

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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INTERNATIONAL EQUIVALENCE

+ + + + +

SUBCOMMITTEE 2

VERIFYING INTERNATIONAL EQUIVALENCE

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August 28, 2008

9:00 a.m.

USDA South Building Cafeteria
Washington, D.C.CHAIR: DR. JOSEPH HARRIS
Southwest Meat Association

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MR. STAN PAINTER
MR. JOSH STULL

ALSO PARTICIPATING:

DR. BILL JOLLY
MR. GARY STEFAN
MR. LLOYD HONTZ
MR. CARL NEILSEN

I-N-D-E-X

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

2 (9:03 a.m.)

3 DR. HARRIS: -- is out running, but I don't
4 want to waste a lot of time here. Tony had
5 requested some copies of the IG report. I have been
6 told that those are happening. Maybe at least the
7 Executive Summary or something. I don't know if
8 they're going to be able to get us copies of the
9 full report because those things are somewhat
10 lengthy. So we may or may not have that.

11 Here's what I'd like to do. Before we,
12 before we jump right into, you know, yes, no, maybe,
13 whatever, you know, in answer to the questions, I'd
14 like to go around and see if those of you -- say at
15 least to start with on the Subcommittee, have any
16 initial thoughts relative to our assignments and
17 your thoughts regarding this in general, if anybody
18 has anything they want to sort of throw out on the
19 table before we get specifically into the questions
20 we're being asked.

21 (No response.)

22 DR. HARRIS: All right. Then we will move

1 right into the questions.

2 Question number 1, what recommendations
3 does the Committee have regarding the objective
4 evaluation of outcomes of a meat, poultry and egg
5 products safety system to determine if equivalence
6 is achieved and maintained? That's the big
7 question, and I think the A and B just help us
8 answer the big question.

9 Part A there is, let's start with it. What
10 objective outcomes are most appropriate to evaluate?

11 So now we're talking about the outcomes,
12 not the processes. Thoughts?

13 DR. DICKSON: I'll start in. Jim Dickson.
14 In the overall scheme of things, what the outcome,
15 objective outcome is, is what the consumer ends up
16 buying in the marketplace. And so whether you want
17 to classify that as product and not process or
18 process and not product, you know, I'm not going to
19 debate the words on it, but I think at the end of
20 the day, what matters is what the consumer ends up
21 being exposed to.

22 DR. MURINDA: Shelton Murinda. I think the

1 most important objective outcomes would be to have a
2 product, of course, that's abundant, nutritious,
3 wholesome, and safe. Safety not just in terms of
4 microbiological contents. We are worried about
5 chemicals that could be in the food, physical
6 hazards and in some instances, radiological hazards.

7 MR. FINNEGAN: Mike Finnegan. What gets to
8 the point, what barriers are in play to determine if
9 there is residues or what kind of system is involved
10 in exporting countries as to what kind of residues
11 are there? I referred to a self-assessment which
12 would at least this be part of it, but I'd like to
13 know how assured that the product is safe.

14 DR. MURINDA: Shelton Murinda again. His
15 contribution is pretty relevant to what I indicated
16 with regards to chemical hazards. Those residues
17 can be anything from hormones, toxins and the like,
18 even chemicals that are used as sanitizers. If they
19 are used at abusive concentrations, they can also
20 contribute to -- I guess to adverse health effects.

21 MR. BUSCH: Frank Busch. I think the
22 outcome we're looking for is the same outcome we

1 looked for for our own products, clean, wholesome,
2 unadulterated, properly labeled safety products and
3 I think that's a must.

4 DR. HARRIS: So that is kind -- the bottom
5 line objective outcome is clean, wholesome,
6 unadulterated product which is what you said in your
7 first statement.

8 DR. MURINDA: One aspect not included was
9 the, I guess, properly labeling. If products aren't
10 properly labeled, they can't be used. I guess they
11 could actually contribute to physical hazards.

12 DR. HARRIS: Of course, the next part of
13 this will be the trick here is now how do we measure
14 that. I mean, that's where it gets tough.

15 I just want to throw out just as I've been
16 thinking about this over the last day and a half,
17 listening to the talks and whatever, one analogy
18 that I continue to run over in my mind is we have in
19 this country and in every country around the world
20 some very sophisticated purchasers of product, and
21 they have very elaborate systems in place to
22 evaluate their suppliers, and when we're talking

1 about imports, we're talking about a similar
2 situation, if you want to think of the U.S. as the
3 customer and the various other countries around the
4 world as suppliers. And so to me it is helpful to
5 think in terms of that model and think, okay, if I'm
6 a customer, and how do I go about then evaluating to
7 make sure that I'm getting all of these things,
8 clean, wholesome, unadulterated, properly labeled
9 products from my customers, as well as products that
10 meet all my specifications.

11 Now, obviously a piece of that is knowing
12 that they have FSIS oversight in their plants if I'm
13 the customer and they're the supplier. That, that
14 when we're talking about another country, now we've
15 got another inspection entity instead of our own
16 domestic one. Stan, you had something.

17 MR. PAINTER: Stan Painter with the
18 National Joint Council.

19 And I want to say that I agree with
20 everything, with every point that everyone has made,
21 but I also think that we need to look at it from an
22 economic standpoint as well, as well as the safety.

1 Of course, that's the most important aspect of it
2 but certainly if I'm a customer, I'm wanting to buy
3 20 pound of product. I don't want it to be 10 pound
4 of water and 10 pounds of product, you know, we've
5 got to look at it from an economic standpoint as
6 well, as well as the safety aspect. I agree
7 completely with what everybody said, with the
8 residues, the safety aspect, but certainly I think
9 what's coming in, you know, and it could go back to
10 labeling. If it says it weigh 40 pounds of product
11 in a box, it should be 40 pounds of product in a
12 box.

13 DR. MURINDA: Shelton Murinda. I think
14 there's probably one component we left off that list
15 of outcomes, nutrition. It jives in what is
16 indicating proper labeling and content of the
17 product.

18 DR. HARRIS: I have a little hesitancy on
19 that one simply because I think nutritious is not a
20 clearly defined term. What is nutritious? Give us
21 your definition. If we want the products to be
22 nutritious, what does that mean?

1 DR. MURINDA: Nutritious? I guess the
2 product is to provide you with something that can
3 maintain or sustain your health. To quench your
4 thirst, if it's water. If it's food, it has to have
5 I guess a good balance of components like protein,
6 carbohydrates, vitamins.

7 DR. HARRIS: Do we require that
8 domestically of our food products?

9 DR. MURINDA: To be defined as food, I
10 think it has to have both components unless you have
11 a dinner with junk food.

12 DR. HARRIS: Cheryl.

13 MS. JONES: Cheryl Jones. Is it nutrition
14 or would that also fall under quality? Because if
15 you provide a quality product, then it should have
16 the nutrition that it's supposed to have. So if
17 you're providing a protein, whether it's -- and it's
18 not watered down, then it should be a protein. It
19 should be a clean protein. So are we talking about
20 that the product should have the nutrition or that
21 it should be a quality product and underneath that
22 is that it contains all the elements it is supposed

1 to contain?

2 DR. MURINDA: I guess quality would embrace
3 that component of nutritiousness.

4 MR. FINNEGAN: Mike Finnegan. If you're
5 talking nutritional labeling, is that what we're
6 talking about here? Nutritional labeling.

7 DR. MURINDA: Composition of the label, I
8 guess.

9 MR. FINNEGAN: Yeah. Which is required for
10 certain products especially if we go into the school
11 lunch programs, hospitals, nursing homes -- but not
12 all products require nutritional labeling, and I
13 can't see where we would require -- it depends where
14 the product's going. I don't know how we could
15 impose something on an exporter that we don't do on
16 ourselves.

17 DR. HARRIS: You had your hand up earlier.
18 No, you're okay. All right. Well, I guess that
19 particular term to me creates some difficulty for me
20 because I might want to import pure lard --

21 MR. FINNEGAN: Right.

22 DR. HARRIS: -- for a product that I'm

1 making. It's not a finished consumer product. I'm
2 going to use this as an ingredient in something
3 else. So to tell me that the lard that I'm
4 importing is got to be nutritious, that's a tough
5 one for me. So I have some problems including a
6 term like nutritious because we're going to
7 inevitably import some things that many would
8 consider not very nutritious or to even be junk food
9 was a term that someone else used. So that doesn't
10 make it any less eligible for import at least
11 currently.

12 MR. CORBO: What Dr. Jones -- this is Tony
13 Corbo. Dr. Jones I think may have hit the nail on
14 the head. The quality issue, the other consumer
15 protections as the -- and what Stan was indicating
16 as well, you know, the economic adulteration that
17 you're trying to avoid as well. So --

18 DR. HARRIS: Do we capture that when we say
19 properly and accurately labeled? Does that capture
20 the bulk of the other consumer protection? Stan,
21 you're shaking your head. I see disagreement down
22 there. How does it not?

1 MR. PAINTER: Stan Painter with the
2 National Joint Council. You could put on there
3 that, you know, that it's 20 percent water content
4 and the customer knows they're going to get 20
5 percent of water, you know, in the box but when they
6 pull the hunk of meat out and they have the box full
7 of water, they're public is not going to be happy
8 because in the fine print, if you put on the label
9 that this contains up to 20 percent water, then it's
10 properly labeled.

11 DR. HARRIS: Okay.

12 MR. PAINTER: But then the economic
13 standpoint is you're not getting what you bought.
14 You've purchased water for the same price that you
15 should have been paying for meat.

16 MR. FINNEGAN: Which comes to another
17 point, you know, that I'm thinking, maybe Bruce or
18 Dan can answer, exporting countries, are they
19 subjected to like, you know, we have restricted
20 ingredients, 156 parts per million for nitrites,
21 things like that? Is that across the board for
22 exporting countries also?

1 DR. ENGELJOHN: Yeah, this is Engeljohn.
2 Yes, an exporting country would have to meet our
3 domestic requirements.

4 MR. FINNEGAN: Okay.

5 DR. ENGELJOHN: However they formulate the
6 product or label it would be the same as what would
7 be here.

8 MR. FINNEGAN: Okay. As far as like he was
9 saying, you know, corned beef for instance, you've
10 got 20 percent and so the same thing applies. So we
11 don't really have to go over that. We've already
12 got it all in place, right?

13 DR. HARRIS: Jim, did you have something?

14 DR. DICKSON: I think they got it.

15 DR. HARRIS: How do we measure these
16 things, wholesomeness, unadulterated, properly
17 labeled?

18 MR. FINNEGAN: Well, one thing that I
19 brought up in the full Committee was I know as a
20 state program, we have self-assessments of our
21 program and included in that self-assessment is
22 certain components. Components of how you're

1 dealing with a new directive that comes out for BSE,
2 SRM, and the exporting country would look at this
3 self-assessment and they would have to answer each
4 component, the specific components I'm not sure, you
5 know, I'm not involved with the exporting. That
6 would be one method that I could think of, kind of a
7 self-assessment from each country. I'd just want to
8 tell you, with self-assessment, and we've got 50
9 some plants, and it includes all of our 50 some
10 plants.

11 DR. HARRIS: Dr. Jolly, I want to ask you a
12 question. I know that states have had problems with
13 the volumes of notices and directives that come out
14 of FSIS in terms of keeping up with all the changes.
15 How do you all deal with that?

16 DR. JOLLY: I think it cuts to the chase.
17 Bill Jolly from New Zealand Food Safety Authority.
18 I think it cuts to the chase what's being asked here
19 about outcomes of the processes. What Mike's been
20 talking about is the processes, the procedures, the
21 details of how you actually did something and with
22 your state programs, it's -- you have to show that

1 you're doing, you know, basically the same as.

2 When you're dealing with a sovereign
3 nation, you're asking a question are they meeting
4 the outcomes? Are they meeting the requirements as
5 far as, you know, what is specified as far as
6 nitrites or water or lack of adulteration, and
7 exactly how you do it is not -- you don't use
8 probably exactly the same procedures or processes.
9 Some of them may be inappropriate from the point of
10 view, it might be something more intensely if you
11 have greater hazard challenge in that country or if
12 you don't have the same sort of hazard challenge or
13 you have a different process, it might be
14 inappropriate from the point of view of being
15 redundant.

16 So the long and the short of it is when
17 these directives and notices come out, we assess
18 them but it's the outcomes that are being met as
19 what we certify to and what we engage with and what
20 we provide the information on and what we're
21 ultimately assessed on. And so, you know, focusing
22 in on those outcomes, making sure that the product

1 is not adulterated, it's truthfully labeled, that
2 it's safe from adulteration in any way and meets the
3 specifications.

4 The only other thing I'd like to say is we
5 heard a little bit about some economic issues, and
6 one of the reasons we got into electronic
7 certification was to prevent -- the New Zealand
8 brand is probably the most highly valued brand in
9 the world, and fraud is increasing. And so we
10 wanted to ensure that with all the security devices,
11 no one tries to market a product that's not New
12 Zealand product at the border.

13 Now, when you start getting a little bit of
14 other economic issues, you know, the same
15 impertinence exists within the United States as may
16 exist for Julius (ph.) exporters or whatever that
17 may be, you know, wanting to shaft the system. Now
18 where's it that, you know, you've got to make that
19 decision. Is this something which is a border
20 inspection issue? Is this something which is new
21 market issues? Is it something which is a -- dealt
22 with supplier and customer space for patience, and

1 the answer is probably a little bit between the two.

2 But if you focus on outcomes and what the
3 federal authority really wants to achieve to provide
4 an assurance at point-of-border check, that the
5 product that they're getting is going to be
6 substantially the same from an outcome base as
7 product that's being produced within the U.S. I
8 mean, that's where you need to focus on.

9 DR. HARRIS: I'd like to ask a question of
10 our regulatory Agency people in the room. Is there
11 a -- I assume there is. What is the regulatory
12 current definition or the legislative definition of
13 equivalency? Because obviously the statute's not
14 going to change. Whatever we're doing, whatever
15 recommendations we make, we still have to have
16 equivalency or product is not eligible for import.
17 Is that term defined? I would assume it's got to be
18 somewhere.

