service. I'll talk about the design of our program  
2 just in broad terms, some general information. And,  
3 then I'll dwell on what we do in terms of our  
4 process for evaluating a foreign country that wishes  
5 to send meat into Canada. So you can use that for  
6 comparison purposes. The steps are there. I'll go  
7 into them later.

8 But the point may be at the end that some  
9 of the comments about equivalency, just to reiterate  
10 some of the key points that I've heard so far today  
11 and maybe some things that I think are important for  
12 the group to keep in their deliberations.

13 Next slide.

14 So in Canada, we organized food inspection  
15 under a single agency back in 1997. Canadian Food  
16 Inspection Agency was created by bringing together  
17 four different departments. The meat program was  
18 one of those groups that was brought into this new  
19 umbrella organization, and essentially in our  
20 management structure, meat inspection is one of many  
21 food inspection and other product certification  
22 activities. So, in a sense, we have to compete with

1 those other program needs and priorities on an  
2 annual basis as we go about putting together our  
3 work plans and setting up our resources. Some of  
4 the activities, we are constrained, and they're all  
5 obviously managed by primacy in terms of our Meat  
6 Inspection Act. Although in Canada the Act  
7 references regulations where the bulk of the  
8 technical materials are required, the Act  
9 essentially sets out the powers for the inspector  
10 and provides for the creation of regulations by a  
11 process that we call Governing Council. Although it  
12 is perhaps less protracted than going to the Hill  
13 here for something, it does involve a very  
14 significant amount of public consultation prior to  
15 any publication of a new change.

16 Next slide.

17 Our Federal Meat Inspection Program, as I  
18 said before, is based on this Meat Inspection Act  
19 and its intended regulations. It applies to all  
20 meat that is exported out of Canada, all meat that  
21 is traded across the inter-provincial boundary in  
22 the country of Canada and all meat that is imported

1 into the country. That's a function of our  
2 Constitution.

3 In Canada, if a facility is engaged in  
4 manufacturing meat for export or inter-provincial  
5 trade, it must be registered with the CFIA. It must  
6 source all its material from a federally registered  
7 plant, much as the case here, and it has to comply  
8 obviously to all of the requirements which I think  
9 you'll see resemble a lot of the things that are  
10 here with mandatory HACCP. So we have rules in  
11 terms of facility construction and design, sanitary  
12 operating practices, animal welfare and humane  
13 slaughter activities, composition, marking, labeling  
14 of products and as I mentioned, there are specific  
15 rules under our regulations about how to go about  
16 operating a HACCP program. That includes  
17 prerequisite programs which are similar to some of  
18 your sanitary operating practices and standard  
19 sanitation operating practices.

20 I'll switch to the next point, which is  
21 what we do when a foreign country approaches Canada  
22 and says I wish to send a product into this country.

1 Now, I don't have statistics, but I would estimate  
2 the number of countries is approximately with what's  
3 taking place with the United States. It's not a  
4 very large group, and it's primarily a function of  
5 two drivers, one of which is an animal health  
6 reality because in Canada our foreign animal disease  
7 status is very similar to yours in the United  
8 States, and that means that the amount of meat  
9 products that can come from countries outside of  
10 North America is constrained by the important  
11 reality that it needs to have freedom from a number  
12 of declarable animal diseases and has to have  
13 control programs to satisfy those conditions as  
14 well.

15           And that's one thing I'm not here to speak  
16 to because there's a whole other process that needs  
17 to be dealt with when those things happen.  
18 Similarly APHIS would have a word to say about what  
19 happens with the United States. It's a similar set  
20 of rules.

21           But once we get that obstacle out of the  
22 way, the next process or the parallel process is

1 meat inspection, rules, requirements and the  
2 equivalency which is the guts of today's discussion.  
3 And we look at it in two ways. We talk about meat  
4 inspection per se. We also talk about chemical  
5 residue control programs which is for us an  
6 important consideration in that exercise.

7           This morning, I think a lot of time was  
8 spent explaining the process with the triad  
9 exercise, with the desk review, the on-site review  
10 and the ongoing audits. We similarly have the same  
11 approach. I'm not sure we could say that we stole  
12 it from you or you stole it from us, but it sort of  
13 evolved in similar directions, one reason because of  
14 the large North American volume of trade and the  
15 exchange of information between both organizations,  
16 but the other one because I think it makes a lot of  
17 sense. There's no sense going to country starting  
18 to review plants on a willy-nilly plant-by-plant  
19 basis if you don't understand how that system works.  
20 And to understand how that system works, you have to  
21 have a very thorough desk review as a first, primary  
22 process. And that's what we do in our country.

1           So there will be an iterate of exchange.  
2 It's on a government-to-government basis. If an  
3 individual plant comes to us, we'll refer back to  
4 that competent authority. We'll exchange  
5 information in terms of act, regulations and  
6 whatnot, and then ultimately we'll go to the next  
7 stage which is the on-site visit. The on-site visit  
8 again is, as was mentioned this morning, to verify  
9 that what was said is what is done, and also to  
10 verify that what is achieved is what was expected  
11 when we did our desk review and we came to our  
12 conclusions. That's something that we do using  
13 officials from CFIA. Typically what will happen is  
14 we'll go to the country on an initial visit and to  
15 go and verify a sampling of plants.

16           Now, if there's only four or five plants  
17 being proposed, that sample will be 100 percent, but  
18 if there are a number of plants, it will certainly  
19 not necessarily be 100 percent. I can't give you a  
20 hard and fast rule on that because we don't have a  
21 firm algorithm, but it certainly is important for us  
22 to get an appreciation of how the system works as

1 opposed to whether or not each individual plant is  
2 passing at 100 percent.

3           And if we have enough confidence in that  
4 system on that first go, and I think it's a function  
5 of what the desk review has told us in terms of the  
6 integration of their different acts and regulations,  
7 it's also a function of where they've shipped  
8 product before. So if they've traded with another  
9 of the major meat producing nations, that being the  
10 European Union, Australia, New Zealand, we're  
11 certainly going to give consideration and weighting  
12 to that as part of our decision making process.

13           And that said, our process when we visit  
14 the country will involve sampling of plants, where  
15 we will go, and we will do two things. We will look  
16 to see how the system is being delivered against  
17 what was proposed in the written documentation and  
18 at the same time, especially at the beginning, we'll  
19 be taking some objective evidence, look at what is  
20 going on in these plants, not necessarily a plant  
21 inspection in the traditional sense, as when I  
22 started to do business 20 years ago, when I'd go

1 through every room and check every record and check  
2 everything in there, and I would spend 12 hours in  
3 the plant. Typically after about two hours, you  
4 have a pretty good idea of what's going on in there.  
5 I had very surprises after that.

6           And in this case, we will take the time  
7 that it takes to get that appreciation. It  
8 certainly won't be in two hours, but it won't be a  
9 two day site visit unless it's a very complex and a  
10 very huge operation, the idea being that we  
11 summarize that information after we get home, come  
12 to conclusions about the system. We may have  
13 questions that we need to clarify before we come to  
14 a final determination.

15           If you can put the next slide up. Thanks.

16           And through that data review process and  
17 potentially with exchange of information with the  
18 competent authority, come to some conclusions and  
19 next steps in terms of the process. If we have  
20 questions that require further elucidation, we will  
21 not hesitate to wait to do a further site visit and  
22 visit that country and see what's going on in that

1 front. But ultimately at the end of that whole  
2 process, we're going to recognize that country's  
3 system.

4 And part of that exercise is to see what  
5 that country's proposing to do in terms of putting  
6 together a list of eligible establishments so that  
7 we know that certification that is being generated  
8 by that country under their official meat inspection  
9 certificate, is giving us confidence in all the  
10 plants in that system, not just the ones that we  
11 happen to visit as part of our control.

12 So if we can essentially go to the next  
13 stage of the exercise, which is how do we maintain  
14 this process, and it sort of equates to your audit  
15 that you were talking to this morning, it really is  
16 a maintain function. We have a confidence level in  
17 what's going on. We want to maintain it, and again  
18 maintenance is not necessarily a question of  
19 repeating the process from scratch. It really is a  
20 question of gathering intelligence, targeting areas  
21 where you want to look at things and then going in  
22 there and asking questions so that you can get

1 enough information again for that overall  
2 appreciation.

