

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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INTERNATIONAL EQUIVALENCE

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PLENARY SESSION

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August 28, 2008

8:30 a.m.

USDA South Building Cafeteria
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P-R-O-C-E-E-D-I-N-G-S

(8:30 a.m.)

1
2
3 MR. TYNAN: The public part of our audience
4 seems to have diminished dramatically from
5 yesterday. Actually I was kind of hoping they would
6 all come back because I think your Subcommittee
7 sessions tend to be more robust having some other
8 individuals in the room and that's able to
9 participate with you.

10 At this particular point, I wanted to point
11 out to you that under Tab 3, I'm pretty sure it's
12 Tab 3, I don't have the notebook in front of me, but
13 under Tab 3 I believe we have the Subcommittee
14 Chairs and the assignments, and immediately behind
15 that we also have the issue paper and the questions
16 that are being asked of each of the Subcommittees.
17 I won't walk through the Subcommittee assignments.
18 You can all read that, but I think Subcommittee
19 Number 1 will be here in this room, and Subcommittee
20 Number 2 will be in Room 1160, and we'll get you
21 guys guided around to Room 1160. Our security gets
22 a little carried away at times. So we'll get you

1 around to 1160 for our breakout room.

2 With that, I'm going to introduce Dr. Bill
3 James and, Bill, if you want to stay right there at
4 your seat, you're welcome to do that, and ask him to
5 perhaps provide a charge to the group and maybe
6 explain a little bit about what his expectations and
7 goal is for the Subcommittee deliberations.
8 Dr. James.

9 DR. JAMES: Thank you, Robert. I trust
10 that you have read the issue paper. It's repeated
11 for both Subcommittees and then there are two basic
12 questions with a couple of subparts to each one.

13 I'm going to just summarize what we covered
14 yesterday in just a few sentences. We essentially
15 made the point that the FSIS import safety system
16 consists of a triad of protections. I think if
17 nothing else came through yesterday I hope that did.
18 The basic elements are equivalence, audits and
19 reinspection.

20 Equivalence has two principal sub-elements.
21 They are initial equivalence and continuing
22 equivalence.

1 Auditing has two principal sub-elements.
2 They are in-country evaluation and out-of-country
3 evaluation.

4 Reinspection has three principal sub-
5 elements, although they are all very closely
6 related, routine reinspection, directed reinspection
7 and for cause reinspection.

8 Now, we in FSIS believe that our import
9 safety system has severed the American public well
10 over the years and is generally recognized as a
11 sound model for assuring food safety. Nevertheless,
12 as the world changes and new technologies emerge and
13 FSIS continues to move forward in its public health
14 mission, we are asking this Committee to consider
15 the existing system that we have and provide FSIS
16 with ideas and advice/counsel regarding areas for
17 improvement.

18 And so for Subcommittee Number 1, we have
19 these questions.

20 What recommendations do you have regarding
21 the FSIS triad of protections? Should each element
22 of the triad be retained or should some elements be

1 dropped? If some elements should be omitted, please
2 identify those for us. Also, should other elements
3 be added in place of or in addition to our basic
4 triad, and if so, please identify these elements for
5 us.

6 The second basic question, for each of the
7 three elements of the triad, sub-elements have been
8 identified. I just reviewed those very briefly with
9 you. Should each sub-element be retained or should
10 some of them be dropped? If dropped, please
11 identify those elements. Should other sub-elements,
12 basic sub-elements be added, either in place of or
13 in addition to what we are doing?

14 Please allow me to summarize in different
15 words. In other words, we are looking for the
16 Subcommittee to either validate our basic approach,
17 validate our basic approach with modifications, or
18 reject our basic approach with recommendations for
19 how we start over. That is essentially what we are
20 looking for from Subcommittee Number 1.

21 Should I ask for questions or move onto
22 Number 2?

1 MR. TYNAN: Let's -- why don't we entertain
2 some questions at this particular point if there are
3 any. Dr. Harris, we'll start with you?