19 DR. ENGELJOHN: It's not defined.

20 DR. HARRIS: It's not.

21 DR. ENGELJOHN: We just use a regular
22 dictionary, which a dictionary would say it's the

1 same as or it gets at the issue of being equal to,
2 that type of thing. So that's really what it is,
3 but in the international arena, it really -- I would
4 say overall we would be looking at the outcome first
5 of all, but there are certain things for which the
6 outcome is a little bit different. The daily
7 inspection in the carcass by carcass. That's pretty
8 hard to come up with something different than that,
9 although we certainly entertain those issues, but in
10 terms of 0157:H7, as an example, states with equal
11 to, the expectation is that they're in essence in
12 compliance. They're doing the same thing that we
13 are in a very similar manner or we make exceptions
14 for small and very small plants versus large plants
15 in terms of intensity or focus, and for the most
16 part, they're small and very small plants and so
17 their level of intensity and focus could be not
18 exactly the same frequency as us, but they still
19 have a targeting system in place.

20 So it really gets down to how are you
21 meeting the intent of the policy by what you're
22 doing. So one is more the compliance issue and the

1 other is looking at the overall system and what
2 they're doing to achieve the same thing.

3 DR. HARRIS: Yes. Tony.

4 MR. CORBO: You know, I follow FSIS
5 through -- with the hearing process on Capitol Hill,
6 and this is boilerplate answer that the Agency has
7 given Congress over and over again. A foreign plant
8 could be de-listed if it were found to have any
9 serious deficiency that shows that it's not meeting
10 standards equal to those achieved in domestic
11 plants. Examples include instances of direct
12 product contamination, poor environmental sanitation
13 that could lead to direct product contamination,
14 lack of a sanitation standard operating procedure or
15 failure to implement an existing procedure, no HACCP
16 plan and an inadequate plan or not following an
17 existing plan, no testing for generic *E. coli*, less
18 than continuous inspection coverage, humane
19 slaughter violations and any other fundamental
20 requirement of equivalence.

21 DR. HARRIS: Okay.

22 MR. CORBO: And that's been the answer for

1 the eight years I've been following this Agency up
2 on Capitol Hill.

3 DR. ENGELJOHN: I don't see that any
4 different from what was just said.

5 DR. HARRIS: Are there other objective
6 outcomes that we've left out? So far here's kind of
7 where I am so far is that, you know, we have that
8 list of terms that we talked about, that that's the
9 product based outcome. Are there other outcomes
10 that we need to be thinking about besides just that
11 the product itself?

12 DR. ENGELJOHN: This is Engeljohn. Just
13 maybe to get at the issue, some countries only want
14 to send specific products. It isn't all meat and
15 everything that they do or all poultry and
16 everything they do. So it does depend in part on
17 what the exporting country chooses to ship to the
18 country. So I do think that's why sometimes it's
19 products focused in other -- the process is always
20 going to be there but the product gets in there
21 simply because that maybe the only product or a
22 limited type of product that the country wants to

1 send.

2 I don't know whether that helps you in
3 terms of thinking about that but it's dependent on
4 what the export country chooses to send to this
5 country I think what defines what we're focused on.

6 DR. HARRIS: Stan.

7 MR. PAINTER: Stan Painter with the
8 National Joint Council. I guess, I have a question
9 based on your question. Are you referring to
10 something like the meat -- container, the box, how
11 it's shipped? In other words, would it be something
12 that could be adulterated in transit if the
13 requirements are different, you know, with the boxes
14 and things of that nature, the storage, how, you
15 know, how it was stored in transit for, you know,
16 product that was incoming? Is that what you're
17 referring to? Are there things that we should be
18 looking at other than the product itself?

19 DR. HARRIS: Well, I think you are headed
20 the direction I was thinking in terms of, okay,
21 we've said that we want a clean, wholesome,
22 unadulterated, properly labeled, you know, et

1 cetera, et cetera, product. Now the question is are
2 there other -- I mean that is the bottom line, you
3 know. Now it's a matter of talking about, okay, how
4 do we get to that in point, and I think to your
5 point right there, properly packaged for the
6 conditions obviously contributes to those other
7 things. And so are there other things then that
8 need to be considered. If that's the bottom line
9 objective, then what are the objective measures, if
10 you will, or, you know, that contribute to that?
11 And this may be very long, and I don't know that
12 we'll ever even attempt to try to do a comprehensive
13 list but maybe we can at least categorize them.
14 Stan.

15 MR. PAINTER: Stan Painter again with the
16 National Joint Council. And following that same
17 train of thought, you know, certainly, you know,
18 regardless of how well it's packaged and things of
19 that nature, you know, we would inspect a truck if
20 it was going intrastate or interstate to make sure
21 the truck is clean, to make sure it's, you know,
22 there's no infestation of rodents or insects and

1 things of that nature. So let's say if we have
2 product coming in from another country, you know,
3 there should be some checks and balances as well, to
4 make sure that that, say it was a ship for instance,
5 the ship met the same standards that we would use if
6 we were, you know, transporting product within the
7 country, you know, the ship didn't have rodents.
8 They had some kind of pest control, you know, that
9 it wasn't in some kind of flimsy box that it wasn't
10 going to make the trip without getting torn open and
11 ripped open and adulterated.

12 DR. HARRIS: Thoughts?

13 MR. BUSCH: Frank Busch. If that was the
14 case though, that would be evident, and it would
15 still affect whether it was clean, cold and
16 unadulterated, if you had sanitation problems with
17 vehicles or you had flimsy cartons, they broke open,
18 that would be obvious when it entered the country
19 here. I'm sure it would be noted.

20 MR. PAINTER: Joe?

21 DR. HARRIS: Sir.

22 MR. PAINTER: Stan Painter again. Yeah,

1 but who's going to be looking at that ship when it
2 left that country for instance, and I'm using the
3 ship for an example. Should we ask for some kind of
4 certification that the -- I'm using a ship for
5 example, that it was clean when it left, that it was
6 free of rodents and they didn't use the ship to
7 transport hazard chemicals and then they throw a
8 bunch of product on it, you know. Should we be
9 looking at that? Yeah, a torn open box is a torn
10 open box.

11 MR. FINNEGAN: Maybe Frank can answer this.
12 You know, even before we get to the box part, is the
13 equivalence, does that mean that the exporting
14 country also are doing product sampling, you know,
15 looking for the O157, *Listeria*, things like that? I
16 don't know --

17 MR. BUSCH: Yes, they are, and I think Don
18 can probably give you a little bit more detail.

19 MR. SMART: Any requirement that we have
20 for industry in the United States is applied in the
21 foreign countries. As soon as we get a change, we
22 notify the foreign country.

1 MR. FINNEGAN: Okay.

2 MR. SMART: If it's complex, we ask them
3 how they're going to do it and then we audit against
4 it during the audit. That's what we've been doing
5 this year with all of the new 0157 protocols that we
6 implemented late last year.

7 MR. FINNEGAN: So you ask them how they're
8 going to do it, and then they respond with some
9 documentation, some assessment --

10 MR. SMART: -- copy of yours, and we do it
11 exactly like you do or we propose a different
12 method, and that's where equivalence comes in.

13 MR. FINNEGAN: Okay. So that it's
14 subjected to at least equivalency of the product
15 sampling.

16 MR. SMART: Exactly.

17 MR. FINNEGAN: Okay.

18 MR. STEFAN: Gary Stefan, HACCP Consulting
19 Group. The ability of a country to be able to track
20 product back in the case there's a need for a
21 recall, and also the ability of a country to verify
22 the origin of animals that they are processing are

1 issues that you may want to think about.

2 DR. HARRIS: But I'll ask a follow-up
3 question to that. Are we -- do we require those
4 things of domestic producers, processors?

5 MR. SMART: I think Gary knows the
6 requirements as well as I do. Under our HACCP
7 rules, there's some trace back requirements, but as
8 far as animal ID, we don't have that in the United
9 States yet, but a number of foreign countries do --

10 DR. HARRIS: What are the trace back
11 requirements in the HACCP Rule?

12 DR. ENGELJOHN: This is Engeljohn. I would
13 just say that in the perspective of anyone who
14 produces meat, poultry and processed egg products,
15 the requirements in the Acts are that you have to
16 provide information, anyone who handles meat,
17 poultry or processed eggs, so who did that come from
18 so that you know the supplying producer --

19 DR. HARRIS: Right.

20 DR. ENGELJOHN: -- or whatever and who you
21 sold it to. Those are the requirements.

22 DR. HARRIS: Those are the two main

1 requirements. It's got to be identified as to who
2 produced it and the producer has to know who it went
3 to.

4 MR. FINNEGAN: And that's already in place,
5 correct, under equivalency?

6 MR. STEFAN: Country of origin is an issue
7 because there are countries that aren't allowed to
8 export animals produced in that country but they're
9 exporting product that they received from another
10 country that's approved for exporting to this
11 country. So knowing where animals came from is very
12 important.

13 DR. DICKSON: Jim Dickson here. But isn't
14 that part of what APHIS does, I mean, from a foreign
15 animal standpoint? Isn't that APHIS'
16 responsibility?

17 MR. STEFAN: It is APHIS, but it's
18 something that FSIS looks at before an establishment
19 is approved to export.

20 MR. CORBO: I already have a copy.

21 MR. SMART: You may want to read it on your
22 own rather than accepting Tony's analysis of the

1 report because when I read it, it didn't sound like
2 what Tony was talking about.

3 MR. CORBO: Well --

4 MR. SMART: Most of it was geared towards
5 -- indicating what we were doing, what we said we
6 were going to do. We just didn't have it documented
7 sufficiently in our management controls and actually
8 it was a follow up to an audit a few years ago I
9 believe initially they declared that 48 of the 50
10 original recommendations --

11 MR. CORBO: Right.

12 MR. SMART: -- were closed and signed off
13 on. So it was only two that weren't, and that was
14 documentation issues, and they went a little
15 further, but we always appreciate their input.

16 MR. CORBO: Right.

17 MR. SMART: But they took months and months
18 and months, and you guys have --

19 DR. HARRIS: A couple of hours.

20 MR. CORBO: And that's unfortunate.

21 MR. SMART: It is.

22 MR. CORBO: That's one of the reasons I

1 don't want to become a permanent member of this
2 Committee because it is rushed. I mean, this
3 Committee is always rushed.

4 MR. SMART: And at least for Mary and I,
5 it's really important what you guys come up with.

6 MR. CORBO: Right.

7 MR. SMART: And for the Agency, too, but
8 being an integral part of OIA, we try to act on
9 whatever you come up with.

10 DR. HARRIS: We can pass these around also.
11 They brought these into me, and we seem to have way
12 plenty of copies. These are some examples of audit
13 checklists. There's plenty more. If that doesn't
14 make it around, here's more. They brought those in
15 and handed them to me. It looks like this is one
16 that was actually done back in '07. Australia.

17 MR. CORBO: The unfortunate thing is that
18 the back part of it hasn't been copied.

19 DR. HARRIS: And what is it that -- you
20 mentioned that to me a while ago. What's on the
21 back?

22 MR. CORBO: One of the issues is the detail

1 of what the auditor found, you know, whether knives
2 weren't being cleaned between, you know, animals
3 being slaughtered, carcasses being dragged across
4 the floor, improper illumination, condensation above
5 the food contact area. So those are the sorts of
6 things that you would see back there, that the only
7 way you're going to be able to figure out whether
8 food safety controls are being met is to physically
9 being there to take a look as to whether the food is
10 being produced in a safe manner.

11 MR. SMART: Within the next few minutes,
12 we'll have two or three copies of a country report
13 with the attachments and with not only the regular
14 attachment, the second page of that, but also our
15 0157 checklist, humane handling checklist,
16 laboratory forms for residue and laboratory for
17 micro. I didn't want to make 20 copies of that.

18 MR. CORBO: Thanks.

19 MR. SMART: We have it here available.

20 DR. HARRIS: I want to make a comment here,
21 and I'm struggling with our questions here. I wish
22 I had in my own mind answers to those questions that

1 I could say here's what I think the answer to those
2 are, but my opinion is that what we have right now
3 is a pretty darn good program. There are probably
4 some implementation things that need to be tweaked
5 so that we don't run into a situation that we talked
6 about before and, you know, a number of shipments
7 showing up that weren't eligible or whatever.

8 And so I'm really struggling with, okay,
9 how does it need to be improved? Well, I'm not sure
10 that I know enough of the details about the
11 implementation to know but when I look through the
12 checklist and, you know, that looks a lot like that
13 customer/supplier relationship I was talking about
14 at the beginning where customers have a lot of
15 requirements and they send in auditors to verify
16 that that supplier is meeting all those things as
17 well as whatever other, you know, particular
18 specifications they want to audit against. And that
19 seems to me like a reasonable approach.

20 And so I'm, you know, the question of
21 objective outcomes to me is really difficult when I
22 think we've identified the key objective outcome

1 that we're looking for, and all of these things you
2 see on this checklist become a means to an end.
3 Yes, Dan.

4 DR. ENGELJOHN: This is Engeljohn. Maybe
5 to -- on something that Mr. Finnegan had said, and I
6 don't know if it -- with Bill Jolly also -- it, we
7 do have a fairly detailed process that we go through
8 on the state program equal to, which is perhaps more
9 defined than what it is in the international program
10 I think because there's more experience there.
11 Again, it's getting more at the level of compliance
12 with regs as opposed to health and -- but I think
13 the self-assessment that you identify each year
14 having to basically review how and why is it that
15 your program meets the expectations of FSIS is
16 something that I don't think is done for
17 international programs for equivalency, but I am
18 interested to know whether or not there is value in
19 that and whether or not that might be a tool to try
20 to get at the issue of how does the country they are
21 actually meeting this in a narrative type of way
22 with information. That's perhaps one way to get at

1 that.

2 Now, I don't know for Dr. Jolly if again
3 having to explain how you believe your outcomes meet
4 the expectations as opposed to every time we issue
5 an FSIS notice our expectation on the foreign
6 country isn't that they do it the exact same way we
7 do it because we know they have different systems,
8 different than what the state program is expected to
9 do. But I do think we have some need to know how
10 and why you believe you're meeting what we still
11 believe to be defining what's adulterated or what's
12 misbranded, because that's really what we're doing
13 through each of our policy issuances is providing
14 further clarity to help make it clear why we think
15 this situation is acceptable, and that was just as a
16 suggestion.