3           The information injects that we would use  
4 when formulating our plan would be volume of trade,  
5 what the audit findings in a previous year were,  
6 what the past performance was and if there are any  
7 other information that was being flagged to us  
8 through our exchange with our partners in terms of  
9 overall information, looking at your website in  
10 terms of your foreign reviews, getting information  
11 from the EU and similar manners, and other exchange  
12 processes that are available to government.

13           The idea here is that we will not  
14 necessarily visit each single country eligible to  
15 ship to Canada every single year. It goes to two  
16 reasons. First of all, the fact of the matter is,  
17 if we have ongoing information on our import side  
18 showing us that there isn't any ongoing trends that  
19 suggest a problem, we can maintain our confidence,  
20 we can maintain our vigilance, but still not  
21 necessarily have to spend the money and the time to  
22 go to that country. We can spend the money and the

1 time going to other countries where there is a  
2 potentially higher risk, and in an agency such as  
3 ours, we can spend those resources in perhaps other  
4 areas in meat inspection to look at other higher  
5 risk priorities than say meat coming from Australia  
6 and New Zealand. And for us, that is a very  
7 appropriate way to go about deploying the resources  
8 that are given to us by the taxpayers of our  
9 country.

10 We'll go to the next slide now.

11 So I think that the last point, and if you  
12 can bring the previous slide up, I sort of omitted  
13 that, was in terms of the reinspection that we do.  
14 That is something that is not done systematically on  
15 every single load coming into Canada. Unfortunately  
16 our regulations bind us to look at every load coming  
17 from Australia, New Zealand and other countries  
18 because of the North American Free Trade Agreement.  
19 We look at 1 in 10 loads coming from your country,  
20 and when I say look, it really is a question of  
21 verifying that what is on that truck corresponds to  
22 that meat inspection certificate.

1           There's a subset of approximately 10  
2 percent that is subject to a further inspection. So  
3 we're really doing a full inspection on  
4 approximately 1 percent of product coming from the  
5 United States, 10 percent of product coming from  
6 other nations.

7           And out of that subset, some of those  
8 samples are being subject to sampling for monitoring  
9 purposes. We're not testing the lot. We're not  
10 testing the load. We're trying to get a national  
11 snapshot in terms of overall country compliance  
12 because it's a systems approach that we're applying.  
13 Should, for whatever reason, we find something  
14 that's untoward, we obviously are going to follow up  
15 on that and we're going to follow up on that on a  
16 plant-specific basis, a priority, and if we see a  
17 trend that goes beyond other plants, we're going to  
18 start asking questions about the country control  
19 system.

20           So in terms of our approach to equivalence,  
21 just the summary notes, and thank you, the key for  
22 us is to have an overall appreciation as to what's

1 going on, to have a dynamic process that is not a  
2 year-by-year snapshot but really an ongoing trends  
3 analysis, and for us to do that efficiently means  
4 that we can take a look at other countries on other  
5 years and not necessarily have to spend five weeks  
6 in your country every year looking at stuff, because  
7 I'll be honest with you, I always enjoyed my visit  
8 to the United States, but I always suspected that I  
9 could be doing other things at home that would be  
10 more productive for our overall system as well.

11 And with that, I'll let Dr. Jolly I think  
12 close off unless Mr. Tynan wants to entertain  
13 questions. Thank you. Robert, do you want to do  
14 questions now or later?

15 MR. TYNAN: I'm sorry, yes. Please, if we  
16 have questions. Okay. Let's try that again. We're  
17 going to start with this side of the room and,  
18 Mr. Corbo, if you have a question and then we'll  
19 come back this way.

20 MR. CORBO: Yes. Tony Corbo from the  
21 consumer group, Food and Water Watch. First of all,  
22 I want to express our condolences for the families

1 who have suffered foodborne illness as a result of  
2 the Maple Leaf situation, and we really truly feel  
3 sorry for what's going on there.

4 I have a couple of questions. On your  
5 export side, as a result of a USDA Inspector General  
6 Report in 2005, FSIS and your agency have entered  
7 into an agreement to conduct a study that would  
8 allow meat and poultry products to come from Canada  
9 to the United States under a less than daily  
10 inspection process. What is the result of -- what's  
11 the status of that study? Has it been submitted to  
12 FSIS?

13 DR. ARESENAULT: I'll try to respond.  
14 There was an attempt to do a study in 2005 but let  
15 me start by saying that currently and for the  
16 foreseeable future, all U.S. eligible plants are  
17 being visited and will continue to be visited at  
18 least once per day. So that has not changed.  
19 There's no plan in Canada that's generating product  
20 for the U.S. that's being visited less than once per  
21 day.

22 We wanted to do a study. We put forward a

1 study design that would have compared a group of  
2 plants being visited less than once per day versus  
3 those that were. There was a challenge put to us  
4 because unfortunately we couldn't compare plants of  
5 similar sizes given that all the large ones export  
6 to the U.S. and it had been decided that none of  
7 them could be visited less than daily as part of the  
8 study.

9           Nonetheless, we did attempt to do a study  
10 and have collected data because we do have a system  
11 in Canada where those non-eligible plants are  
12 visited less than daily. There was data collected  
13 but due to the fact that we're comparing apples and  
14 pretty much pomegranates here. A lot of the  
15 indicators were virtually unusable and we're still  
16 trying to figure out if we can actually compare the  
17 plants in a meaningful manner. We'll continue to  
18 work at that but I wouldn't put a great amount of  
19 credence in getting any meaningful results out of  
20 it.

21           MR. CORBO: Thank you. The second question  
22 is there's been a lot of talk in the Canadian press

1 about changes to your inspection system, and there  
2 are all sorts of speculation as to what that is. Do  
3 you anticipate major changes to your inspection  
4 system, and what impact will that have on any  
5 equivalence discussions with the United States?

6 DR. ARESENAULT: Well, a lot of the changes  
7 that we have been doing the past number of years  
8 were for two reasons. One, because the mandatory  
9 HACCP and the fact that we had all our  
10 establishments operating in that model. Instead of  
11 designing a system where we had a PBIS model that  
12 started using the inspector to verify through a more  
13 audit oriented process, what was going on with the  
14 HACCP plan, our original attempt was to layer on a  
15 food safety enhancement process audit in addition to  
16 the day-to-day inspection that was being done. We  
17 had started working that in the early nineties  
18 before we sort of hit the less than daily wall. And  
19 when that happened, we essentially had to make a  
20 reengineering of the process and make a decision  
21 that if we had to continue to have someone in there  
22 on a day-to-day basis for reasons that may or may

1 not relate to food safety but pragmatically  
2 remained, we wanted to make sure that we could get  
3 up front, advance information about how well that  
4 HACCP system was working, and the best tool was to  
5 rely on that day-to-day inspector.

6           So the change that we've been driving is to  
7 try and get that inspector to operate ironically  
8 enough more like a U.S. inspector is doing with the  
9 PBIS system. And that is a change and for some of  
10 the inspectors who were used to having the old  
11 command and control system, it's been something that  
12 they've had some difficulty acclimatizing to, and I  
13 know that there have been some comments that were  
14 mainly ironically driven by that fact.

15           So if at all anything, our system probably  
16 resembles yours more than anything else right now.

17           If we want to do further changes, I think  
18 those will be changes that hopefully will be a  
19 modernization that go to outcomes more so than  
20 prescriptive regimes, primarily also I think by  
21 trying to get some metrics that are more objective  
22 and to start looking at using maybe performance

1 standards in a more systematic way than we currently  
2 have been able to do, but that's a process that  
3 really is very, very early on. I mean we're talking  
4 embryonic ideas as opposed to formalized plans and  
5 change.

6 MR. TYNAN: Okay. Mr. Elfering, do you  
7 have a question?

8 MR. ELFERING: Just one quick question. Do  
9 you have provincial inspection as well?

10 DR. ARESENAULT: Yeah. We do have a system  
11 in Canada. Because of the way that the Constitution  
12 is set up, in Canada what happens is that if a  
13 product remains within a territory of a province,  
14 province being equivalent to a state, it's under the  
15 jurisdiction of that local authority. So it's an  
16 issue of local trade, and they do have to comply  
17 with our Food and Drug Act and Regulations. So  
18 there are some -- link provisions, sort of like what  
19 FDA does across the board here, but in terms of meat  
20 inspection, it's not a trade issue, and they can  
21 come up with standards that they deem appropriate  
22 and delivery models that are suited to their

1 resource base.