4 DR. HARRIS: Thanks. Dr. James, during the
5 introductory comments yesterday, Dr. Raymond
6 discussed sort of the two concepts of product versus
7 process based equivalency determination. In his
8 comments he seemed to indicate that the basic
9 program that is in place right now is very process
10 oriented, that most of the focus is on an exporting
11 country's processes and inspection processes, et
12 cetera. And that it was time to become more product
13 focused. Should we as a Committee and Subcommittees
14 assume that that is the direction that it's headed
15 or is that open -- or is that a question that you're
16 interested in getting feedback from the Committee
17 on, whether or not it should be process or product
18 related or both?

19 DR. JAMES: That is exactly to the point
20 that I want to address for Subcommittee Number 2.

21 DR. HARRIS: I'm sorry I got ahead. I
22 guess I'm an overachiever. (Laughter.)

1 DR. JAMES: Who is the Chair of
2 Subcommittee Number 2? (Laughter.) You're right on
3 target. You're just two minutes too eager.

4 MR. TYNAN: I think he just wanted to see
5 if we were paying attention. I'll start with
6 Mr. Corbo over here and then come back down this
7 end.

8 MR. CORBO: Tony Corbo. Sort of as an
9 addendum to what Joe just asked, yesterday an
10 allusion was made to the Inspector General's Report.
11 That did come out yesterday. And in terms of the
12 process versus product evaluation of import
13 inspection, you know, one of the bases is the need
14 for accurate and complete data, and the IG Report
15 which I read last night, I think would be very
16 helpful to this Committee in terms of making an
17 analysis and giving the Agency recommendations in
18 terms of how to proceed because I think there's some
19 serious problems with the way the Agency conducts
20 equivalency. Getting back to my question about how
21 equivalency can be challenged when a country does
22 not meet the standards. I think this document is

1 important for this Committee to have today before we
2 meet.

3 MR. TYNAN: I can get copies of the report
4 made but I don't want to delay. I think there was
5 enough information that we provided yesterday
6 that --

7 MR. CORBO: I don't think so, Robert.

8 MR. TYNAN: I'm going to have to use my
9 power microphone.

10 MR. CORBO: You took it away from me.

11 MR. TYNAN: We have enough information from
12 yesterday that we can at least begin the
13 deliberations. I will get the copies of the reports
14 and we'll get them to the Subcommittees and to the
15 extent you're able to glean from those, at this
16 particular point, additional things that we want to
17 build in, that will be fine. So I think in the
18 interest of time, because we are up against a little
19 bit of a time constraint, that if we could begin the
20 deliberations based on the information from
21 yesterday, and then I'll get those copies made and
22 to you for this morning. Mr. Kowalcyk.

1 MR. KOWALCYK: Okay. I guess my question
2 is really to Joe's question about Subcommittee 1 and
3 the focus on outcome based, okay. Where is see part
4 of outcome based would be in the reinspection part
5 of the triad. Am I correct to assume that? And
6 then any recommendations on what is done during
7 reinspection and how those results are used, because
8 it seems like the audit, in-country and out-of-
9 country audits, really focus on the process. I'm
10 struggling with how we can determine outcomes based
11 on those two procedures.

12 DR. JAMES: There is I think necessarily so
13 some degree of overlap of what the two Subcommittees
14 will be looking at, and I don't know that you need
15 to be afraid to trespass on each other's work
16 because I think we can make use of whatever comes
17 out of both Committees. The first group or
18 Subcommittee Number 1 though, we're looking at some
19 principles principally. Basically we're looking at
20 principles. This is our triad of protection. Are
21 these the right things to be doing? We have certain
22 sub-elements under each of those three elements that

1 we use as our principles for work. Are they the
2 right things to do? So Subcommittee Number 1,
3 perhaps a way to characterize it is, are we doing
4 the right things? And then when Subcommittee Number
5 2, when we address it, we're going to be asking a
6 couple of other questions which perhaps could be
7 characterized, are we doing the things in the right
8 way? So hopefully that's helpful.