17 MR. FINNEGAN: On what Dan was saying, too,
18 in a deal like that, I don't know, Mr. Jolly, if it
19 would even, you know, work, where there would be an
20 assessment, how you could explain how you meet
21 certain standards, even though you're not going to
22 do things the same, and I understand that

1 completely. You don't want to be the same as, but
2 how you would meet the end results.

3 DR. JOLLY: Bill Jolly from New Zealand
4 Food Safety Authority. There's a fair amount of
5 consensus that the outcomes -- O157, you know,
6 meeting the -- standards -- standards, all the rest.
7 The real debate we're talking about is the how that
8 it's done. Now there are certain things which are
9 sacrosanct in as far as you want to see in the
10 program. You know, you want to see it being HACCP
11 based. You want to see the SSOPs, the SOPs. You
12 want to see government oversight. You want to see
13 government inspectors. You can list those sort of
14 seven or eight components.

15 Now, the difference between a state program
16 and a sovereign program is you have 140 countries.
17 The U.S. -- some commodities. The EU dictates a lot
18 more requirements on us than you do for some, and
19 sometimes there's a conflict inasmuch as the EU will
20 not allow chemical sanitizers on -- whereas you
21 almost want -- and so, you know, it's really a
22 conflictive situation.

1 But the truth of the matter is we have our
2 own law. Our law is 1999. The EU's law is 2002.
3 Yours is 100 years old. I mean, you talk to anyone
4 in the Agency, if they had a chance to actually deal
5 with more modern law, they would do things slightly
6 different. So some of the directives and procedures
7 and notices you get, is a way of implementing a very
8 old law and if you had a chance to actually put it
9 in a more outcome focused way, you would. So you
10 need to remember that. It's not just about, you
11 know, the procedures are often reflecting, you know,
12 the things which are specific in the country.

13 So an example, and Don Smart used it with
14 the recent *E. coli* sort of escalation of things
15 shall we say last year, and we all went into quite a
16 detail of the explanation of exactly what we were
17 doing in that respect, and that's a very important
18 aspect of it, but if you want us to explain each and
19 every single procedure, to some extent that's what
20 the auditors do, a result of looking at, you know,
21 whether they're meeting those outcomes. But at the
22 end of the day, it's whether that product is safe,

1 whether you can be assured it's safe, whether it's
2 been consistently coming in safe, and we've got over
3 40 year records, actually 100 record but 40 years on
4 the current paradigm. It's unequal.

5 We get end users like Keystone Foods or
6 McDonald's or Burger King or the others, and they
7 published papers comparing our microbiological
8 performance versus U.S., versus Australia, Uruguay,
9 or whatever. There's all these objective measures
10 in place. It's not something which you have to do,
11 you know, each and every time looking at carton by
12 carton. It comes out of the credibility of a system
13 as a whole, you know, the legislative base with a
14 hefty power, with hefty resources, free of conflict
15 of interest, with their credible, with their
16 demonstrated taking -- kind of action, whether they
17 have the same public health -- as your agency here.
18 Those are some of the things --

19 Those are the components of the system
20 which will give you the assurance of those outcomes
21 being met.

22 Now, you also have some of the other

1 objective measures. Every year we submit a residue
2 program. Now every year we request one from the
3 United States. We very rarely get one back in
4 return and the same with the EU, and so reciprocity
5 is something. Every time someone exports to 140
6 countries, how much are you going to supply to the
7 Koreans, the Japanese, the Chinese, the Russians,
8 and you've got to chalk it up a little bit to say
9 what's important.

10 You know, we're talking with the FSIS of
11 what other information, but the Public Health
12 Inspection System, we've already got a very similar
13 system in place. And, you know, we're looking at
14 giving each other risk -- online. Now, I guarantee
15 there's going to be more commercial sensitivities on
16 the U.S. side giving us the information than on our
17 side. We've already, you know, one that vetted with
18 our entry a long time ago is all transparent, but we
19 can give dock -- whatever information they want. We
20 can give them right down to the daily inspection
21 reports and inspectors filling online right now, you
22 know. We can get them the national market volatile

1 database which is all of that data gets looked at
2 nationally and profiled nationally, and this is all
3 the industry data as well as the government data,
4 you know.

5 So when you start looking at objective
6 outcomes, it's not just about the details or the
7 how. It's what delivers the -- that, you know,
8 those real food safety and adulteration things do
9 you need, and as I presented in my presentation,
10 it's things like, you know, whether you've got
11 adequate resources, adequate law and, you know,
12 demonstrated -- and, you know, willingness to take
13 safeguard actions, freedom from conflict of
14 interest. Those sort of things are what you're
15 after, and especially when you start to
16 differentiate between the, you know, the countries
17 that are in the high performing, and your next
18 question versus those that you haven't got so much
19 experience with.

20 DR. HARRIS: Okay. I'm going to take us
21 back to question -- someone has their hand up. I'm
22 sorry.

1 MR. BUSCH: Frank Busch with ATSP again.
2 Just to follow up on what Dr. Harris said, I think
3 we do have a good program in place. And I think our
4 objective is to find out, you know, we're aware of
5 what we're looking for. What outcomes do we want?
6 Clean, wholesome, safe, unadulterated product.

7 Now, in order to do that, we still have to
8 do record or review the documentation to see how
9 they're doing things, what they say on paper how
10 they're doing it, which we do that. And sometimes
11 it's very challenging, going back and forth with the
12 country for months and months and months. Then I
13 think on-site audits are a must also because we have
14 to verify what they're telling you in their
15 documents, and a lot of times, you know, they can
16 tell you one thing and then when you go down and
17 personally experience, like a couple of these
18 initial equivalency audits, you go there and they
19 don't have anything that they said they had in the
20 documents.

21 DR. HARRIS: Right.

22 MR. BUSCH: And so to insure that they have

1 these things, you have to do an on site. I think
2 the question is how many times, how frequently do we
3 have to do those items like audits. I mean we do
4 the same thing with our own plants. We go in there.
5 We make them have HACCP plans and the processes that
6 we go through. On the processes, because their
7 HACCP plan says we're doing this and this and this,
8 and we have to do this to insure we're going to get
9 a safe product at the end of production. We also do
10 end product tests.

11 You know, I think all of these are things
12 that we have to continue to do, but it's just that
13 the frequency is what we're looking for.

14 MR. CORBO: Yeah. Tony Corbo. You know, I
15 have no problem, and I think I said it yesterday, I
16 have no problem with the way the program is laid out
17 for FSIS. I mean it's light years away from what
18 FDA does. And that's, you know, I have real
19 problems with the direction that they're going in.
20 But sometimes there's an inconsistency in an
21 application, you know, you're getting consumers very
22 concerned about the safety of imported food and

1 when, you know, your auditors go abroad to do their
2 annual visits, and they find problems year after
3 year after year, and no action is taken to correct
4 those deficiencies and yet we're still allowing
5 these countries to export to the United States,
6 that's a serious problem.

7 You know, you all used to do what?
8 Quarterly audit visits in some parts of the world
9 and over the years, I guess starting in the
10 eighties, it got curtailed to annual visits. I
11 think you would have real problems with consumers if
12 all of a sudden USDA decided to scale back even
13 further.

14 DR. HARRIS: Jim.

15 DR. DICKSON: Yeah, I think and I hate to
16 bring this up, because I know the controversy that
17 comes around it, but somewhere you have to factor in
18 the risk. I mean, if you look at a history of a
19 country, hypothetically any country, and you
20 consistently see compliance with the guidelines,
21 compliance with the programs, high quality product
22 coming in, where it seems like from a resource

1 standpoint, maybe you should shift resources from a
2 country that has been getting it right for five
3 years in a row, maybe you should shift some of those
4 resources to the countries that consistently get it
5 wrong. And, you know, that concept is embodied in
6 microbiological sampling where you go from intense
7 to routine to reduced sampling, and basically that's
8 all we're saying here is if you have a country
9 that's getting it right consistently, maybe you
10 should take some of those resources and invest them
11 in the countries that aren't getting it right
12 consistently.

13 And somehow we need to incorporate that
14 into these comments, or at least I'd like to see
15 that incorporated into the comments because we can
16 address those countries that consistently have
17 violations.

18 DR. HARRIS: I think in question 2, we'll
19 get into that pretty extensively. Stan.

20 MR. PAINTER: Stan Painter, NJC. You know,
21 I agree with, with a part that Jim just said and
22 certainly it goes back to what Tony said. Why are

1 we wasting our time dealing with these countries
2 that don't comply? You know, it sounds like to me
3 that we're wasting time, effort, energy and resource
4 dealing with someone, we're thinking maybe somewhere
5 down the road, well, they're going to comply
6 somewhere down the road, and we'll continue to
7 accept product. We'll continue to let things in.
8 We'll continue to let it go until they comply. And
9 if it continues to go and go and go, what incentive
10 do they have to comply.

11 And then on the other hand, then you have
12 other countries that do comply and, you know, so
13 what incentive do they have to continue to comply if
14 they seen another country that's not complying?

15 DR. HARRIS: Don, do you want to answer
16 that?

17 MR. SMART: I missed the first part of it.
18 Based on some of the things that were said
19 yesterday, and Dr. Raymond said that on his watch
20 there had been three countries that have been
21 suspended, and maybe that a decade or more ago, we
22 allowed things to continue. Today, with this

1 system, and with our current Under Secretary, he
2 knows audit results before we're done with the
3 audit. If it's looking bad, we've already briefed
4 him, the Administrator, and all -- you're shaking
5 your head, Dan, but it's true, and by the time our
6 auditor gives the exit conference, we're ready to go
7 to the Secretary to say, you know, we're proposing
8 an action.

9 MR. CORBO: Yeah. Okay. Then what
10 happens? See, the thing is, and is -- I think you
11 were out of the room. I like your system. I think
12 it's great on paper but it's when you're on-the-
13 ground auditors come back with serious problems and
14 recommendations are made and then nothing happens.
15 The 2005 IG report on Canada was a prime example,
16 and then you've got a current situation right now
17 with Mexico has a similar problem, and that's where
18 the flaw is. That's where I see a problem.

19 I mean, the career staff is doing its job.
20 I'm going to be very blunt. It's the political
21 people over here that are interfering with the
22 proper implementation of the equivalency program

1 here.

2 MR. SMART: I won't go back to 2005, but
3 I'll go back to what you're saying about Mexico.
4 We're today 28 days past the end of the audit, and
5 something's going to happen --

6 MR. CORBO: Okay.

7 MR. SMART: -- momentarily one way or the
8 other --

9 MR. CORBO: Okay.

10 MR. SMART: -- and there was mention before
11 about trade and trade getting in our way. At least
12 since Dr. Raymond came on board, trade has not been
13 an issue. Food safety is the issue. We inform the
14 people that are involved in trade what's going on
15 but it does not affect the decision with how to deal
16 with the country. And the only reason we let a
17 country continue to operate is if they make a
18 concerted effort to fix what the problems are and
19 tell us in writing on our timeframe what it is, and
20 if they don't do that, they're going down. And we
21 make it clear to them. I'm not running the show
22 here, and I don't want to be pointing to anybody.

1 DR. HARRIS: Okay. Go ahead, Stan.

2 MR. PAINTER: Stan with the National Joint
3 Council again. And I respectfully disagree with my
4 fellow southerner. And we all know with all due
5 respect, Dr. Raymond is a short-termer because he's
6 is a political appointee. He will be gone in a few
7 months, probably by January or February. He is a
8 political appointee, and then you're going to come
9 in and, you know, you said Dr. Raymond is this and
10 Dr. Raymond is that, what have you, and that's all
11 well and good, but what's the next person going to
12 do, you know, and is the policy going to be looked
13 at in the same manner. We don't know that. We
14 don't know that that's going to be the case, but,
15 you know, personally I've had it out the wazoo with
16 China and, you know, it appears anything goes, you
17 know, with whatever product comes from China, and if
18 we get in the same situation with our food, with
19 someone else as we have with everything else from
20 China, you know, then we're going to be in a
21 critical mess, and everybody's holding hands and
22 sing Kum Ba Yah, and things are going on under the

1 table. And I respectfully disagree.

2 DR. HARRIS: Okay. Hold on a second. Let
3 me throw something out, and then I'll come back to
4 you because I want to keep our focus on our
5 questions that we are duty bound here to answer.

6 I'm going to throw something out to you,
7 that I want to expand our answer I guess a little
8 bit that, you know, the most basic objective outcome
9 that must be achieved is as we've written up there
10 on the screen, clean, wholesome, unadulterated,
11 labeled products. As a means to achieving that
12 outcome, another objective, and I'm hurting a little
13 here on my wording here, but that, you know, an
14 exporting country should be able to demonstrate, and
15 I listed about six things here, that the country
16 should be able to demonstrate effective hazard
17 control measures including physical, chemical and
18 biological hazards; effective sanitation of
19 facilities and sanitary operation of those
20 facilities. It should have robust testing and
21 verification programs in place whether that be for
22 microbiological or chemical hazards. It should have

1 effective government oversight, and it should have
2 programs in place to prevent any adulteration of
3 product, and that's sort of a catchall if I didn't
4 cover it in the first few things.

5 I want to throw that out as a suggestion of
6 some additional things we can put in there on
7 objective outcomes, that an objective outcome that
8 will hopefully lead to our most base one is that
9 they have effective programs in place to insure, you
10 know, sanitation of the facility and sanitary
11 operation of it.

12 And again, that list may be longer or
13 shorter as your pleasure, but I'm trying to at least
14 get us to a final answer. And by the way, I'm
15 putting this all under A.

16 UNIDENTIFIED SPEAKER: Oh, you are.

17 DR. HARRIS: Yeah, on how we measure those
18 things is what we're going to get to on B. So I
19 want to throw that out as a suggestion, and just get
20 your guys reaction to it. Tony.

21 MR. CORBO: I want to throw another fly
22 into the ointment, and I promised my sister consumer

1 organization, Safe Tables Our Priority, I would
2 raise this.