2           So we have a bit of a differentiation, a  
3 patchwork in some ways. Now, 95 percent of the  
4 animals that are slaughtered in Canada, go through  
5 the federal system, and none of the meat that's  
6 exported or enters in inter-provincial trade goes  
7 through the provincial system.

8           However, there is still that gap that we  
9 know about, and we've been working with the  
10 provinces to try and find a mechanism to level that  
11 whole process up to fix that discrepancy that might  
12 exist. There was work on a draft national Canadian  
13 meat hygiene standard that was underway. It's work  
14 that has encountered certain obstacles, but none of  
15 them I think are insurmountable. It is something  
16 that we're going to progress on over the next 5, 10  
17 years. It's going to take some time because of the,  
18 you know, 13 different jurisdictions.

19           Fortunately for your country, you have a  
20 different paradigm where you have the equal to or  
21 the equivalent to at the state level. We  
22 unfortunately I think, because it's a lot easier

1 sometimes when you have that, don't have that.

2 MR. ELFERING: But those plants are not  
3 eligible to export?

4 DR. ARESENAULT: None of those plants are  
5 eligible for federal inspection. None of them are  
6 eligible for export to any country, U.S. or  
7 otherwise. They can't ship out of their province of  
8 origin. That's right.

9 MR. TYNAN: Mr. Painter, I'll let you have  
10 the last word.

11 MR. PAINTER: Yes, Stan Painter, National  
12 Joint Council Chairman. I read a number of articles  
13 that involved some of the food inspectors or meat  
14 inspectors from Canada, and I think you referred  
15 back to some blended systems that happened in 1997,  
16 and then in some of the articles that I read in  
17 1998, there was a *Listeria* outbreak where up to 15  
18 people died. And those inspectors basically  
19 referred to themselves as paper pushers. They  
20 weren't able to perform inspection duties, and one  
21 question would be, did that result in the deaths of  
22 those people, and is that attributed to the up to 12

1 people that have died recently due to *Listeria*?

2           The addition question, you mentioned the  
3 HACCP process and it kind of mirrored what we have.  
4 Was there a pre-shipment review that was done prior  
5 to shipping the product out, the recent issue that  
6 happened with the deaths? And is there a tracking  
7 mechanism for imported product coming into Canada?  
8 And is there a tracking mechanism for product going  
9 out of Canada, say something that was shipped here?  
10 If tainted product was shipped here, how would we  
11 track that back?

12           DR. ARESENAULT: Okay. Well, I'll try to  
13 answer all of your questions, although if I lose  
14 track, you know, you'll have to bear with me.

15           First of all, for the benefit of those that  
16 aren't aware, we have had and we are under a  
17 situation where approximately a month ago, there was  
18 a person in an old age home who passed away from  
19 *Listeria*, and about a month later, two other people.  
20 Our public health network in Canada was very quickly  
21 able to identify meat in sandwiches coming from a  
22 Canadian federal plant, that does not export to the

1 States I might add, as a potential source. CFIA was  
2 alerted and we went in there within two days of  
3 being notified of a potential problem. There was  
4 not enough information to conclude anything right  
5 away. This was an investigation, a follow-up thing  
6 and I think it points to the efficacy of the public  
7 health system that within less than a month, we were  
8 able to identify the cause of that problem, have all  
9 of the meat product from that plant pulled off the  
10 marketplace, and to move into a phase where we can  
11 start figuring out why this happened and what we can  
12 do to prevent it.

13 Now, this is an absolute tragedy. I mean,  
14 at the current moment, I think that there was, as of  
15 yesterday, the count was that there were 12 people,  
16 all elderly people, of course, because *Listeria*  
17 having that target population, who had Listeriosis  
18 at the moment that they passed. It's not  
19 necessarily clear that all of them were made ill to  
20 the point where they died by that bacteria. Some of  
21 them could be coinfection, but regardless, I mean  
22 the point is in a North American integrated kind of

1 model, because in 1998, these 15 people who died  
2 were in the United States I might add. But in this  
3 North American type of model where you have  
4 integrated distribution chains, where you have  
5 coast-to-coast distribution, where you have huge  
6 plants that operate 24/7 or basically virtually, if  
7 there is a small mistake, albeit a small mistake,  
8 you have a bacteria that can grow out over 60 days  
9 to a point where there are people that are going to  
10 get very, very sick, and that's a serious situation.  
11 That's something that is really not anything that  
12 anybody would ever wish, and I'm very, very sorry  
13 and my heart goes out to those families as well as  
14 Tony made clear earlier before.

15 Our goal now is to find out with the plant  
16 what took place in there, and we have teams on the  
17 site looking into that. And the next step is to  
18 take a look at how we can improve our system in case  
19 there was anything that we might have been able to  
20 do differently to prevent this.

21 Now, I have to add that prior to 2005, we  
22 were doing environmental testing in these

1 facilities, and the government was collecting  
2 samples on contact surfaces to look at that. We  
3 were advised by FSIS at the time that the U.S.  
4 approach was to go after product as opposed to  
5 surfaces. And so all things being equal, we chose  
6 to use that approach as opposed to looking at  
7 product surfaces.

8           And so our approach in terms of our  
9 *Listeria* control in these facilities is virtually  
10 identical to what would be taking place in a U.S.  
11 plant. And, you know, there but for the grace of  
12 God, that it only happened once in the last five  
13 years in this kind of way. But there's nothing to  
14 guarantee that it couldn't happen here, you know.  
15 I'll let your American colleagues speak to that and  
16 I'm sure that they have one the best systems in the  
17 world as do we but these things will and potentially  
18 can happen.

19           Our next step is to figure out what can we  
20 do as a regulator to frame and enhance a stronger  
21 preventative net, to tighten it up so it doesn't  
22 slip through the cracks.

1           Now, that I needed to get out about  
2 *Listeria* because this is an important situation for  
3 us, and it's something that we're dealing with.

4           Now, you had some questions about imported  
5 product. *Listeria*, of course, is something that  
6 happens after cooking. So it has nothing to do with  
7 this question that you brought up.

8           Traceability of product coming into the  
9 country, of course, all product coming in has to  
10 come under an Official Meat Inspection Certificate.  
11 It has to be signed by a competent authority. And  
12 at that point when it enters the country, if it is a  
13 skip lot, it can enter into distribution because it  
14 has essentially met all the requirements for sale in  
15 this country. If it is subject to a full  
16 inspection, it will go to a facility. It will be  
17 looked at, controlled against the Meat Inspection  
18 Certificate if it's a partial reinspection. Samples  
19 may be taken if it's a full reinspection. And  
20 that's very similar to what you do with samples  
21 coming into your country, although to be fair, I  
22 think that our percentage of review of U.S. stuff

1 based on our knowledge of past performance is  
2 reduced compared to what you require.

3           It's a source of contention for our  
4 colleagues in Australia and New Zealand because they  
5 feel that they have as good a system, and they would  
6 like to do the same thing. To be quite honest with  
7 you, that's something that we are going to look at  
8 very closely because we have trouble explaining the  
9 difference to ourselves.

10           If you have a country that has a large  
11 volume of trade, that has good results, that has  
12 data that you can see, and that when you do your  
13 periodic and not necessarily systematic annual  
14 visits, tells you that things are under control,  
15 there's really no reason to have to go and  
16 triplicate an inspection on top of what they've  
17 already done for you. And that's an important point  
18 that we've taken to heart, because the resources  
19 that we spend doing those reinspections are  
20 resources that I would much prefer to use to try and  
21 prevent some of those foodborne outbreaks that you  
22 spoke to earlier.

1 I don't know if I answered all of your  
2 questions, but I think I got most of them.

3 MR. PAINTER: Pre-shipment review with  
4 HACCP. Is there a pre-shipment review? In the  
5 cases that we just spoke of, was there pre-shipment  
6 review? Did the product pass the pre-shipment  
7 review?

8 DR. ARESENAULT: Yeah, that plant was not  
9 exporting to the U.S. but it was on the list of  
10 eligible plants. It wasn't a shipment in the 12  
11 months for the record. But as part of those  
12 requirements, there were pre-shipment reviews being  
13 done on every load, yeah.