9 MR. KOWALCYK: Okay.

10 MR. TYNAN: Mr. Elfering.

11 MR. ELFERING: I have a question on this, I
12 think it was for like the 156 some odd shipments
13 that were not eligible for export that were found
14 during routine inspections in the last fiscal year.
15 Is that correct? If you were to modify your system
16 to the point where, for example, not doing routine
17 reinspection, would those 156 shipments still have
18 been somehow found and rejected for importation?

19 MS. STANLEY: Yes, they would have been
20 found because the information that we used to detect
21 those shipments was Customs and Border Protection
22 entry data, and so we're able to use those data to

1 target shipments that entered the country that are
2 not eligible. And with the design of the new
3 system, the ACE/ITDS system, the Customs system will
4 actually block the entry of the product. It will
5 fire off of rules that we have defined to Customs to
6 not even allow the entry of that product. Currently
7 the system is silent on that. So --

8 MR. ELFERING: So all of these products
9 were either from countries that were not eligible or
10 the product itself was not eligible for export.
11 None of these products came from countries that are
12 major trading partners as far as meat and poultry.

13 MS. STANLEY: Very few of these shipments
14 are classified as a failure to present. We have the
15 reasons for why they violated the entry process and
16 the few shipments out of the 156 that are identified
17 as failures to present are shipments that we had
18 prior notice that they were coming, but they did not
19 stop at the import establishment to be reinspected.
20 So they are captured in those data of the 156
21 shipments.

22 MR. TYNAN: Are you okay? Ms. Conti, I

1 think you had your card up and then put it back
2 down. Did you have a question?

3 MS. CONTI: I was just wondering about the
4 date of the IG Report he was referring to?

5 MR. TYNAN: The date of the IG Report was
6 probably yesterday afternoon --

7 MS. CONTI: Okay.

8 MR. TYNAN: -- when we started the meeting.
9 Yesterday morning I think Dr. Raymond referred to
10 the report. At that particular point in time, it
11 had not been published. It was published later on
12 in the afternoon.

13 MS. CONTI: All right. Thank you.

14 MR. TYNAN: Okay. Mr. Covington, I
15 apologize.

16 MR. COVINGTON: Going on what my
17 understanding of what Dr. James said, Subcommittee 1
18 is to address whether or not the triad of activities
19 today are the right activities to be conducting.
20 How should the Subcommittees address, particularly
21 Subcommittee Number 2, how should they address if
22 Subcommittee 1 comes back with a different

1 recommendation for another element as far as trying
2 to put an objective criteria to an element? In
3 essence, if we come up with something different, how
4 do we communicate with Subcommittee Number 2 who my
5 understanding is to address what a level of
6 acceptance may be.

7 MR. TYNAN: I've got that one. This
8 afternoon, what we normally do in the sessions and
9 probably in a couple of last ones, I think in the
10 last one we didn't really get an opportunity but
11 normally what we have the Subcommittees do, develop
12 their draft reports. We come back here to this room
13 and discuss those reports in plenary session. If
14 for whatever reason you don't agree with any of the
15 report from the other Subcommittee, you can then
16 weigh in at that particular point in time and ask
17 your questions, and the Subcommittee Chair and the
18 entire Committee will make adjustments to that
19 particular report.

20 Similarly, if there's a conflict with what
21 you come up with and what the other Subcommittee
22 comes up with, we can resolve it during that plenary

1 session. But obviously we'll have people in each of
2 the Subcommittee rooms. So if we see that starting
3 to happen, we'll try and alert the other
4 Subcommittee and see if we can't do a little
5 resolution before you get back here for the plenary
6 session. Does that help, Brian?

7 MR. COVINGTON: Yes.

8 MR. TYNAN: Okay. Any other questions at
9 this particular point on Subcommittee 1?

10 (No response.)

11 MR. TYNAN: Bill, you want to talk about
12 Subcommittee 2.

13 DR. JAMES: Yes, Subcommittee 2. The same
14 preamble to the questions. So I will go straight to
15 the questions.

16 What recommendations does the Committee
17 have regarding the objective evaluation of outcomes
18 of the meat, poultry and egg product safety system
19 to determine if equivalence is achieved and
20 maintained? Two questions under there, what
21 objective outcomes are most appropriate to evaluate?
22 What means are most appropriate for evaluating

1 objective outcomes?