3 When there are pathogens in foreign
4 countries that are not present here, like the non-
5 O157:H7 STECs --

6 DR. HARRIS: Correct.

7 MR. CORBO: -- how does get played into the
8 mix in terms of what that country is doing to deal
9 with those pathogens as opposed to us, when we don't
10 have a similar standard?

11 DR. HARRIS: In my mind, I had that, must
12 have effective hazard control measures for physical,
13 chemical and biological hazards, but we might want
14 to expand that and say both hazards appropriate for
15 that country as well as, you know, what the U.S.
16 considers biological hazards. We don't have to deal
17 usually very much with O111, *E. coli* O111 but other
18 countries have a bigger issue with that particular
19 strain. So, yes, in my mind I was thinking that,
20 you know, controlling the hazards present, you know,
21 it would be appropriate for that country.

22 MR. CORBO: Well, I want to ask, do you

1 know of any testing protocols for some of these non-
2 O157:H7 --

3 DR. JOLLY: Well, it's a touchable issue
4 and both from -- and regulatory samples and some of
5 the methodology that we're using, you know, for the
6 O157 is very specific for product. With some of the
7 recent changes -- a little bit wider and so in the
8 submissions last year, we talked about some of the
9 other non-O157:H7 that we picked up but I think it's
10 something which all of us are actually pushing
11 towards and it will come out in due course.

12 What we don't know, of course, is some of
13 the attribution data as far as are they true risk,
14 and we've seen in the past like the other one, the
15 garabola (ph.) symptom in Australia in salami, that
16 there hasn't been anything like that, you know, ever
17 since, and that wasn't so much a pathogen issue as
18 actually a process item. So, you know, pathogens
19 will pop up anywhere if you have, you know, really
20 bad process -- critical control point. But I think
21 in the EU they're a little more advanced with the
22 non-O157 STECs but again, you know, your product --

1 you missed the pathway. The reason why O157 is so
2 important is because you have this habit of eating
3 slightly undercooked hamburger whereas the -- other
4 countries, you know, might be more delicatessen
5 meats or in -- so, you know, it's a little bit
6 different that what occurs in some countries. It's
7 not about -- it's about the risk and whether that
8 pathway exists and whether it's important.

9 DR. HARRIS: Thank you. I promised I'd
10 come back to you after I --

11 UNIDENTIFIED SPEAKER: Wake him up.

12 DR. HARRIS: Okay. Yes, Stan.

13 MR. PAINTER: Stan Painter, NJC. Maybe we
14 should be looking at diseases as well, hoof and
15 mouth, you know, Europe had a problem a number of
16 years ago with hoof and mouth, killing animals,
17 digging holes, burying them, you know, by the
18 hundreds, BSE, avian influenza.

19 DR. HARRIS: Correct me if I'm wrong? Does
20 that get into APHIS purview rather than FSIS
21 purview?

22 DR. ENGELJOHN: Engeljohn, but in the

1 equivalence process, when we go through that, we do
2 work with our sister agencies to see if they have
3 any other additional animal disease regulations or
4 policies that we need to be aware of and inform them
5 about.

6 DR. HARRIS: Does FSIS as part of its audit
7 procedure when they are doing these foreign audits,
8 does that enter into it or is that strictly an APHIS
9 function?

10 MR. SMART: We're firm believers in using
11 the APHIS website, but in addition, we talk to an
12 APHIS individual as we prepare for the audit, for
13 the emerging issues, and then when we're in the
14 country, one of the aspects that we go over is
15 animal health to find out if there's something that
16 hasn't even made it to APHIS yet. So it's very much
17 a part of the --

18 DR. HARRIS: Yes.

19 MR. STEFAN: APHIS has a completely
20 separate review for countries that want to export
21 meat or poultry products to the United States, and
22 it's just as elaborate as the FSIS review. And both

1 of them should proceed on separate tracks but a
2 country cannot export to the United States until
3 it's completed its review with APHIS as well as with
4 FSIS.

5 DR. HARRIS: So I guess the analogous
6 situation would be I guess like FDA approving food
7 additives and then FSIS could approve that for FSIS
8 regulated products after the fact but not until FDA
9 has blessed it.

10 DR. ENGELJOHN: This is Engeljohn. But I
11 think to be specific about a country, the products
12 allowed into the country, meat products or poultry
13 products from another country, are contingent upon
14 what the animal disease things are there. So that's
15 why for some country only cooked products can come
16 in as opposed to raw. So that does set some
17 criteria as to what would be allowed in from another
18 country. So there's some dual activity for which we
19 as a Federal Government work together on.

20 DR. HARRIS: I know Stanley mentioned BSE
21 and the example I was thinking of there is the
22 Canadian rule and that was an APHIS rule. That

1 wasn't even an FSIS rule. APHIS controls, you know,
2 on foreign animal diseases what can and can't come
3 in. So -- I'm sorry. Behind me.

4 MR. BUSCH: In your six things you
5 outlined, sanitation, HACCP and government oversight
6 and things like that, what you didn't cover, my area
7 of expertise as far as enforcement? What are they
8 doing? We have administrative, simple criminal
9 sanctions and that's how I had the opportunity to go
10 with some of Don's folks before for the enforcement.

11 DR. HARRIS: How would you like this
12 language if I said effective government oversight
13 with enforcement provisions.

14 MR. BUSCH: That's better. Good.

15 DR. HARRIS: Yeah, we don't want to leave
16 compliance guys out of the party.

17 MR. BUSCH: You've got to have some way for
18 enforce -- laws but you're not enforcing them.

19 DR. HARRIS: Okay. Everybody look at what
20 we've got for A up here and let's talk about it. Is
21 it what we need? Do we need to add to that? What
22 objective outcomes are most appropriate to evaluate?

1 MR. FINNEGAN: It looks good so far to me.

2 DR. HARRIS: I mean like I said, we can't
3 do a comprehensive detail. So I've tried to do more
4 broad categories. For example, on hazard control
5 measures, we already know that they're required to
6 have HACCP. That's already part of the thing
7 because they have to have everything we have to
8 have. Sometimes in my own mind, I don't know that
9 that would be necessary but maybe they've got
10 something better than HACCP to control hazards but
11 the rule is the rule.

12 MR. FINNEGAN: We might want to go back to
13 A after we talk about B.

14 DR. HARRIS: Let's skip down and talk about
15 B. Dr. Jolly has something.

16 DR. JOLLY: Okay. Bill Jolly, New Zealand
17 Food Safety Authority. One thing we look for is
18 whether the country is taking a science and risk-
19 based approach because that's the key where their
20 program will be effective in their evaluation, you
21 know, dealing with HACCP protocols they have. So a
22 science and risk-based approach is the key issue for

1 which we look for, not just replication. Otherwise,
2 you know, you can make -- we used to talk about the
3 ISO system. The ISO system can make a really good,
4 concrete objective, the system is truly risk based
5 or science based and risk based, then it will adapt
6 to emerging hazards and to the specifics to your own
7 situation. And that's what we focus on.

8 DR. HARRIS: How about this? We add a last
9 bullet there underneath the one, under where it says
10 programs, add a bullet that says commitment to a
11 science-based approach that takes into account risk.

12 JOSH: That takes risk into account.

13 DR. HARRIS: Yeah, something like that.
14 You can wordsmith it however you want. I'm okay.

15 For Part B then, what means are most
16 appropriate for evaluating these outcomes? A couple
17 of times today we've had -- we've got current three
18 means, right? We've got audits. We've got import
19 reinspection? And what was the third one? I've
20 forgot one part of the triad already. Determination
21 of equivalency. What other means of -- Mike
22 Finnegan two or three times has mentioned self-

1 assessment by the exporting country, and I think I
2 would like us to consider that one. That sounds
3 like a reasonable thing.

4 MR. FINNEGAN: Yeah, I would, too. And
5 what Dr. Jolly said, the self-assessment, not into
6 details of how you answer each and every directive
7 but how you as an exporting country would meet the
8 equivalency general, you know, I mean I don't want
9 to get into details because I know it's a living
10 hell when we have to do it.

11 DR. HARRIS: I want to ask -- how much of
12 that is already done? When you're doing a country,
13 how much of that is already captured in terms of
14 asking that country to show you how they're meeting
15 all these requirements?

16 MR. SMART: Well, when they originally
17 apply for equivalence, there's five questionnaires
18 that cover all of the things that the states are
19 addressing now. However we tack something new on it
20 as I mentioned before. We sent that to the country
21 to say you have to address this, too. And they do
22 and we're, you know, when we do our in-country

1 audit, we're auditing against the application of all
2 the things that are in effect. So all the laws,
3 regulations procedures. So we just don't have them
4 resubmit every year the stuff that we already have.
5 We just ask them for what's new. If it's not
6 something that we've imposed on them, but they
7 change themselves, we want to know about it because
8 then we can our assessment as to whether, you know,
9 it takes away from what they were doing before or
10 adds to.

11 MR. FINNEGAN: Which is a good point, and
12 that's what I'm trying to get at where if you do a
13 self-assessment type deal, it's where you write down
14 and you have it in writing that I'm going to do this
15 and this and you go and say, well, let's see how
16 you're doing this and this, or they say, well, I'm
17 going to do that, well, right there, that's a
18 deviation that raises a red flag.

19 DR. ENGELJOHN: This is Engeljohn. Part of
20 what the states do when they do that is we do issue
21 a lot of policy clarifications throughout the year,
22 and I think what's captured though in the year end

1 issue is here's how we still demonstrate. We may
2 not have adopted this notice or that directive --

3 DR. HARRIS: Right.

4 DR. ENGELJOHN: -- because we don't have a
5 need to do that or we've already captured addressing
6 your intent by this other policy and here's why. So
7 it's sort of a way of reaffirming on a continual
8 basis why their system still is, in fact, meeting
9 the objective I think is more what it does.

10 MR. FINNEGAN: Right.

11 DR. HARRIS: The Agency in their question
12 to us specifically raised the issue of third-party
13 audits.

14 MR. FINNEGAN: Well, I think that's --

15 DR. HARRIS: It's in Part B of question 1.

16 MR. FINNEGAN: Right. As an example, but
17 the third-party audit is an example along with the
18 self-assessment.

19 DR. HARRIS: But they don't currently use
20 third-party audits. So I guess that's --

21 MR. FINNEGAN: Right, right. That's one of
22 the --

1 DR. HARRIS: I think they'd like some
2 feedback from us as to whether or not they should --

3 MR. FINNEGAN: Exactly.

4 DR. HARRIS: -- just based on them sticking
5 it in that question.

6 MR. CORBO: Personally I have a problem
7 with it.

8 DR. HARRIS: Okay.

9 MR. CORBO: You know, the one area that I'm
10 more familiar with, with the third-party auditing
11 procedure is with the organics program and -- and I
12 mean there are problems and they just put out a
13 report, AMS did, where they questioned the
14 qualifications of some of their third-party auditors
15 and, you know, I brought up the example of the local
16 television station here that did its own testing of
17 so-called organic ginger from China and it had a
18 pesticide. It had an illegal pesticide on it. So,
19 you know, I appreciated the presentation that Jill
20 Hollingsworth made yesterday. I think we're still a
21 ways away from -- at least my own organization's
22 standpoint is that we're a ways away from accepting

1 that.

2 DR. HARRIS: Okay. Well, let's tramp along
3 Subcommittee 1's toes here for a little bit. I
4 think they were supposed to be talking about whether
5 or not the three pieces of the triad are
6 appropriate. That seems like it might be a part of
7 Part B there also. Are those three appropriate?
8 Are there more that need to be added?

9 MR. CORBO: Well I --

10 DR. HARRIS: Or are there other objective
11 measurements or objective means of evaluating these
12 outcomes? Or maybe I phrased that wrong. Are there
13 other means of evaluating these objective outcomes?

14 DR. JOLLY: Bill Jolly, New Zealand Food
15 Safety Authority. Put a suggestion to the
16 Committee, you can do it by coming, you know, a two-
17 week visit or three-week visit. You can do it by
18 asking for a comprehensive submission which we all
19 hate. Or you can do it by actually having a
20 transparency of what you're doing, and this is where
21 we're going internationally is the public health
22 agencies, I mean we put those things in the public

1 domain, and some of -- which is a little more
2 commercially sensitive. We've put them in the
3 public domain. We put them in the regulatory
4 domain, and so more and more what we want to do is
5 have access to your Public Health information System
6 like you have access to ours. So that results in a
7 national microbiological database, our, you know,
8 quality results of residues rather than annual
9 results, if you like, summaries of system audits
10 which we do because we do not just an establishment
11 audit but we -- but if all this information is
12 relevant and gives confidence that a country is
13 taking a credible approach and is maintaining --
14 you know, one thing you need to keep in mind is when
15 you're dealing with sovereign nations, you know,
16 you're dealing with regulatory authority by the most
17 part of it. Share the same objectives. They serve
18 the consumers. They're established in statute. You
19 know, they're not trying to hide --

20 Now, it's a little bit different when
21 you're dealing with countries where maybe the export
22 authority is an offshoot and is not competent

1 authority, and this is a debate we had with the FDA.
2 We actually don't want assurances from a third
3 party. We actually want assurances from the FDA.

4 (Mr. Corbo clapping.)

5 DR. JOLLY: And the same with -- and that's
6 one of the things we've been working with Mary's
7 group in as far as the upcoming certification. We
8 want that direct government-to-government
9 communication. But it's not -- we just don't want
10 layers and layers added on top. This is a
11 substitute to you using some of the least effective
12 mechanisms. Basically we've got this correlation of
13 systems and credibility of approach, and then
14 somewhere down the line should result in effectively
15 have a green light for your product, you have more
16 of sort of a one market type of approach. That's
17 why we don't want to actually keep stopping the
18 American or Canadian or Australian product at the
19 border, continuing to double inspect or double
20 regulate, you know, it's mean to come out of a
21 credible system in the first place. And so it's
22 more about just understanding the system and keeping

1 that generic correlation and understanding that, you
2 know, when you do get emerging issues or hazards,
3 that you take an action and you had your action with
4 *E. coli* last year. It would have been of some
5 concern if you hadn't. But, you know, United States
6 and the Food Safety and Inspection Service
7 especially is very credible, and so we saw an
8 appropriate response.