14 MR. PAINTER: Let me do a follow-up  
15 question on something you said. You said that  
16 Canada went to a system of testing the product  
17 versus testing product contact surfaces. In your  
18 opinion, is that a better system?

19 DR. ARESENAULT: I don't have the answer.  
20 I'm not going to profess to be the expert on  
21 *Listeria*. I know enough to ask the right questions  
22 to the right people, and that's what we are going to

1 do. I think it's probably a blended approach that  
2 we're looking at. I think we have to look at having  
3 a system where scale and volume is something that is  
4 going into the equation, not just necessarily risk  
5 which is what we were currently doing. And without  
6 prejudging the matter, these are all things that we  
7 have to take a very close look at. I think it's  
8 important for us to think about our approach to act  
9 quickly but not to react too quickly. Thank you.

10 MR. TYNAN: I know you probably have more  
11 questions but I'm cutting you off. Okay. Thank you  
12 very much, Dr. Aresenault.

13 Our next speaker to finish up the  
14 international component is Dr. Bill Jolly. I'm  
15 going to apologize to him. We've made his name tag  
16 Billy Jolly. (Laughter.) We just wanted to see if  
17 he was paying attention, and he evidently was. So I  
18 apologize, Dr. Jolly.

19 Dr. Jolly is the Deputy Director of the  
20 Export Standards, New Zealand Food Safety Authority.  
21 He has direct accountability for managing market  
22 access to worldwide for New Zealand food products as

1 well as supporting export assurance programs and the  
2 domestic standards for all animal byproducts. The  
3 key components in this role include managing  
4 bilateral agreements, trading partner relationships  
5 and equivalency negotiations.

6           So with that, Dr. Jolly, if you could come  
7 on up and talk a little bit about the New Zealand  
8 program.

9           DR. JOLLY: I said to Bill James earlier  
10 that if he was going to call me Billy, I was going  
11 to call him Willy. (Laughter.)

12           I'd like to thank especially Dr. Raymond  
13 for inviting us here today. It's a long way to come  
14 but it's an important thing you're looking at and  
15 consideration, and so hopefully I can give New  
16 Zealand's 10 cents worth.

17           With some of the accolades we've heard  
18 today about New Zealand's system and results, you  
19 know, part of me thinks I should probably just sit  
20 down before I put my foot in it because it's been  
21 quite good to hear some of the comments that have  
22 come today.

1 I'd also like to state up front that much  
2 of the progress over the last 30 to 40 years in meat  
3 inspection and public health gains has been  
4 pioneered by the Food Safety and Inspection Service  
5 under the Federal Meat Inspection Act. Now, the  
6 last substantial effort in the mid-nineties when we  
7 had the pathogen reduction, HACCP final rule was  
8 perhaps squeezing the bit of blood out of a 102-  
9 year-old Act. And, you know, the question today is,  
10 you know, how much more can you go there or how much  
11 is that Act starting to hold the United States and  
12 the world back? And I think that's also important  
13 for your consideration.

14 So the New Zealand Food Safety Authority,  
15 single food agency, formed in 2002 from part of the  
16 Ministry of Health and part of the Ministry of  
17 Agriculture and Forestry.

18 We're a regulatory agency. We don't  
19 support or promote industry in any way. In fact, we  
20 cost recover. We regulate all domestic food  
21 production. We regulate the food safety of all  
22 imports.

1           We also negotiate and provide export  
2 assurances. We're heavily involved in international  
3 standard setting. We host and Chair the CODEX  
4 Committee on Meat Hygiene which was very important  
5 to most of the countries that are represented today  
6 around this room. We also host and chair the CODEX  
7 Committee of Milk and Milk Products. And we're very  
8 involved in developing and implementing cooperative  
9 arrangements with some sister competent authorities  
10 which is one of our preferred mechanisms.

11           Food and Agriculture are New Zealand's  
12 largest businesses. We export 80 percent of our  
13 food and 50 percent of our income is from food. So  
14 we take it very seriously. The whole economy  
15 depends on it, and the commercial imperative far  
16 outweighs any regulatory imperative. And that's in  
17 a positive sense, not a negative one. Has Caroline  
18 left? (Laughter.) When I stood up here, I sort of  
19 saw Don Smart leave the room and then Dick Raymond  
20 leave the room, and I was looking around for  
21 Caroline and thought she was leaving the room, so I  
22 thought I was going to get a home run.

1           Anyway, we're a little country of 4.4  
2 million people, but to give you some comparative  
3 figures, we export over 90 percent of our sheep  
4 meat. That constitutes about 7.2 percent of the  
5 world's production of sheep meat, and it constitutes  
6 about 51 percent of the trade of exported sheep meat  
7 around the world. So we're a major player in the  
8 export of sheep meat. So when people tell us about  
9 prices in sheep meat, you know, we listen but we  
10 also say we've got a little bit of experience.

11           Beef and veal, again we export about 80  
12 percent. It's only about 1 percent of the world's  
13 production but it's between 8 to 10 percent of the  
14 internationally traded beef. So again we're a major  
15 player in that area.

16           Venison is a monarch commodity for the  
17 U.S., but it's again a major area we're involved in,  
18 and dairy, we're the world's largest exporter of  
19 dairy products.

20           So again food safety and food safety  
21 systems and certification systems are core to the  
22 New Zealand Food Safety Authority.

1           Importantly, we also import 20 percent of  
2 our food including 40 percent of the pork consumed.  
3 So we're not just an export country.

4           And this is not from a developing country.  
5 Speaking about where we import our food from, yes,  
6 we import beef from the European Union. Yes, we do  
7 import beef from Canada, from the U.S. and from a  
8 number of other countries. So we walk the talk as  
9 far as looking from a risk perspective rather than  
10 getting caught up in the politics of BSE.

11           So New Zealand's policy on the recognition  
12 of equivalence of foreign food and regulatory  
13 systems, the first question I'd like to ask, how can  
14 you deal with different HACCP profiles between  
15 countries? You know, vet drugs and pesticides,  
16 multidrug resistant bacteria, *Cysticercus bovis*,  
17 *Salmonella* and *E. coli* O157:H7 or BSE, and these are  
18 just differences the U.S. has from us. You know, so  
19 how can you have equivalence when you've got all  
20 these differences in hazards.

21           Well, the answer is that with the  
22 globalization of world trade, we're actually to have

1 the SPS Agreement, and it sort of sets a rules-based  
2 environment. It covers the key health aspects and  
3 sets some principles and rules and obligations.

4 So as you heard from Sally earlier in the  
5 day, there are some key concepts. Appropriate level  
6 of protection, human health outcomes that are  
7 achieved. That's the most important thing we're  
8 after. It's also outcome focused, not process  
9 focused. So just again focusing where we put our  
10 efforts.

11 Requirements, obligations, they have to be  
12 science and risk driven, only as necessary and  
13 appropriate. So you have to justify them. Based to  
14 the maximum extent possible on international  
15 standards, and we've heard some presentations today  
16 about CODEX. The CODEX Committee on Meat Hygiene  
17 and the guide that came out of that, I mean we put  
18 as a collective, Canada, U.S., New Zealand,  
19 Australia, the EU, an incredible amount of effort  
20 into that. It was setting the bar where we wanted  
21 it to be. It wasn't being restricted by IX (ph.)  
22 that we're actually currently regulating. It

1 was setting the bar where we want to be, and it was  
2 meant to be the international harmonization. The  
3 challenge for us all is to actually implement that  
4 in the trading environment between us as well as  
5 domestically.

6 And it also has the concept of equivalence  
7 which we were talking about to a large extent today.

8 I thought I'd fire a few questions about  
9 appropriate level of protection. Have you  
10 quantified it? Is it consistently applied across  
11 food types? Are your regulatory systems to meet it  
12 risk-based or are they hazard focused? Have we  
13 quantified what effect individual components of a  
14 system have on risk? Are these extrapolatable to  
15 different countries?

16 Well, the reality check, there is no common  
17 appropriate level of protection across a country's  
18 food supply. I can tell you now. You can look at  
19 all the different things in your market basket.  
20 There's no consistency. This applies similarly to  
21 foods traded between countries that have similar  
22 regulatory regimes, industry practices and consumer

1 demographics, and Wolf presented the differences in  
2 just a couple of examples in *Salmonella*.