2 Now, the question was already asked and the
3 system that we currently have in place is
4 essentially a series of individual measures that we
5 are evaluating rather than the system as a whole.
6 And so we look at the objectives of individual
7 measures and try to evaluate any changes to specific
8 measures to determine whether or not the objectives
9 of that measure are being met. The concept that you
10 hear repeated a number of times in presentations
11 yesterday is should we rather instead be trying to
12 evaluate, recommendations actually were made in
13 several of the presentations yesterday, that we
14 should be evaluating the outcomes of the entire
15 system rather than the objectives of particular
16 measures.

17 And so we would be interested in this
18 Subcommittee's opinion as to what objective outcomes
19 of a system are useful and important to evaluate, so
20 that systems might be compared rather than
21 individual segmented measures of a system.

22 Question 2, countries vary with information

1 sharing capabilities and compliance history in
2 demonstrating equivalence. What recommendations do
3 you have regarding the effects that information
4 sharing and compliance history should have on audits
5 and reinspection? Should in-country audits be
6 adjusted by scope and frequency based on information
7 that comes to us during the year and the compliance
8 history at port-of-entry and from previous audits?

9 The second question is, should routine and
10 directed reinspection at port-of-entry be adjusted
11 by frequency based on the information that is
12 provided to us throughout the year from a country
13 and its compliance history?

14 This is taking into account the idea of a
15 365-day audit that you heard mentioned yesterday.
16 What kind of information should be coming in from a
17 country that would be useful to us, and should that
18 information and everything else that we generate
19 during the year affect the scope and frequency of
20 in-country audits and the frequency of routine and
21 directed reinspections for countries.

22 Questions on that?

1 MR. TYNAN: Mr. Corbo.

2 MR. CORBO: Could you provide us with
3 copies of past audit checklists, you know, that you
4 can pull off of the website, just to give us an idea
5 in terms of what your auditors look for, give us an
6 example of where they found no problems and an
7 example where they did find problems in a plant
8 audit.

9 DR. JAMES: I think we can get something to
10 you that shows the basic checklist that the auditors
11 use and then a couple of final audit reports off the
12 website.

13 MR. TYNAN: Mr. Finnegan.

14 MR. FINNEGAN: Yeah, Mike Finnegan. In
15 regard to what Tony was saying, the exporting
16 countries, do they have to perform like a self-
17 assessment type deal? I know in the States we do.
18 We have a yearly self-assessment. Is there anything
19 similar to that that exporting countries have to do?

20 DR. JAMES: Mr. Finnegan, are you speaking
21 to countries that have already been found equivalent
22 and are continuing to export to us?

1 MR. FINNEGAN: Yes, ongoing.

2 DR. JAMES: Yeah. I'm not certain what you
3 mean when you're referring to an assessment but each
4 country has in place an inspection program that has
5 been found equivalent and our practice has been to
6 perform annual audits. That is what we usually do
7 to help us determine whether or not a country is
8 maintaining its equivalent system, and then that
9 information, of course, is supplemented by what we
10 get at port-of-entry. But I'm not certain that
11 answers your question because I'm not certain what
12 you mean by a self-assessment.

13 MR. FINNEGAN: In the States every year, it
14 just started through Bill Smith, where we have to
15 answer certain questions, components, on how we
16 handle certain situations like residual sampling,
17 BSE, and a lot of these directives and notices that
18 we get, and how we handle them. That's more what I
19 was asking, if these exporting countries have to do
20 the same thing, a similar type basis.

21 DR. JAMES: The answer is no. We don't
22 have anything quite like that. I wonder if that

1 might end up being a recommendation.

2 MR. FINNEGAN: Thank you.

3 MR. TYNAN: We're just helping you out,
4 Michael, so you've got one of the questions already
5 answered. Do we have other questions from the
6 Committee on issue number 2 or for the questions for
7 issue number 2?