9 Do you have high levels of O157? Yes. You
10 know, but are you taking appropriate actions? Yes.
11 And you saw the presentation about -- today.
12 Supposedly EU has higher *Salmonella* than you've got.
13 Is that true? I don't know, but I'm actually
14 responding in a credible regulatory authority
15 fashion, very much so. Their public health -- is
16 very, very strong. That's something which is
17 important for equivalence at the time. It's not
18 about product, you know, consignment disposition.
19 It's about that system actually being, you know,
20 comparable to your audit, especially when you start
21 getting into the high level of equivalence action,
22 you know, which is more or less a mutual recognition

1 of comparability which you should have with your
2 major suppliers, and 85 percent of your meat coming
3 into this country comes from Canada which is 45
4 percent, Australia which is 22 percent and we're
5 something like 11 percent. And, you know, you've
6 got a very high correlation there.

7 DR. HARRIS: I think I would throw out also
8 that something to kind of tag onto what you just
9 said. International trade by definition, the rules
10 surrounding the international trade, if you will,
11 are government to government. And I'm not sure that
12 we're to a point where a third-party audit system
13 needs to be thrown into the mix relative to that
14 government-to-government thing. We do a lot of
15 things in this country with third-party audits and
16 they're very effective, and there's probably a spot
17 within international trade in the customer supplier
18 relationship to do third-party audits. I'm not sure
19 in a regulatory scheme that we're quite there yet.

20 MR. CORBO: Frank's back there --

21 MR. BUSCH: I agree with that. When you
22 share data systems and they're up to date and you

1 have accurate information and competent information,
2 I think that goes a long way towards trust in a
3 product, in the safety of a product, and I think
4 that goes to a moral question, too. I mean we air
5 our dirty laundry on CNN tonight, you know, so --
6 and a lot of people don't do that, and if you're
7 relying on them for information through a data
8 system or whatever, and they're not being
9 forthcoming with you, I know I don't want to be
10 standing up in Congress and saying, well, we didn't
11 know we had a problem. They told us everything was
12 okay, and you couldn't verify that for yourself. I
13 don't think anybody wants to be in that position. I
14 mean there's probably some -- that you can do that
15 with and probably most of them you probably can't.

16 DR. HARRIS: I want to welcome Dr. Scott
17 Hurd to our group. He's the deputy -- assistant or
18 deputy?

19 DR. HURD: Deputy Under Secretary.

20 DR. HARRIS: Deputy Under Secretary.

21 DR. HURD: Deputy Under Dog. (Laughter.)

22 DR. HARRIS: I want to welcome him to our

1 little powwow here.

2 DR. HURD: Thanks. I hear there's some
3 serious deliberations going on over here. So I
4 wanted to --

5 DR. HARRIS: Dr. Dickson.

6 DR. DICKSON: Yes, Jim Dickson here. The
7 only comment I would add on third-party audits is a
8 possible role for third-party audits in addition to,
9 not a replacement for the existing reviews. If
10 we're only getting into a country once a year, and
11 there are issues that we would like followed up on,
12 then there may be a role for a third-party audit to
13 come in between the official USDA audits. And as I
14 said, not a replacement for but in addition to our
15 own USDA audits. That's just a comment that people
16 can agree or disagree with.

17 MR. HONTZ: Can I make a comment about
18 that, too?

19 DR. HARRIS: Absolutely.

20 MR. HONTZ: Lloyd Hontz with the Grocery
21 Manufacturers Association. I would share some of
22 your concerns about third-party certifications in

1 that it's kind of an unknown at this point. Even
2 though an awful lot of it goes on, we don't know
3 exactly what the system would be at this time or how
4 it would be carried out.

5 But I think before we just eliminate it as
6 a possibility, Dr. Dickson had a good suggestion
7 there. I think a lot of it would have been on
8 exactly how much regulated and set up. There were
9 discussions yesterday by Mike Robach and Jill
10 Hollingsworth, I think they were very informative
11 but when Mike was talking about a system where
12 standards would be very transparent and they would
13 be set with involvement from all of the
14 stakeholders, including government, industry,
15 consumers, et cetera, and again I just hate to see
16 you rule it out that if an appropriate procedure
17 could be developed and workable, and guidelines set
18 up, transparent standards and methods for double
19 checking this, I think that it certainly could have
20 usefulness. You couldn't do without the
21 government --

22 DR. HARRIS: Let me read the sentence to

1 you and you guys tell me if you agree.

2 Subcommittee sees a potential supplementary
3 rule for third-party audits as an enhancement to the
4 current system in some situations.

5 UNIDENTIFIED SPEAKER: Sounds good.

6 DR. HARRIS: I mean is that --

7 MR. BUSCH: That means in addition to.

8 UNIDENTIFIED SPEAKER: Supplementary, yeah.

9 DR. HARRIS: Yes, ma'am.

10 MS. STANLEY: One point on that, because it
11 sounds through the discussions, and this is Mary
12 Stanley with FSIS, on whether or not you're thinking
13 industry third party or government and industry as a
14 third party because, you know, the EU audit would be
15 a third-party audit. And so I just wanted to make
16 that distinction that if you are thinking only the
17 use of industry, you should qualify that or make it
18 clear.

19 DR. HARRIS: Okay. And we'll add that to
20 the end. In my mind, I was thinking both. I was
21 not thinking necessarily just private because as you
22 say, there's a lot of tools out there, and it was

1 brought up yesterday by I think it was our Montana
2 friend, and then we were talking about his Armenian
3 friends and their ISO9000 certification, that that
4 might be another additional piece of information
5 that you could gather on a country to supplement
6 what you're already evaluating and that would be
7 basically in my mind a third-party audit type
8 situation. Dr. Jolly.

9 DR. JOLLY: Bill Jolly from New Zealand
10 Food Safety Authority. Someone made a comment. I
11 didn't want to take it out of context. Third-party
12 audits, especially when they're another country, are
13 actually very valid. The one thing about an audit
14 is they'll always find something wrong, and it's
15 usually -- it's defect or a systemic issue. That's
16 the -- part of mine. So we use third-party audits
17 instinctively. We look at your audits of other
18 countries. We look at the EU's audits. We look at
19 Australia or Canadian audits because we don't have
20 the resources to get all the way around the country.
21 So third-party audits from another country are very,
22 very --

1 Similarly, we don't put a lot of
2 credibility in the ISO17025 accreditation and
3 auditing for laboratories and so ISO17025 for
4 laboratories has been a very, very valuable tool
5 internationally. Now, I think -- a comment as well,
6 and it's a great international. So those audits are
7 very valuable.

8 And lastly, we've actually imposed a -- of
9 ISO17020 on verification agencies, and Jill
10 Hollingsworth talked about certification and what
11 she was really talking about was verification bodies
12 because certification is more so a government thing,
13 but 17020 actually allows you to get some measure of
14 credibility of your verification body, whether it's
15 government or whether it's an independent party
16 working for government, and so we use that in
17 countries and again, the European Union has done a
18 lot of work in this area, but we actually require
19 our own government inspection and verification body
20 to be ISO17020 accredited or work through that
21 system, and that gives us a lot of confidence that
22 they'll be doing things consistently. They have all

1 of the components there. It covers the whole
2 conflict of interest, the document of standards and
3 things like that.

4 ISO9000, you know, that's more of a -- but
5 the 17000 series are really quite good.

6 DR. HARRIS: Josh, could you add a little
7 caveat there, that the third party can be either
8 government or private depending on the situation.

9 MR. FINNEGAN: And the government part, I
10 mean really the CODEX, my God, with the CODEX,
11 there's so much information in that, and the ISO
12 series would be included in the government.

13 And my experience with third-party audits
14 is the bottom line is the pocketbook. Like they're
15 going to find something, but they're -- I mean, you
16 know, you've paid, paid well. I don't have the best
17 experience with third-party audits.

18 DR. HARRIS: In defense of my friends that
19 are auditors, they're obviously delivering some
20 value for that money for they --

21 MR. FINNEGAN: They are.

22 DR. MURINDA: Just a question. Shelton

1 Murinda. When we say supplementary there, do we
2 imply that they're done occasionally or every same
3 prevalence as the, as the single company or FSIS
4 audits?

5 DR. HARRIS: I intended that word to mean
6 something that's done on top of the existing system.
7 I did not -- when I used that word, I was not
8 thinking about a frequency. I was thinking more of
9 this would be something added to the existing
10 system, not replacing a piece of the existing
11 system.

12 MR. FINNEGAN: In other words, it's
13 information that's being transmitted.

14 DR. HARRIS: Right. So I didn't really --
15 I didn't think of that in terms of a frequency.

16 DR. MURINDA: I thought probably we need to
17 have an indication that there is an element of
18 frequency which is probably at less rates than the
19 regular audits.

20 DR. HARRIS: That's probably a good segue
21 into question 2, and we're going to come back and
22 revisit both A and B up there and to change --

1 MR. FINNEGAN: Are we going to leave the
2 self-assessment part in B?

3 DR. HARRIS: Do we have it there?

4 JOSH: I took it out.

5 DR. HARRIS: Okay. I think there's a
6 potential role for self-assessment.

7 MR. FINNEGAN: I do.

8 UNIDENTIFIED SPEAKER: If the states have
9 to do it, foreign countries need to do it.

10 DR. HARRIS: We have an hour remaining. So
11 we spent a little over an hour on this topic. So I
12 have a feeling this next one might go a little more
13 quickly. An hour's not a drop in a bucket compared
14 to the time you guys have spent on this topic lately
15 I bet.

16 Okay. Countries vary with information-
17 sharing capabilities and compliance history in terms
18 of demonstrating equivalence. What recommendations
19 does the Committee have regarding the effects that
20 information sharing and compliance history should
21 have on audits and reinspection?

22 And then specifically, Part A here, should

1 in-country audits be adjusted by scope and frequency
2 based on the capability of a country to share useful
3 information and its compliance history?

4 I was going to say yes. I can't think of
5 any other way to answer that question except an
6 additional yes, and then the second piece of it
7 though is, okay, if yes, how? Now, that's probably
8 the more pertinent question.

9 MR. FINNEGAN: I think Jim Dickson hit the
10 nail on the head. He talked about risk-based
11 inspection, you know, I mean if a country is not
12 compliant, that's what we're talking here, if you
13 double up, you'd go every quarter.

14 DR. HARRIS: Well, when they ask how should
15 it be adjusted, I would have to recommend
16 specifically frequencies. I'd just -- I don't think
17 that we've got enough information at our disposal to
18 say it should be annual, semiannual, quarterly or
19 whatever what it is.

20 MR. FINNEGAN: Right. I'm talking more --

21 DR. HARRIS: What I would like to see, and
22 I keep going back to private audits because that's I

1 guess because I deal with them more, when I have a
2 processor and I get a third-party audit that's done
3 for one of my customers and they send, you know, a
4 third party in there, whether that's Food Safety Net
5 and the Hazard Consulting Group who's here or
6 Silicur (ph.) or whatever audit they send in, and
7 they have standards they audit against, I get a
8 score. It's usually a numerical score on a 100
9 point scale, and depending on how I score on that,
10 or how my relationship then is affected in terms
11 when's the next audit going to happen, what do I
12 have to change, there is a minimum level of
13 acceptable score that, you know, that's sort of the,
14 you know, we're not doing business anymore if you're
15 below here, but if you're between here and here,
16 we're going to do a little more intense scrutiny, or
17 if you're 90 and above, hey, we'll see you next year
18 or what do you think about an approach like that,
19 that's more of a scoring type system? Of course,
20 the challenge will be to figure out how to do it
21 but -- Tony.

22 MR. CORBO: What do you do now? As far as

1 when you go in, you find a systemic problem, you do
2 enforcement audits. Some countries I've seen in one
3 year's time, you've done three, four. Explain what
4 you do now.

5 MR. SMART: I think that's the reason that
6 we're here is that you get the extremes of three or
7 four years, you get what Dr. Jolly has covered in
8 great detail, we admit, we don't have a need to go
9 as often to New Zealand as we do to some of the
10 other countries where we find the problems, but we
11 analyze all the information and then typically if
12 it's a serious issue, they get a corrective action
13 plan, and so we're not going to wait a year to go
14 back to verify what they put in writing is what
15 they've actually done. So it depends on the
16 severity of what landed that corrective action plan,
17 whether we're back in six weeks or whether we're
18 back in three months, and no two cases are alike. I
19 mean no two countries are alike, and that's what
20 brought all of you here today is the countries
21 aren't alike. They all have different ways of
22 meeting our FSIS requirements, and as I said, New

1 Zealand is at one end, and we've got other countries
2 at the other end and our current system doesn't
3 address them as well as we think we could.

4 DR. HARRIS: Dr. Engeljohn, you had
5 something?

6 DR. ENGELJOHN: This is Engeljohn with
7 FSIS. Just something for you to think about perhaps
8 as your group is deliberating, that the Agency is
9 part of the OIG audit with regards to the RBI system
10 that we were setting up. We came forward with a lot
11 of solutions as to how we're going forward in the
12 future to measure this excessive hour inspection
13 system. And I would just suggest that for a variety
14 of reasons, we identify that every plant that we
15 have will have a comprehensive food safety
16 assessment once every four years, just because
17 that's when we can do it, and we think it's
18 appropriate to do it in some kind of cycle, and we
19 do for cause when there's a need to do so. So that
20 that changes it. Sort of the same situation you're
21 about here at internationals. We've established
22 some framework that we're going to have more

1 intensified information about a system over the
2 course of time, performance in that time period of
3 whether or not we go in or more intensely in the
4 intervening period.

5 But it would seem to me that it might be
6 good for you to at least touch on, if that's how we
7 measure the domestic program or whether or not it's
8 achieving the goals that we have, how could that be
9 done in the perspective of the international foreign
10 countries anyway that are shipping here and can that
11 be a part of that overall system approach. Just
12 something for you to think about.