3           Nevertheless, in the developed world, most  
4 food risks are within a reasonably comparable range.  
5 When I go to Europe, and when my family lived in  
6 Europe with me, we didn't take food parcels. When I  
7 lived in the United States for four years, again we  
8 didn't bring food parcels. In fact, there's about a  
9 dozen countries that I travel to regularly around  
10 the world where I actually look forward to a steak  
11 or a pork chop or some other food commodity.

12           Overall exposure to a standard dietary  
13 based of foods is unlikely to result in  
14 significantly overall risks in different countries,  
15 where we're talking about developed countries. So  
16 rather than focusing on the differences, we need to  
17 start focusing on what's important.

18           Okay. So what is equivalence? Do your  
19 production systems look like this? Maybe if you're  
20 Mike from Montana they do.

21           Equivalence, CODEX and CCFICS, and we heard  
22 from Mark about CCFICS, defines the capability of

1 different inspection and certification systems to  
2 meet the same objectives.

3 I thought I'd put just a couple of little  
4 reality checks on microbial risks. In our systems,  
5 none of our systems are that advanced. We don't  
6 actually have much quantitative data. We're only  
7 just starting to go there. The risks are normally  
8 apparent in the importing country regardless, you  
9 know, Salmonellosis. So what is the country's  
10 appropriate level of protection? It's not just  
11 about, you know, presence or absence or relative  
12 level of control, you know. How a hazard actually  
13 confers a risk is really a big debatable issue and  
14 how important that is in making a judgment.

15 Next slide please.

16 So it's not about looking for the  
17 differences. Most regulatory systems still can be  
18 process prescriptive and hazard focused and not risk  
19 based. International trade, it's difficult in  
20 judging equivalent outcomes when sanitary measure is  
21 a process. So it makes the job that sort of Sally's  
22 team sort of does very, very difficult. It's a very

1 qualitative job to some extent, and you have to ask  
2 yourself what's really being achieved when you go  
3 too detailed, and again we heard from both Mark and  
4 Richard, how deep do you go in equivalence decisions  
5 for prior approval when you're changing your  
6 systems?

7           So as New Zealanders, what we do is we tend  
8 to look for comparability of objectives and approach  
9 because that's the thing which is going to be  
10 consistent and we heard again from Wolf earlier in  
11 the day.

12           So this is a regulatory model we use, and  
13 the important thing to recognize in this is, it's  
14 not regulator on top. The regulator provides the  
15 underpinning standards, the underpinning approvals,  
16 the underpinning recognition of independent  
17 verifiers or government inspectors, and you know,  
18 the requirement for risk-based systems in industry.  
19 But the relationship still exists between the  
20 industry and the consumers. It's still the  
21 industry's responsibility to produce safe food. You  
22 can't inspect safe food.

1           Okay. So the competency of the competent  
2 authority. These are key issues for us. Whether  
3 they have shared public health goals, whether they  
4 have adequate resources, whether there's a freedom  
5 of conflict of interest, whether there's a  
6 transparency of standards and verification activity,  
7 whether there's a demonstrated willingness to take  
8 safeguard actions, the commitment to science and  
9 risk assessment and whether they have ongoing  
10 monitoring and surveillance. It's about their  
11 approach. It's not just about individual measures.

12           So risk management, Wolf already mentioned  
13 you should audit how a country applies its own  
14 standards, not whether they have exactly the same  
15 process or procedures as yourself. So accordingly,  
16 you know, risk management is all about the situation  
17 that exists in their country. Their system has to  
18 be free to continually evolve in depth as  
19 appropriate. You can't hold it back by the  
20 constraints of your own system. Otherwise, you will  
21 not have a science-based and risk-focused system.

22           It has to be independent of us having to

1 intervene. When we import from a country, they are  
2 constantly acting as our risk manager. You have to  
3 have that relationship there.

4 We don't reinspect. New Zealand doesn't  
5 reinspect at the border for meat. What we do do is  
6 we do a level of monitoring surveillance, sample and  
7 release if you like, and the results are a measure  
8 of the system, not the compliance of a consignment.  
9 And again we heard a little bit from Richard about  
10 that concept.

11 When we do audit, it's about developing the  
12 relationship. It's centrally and system focused,  
13 and it's not about defect checking at the  
14 establishments. It's all about the relationship,  
15 whether we can trust, whether they have the same  
16 approach, and whether we're working towards shared  
17 objectives.

18 So our preferred model for foods of high  
19 regulatory interest, such as meat products, is the  
20 development of equivalence agreements. We emphasize  
21 increased cooperation and communication between the  
22 parties. The focus is on getting the relationship

1 right rather than trying to reinspect their  
2 establishments or product. If the relationship's  
3 not right, nothing's going to work. That's where we  
4 put a lot of effort in with the EU and subsequently  
5 we've got a very high level of confidence, trust,  
6 knowledge and experience of each other's systems.

7           So I have some challenging questions for  
8 the Committee. Does or should one size fit all?  
9 We've been trading under the current paradigm for  
10 over 40 years. We're not aware of many problems.  
11 In fact, I'm not aware of a single health problem  
12 that has directly implicated New Zealand exports.  
13 Forty years ago, FSIS did the initial assessment of  
14 New Zealand's system. They've come back annually  
15 ever since.

16           Should higher level relationships and  
17 performance be rewarded by a modified approach? We  
18 don't go to Canada very often to audit. We don't go  
19 to the EU very often to audit. The EU no longer  
20 comes very often to New Zealand to audit the meat  
21 system. It's basically every three to four years  
22 now. And the same with Australia.

1           What does the annual audit really achieve?  
2 In fact, I could tell you some stories and I won't  
3 go into any stories about Food Safety and Inspection  
4 Service because they're actually the good guys, and  
5 I'm not going to mention the Europeans either  
6 because Wolf was here, but a lot of auditors  
7 actually come to our country always over the summer,  
8 biggest holiday period, the selection of plants are  
9 always in the nicest locales. They usually come  
10 with a big camera and some of them, and especially  
11 it's increasingly happening with some of the Asian  
12 markets and Central American markets, they ask us to  
13 pay for the privilege, they ask for us to pay them  
14 per diems in advance, in American dollars, while we  
15 actually still pick up the hotel bills and pay for  
16 their dinners as well.

17           So I ask again, what does the annual audit  
18 really achieve? And do you need six weeks to go  
19 around to as many establishments or can you focus  
20 more on the system and the control of the  
21 controlling authority?

22           If the system is science based and risk

1 focused, should we impose our systems on other  
2 countries? We've got different risk profiles.  
3 We've got different hazard profiles. We've got  
4 different cultural contacts. We've got different  
5 political contacts. You've got to have a system  
6 adapted to your own country.

7           What does the so-called reinspection at the  
8 border really achieve? Well, I'll tell you now most  
9 of it is picking up, you know, differences in  
10 shipping marks, occasional carton damage. Half of  
11 that is caused by actually product being moved on  
12 the inspection floor by forklifts, some labeling  
13 issues. A lot of that stuff is actually in the  
14 commercial domain, not really food safety stuff, and  
15 it could be handled commercially. What would you  
16 achieve if you reinspected your own product in the  
17 same way? Would it show any difference?

18           So New Zealand's approach is to focus on  
19 relationships, assess the equivalence of the  
20 approach, then leave it to operate and evolve. We  
21 try not to double regulate. We audit and review the  
22 relationship every three to four years while staying

1 in constant communication in the interim, of course.  
2 We do not reinspect at the border. It just isn't  
3 sensitive, and it's neither an effective or  
4 efficient use of resources. You can't inspect  
5 quality or safety I should say into a product,  
6 especially at the end of the chain there.

7 We do, however, continue to monitor and  
8 review the system and some product sampled and  
9 released at the boarder. I think it was one of your  
10 Presidents who said trust but verify.

11 So our regulatory model, if you can just  
12 click this a couple of times to bring it up, whoops,  
13 go back. We ask that countries focus on looking at  
14 us. At Head Office, we have an audit group similar  
15 to Don Smart's group that audits all of our  
16 inspectors. Our inspection agency or verification  
17 agency also has their own internal audit which  
18 audits all of their own inspectors that also have  
19 technical groups that go out and provide technical  
20 resources.

21 So when a country comes to us, they can get  
22 all the information that we have essentially. We

1 have a whole lot of central databases as well, and  
2 they're welcome to go out and visit a few premises  
3 if they like but it doesn't have to focus on the  
4 establishment level. It should focus on the level  
5 of control.

6           Next one please.

7           So the advance is already available and  
8 Mark Schipp touched on this a little bit. So did  
9 Mary Stanley. Electronic certification, 100 percent  
10 of our meat to this country is currently populating  
11 your AIIS system electronically. So there's no  
12 manual input by the inspectors. What that provides  
13 is advance notice of product coming in. You can do  
14 a risk-based inspection assessment if you like. It  
15 provides far greater security and there's a lot of  
16 food going around the world at present, a lot of  
17 food.           Direct           government-to-government  
18 communication. Electronic availability of internal  
19 order summaries, all of these are currently  
20 available.       Microbiological databases, residue  
21 databases,       disease       and       defect       performance  
22 monitoring. We have an electronic system where this

1 is all collected centrally, and we can make it  
2 available to the Food Safety and Inspection Service  
3 if they like.

4           One thing we are going to say is that as we  
5 start talking about these things, we want to look at  
6 reciprocity. So when you start looking at what's  
7 relevant for the United States, we'll say, well,  
8 okay, if you think that's relevant, maybe we should  
9 be, you know, can you supply us the same  
10 information? And with your Public Health Inspection  
11 Service coming on line, a lot of that information  
12 will be available in the future. All of that  
13 information that I put up there is currently  
14 available.

15           So increased communication, cooperation and  
16 transparency is key to advancing any relationship  
17 and evolving the relationship and that's part of  
18 your charge today.

19           So prerequisites for comparability, a  
20 demonstrated willingness to take safeguard actions  
21 in situations where there's a possibility of  
22 unexpected risks to human health, e.g., new and

1 emerging hazards in the food chain. So you've got  
2 to make an assessment of whether you can trust the  
3 country there. An ongoing commitment to risk  
4 assessments by exporting and importing countries to  
5 service continuous improvement in food safety.  
6 We're not talking about abrogating our  
7 responsibilities as regulators here. We are only  
8 talking about evolving them where we have a high  
9 level of knowledge, confidence and experience.

10 Mutual recognition of food safety measures  
11 at a level where there is sufficient experience,  
12 knowledge and confidence to accept such measures as  
13 likely to produce comparable food control outcomes.  
14 And replication of specific requirements by the  
15 exporting country if the importing country has  
16 scientific justification and no equivalence  
17 determine is sought.

18 Those two points are very important from  
19 the point of view of what level do you do it, you  
20 know. We tend to replicate the components in the  
21 system. Do you have to replicate exact methods,  
22 exact procedures? Do you have to ask for prior

1 approval? And I'd say no. I'd say that it's an  
2 efficient system and it's an appropriate way of  
3 doing it if you've got a long-term relationship, if  
4 you've got to trust in the system, if you've got to  
5 trust in their approach and it is truly science and  
6 risk based.

7 So transparency in all aspect of food  
8 control again are key.

9 So as I say our preferred approach is to  
10 use cooperative agreements. They're increasing in  
11 number and scope. You don't do them unless you have  
12 the experience, knowledge and confidence, and they  
13 must ultimately reward performance. Canada and  
14 ourselves are currently working up one because we've  
15 had a very long history and Richard had talked about  
16 what NAFTA negotiated for the U.S. and Canadian  
17 environment, whereas, you know, we think we should  
18 be awarded on performance rather than what the trade  
19 negotiators can do around the table.

20 Again, in cooperative arrangements or  
21 agreements, comparability of likely outcomes of food  
22 regulatory food control system will always be a

1 qualitative judgment. None of our systems have  
2 enough of that quantitative data to really be that  
3 objective. Where significant differences in hazard  
4 status exists, there will always be some specific  
5 technical requirements that we consider separately.

6 So in conclusion, in the developing world,  
7 the public health goals and outcomes achieved are  
8 broadly similar. Those of us who travel a lot can  
9 actually testify to that.

10 In food safety, it's difficult to define  
11 and directly compare a country's appropriate level  
12 of protection with another. That's reality.

13 Where a higher level mutual recognition can  
14 be based on the comparability of public health  
15 outcomes and programs of measures or groups of  
16 measures, this is a much more efficient and  
17 effective relationship. It allows you to prioritize  
18 resources without affecting your level of  
19 protection.

20 So where we're at, we're moving towards  
21 mutual recognition, or the highest possible level of  
22 equivalence, between trading partners that we have

1 long-term relationships with and trusting  
2 relationships with. It requires, as I say,  
3 experience, knowledge and confidence of each other,  
4 ongoing transparency and a willingness to take  
5 safeguard actions and/or otherwise minimize risks  
6 where specific hazards exist in the exporting  
7 country to start this journey. So it's not for all.

8           So in consideration of your charge, it's  
9 something we'd like you to think about. What you're  
10 looking at is a risk-based system if you like, and I  
11 know that term is an anathema in this country to  
12 some extent, but as far as, do you put all your  
13 resources in the countries that have performed 40  
14 years or do you put them in the ones where you're  
15 actually just starting a relationship.

16           So I thought I'd just finish with a couple  
17 of very lighthearted slides. Just putting risk in  
18 perspective, if you're going to intervene, you need  
19 to know what you're doing, or else. It's one for my  
20 Canadian colleagues. (Laughter.) And then all of  
21 us international traders, there are cultural  
22 differences. The mark of inspection can mean

1 different things to different people. (Laughter.)

2 So some questions.

3 MR. TYNAN: Thank you, Dr. Jolly. I'm  
4 going to open it up for just a few questions at this  
5 particular point, and I'll start with Mr. Kowalcyk.

6 MR. KOWALCYK: Thank you. Dr. Jolly, I do  
7 have a question about New Zealand's system where you  
8 do not reinspect when you're importing product but  
9 you do some sampling. I'm assuming, is that  
10 microbial testing done at that point? And if that's  
11 part of the sampling, what you mean, and also a  
12 follow-up question to that is, when your country  
13 finds an adverse result from that testing, what then  
14 happens? What's the next steps in your process?

15 DR. JOLLY: Okay. I'll give you as an  
16 example, the 40 percent of the pork consumed in New  
17 Zealand which is imported, the countries in order of  
18 greatest significance in the export of pork to us  
19 are Australia, it used to be Canada, but it's now  
20 the U.S. and then it's Canada and then it's Denmark  
21 and then it's Finland. With that product, we don't  
22 hold it up and send it off to an inspection facility

1 and delay the entry into commerce. We've already  
2 had it certified. We've assessed the systems, and  
3 so there is a low grade sampling of it, and we run a  
4 variety of chemical analyses and microbiological  
5 analyses.

6 We're careful in what we look for. Now,  
7 with the latest LCMS methodology, you can screen for  
8 over 240 veterinary drugs and pesticides in one  
9 analysis like that. This is what Japan and Korea  
10 are doing and China to some extent.

11 Now, the likelihood of finding a  
12 difference, an especially in a country that has more  
13 pesticides or veterinary drugs registered than you,  
14 like the United States, is quite high. So we're  
15 very targeted in what we look for and it has to be  
16 something which we consider may be a potential risk.  
17 So we tend to look for hazards of significance  
18 rather than just go after any hazard. I hope that  
19 answers the question.

20 MR. KOWALCYK: I guess just the one follow  
21 up I had is if you do find an acceptable hazard --

22 DR. JOLLY: Sorry.

1           MR. KOWALCYK:   -- what is your process  
2 then?

3           DR. JOLLY:   Okay.   I'll give an example  
4 with residues.   For residues, first of all, our  
5 domestic law defaults to CODEX standards for imports  
6 and CODEX standards are usually several times higher  
7 than our standards but they've been assessed as  
8 safe, and from an exposure point of view, there's no  
9 difference.   Where we do find a residue level higher  
10 than the CODEX or the domestic standard of the  
11 exporting country, we do not automatically go into  
12 an -- regime.   We do an exposure calculation to see  
13 whether there is any possibility of an acute health  
14 risk.   We look at it from whether it's an illegal  
15 drug residue as far as whether it's legal in that  
16 country exporting or whether it's illegal because if  
17 it's illegal in the exporting country, then they  
18 usually want us to take some enforcement action as  
19 well.   But we take it from a toxicological point of  
20 view.   That's why we do a sample and release.   So  
21 it's a monitoring.   The target of that sample is not  
22 the consignment.   That sample is representing the

1 assurances of the controlling authority.