13 DR. DICKSON: Go ahead.

14 DR. JOLLY: Bill Jolly, New Zealand Food
15 Safety Authority. Again, I just want to bring
16 people up to the national level here. Everything
17 you do on a national level here, what Dan has talked
18 about, is already done in my country and in
19 Australia and Canada and others, you know, at the
20 national level. I mean, we do these system reviews
21 ourselves of our own systems, and we can make that
22 available. So it's not like a country is the same

1 as an individual establishment in the U.S. or even a
2 state system. A country is working at the FSIS
3 level, and you need to understand that if the
4 country's not doing -- system, and we've got -- it's
5 about three or four -- for a long time and so one of
6 the great advantages -- his team and colleagues of
7 mine, is you've actually integrated your audit
8 system across and you've got a lot more national
9 consistency over time.

10 So don't just don't think of an
11 international country as being like another state or
12 another establishment here. They already have that
13 sort of integrated audit system and furthermore, I
14 mean it's probably not a week that goes by that we
15 don't get some sort of foreign or commercial audit
16 on our premises, you know.

17 So, you know, the need for that
18 comprehensive -- versus whether you can get that
19 information in other ways, we anticipate, when --
20 comes down there every three or four years for our
21 meat premises, they come down for seven to eight
22 days, and they focus very heavily on our systemic

1 audits, what we found, and then go and validate it
2 across a few premises and a few of our regional
3 offices, they don't try and validate it at sort of
4 20 establishments. They try to look at how we are
5 exerting control, how we collect information,
6 whether we're taking a critical -- all the way down,
7 and that's the sort of evolution that -- and whether
8 that's -- So what do you expect the other countries
9 to do if you and, Mike, some of your premises, maybe
10 they're listed for international trade, so do you
11 want to do the same thing to your international
12 counterparts that you do through FSIS and do you
13 want to do that 140 times?

14 MR. CORBO: FSIS likes coming there in
15 January and February, don't they?

16 DR. JOLLY: -- some very good audits --
17 hopefully we've taught them some stuff as well --

18 DR. HARRIS: Okay. Dr. Dickson.

19 DR. DICKSON: I've just got a comment on
20 this. Maybe -- is to think of a tiered system where
21 you have sort of top tier countries that share
22 everything they've possibly got with you, everything

1 from inspections records and micro testing and
2 public health data, and then sort of an intermediate
3 tier that shares some but not everything you'd like
4 to see, and then the third tier that might be the
5 more bothersome group that doesn't share anything
6 beyond what they're mandated to share. And kind of
7 ranking the countries in that way, then maybe that
8 breaks out the frequency of audits and inspections.
9 Then that lets you prioritize which countries are on
10 top of the situation and then which countries may be
11 partially but not quite and then -- again, it's just
12 ranking system to allow FSIS to look at where they
13 put their resources.

14 DR. HARRIS: Okay. Throw this out here of
15 some potential language. As the clock ticks on us
16 here, I keep trying to focus on getting something on
17 paper here. So based on the discussion we've had up
18 to now then, for that first one, on A, we're talking
19 about in-country audits. The Committee believes
20 that -- well, the first sentence probably doesn't
21 make sense but basically would the Committee support
22 a risk-based determination of in-country audit

1 frequency and scope, consideration should be given
2 to the transparency of the exporting country's
3 system including its ability and willingness to
4 share information on an ongoing basis as well as its
5 compliance history.

6 Now, that last comment, Dr. Dickson
7 suggested the possibility of a three-tiered system
8 that would sort exporting countries based on their
9 compliance history, transparency and data sharing.

10 Did I capture what I heard first of all?

11 DR. DICKSON: Yes.

12 DR. HARRIS: And second of all, how does
13 the rest of the Subcommittee feel about that
14 language?

15 DR. ENGELJOHN: Could I suggest maybe just
16 to get one point that you made is instead of just
17 data sharing, it's the degree I think of sharing.

18 MR. CORBO: And the quality of the data.

19 DR. ENGELJOHN: Yeah, you're putting some
20 parameters around that. So perhaps --

21 DR. HARRIS: Based on compliance history,
22 transparency and degree/quality of data sharing.

1 That's what I -- if you can decipher my scribbling.

2 Dr. Dickson, can I impose on you to take
3 over as Chair for just a few minutes? I've got to
4 step out for a second.

5 DR. DICKSON: Certainly.

6 DR. HARRIS: I'm advocating the throne --

7 DR. DICKSON: Just trying to follow up on
8 this, other comments on in-country audits, specific
9 to scope and frequency?

10 MR. BUSCH: Tony, from the very beginning,
11 you were very adamant in saying --

12 MR. CORBO: Right.

13 MR. BUSCH: Now, we all know -- things of
14 that nature. Do you have any information or data as
15 far as meat and poultry products?

16 MR. CORBO: Well, I think, you know,
17 Caroline yesterday did present some polling data
18 and, of course, it didn't identify, you know,
19 product specific but you do have concerns with, you
20 know, you have the recent case with the imported
21 jalapeno peppers, and a lot of the food safety
22 issues that have surfaced happen to fall under

1 FDA's, you know, jurisdiction. But the fact that
2 there's been an import alert on certain types of
3 imported Chinese seafood, I mean you do have
4 concerns out there about imported food. And, you
5 know, last year FSIS did have the problem with the
6 imported trim from Rancher's Beef in Canada and so,
7 you know, it's out there. I mean the consumer
8 concerns are really -- well, imported food safety is
9 on the consumers' radar screen and the fact that it
10 keeps on getting reinforced, this is a globalized
11 trading system and we're importing more of our food,
12 I think you're going to have some concern about
13 adjusting -- reducing the level of surveillance.

14 MR. BUSCH: That's what I thought you were
15 saying.

16 MR. CORBO: What was that?

17 MR. BUSCH: That's what I thought you were
18 saying.

19 MR. CORBO: Yeah, yeah.

20 MR. BUSCH: I just want to make sure we
21 distinguish between meat and poultry and egg
22 products.

1 MR. CORBO: Oh, no, no. But the thing is I
2 think people, you know, again people are looking at
3 imported food, whether it's the FDA, USDA, it's the
4 same thing. I mean it's the same thing, and I know
5 that it winds up, and it rankles me, too, when I see
6 in the press reports we're only inspecting 1 percent
7 of imported food. Well, that's FDA. It's not USDA,
8 but the thing is, that's out there. I mean that
9 perception is out there. And it's unfortunate the
10 media is erroneously reinforcing that image or the
11 misinformation that's out there, but I mean people
12 are very, very concerned.

13 MR. BUSCH: Well, I guess before we can
14 say, you know, people from other countries sharing
15 information with us is going to determine the
16 frequency and it's already been determined that
17 we're going to visit them any less frequent, then
18 what's the point of even sharing it. The only thing
19 it can do is hurt them.

20 MR. CORBO: Yeah, but I think, you know,
21 the thing is that I see, you know, I see the merit
22 in terms of doing the information, you know,

1 sharing, the quality of the data, you know, has to
2 be good like I just, you know, I come back to the IG
3 report. We're not even -- the quality of our data
4 system is not good, and that's what, you know, the
5 whole exercise with RBI and having the Inspector
6 General step in and FSIS responding with, you know,
7 the Public Health Information System is trying to
8 address all of those concerns. I think we're a ways
9 away because we our own data system is screwed up.

10 The thing is when I look and, you know,
11 maybe I'm stuck in the paradigm. When I look at the
12 audit report, and I look -- I read the back page of
13 these audit reports and I see what the auditors find
14 in terms of, you know, condensation above food
15 contact areas. I mean, that starts to cause alarm
16 bells to go off in my own head about, you know,
17 possible, possible food safety issues that could
18 emerge. You're not going to get that unless,
19 unless, unless you get similar, you know,
20 noncompliance reports being transmitted as part of
21 your data system, but that the exporting country is
22 furnishing us. I don't see a substitute for our own

1 people going over there. I think that there has to
2 be adequate data that's provided to us to make an
3 assessment that, okay, this year we're not going to
4 go over to New Zealand.

5 DR. HARRIS: I think there are some
6 countries that may be to the level of being able to
7 share that kind of daily information. I don't know
8 that with certainty, but based on discussions that
9 we've had this week and some of the, you know,
10 conversations I've had, it sounds to me like there
11 may be some countries that are already absolutely in
12 a position to be able to provide that level of
13 transparency and data sharing. I don't know that.
14 We have some of them in here. Dr. Jolly is -- are
15 there countries that are getting close to that level
16 of information sharing?

17 DR. JOLLY: Bill Jolly, New Zealand Food
18 Safety Authority. Again I want to chunk you up
19 again, guy. It's not about the individual
20 inspectors here. It's about assessing the system
21 and the competency, you know. If Don Smart wants to
22 look at any of our premises daily inspection

1 reports, we would share it if they want to. But is
2 that relevant? Is that going to be cost effective
3 of your use of resources? No. You know, what he
4 really needs to look at is how we're actually
5 exerting control over our system, how we're
6 actually, you know, working towards continuing
7 improvement.

8 Now, on the policy side, Bill James wants
9 to look at how our system design is encompassing the
10 principles of science and risk. That's different
11 from the compliance altogether.

12 So those two assessments are the things
13 that the transparency and the sharing has had.

14 Now the ability to actually drill down, you
15 know, it's there for some countries. It is there
16 for us but it's not there for others. The
17 Australian system is, and you heard from Mark Schipp
18 yesterday, it's a -- system, and it's quite good
19 but, you know, the information that you can collect
20 on a national basis that's relevant to outcomes is
21 still reasonably limited. It's still a damn sight
22 better than, you know, having a once-a-year sort of

1 snapshot. It gives you a much more systemic
2 overview.

3 So please don't even talk, don't even put
4 this sort of daily time thing. It's about
5 credibility and how much you need to go out to see
6 and I know the -- and also whatever you ask of us,
7 and you made the point in the OIG report, what can
8 you do yourself?

9 MR. CORBO: Correct. That's right.

10 DR. JOLLY: You cannot ask of another
11 country --

12 MR. CORBO: Right.

13 DR. JOLLY: -- what you're not delivering
14 yourself.

15 MR. CORBO: Absolutely.

16 DR. JOLLY: Now, you know, I think it's --
17 this stage, we're at a stage where we can substitute
18 a level of on site for some offsite information
19 sharing. Now we can make it available this way.
20 What we would suggest with the Don's group is that
21 they focus on the -- There will be some learning in
22 the interim, and we've had an example of that this

1 year where we actually shared a lot more data, you
2 know, see what level of detail they want.

3 But I think the Canadians aren't too far
4 away. The Australians are probably not too far
5 away, and again it's a difference between having
6 this real time on the -- you know, management
7 reports.

8 DR. HARRIS: Stan.

9 MR. PAINTER: Stan Painter with the
10 National Joint Council. Backing up here to A, and I
11 just wanted to share some concerns with this risk-
12 based system under A, and I apologize with the phone
13 thing. Risk-based determination of in-country audit
14 and frequency. Who's going to determine the risk?
15 Is the country going to determine the risk or the
16 country of origin going to determine the risk?

17 DR. HARRIS: Well, the United States, in
18 the case we're discussing here, the United States
19 will be the one determining the frequency of the
20 audit. So it would be the United States determining
21 the risk basis for deciding how frequently a country
22 gets audited.

1 MR. PAINTER: How's that any different than
2 what we're doing now, just giving it a new title of
3 risk based? I mean we determine now the number of
4 audits and things of that nature. So what is adding
5 the words risk based in there going to add to it?

6 DR. HARRIS: Nothing. The question is --
7 the question we were asked was should the
8 frequencies be adjusted either in their scope or
9 their frequency based on the capability of the
10 country to share information, et cetera, et cetera.

11 MR. PAINTER: Okay.

12 DR. HARRIS: I think that the Agency or --
13 here's what I think and then I'll let other
14 Subcommittee members weigh in. I don't necessarily
15 have a sticking point on those words one way or the
16 other but my interpretation of that then is that the
17 Agency would consider use a risk-based approach to
18 determine whether or not that country needs a higher
19 frequency or a lower frequency. When I say risk,
20 I'm thinking risk to the U.S. population of this
21 imported product. We haven't even talked about
22 what -- we haven't even talked about risk associated

1 with specific products.

2 MR. PAINTER: Okay.

3 DR. HARRIS: And that may be something that
4 needs to come into this discussion at some point is,
5 are these things -- is that another factor that
6 needs to come in? What are the product we're
7 talking about, not just what country.

8 MR. PAINTER: All right. Let me share my
9 concerns with that. We, being the Union, has had a
10 lot of -- we have a lot of concerns and a lot of
11 problems with the Agency's "risk-based initiative."
12 Personally I don't want to get into a situation of
13 the Union battling some of the concepts of risk-
14 based inspection and then the Agency said, oh, we
15 use that same concept. We use risk-based inspection
16 for imported product, and it's already in there, and
17 it's already established. So personally that's a
18 thorn in my side and a pain in my butt over -- for
19 those words. And that's the Union's two cents worth
20 on that.

21 So, you know, I think that, in my opinion,
22 it's a dangerous territory to get into and it opens

1 up a Pandora's box.

2 DR. HARRIS: Help me out here. Suggest
3 some alternative language.

4 MR. PAINTER: I mean in my opinion, you
5 could say the Subcommittee believes there should be
6 a determination of in-country audit frequency and
7 scope.

8 DR. HARRIS: Okay. Subcommittee members,
9 any thoughts? Yea, nay, up, down, what do you
10 think?

11 DR. DICKSON: And what is the basis for the
12 determination?

13 MR. PAINTER: I guess the basis for the
14 determination will be the beauty's in the eye of the
15 beholder. The Agency would look at it on a case-by-
16 case basis.

17 MR. FINNEGAN: We put risk based in there
18 just because there are certain countries that, you
19 know, they're continually above board continually,
20 and other countries need to be audited more. That's
21 just what we mean by risk based.

22 MR. PAINTER: And, you know, I understand

1 that and I appreciate that, and I know the intent of
2 the Committee but when it gets with this Agency and
3 I know we get into the arguing like there was a
4 hearing a few years ago of what the definition of
5 "is" is.

6 DR. DICKSON: We're just dealing with
7 verbiage here. Is that what you're implying, Stan?

8 MR. PAINTER: Yeah, and I don't mean to be
9 gagging at an and here, but it just -- I think we're
10 opening a Pandora's box with those words to say that
11 we've accepted that for other countries, we've
12 accepted a risk-based inspection type approach with
13 other countries.