2           Now, we all know if we look at the  
3 country's residue reporting results, they'll have  
4 say 1 percent positive of a variety of veterinary  
5 drugs. And so if you take 100 samples from a  
6 country that's exporting to you and you find 1  
7 percent non-compliant, you've just confirmed exactly  
8 what the country's found itself. So we tend to take  
9 a very measured response. Now, if we keep finding  
10 an issue which is starting to be of concern, then  
11 our next response is to openly communicate with that  
12 country, where we results irrespective, but engage  
13 in a dialogue to say, well, you know, can you please  
14 manage that down to make it into our acceptable  
15 levels.

16           MR. TYNAN: Mr. Elfering.

17           MR. ELFERING: One question that I have is  
18 even though it's not required, the products red deer  
19 and other venison products do not fall under FSIS  
20 jurisdiction as far as import. Are they still  
21 processed under the HACCP system using pretty much  
22 the equivalent system or is it a completely

1 different system? I recall at one time that a lot  
2 of the red deer are harvested in the field and then  
3 have these mobile abattoirs that are doing the  
4 processing but are they meeting all the other  
5 requirements?

6 DR. JOLLY: Okay. This is the beauty of  
7 having a single food safety agency. They're all  
8 processed under the same law, the Animal Products  
9 Act. So they all have a risk-based system. They  
10 all have government inspection. They're all subject  
11 to the same National Mark Biological Program.  
12 They're all subjected to the same disease and defect  
13 database. Effectively, they have exactly the same  
14 processing controls and government inspection.

15 I might add that New Zealand lives in very  
16 much of a glass house because we explore all around  
17 the world. Just about all our premises, and I know  
18 deer premises don't need to be listed for the U.S.  
19 because it's a FDA regulated food, but for other  
20 countries they do. Just about all of our premises  
21 are listed to just about every country. So I think  
22 we've got one premises that mightn't have both

1 the -- U.S. and EU listing as well as Japanese,  
2 Korea and Russia, you name it. I mean, so there is  
3 no sort of lower standard applied.

4           With respect to your statement about wild  
5 deer or game versus farm deer, just most of the deer  
6 in New Zealand, the deer meat is actually farm deer,  
7 and so it's just like any other farmed animal. We  
8 do do some wild game, shot deer, and it's fallen off  
9 over recent years, and that almost exclusively goes  
10 to Germany where they quite like that sort of gamey  
11 taste but again, that's subject to very strict  
12 criteria. They've got to get a game deer to a cold  
13 store very, very quickly. It's got to have certain  
14 of its organs still there so that a postmortem  
15 inspection can be applied, and then all the same  
16 sort of microbiological criteria and postmortem  
17 inspection apply from that point in time. So it's  
18 quite good for wild game, but in the '80s, there  
19 were more wild game being exported than there was  
20 domestic, but that changed in the '90s and the  
21 2000s.

22           MR. TYNAN: Mr. Corbo.

1           MR. CORBO: Tony Corbo from Food and Water  
2 Watch. Dr. Jolly, as the CSPI poll indicated,  
3 American consumers are very concerned about food  
4 imports from China. Does New Zealand import very  
5 many food products from China?

6           DR. JOLLY: We're increasing importing food  
7 products from China as is the rest of the world.  
8 Some of the Chinese systems are world class. They  
9 now have some world class poultry processing  
10 premises, and we've recently signed a free trade  
11 agreement with China which is a very high quality  
12 free trade agreement. It's got a large SPS chapter  
13 in it. And one of the things we made very clear to  
14 the Chinese is with 1.3 billion people, versus our  
15 4.4 million, there's no way we can either have a  
16 hope of inspecting, you know, any of their millions  
17 of premises.

18           And so one of the things we do with our  
19 equivalence arrangements around the world is we try  
20 and triangulate. And so the Europeans especially  
21 have been very much involved in auditing Chinese --  
22 I'll use Chinese poultry as an example, even though

1 they're not exporting poultry to us. But they've  
2 been very much involved in auditing the Chinese  
3 poultry premises and they really are world class  
4 now, and so where the Chinese have gained  
5 accreditation from the Europeans to export to the EU  
6 under EU certification, then we would consider, if  
7 it complied with our animal health requirements,  
8 having that same product certified in the same way  
9 because we've already recognized the EU systems as  
10 being equivalent to ours.

11           So we intend to use the meager economies if  
12 you like, such as the U.S. and the EU and others, to  
13 act as a source of placement if you like in the  
14 international trade with China. But it needs to be  
15 said that while you can get anything you want in  
16 China, at the top end, you can get the very, very,  
17 you know, best. It's no longer third world, you  
18 know, across the whole spectrum. It's producing,  
19 you know, some of those plants are just fantastic.

20           MR. CORBO:     Have you encountered any  
21 problems in your dealings with the Chinese?

22           DR. JOLLY:     At the time of the melamine

1 issue, we, like a lot of countries, thought it was  
2 about time we sort of did a bit of a survey for a  
3 variety of residues for Chinese products, and we did  
4 it, and we did it as a sample and release, and then  
5 we published the results. But we thought we'd be  
6 fair and we'd do a bit of a market basket survey of  
7 our own produce at the same time, and it was a  
8 really funny one, and I think I was in the States at  
9 the time, and Murray Lumpkin is the one that  
10 actually showed me the media article, and it came  
11 from our own media and it was, "Chinese food okay,  
12 New Zealand food dodgy." (Laughter.) And we picked  
13 up something like, you know, there was three or four  
14 noncompliances in broccoli or strawberries or  
15 something, you know, like that, and the Chinese only  
16 had one. And but that for us was, we did it for  
17 political reasons because there was a lot of  
18 political pressure but we thought, well, we'll put  
19 this in context and we'll do a like with like. And  
20 the Chinese were really appreciative of that because  
21 it's very easy to pick up on difference and, you  
22 know, for the most part, if you empower AQSIC (ph.)

1 to certify, then they do the job very, very well  
2 and, in fact, their sort of range of sanctions far  
3 exceed ours. (Laughter.) Those of you who are  
4 laughing know what I mean.

5 DR. CORBO: Thank you.

6 MR. TYNAN: At least Tony didn't advocate  
7 any sanctions like that. (Laughter.)

8 Mr. Painter, I'm going to let you have the  
9 last word again.

10 MR. PAINTER: Yes. Stan Painter with the  
11 National Joint Council. I'm looking at your slide,  
12 it's entitled New Zealand's Approach, and it says,  
13 focus on the relationship and it says, audit/review  
14 the relationship every three to four years. What is  
15 meant by review the relationship?

16 DR. JOLLY: It was really from a point of  
17 view of considering an audit or considering a more  
18 in depth review of results. In a lot of our MOUs  
19 and I'll give as an example, we have a seafood  
20 equivalency MOU with Canada which had stipulated  
21 that frequency that we reviewed each other's results  
22 and each other's programs. Now, in the intervening

1 period, we had no reason to suspect, we had no  
2 problems with each other's exports but, you know,  
3 it's not something you give a license for life. You  
4 always put in some form of review criteria.

5           So for the EU, again they come out and  
6 review us, individual parts. So the meat program  
7 might review every three, four years. The dairy  
8 program might review every, you know, two or three  
9 years on a different sort of basis, and what we've  
10 done with the EU is rather than actually trying and  
11 going review all 27 member states, we actually sent  
12 one of our national auditors to be -- to their Food  
13 and Veterinary Office for three months, and be part  
14 of their own audit system to actually assist the  
15 competency of the controlling authority in its own  
16 audits.

17           So that's an example, if you like, of what  
18 we've done. If you ask us when was the last time we  
19 actually did a physical audit of the United States,  
20 or Canada, I couldn't tell you. If you ask me the  
21 last time one of my inspectors walked around some  
22 premises in the United States, I'll tell you last

1 year and there will probably be another one soon,  
2 because we send them over to the inspector's course  
3 and they go through some of your premises. We have  
4 a lot of people come over, you know, for technical  
5 exchanges and things like that. So there's lots of  
6 different ways of maintaining that confidence other  
7 than physical audit.

8           In saying all of that, we're a small  
9 country for imports as well, and so the rigor of  
10 what the United States does probably is justified  
11 being a little bit higher and especially for certain  
12 countries.

13           Now, the question that you guys need to  
14 deliberate is whether one size fits all, whether you  
15 need to do that for the countries such as Canada,  
16 Australia or New Zealand, who have been exporting to  
17 you for a long, long time, and for which there is a  
18 very high level of knowledge, confidence and  
19 experience. Is it a law of diminishing return? Is  
20 that the most efficient use of your resources? And  
21 with these, you know, more modern ways of exchanging  
22 data and measuring each other's systems, or having a

1 measure on the system, is that going to provide a  
2 similar level of confidence? Is that a way to  
3 evolve the system in a more effective way, more  
4 effective use of resources, and will that then allow  
5 you to focus where you see the potential for real  
6 food safety risks coming into this country?

7 MR. TYNAN: Thank you, Dr. Jolly. I'm  
8 going to close out all the questions right now. And  
9 we have on our agenda at this particular point  
10 probably actually a good hour ago, we were supposed  
11 to enter the public comment period, and according to  
12 the note that I have, we only have one person that's  
13 registered, and I think the gentleman's name is  
14 Christian Ouzts. I'm sorry if I did your name  
15 incorrectly. We have a handheld microphone. So  
16 we'll bring that over to you. Maybe you could stand  
17 and give us your name correctly this time, and  
18 you're affiliation.

19 MR. OUZTS: You did good. It's Christian  
20 Ouzts, and I'm with the industry. I actually work  
21 with Amick Farms, poultry industry in South  
22 Carolina.

1           So I apologize for taking the time, kind of  
2 veering away from the main event, but there was a  
3 lot spoken to risk-based inspection and things this  
4 morning. So I think it is due some questions.  
5 Again, I apologize for getting away from  
6 international equivalence, but my questions are more  
7 for Dr. Dreyling and I actually have four. So I  
8 don't know how -- okay. I'm not sure how you want  
9 me to approach it.

10           MR. TYNAN: Well, Erin, did you want to  
11 come up. We have a microphone right here for you.

12           MR. OUZTS: The first question is in  
13 reference to the *Salmonella* and microbial resistance  
14 referred to in the slides presented this morning.

15           DR. DREYLING: Uh-huh.

16           MR. OUZTS: What role, if any, will this  
17 play with allocation of resources, FSAs, things like  
18 that?

19           DR. DREYLING: Yeah. At this point, we  
20 have not made any determinations about how we're  
21 going to use antimicrobial resistance information in  
22 our risk ranking algorithm. And so we're not using

1 it at this point in determining how to allocate any  
2 of our resources or to use it as an establishment  
3 risk factor.

4 MR. OUZTS: Okay. Thank you. Second  
5 question is in reference to the statement and the  
6 slides about data infrastructure.

7 DR. DREYLING: Uh-huh.

8 MR. OUZTS: As far as *Salmonella*, the most  
9 frequently found in FSIS establishments, not being  
10 part of the top serotypes of human illness by the  
11 CDC I think.

12 DR. DREYLING: Right.

13 MR. OUZTS: And the question in regards to  
14 that, can you expound on how the statement relates  
15 to the attribution gap that has been spoken of in  
16 past meetings?

17 DR. DREYLING: So our attribution  
18 methodology that we proposed at the last meeting did  
19 not take into account *Salmonella* serotypes. We are  
20 taking to the National Academy actually the question  
21 of should we consider serotypes in our attribution  
22 methodology? Do they think that we should be

1 thinking about serotypes in methodology? So we have  
2 proposed that question to them, and we are thinking  
3 about how we can take that information into account  
4 as we move forward.

5 MR. OUZTS: Okay. Two more. The last one  
6 is in reference to the NAS. In reference to the  
7 non-establishments that were visited and spoken of  
8 in the slide 4, the improvements for processing and  
9 slaughter inspection, can we know exactly what the  
10 focused items were in those non-establishments that  
11 were visited?

12 DR. DREYLING: The focus --

13 MR. OUZTS: Has it been made public with  
14 what was focused on when the Agency went into --

15 DR. DREYLING: What we did in each  
16 establishment was that we were not there to evaluate  
17 the establishment. We were there to walk through  
18 the methodology with our inspection personnel. And  
19 what we did is we had a frontline supervisor or a  
20 circuit supervisor from the district that the  
21 establishment was in walk through the focused  
22 inspection methodology. So we reviewed the plant's

1 hazard analysis, the decisions that it made in its  
2 hazard analysis, any prerequisite programs, and then  
3 we walked through the floor to observe what they  
4 said they were implementing was being implemented.

5 MR. OUZTS: Okay. The last question, and I  
6 appreciate your time. I would like to commend the  
7 Agency in soliciting the NAS for advice and  
8 recommendations, and I was wondering what makes the  
9 decision about what is followed, what  
10 recommendations that they make, which one of those  
11 recommendations, if any, are followed? What's the  
12 decision-making process with that?

13 DR. DREYLING: I mean, we certainly will  
14 take their recommendations into account, and we will  
15 refine our methodology as we best can according to  
16 their recommendations.

17 MR. OUZTS: Thank you.

18 MR. TYNAN: Thank you, Mr. Ouzts. Do we  
19 have any other comments from the public? Yes, sir.  
20 If you could identify yourself and your affiliation  
21 please.

22 DR. SUPPAN: I'm Steve Suppan. I'm from

1 the Institute for Agriculture and Trade Policy in  
2 Minneapolis.

3 In the December 2007 Inspector General's  
4 Report, there was a discussion about why wasn't or  
5 what was the trigger for enforcement actions as a  
6 result of noncompliance reports, and an answer  
7 unattributed to the specific FSIS Administrator was  
8 we don't have decision criteria yet for determining  
9 when to trigger enforcement actions, but personal  
10 judgment was that it would take a higher management  
11 level than a district supervisor. So I would  
12 suggest to the Committee that they try to get some  
13 answers concerning when do noncompliance reports  
14 trigger enforcement actions because this problem's  
15 going to become obviously an issue with import  
16 reinspection as well as with domestic inspection.  
17 Thank you.

18 MR. TYNAN: Okay. Thank you. One last  
19 call for public comment? If we have any public  
20 left. I think a lot have already worked their way  
21 out.

22 (No response.)

1           MR. TYNAN:   Okay.   If there's no further  
2 public comments, I'm going to suggest as I have all  
3 day sort of a modification of the agenda.   I think  
4 we originally had talked about getting into our  
5 groups now and having some beginning dialogue, but  
6 obviously at this point in the day, I think  
7 everybody's had a full day, and I appreciate  
8 everyone's participation and sitting through all of  
9 the discussion.   This was not quite the way I had  
10 envisioned the agenda playing out, but I do think it  
11 was better.   At the end of the day, I think it was a  
12 better process by having questions after each of the  
13 presentations.   It took a little bit longer, but I  
14 think it was a better result.

15           So with that, what I would propose is that  
16 we gather back here before 8:30, maybe as early as  
17 8:15 if we could, so that we can be in the groups  
18 and ready to go because we are going to divide up  
19 tomorrow into Subcommittees and I'll ask Dr. James  
20 if he can come back at 8:30 to give us the charge.  
21 I think he wants to go through the issue and  
22 specifically the questions.

1           I will tell you that we have met with the  
2 two Subcommittee Chairs. We've talked a little bit  
3 with them about what we're looking for. I think  
4 they're sort of lined up to work forward. That may  
5 mean that tomorrow, we're going to have to work a  
6 little bit later in terms of your Subcommittee  
7 activities. But I think we have on the agenda maybe  
8 a 3:00 close.

9           So again, I would suggest for today, we  
10 adjourn and that we meet back here absolutely no  
11 later than 8:30 so that we can get started for  
12 tomorrow, and we'll have Dr. James at that  
13 particular point to give you the charge and get us  
14 started for tomorrow.

15           Thank you very much.

16           (Whereupon, at 5:00 p.m., the meeting was  
17 concluded.)

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C E R T I F I C A T E

This is to certify that the attached  
proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON  
MEAT AND POULTRY INSPECTION

INTERNATIONAL EQUIVALENCE

PLENARY SESSION

Washington, D.C.

August 27, 2008

were held as herein appears, and that this is the  
original transcription thereof for the files of the  
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and Inspection Service.

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TIMOTHY J. ATKINSON, JR., Reporter  
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