14 DR. HARRIS: Okay. I understand where
15 you're coming from and the heartburn that you're
16 going to pass with the term risk based.

17 MR. PAINTER: Thank you.

18 DR. HARRIS: Let me put out maybe some
19 compromised language here basically that would say
20 that the Subcommittee believes the frequency and
21 scope of in-country audits should be determined
22 considering those things --

1 MR. CORBO: Right.

2 DR. HARRIS: -- the transparency of the
3 exporting country system, including its ability and
4 willingness to share information on an ongoing
5 basis. It should be tiered based on compliance,
6 history, you know, so it just means rewording that
7 to get those words out of there because I do
8 understand those are loaded words for you guys.

9 MR. PAINTER: Thank you.

10 DR. HARRIS: That causes heartburn and so
11 we -- I think we can do that without changing the
12 meaning and without using those particular words.

13 DR. ENGELJOHN: This is Engeljohn. Does
14 adding science based help or hurt?

15 DR. HARRIS: Well, I have -- I'm good with
16 it but --

17 MR. PAINTER: This is Stan, and I ask the
18 question directed to Dr. Engeljohn. There you're
19 going to turn around and say that risk based is a
20 science-based approach?

21 DR. ENGELJOHN: I think, I mean, this is
22 Engeljohn, that the issue here is you've got to have

1 some parameters to make your decisions and, you
2 know, a rationale, a science rationale at least gets
3 at the issue of explaining why you made the decision
4 that you made. I'm just offering it as a solution.

5 MR. PAINTER: Would you say under science-
6 based microbial testing, residue testing, pesticide
7 testing? Is that what you mean by science based?

8 DR. ENGELJOHN: I was really getting more
9 at a rationale basis to justify what you're doing.

10 MR. PAINTER: I understand, but my question
11 to you is what is science based in your mind?

12 DR. ENGELJOHN: Well, it's everything you
13 have there. I mean, part of the issue here is what
14 are the risks, and it's hard to get around that word
15 but the system that's being assessed here of sending
16 food products to the United States, presents some
17 element of risk with regards to importing that
18 product, and you need to put some parameters around
19 what you mean by that.

20 DR. MURINDA: If I could chime in. Shelton
21 Murinda. I think our definition of risk still
22 embodies the chemical, biological and the physical

1 hazards, and how do we determine those? We
2 determine those with qualitatively or quantitatively
3 using science-based methods.

4 MR. CORBO: Dan, I have a question. How
5 far are we with the Public Health Information System
6 of being able to deal with this?

7 DR. ENGELJOHN: Well, I would say from the
8 perspective of FSIS and the Public Health
9 Information System, it's a means to capture data --

10 MR. CORBO: Right.

11 DR. ENGELJOHN: -- is what the Public
12 Health Information System is. To be able to better
13 understand what is happening, you know, in a local
14 or national basis. So the Public Health Information
15 System really is the mechanism that captures all the
16 data that we would have access to help make --

17 MR. CORBO: But you're talking about third
18 quarter 2009, the thing will be up and running.
19 Would it be able to deal with capturing
20 international data?

21 DR. ENGELJOHN: That's the intention is --

22 MR. CORBO: Yeah.

1 DR. ENGELJOHN: -- to have it able to, but
2 now we do it manually.

3 MR. CORBO: Yeah.

4 DR. ENGELJOHN: Now, we take that same
5 information and you have humans, large number of
6 humans sitting there and analyzing the data and
7 assessing it in a very time consuming way, pulling
8 it up from various sources. The PHIS system is a
9 means by which that can be more automated and more
10 programmed so that that's done in a means that
11 doesn't require so much human element in making
12 decisions but it's being assessed. So it's really
13 more of the IT part of capturing and analyzing. We
14 do that today in a very labor-intensive manner.

15 So I wouldn't say we're not doing it now.
16 We are doing it now but it takes a long time to
17 generate reports and an understanding of about
18 circumstances. That's how I see it.

19 DR. JOLLY: Can I suggest, Bill Jolly, New
20 Zealand Food Safety Authority, Just add it after the
21 word basis at the end there and the outcomes being
22 achieved, because that's what you're, you know,

1 you're interested in what the outcomes are and, you
2 know, science is just a process and the outcomes
3 being achieved. We can at least get away from
4 the -- language.

5 MR. FINNEGAN: I would like to add one more
6 caveat to this thing. There should be a consistent
7 across the board audit or whatever form you use
8 should be consistent, you know, everybody would
9 be -- treat everybody the same. Use the same
10 format.

11 DR. ENGELJOHN: If they're in these three
12 tiers. I'm sorry. Is that what you mean?

13 MR. FINNEGAN: Right.

14 MR. ENGELJOHN: Depending on which tier you
15 were in.

16 MR. FINNEGAN: Right. You know, the audit
17 itself would be consistently even. I think that's
18 important. We should add that in there.

19 DR. HARRIS: I'm sorry. Help me. I'm
20 sorry. I was trying to write down the suggestion
21 here. Are you talking about a standard audit form?

22 MR. FINNEGAN: Not standard. Consistent.

1 MR. CORBO: I think what Mike is getting to
2 is a consistent application of the policy --

3 MR. FINNEGAN: Right.

4 MR. CORBO: -- and I think that's where
5 sometimes FSIS now gets itself into trouble. If
6 you're going to have a three-tiered system, then you
7 better make sure that those people in the various
8 tiers, you can justify why you placed them there.

9 MR. FINNEGAN: A consistent application.
10 That would be a better word I supposed, yeah. But
11 that's what I'm getting at. And I agree with Tony.
12 When I look at this checklist, I see there's a check
13 on records. It's a deviation on records. Well,
14 that could be something as simple as a little
15 clerical error, where the monitoring guy could have
16 put the wrong initials in or something, you know.
17 To me this means nothing. You know, I have to read
18 more into it than what's there.

19 MR. CORBO: Yeah, well, that's what I'm
20 saying. The backside is very important because
21 that's where the auditor will go into detail.

22 MR. FINNEGAN: It would divide a very

1 minute, minor thing compared to something, hey,
2 that's kind of a serious deal.

3 DR. HARRIS: Okay. Let me read something
4 to you and maybe I've got my arms around some of
5 this and tell me, A, if I left anything out and, B,
6 if you think or if you agree that it captures what
7 we've been saying here, and we can all support it.

8 The Subcommittee believes that the scope
9 and frequency of in-country audits should be
10 adjusted based on consideration of the following:
11 transparency of the exporting country's food safety
12 system and outcomes, the exporting country's ongoing
13 ability to and willingness to share and the quality
14 of the data shared. I left off compliance history,
15 excuse me. That would be the other thing.
16 Compliance history. The Subcommittee suggests a
17 three-tiered system maybe appropriate, standardized
18 application of the audit criteria will be important
19 to the success of a tiered approach.

20 MR. FINNEGAN: Good.

21 DR. HARRIS: Suggestions? Comments? Did I
22 miss any of our points or --

1 MR. FINNEGAN: Standardized I think --

2 DR. HARRIS: -- any of them?

3 MR. FINNEGAN: That standardized is what my
4 concern was. So --

5 DR. HARRIS: Standardized or consistent. I
6 don't know.

7 MR. FINNEGAN: I like the word
8 standardized.

9 DR. HARRIS: Okay.

10 MR. FINNEGAN: That's a Texas A&M word.
11 (Laughter.)

12 DR. HARRIS: Again. Sorry, Josh. I
13 completely redid that.

14 UNIDENTIFIED SPEAKER: I'll make sure
15 President Murano heard that, Mike.

16 DR. HARRIS: Have we captured Part A of
17 Question 2?

18 Okay. Now we're going to talk about the
19 same question only substitute reinspection instead
20 of in-country audits. Again, as a reminder, the
21 product reinspection, those are those inspections
22 that occur as the product enters at the port-of-

1 entry to the United States. Dr. Dickson.

2 DR. DICKSON: Dr. Harris, I believe with a
3 little bit of editing, you can almost use the same
4 answer for reinspection as you can with on-site
5 audits.

6 DR. HARRIS: I mean, it follows the same
7 logic. If a country has been doing a really good
8 job or let's put the shoe on the other foot. If a
9 country's doing a really bad job, then you'd
10 approach 100 percent of reinspection.

11 DR. DICKSON: Absolutely correct.

12 MR. FINNEGAN: That's correct.

13 DR. DICKSON: Put the resources on the
14 people that are the problem rather than spending a
15 lot of time reinspecting something that doesn't
16 cause problems.

17 MR. BUSCH: But I don't think it addresses
18 the things that, for example, -- if something
19 happens in transit -- exporting doesn't have any
20 control over that or even know about that. You
21 wouldn't know if you're going to have temperature
22 issues or rodent infestation or whatever on the

1 vessel and --

2 DR. DICKSON: I agree with you 100 percent
3 with you but at some point the company or entity
4 that is buying the product, that is receiving it, I
5 mean if it's a question of they open the Connex
6 (ph.) box and the packages are damaged or the
7 refrigeration unit is off, that's where the company
8 that's buying the product needs to step in and say
9 this doesn't meet our specifications, and it needs
10 to go back. That's what happens to our product when
11 it goes overseas. If you want to put an inspector
12 there, that's fine. I don't really, you know,
13 that's not an issue really with me, but the reality
14 with our product when it goes overseas, if it comes
15 off the container ship, and it's over temperature,
16 it's the company that's receiving that product that
17 calls the supplier and says, hey, we're not taking
18 this stuff. You need to buy it. Like I said, if
19 you want to have it reinspected, that's not an issue
20 but most of those issues are self-correcting, at
21 least with our product going overseas.

22 MS. STANLEY: This is Mary Stanley. Just

1 to help you out on that, that decision by industry
2 would be made before the product would be presented
3 to us. If there's a temperature violation and the
4 product was impacted, the importer of record could
5 make that decision before it even came through the
6 Customs -- to us --

7 DR. HARRIS: Okay.

8 MS. STANLEY: -- and they could adjust it
9 from a commercial viewpoint.

10 DR. HARRIS: Okay. Yes, sir.

11 DR. JOLLY: Bill Jolly of New Zealand Food
12 Safety Authority. Just so people understand a
13 little bit of how commodities are traded
14 internationally. Most of, in fact, just all meat
15 that I know is traded internationally is
16 containerized. Okay. Those containers get security
17 seals put on them and the security seal is -- In
18 addition to that, our product also has carton seals
19 which are -- And so the actual security of a
20 consignment is almost a Homeland Security type issue
21 because of the potential for bioterrorism inside of
22 that. That's not something -- by the time it's

1 entered into the -- territory, that sort of
2 consideration has already been made as far as the
3 potential for substitution or -- because the
4 container seals changing and the systems that
5 revolve around that. So perhaps -- issue.

6 The one thing that Mary and us have been
7 working on is the electronic certification just to
8 make sure that there's no chance of fraudulent
9 certificates showing up, and those countries that
10 are involved in electronic certification -- are
11 really pushing things out there. There are a few
12 country that have -- with Russia lately, because
13 there's been a lot of fraudulent certification.

14 Now, where that certification is being
15 generated from Russian importers is not really the
16 issue but I can tell you now that we haven't had the
17 problem because we've got the electronic
18 certification system and they can check out the --
19 certificates across the database straight-away. So
20 again you can almost have a tiered system here if
21 there is a concern, but it's probably not a concern
22 in any way because it was already dealt with by

1 agents in Customs before FSIS gets involved.

2 MS. STANLEY: Well, FSIS is involved
3 because we didn't target. So the Agency is involved
4 in that step.

5 DR. HARRIS: Should we make it clear that
6 we're talking about a range here that doesn't
7 include 0, and I don't know what the minimum should
8 be, but, you know, there should be some level of
9 reinspection regardless of what tier we're in.
10 Would everyone agree with that?

11 MR. CORBO: Let me ask a question because
12 the IG report got into this skip inspections and --
13 explain the tiers of inspection that you use now at
14 the ports-of-entry.

15 MS. STANLEY: It is a little confusing as
16 you read that report because Bill opted to change
17 the language a little bit since skip doesn't show up
18 in what I presented to you yesterday, but when we
19 use the terminology skip, as it will be in the OIG
20 report, those are shipments that have received the
21 routine inspection, which is the basic evaluation of
22 the shipment that has not been subjected to a more

1 intensive evaluation of product examination on
2 laboratory testing. And the point in the OIG report
3 is if you have a lot, a broker or importer of record
4 can split a lot and present it in two separate sub-
5 lots. So if one of those sub-lots receives a more
6 intensive inspection for like product exam, and the
7 other one is a skipped, the OIG is saying you should
8 do your product examination on that sub-lot before
9 you release the skipped lot. That's the only
10 finding that they had there.

11 MR. FINNEGAN: Do you guys know every
12 shipment, you know, of meat products coming in ahead
13 of time?

14 MS. STANLEY: Not at this time. With
15 Canada, we have an advanced notice rule.

16 MR. FINNEGAN: Okay.

17 MS. STANLEY: With New Zealand, with the
18 ecert, we know three weeks in advance that the
19 products are coming.

20 MR. FINNEGAN: That the shipment's coming
21 in.

22 MS. STANLEY: Yeah. Because they've

1 certified them and they've indicated that they've
2 shipped. But that's what the ACE/ITDS system will
3 deliver to us --

4 MR. FINNEGAN: Okay.

5 MS. STANLEY: -- is that advanced notice,
6 and that prior notice will be aligned with the FDA
7 BT legislation in whatever the timeframes are for
8 the mode of transportation.

9 MR. FINNEGAN: So you're looking for in the
10 future every exporting country to let you know in
11 advance, let FSIS know?

12 MS. STANLEY: No. The responsibility of
13 the prior notice is a burden on the importer of
14 record --

15 MR. FINNEGAN: Okay.

16 MS. STANLEY: -- through the trade side,
17 through Customs, filing with Customs and Border
18 Protection.

19 MR. FINNEGAN: Okay.

20 MS. STANLEY: The advantage of our
21 electronic certification system government to
22 government is we'll deliver what you said but we're

1 not mandating an electronic certification system.

2 MR. FINNEGAN: Okay.

3 MS. STANLEY: That's if the country has it,
4 we'll certainly provide to receive the data and will
5 benefit from that information.

6 MR. FINNEGAN: Thank you.

7 MR. TYNAN: While everybody's taking a
8 breath, I just wanted to remind you that we had
9 talked a little bit earlier about finishing up at
10 11:30. Do you think you will be on time, Joe?

11 DR. HARRIS: I think so. I think we're
12 getting pretty close.

13 MR. CORBO: Even with the IG report, we're
14 going to be on time.

15 DR. HARRIS: Okay. I'm working on
16 something to read to you guys and then I'm going to
17 ask a question. Okay. We're on 2(b) here. So I
18 just put in sentence form what we just said.
19 Routine and directed reinspection frequency should
20 be adjusted based on the same factors as outlined in
21 2(a) above, instead of retyping those same factors
22 again.

1 Now, the question I have and, Stan, forgive
2 me. I'm going to use your word here.

3 MR. PAINTER: La, la, la, la. (Laughter.)

4 DR. HARRIS: Should any consideration here
5 be given to the -- God, this is going to sound a lot
6 like risk-based inspection, but to the inherent risk
7 of the particular product. For example, are we
8 talking about a cooked, dried jerky product from
9 Brazil or a canned meat product from somewhere else,
10 versus, you know, fresh trimmings or --

11 MR. FINNEGAN: Right.

12 DR. HARRIS: -- do we need some sort of
13 product consideration built into this?

14 MR. PAINTER: Stan Painter, NJC. If I'm an
15 inspector and I know that I have canned product
16 coming in versus packaged product, I'm going to use
17 a little bit of common sense here to know that more
18 than likely there was nothing that was able to get
19 inside that canned product in order to adulterate,
20 contaminate, whatever that product.

21 Having the knowledge that this product is
22 coming in canned, you know, I'm going to adjust my

1 schedule accordingly as an inspector that may be
2 coming in, you know, with the product coming in to
3 know whether I need to spend more time with that
4 versus spending more time with something else.

5 So I think it goes back to just a little
6 bit of a common sense approach to the inspector
7 that's there.

8 DR. HARRIS: Do the inspectors on site have
9 that discretion currently or is it sort of -- is
10 that built into the way they go about it now I guess
11 is my question?

12 MS. STANLEY: It being consideration of the
13 inherent risk of the product?

14 MR. CORBO: So we're doing that now.

15 MS. STANLEY: Yes. The types of inspection
16 are assigned to products ending on -- well, it's
17 following the domestic policy. We're assigning the
18 micro to the ready-to-eat product or to the raw
19 ground beef. We are assigning product examinations
20 on a sliding scale based on how much volume of
21 product is coming in, and I think that that's what
22 this question is directing towards is if a country

1 shows good compliance over time, at port-of-entry,
2 should they be held to that annual plan that's
3 applied to all countries or should there be a
4 different inspection frequency --

5 MR. FINNEGAN: Uh-huh.

6 MS. STANLEY: -- based on individual
7 country.

8 DR. HARRIS: Well, we answered that to some
9 extent. The sentence I added here regarding the
10 product, and you'll be proud I didn't use the word
11 risk, I said consideration should also be given to
12 the characteristics of the specific product being
13 imported. I said characteristics. That could
14 include whatever but --

15 MR. FINNEGAN: I have one correction. If
16 you have a country and they have 10 different
17 products, and from 10 different plants, one fails,
18 is there reinspection to the whole country or
19 specific to that particular product from a different
20 plant?

21 MS. STANLEY: The violation is applied to
22 the establishment --

1 MR. FINNEGAN: Okay.

2 MS. STANLEY: -- and then it is applied to
3 that product category. So as I mentioned yesterday,
4 these are organized by HACCP process categories. So
5 if you have a failure of *Listeria* on a product
6 that's in a subcategory --

7 MR. FINNEGAN: Okay.

8 MS. STANLEY: -- the violation applies to
9 all products that are prepared from that
10 establishment in that process category, ready-to-eat
11 category. So it's applied to the establishment, to
12 the product.

13 MR. FINNEGAN: Okay. So we don't have to
14 worry about reinspecting other products from the
15 same country or different products. Yeah, that's
16 what I was getting at, if we had to address, you
17 know, the country as a whole or --

18 MS. STANLEY: Well, an example of where,
19 you know, where this is going I think would be what
20 is the value of doing a product examination of a
21 soup-based mix. I mean what are you looking for.
22 It's a pretty homogenous powdery product that has a

1 meat-base in there. The inspectors will do that
2 because it's an assignment but is that a good use of
3 their time or should we limit that to just a
4 chemical analyses of applicable types of inspection.

5 DR. HARRIS: Okay. We have something on
6 paper for all of this right now. I want to ask a
7 couple of questions first of the Agency personnel
8 here.

9 Don pointed out earlier you're relying on
10 us to give you some direction here that you can --
11 that will be useful to you going forward. Do you
12 think that we've achieved that? Is there something
13 that you need from us that we didn't provide? And
14 we can scroll up and down if you want to read the
15 top part of it.

16 DR. ENGELJOHN: From my perspective from
17 the Policy Office, I think, yes, you've given us
18 some helpful guidance.

19 DR. HARRIS: Now from the Subcommittee
20 standpoint, obviously limiting to the two questions
21 we're assigned here, we can't, we can't venture too
22 far outside of that, but are there other

1 considerations, other things that we haven't touched
2 on that need to be?

3 DR. ENGELJOHN: Can I just -- I'm not part
4 of your Committee, but --

5 DR. HARRIS: We welcome input from anybody.

6 DR. ENGELJOHN: Well, again Engeljohn from
7 the policy side of FSIS. I mean I appreciate the
8 things that Dr. Jolly has raised in terms of trying
9 to look at this in the bigger, broader scheme of
10 things, and I do think there should be -- from my
11 perspective, it's captured here, but I leave it to
12 you, but I think there should be goal towards
13 getting all countries into this category of being
14 able to truly have high confidence in what they're
15 doing as opposed to just leaving it that there's
16 tiers. I mean, there should probably be some
17 direction to the Agency of working towards that as
18 being the goal, you want to get to that point. And
19 I don't know whether that thought is captured.

20 DR. HARRIS: Yeah.

21 DR. ENGELJOHN: You've got the structure
22 there, but I think that's a good direction to

1 probably push us.

2 MR. TYNAN: So a goal would be to encourage
3 or to, you know, encourage I guess is the word here,
4 to take countries up to the next tier from wherever
5 they --

6 DR. ENGELJOHN: FSIS and other countries.
7 It's both ways. We have a lot of improvement to
8 make --

9 DR. HARRIS: Sure.

10 DR. ENGELJOHN: -- to get to that goal.

11 DR. HARRIS: Dr. Dickson.

12 DR. DICKSON: I think continuous
13 improvement, if we can work that phrase in there
14 somewhere. Continuous improvement not only for our
15 domestic system, but also for the external
16 countries. Does that capture what you're --

17 DR. HARRIS: Well, we've got about 10
18 minutes here. With your permission, I'll try to
19 work on it, kind of an introductory sentence here to
20 what we're doing that says something like that I
21 mean and see if we can get that captured, that
22 thought of continuous improvement.

1 MR. TYNAN: We should be able to print
2 copies out for you so that you'll have them over
3 lunch and if there's some other ideas that come up
4 when we get into the plenary session, there's
5 nothing that prevents you all from bringing up other
6 issues as we talk about the other Subcommittee as
7 well. So you're not necessarily confined to what we
8 talked about here this morning. You'll have another
9 bite of the apple in about an hour.

10 DR. ENGELJOHN: Again, it is just my
11 opinion that I think that continuous improvement
12 would be a great statement to add, but I think you
13 should hold FSIS to that as well, not just the
14 countries, but FSIS.

15 MR. CORBO: I will make sure Phyllis knows
16 that, too.

17 DR. JOLLY: Bill Jolly, New Zealand Food
18 Safety Authority. One of the things we've looked at
19 in our own import system is, you know, it's the old
20 carrot and stick situation. Part of it is incentive
21 and the other is to have the stick, and so if you do
22 have a differentiation like a green line versus an

1 orange line versus a red line, then you, you know,
2 would encourage performance.

3 One of the problems with the count system
4 which has served the United States very well is
5 you've got to a level and you've plateaued and it
6 was too easy to get to that level to some extent,
7 and there was no incentive for countries to perform
8 any better. And you actually had that gradation,
9 actually serves you well, too.

10 Now, one of the things that Tom Billy used
11 to do very well was he used to keep moving the bar
12 and so you might have tiers, but you just keep
13 moving the bar, and that's another way of achieving
14 continuous improvement, even not just swapping
15 countries between the bar either, the different
16 tiers.

17 DR. HARRIS: I've almost got it here.

18 DR. ENGELJOHN: Are they going back to the
19 cafeteria? You said they would be getting back by
20 12:30. Is that what you mean?

21 MR. TYNAN: The other group should be
22 finished. So we probably ought to go back to the

1 cafeteria at 11:30, drop the materials off and then
2 take a lunch break and be back at 12:30 actually,
3 get back to the room.

4 DR. HARRIS: Okay. Here's the sentence I
5 came up with, kind of an introductory sentence to
6 our report. The Subcommittee generally supports the
7 Agency's current triad of import oversight
8 activities. The Subcommittee strongly encourages
9 additional and continuous improvements to FSIS
10 implementation of its program and recommends the
11 Agency work diligently with exporting countries to
12 encourage their continuous improvements in
13 compliance, data sharing and transparency.

14 Josh, he can put it on paper, and then you
15 can take another look at it and see if I've captured
16 that.

17 MR. CORBO: Not to embarrass him, but the
18 gentleman who just walked in, used to be the
19 Director of Import Operations for FDA. So he's
20 responsible for only 1 percent of the food supply
21 over there being -- (laughter). Carl Nielsen.

22 DR. MURINDA: Haven't we left out safety in

1 the objective outcome there, the first line. Clean,
2 wholesome, unadulterated, properly labeled product.

3 DR. HARRIS: I'll tell you what -- yeah.
4 Let's include safe in that. I agree. Put it first.
5 How about that? Safe, clean, wholesome,
6 unadulterated, properly labeled product.

7 DR. ENGELJOHN: Joe, the only thing again,
8 this is Dan Engeljohn's opinion, in what you're
9 adding there in that sentence where you said
10 continuous improvements to the FSIS implementation
11 of its program, do you mean of the equivalence
12 program?

13 DR. HARRIS: Yes.

14 DR. ENGELJOHN: Because I think that's
15 fine, but I also think it should be improvement of
16 the FSIS domestic system, what we have in place here
17 and the --

18 DR. HARRIS: I completely agree with that
19 concept.

20 MR. CORBO: And filling all the inspector
21 vacancies.

22 DR. ENGELJOHN: You're not going to get

1 improvement if you don't also ensure you're going to
2 improve the domestic system because that's what
3 we're -- equivalence to. So I'm just suggesting
4 perhaps you need to capture that.

5 DR. HARRIS: How about this? Let me just
6 type for a second here. I don't want to keep
7 writing and see if you think this would work.

8 DR. ENGELJOHN: You don't have to say that
9 but I think --

10 DR. HARRIS: You stand and watch. I'm
11 going to type risk if I can find a way to do it.

12 MR. PAINTER: People have just said it
13 without saying it here. And if it meant what it was
14 supposed to mean, I could probably support it. It's
15 supposed to mean what I said. There's more
16 politicians in the room than up on the Hill.

17 DR. HARRIS: Okay. Dan, I stuck a
18 parenthetical right there next to program, both
19 domestic and import equivalency.

20 DR. ENGELJOHN: I like that. I think it
21 gives us some direction to do that.

22 MR. CORBO: Okay. What does domestic

1 equivalency mean?

2 DR. ENGELJOHN: Domestic meaning that the
3 transparency and all that stuff related to the
4 domestic program, how we implement it, measure its
5 success, all that stuff needs to be included. So I
6 think our domestic --

7 MR. CORBO: I don't want, I don't want, you
8 know, because then you may want to -- some of the
9 state guys are saying, well, wait a second. What
10 are you talking about here? We just went through
11 this exercise in the farm bill. I think you better
12 think about that a little bit.

13 DR. ENGELJOHN: Tony, the only thing I was
14 trying to get at is there's room for improvement in
15 how FSIS operates its programs.

16 DR. HARRIS: Tell you what. Tony, to
17 alleve your fears, let me point out that equivalency
18 doesn't apply to states anyway. They have to be
19 equal to. So if someone were to interpret it that
20 way, we would say, no, we weren't even talking about
21 states because you used the word equivalency. Do
22 you buy that?

1 DR. ENGELJOHN: I'm fine with that and you
2 don't have to add it, but there's room for
3 improvement for FSIS. I don't think it should be
4 necessary. We just -- everyone else needs to.

5 MR. STEFAN: Well, take out equivalency and
6 just say domestic and import programs.

7 DR. HARRIS: How about this? Both domestic
8 and import.

9 MS. STANLEY: Just put the word import in
10 front of --

11 MR. CORBO: Yeah, yeah, yeah, yeah, I
12 think -- import programs.

13 DR. ENGELJOHN: I like that.

14 DR. HARRIS: Okay.

15 JOSH: I'm going to try to fit it on one
16 page.

17 DR. HARRIS: Okay. That will be good.
18 Stan, two pages and not the word risk to be found.

19 MR. PAINTER: Yea! You're all right with
20 me, Joe. I don't care what Tony says.

21 DR. HARRIS: Is our work done here guys?
22 Is everyone comfortable with what we've got?

1 MR. FINNEGAN: Yeah. I am.

2 DR. HARRIS: If the full Committee rips it
3 to pieces and rewrites it, you know, we've at least
4 got something.

5 MR. FINNEGAN: Right.

6 DR. HARRIS: Well, let's stand adjourned
7 and have lunch, and what time are we starting back
8 up?

9 MR. TYNAN: 12:30. And Josh will print out
10 some copies, and we can get some copies to you
11 before we reconvene.

12 (Whereupon, at 11:34 a.m., the subcommittee
13 was 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
SUBCOMMITTEE 2
VERIFYING INTERNATIONAL EQUIVALENCE

Washington, D.C.

August 28, 2008

were held as herein appears, and that this is the
original transcription thereof for the files of the
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