8 DR. JAMES: Mr. Finnegan, did the question
9 about lab ISO accreditation come from you yesterday?

10 MR. FINNEGAN: Would you repeat that?

11 DR. JAMES: There was a question somebody
12 over in your corner of the table asked about
13 laboratory ISO accreditation?

14 MR. FINNEGAN: It might have been
15 Mr. Henry.

16 DR. JAMES: All right. I will address that
17 to him at another time then. Thank you.

18 MR. TYNAN: Okay. If there are no other
19 questions on -- do you have one, Joe?

20 DR. HARRIS: Sure.

21 MR. TYNAN: I'm not encouraging him. I
22 don't want --

1 DR. HARRIS: I don't want, you know, I
2 don't want to be too far out in front here or
3 whatever, but I was going to ask first what the
4 timeline is and then maybe make a request relative
5 to the timeline for our deliberations this morning.

6 MR. TYNAN: Well, the deliberations for
7 this morning were intended to go during the morning,
8 and I will just talk about the timeline, so you're
9 ahead of us again. And the expectation was that we
10 would do a report out at 12:45, but that was based
11 on the assumption that you guys were going to have
12 about an hour and a half yesterday to sort of get
13 organized and start thinking about the questions in
14 an orderly fashion. You did not have that
15 yesterday.

16 So we'd like to continue to look at 12:45,
17 1:00, as the time to come back for the Subcommittee
18 reports, but I recognize you're an hour shorter than
19 you should have been. So having said that, if you
20 need some additional time, we'll push it back and
21 start the reports later. So if your request is can
22 we do the reports later, I'll certainly welcome

1 that.

2 DR. HARRIS: It was the opposite. I'd like
3 to try to get the Subcommittee work wrapped up a
4 little sooner and have more time with the full
5 Committee and the two reports because I'm concerned
6 that there is a significant amount of overlap
7 between the two Subcommittees, and I think it may be
8 useful to have some additional time as a group with
9 both Subcommittee reports. That's my only concern.
10 I'm not concerned that we won't be able to get our
11 job done in the Subcommittees. I just want to make
12 sure that we're not too pressed for time on trying
13 to bring the two back together because of what I
14 think is going to wind up being quite a bit of
15 overlap in these two reports.

16 MR. TYNAN: Okay. Well, what would you --
17 is then 12:45 still a good time to come back
18 together and start our dialogue in the plenary
19 session? Okay. Can I ask the Chairs to sort of
20 target for 12:45? Does that work for you, Michael?

21 MR. KOWALCYK: Yeah, I think we can work
22 towards that and hopefully maybe a little earlier

1 because I do agree with Dr. Harris that having these
2 ideas that come out of the Subcommittees vetted in
3 front of the full Committee, I think will make our
4 work stronger coming out of this meeting. So I
5 certainly agree with that approach.

6 MR. TYNAN: Okay. Would a better
7 alternative then, get back together at 11:30 and
8 just sort of see where we are. We can break for
9 lunch and then do the plenary after? Does that work
10 for everyone? So we'll target for 11:30 to sort of
11 be finished with the Subcommittee deliberations and
12 we'll meet them, take an hour for lunch and then
13 come back and start the plenary discussion of the
14 two Subcommittee reports. Does that work?

15 (No response.)

16 MR. TYNAN: I see no dissenting voices. So
17 Subcommittee Number 1 will be here in this room.
18 Subcommittee 2 will be in Room 1160, and we'll start
19 right now. Okay. Let me get someone to help you to
20 1160 for Group 2, and is that your group, Joe? I
21 can't recall.

22 DR. HARRIS: Yes.

1 MR. TYNAN: Okay. And in the meantime,
2 I'll get the report that you were talking about,
3 Tony, and see if I can't get copies down to the room
4 as quickly as possible.

5 (Off the record for Subcommittee meetings.)

6 (Whereupon, at 12:15 p.m., a lunch break
7 was taken.)

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1 yesterday, we'll be flexible and if something else
2 comes that's a better idea, we'll go with that
3 instead.

4 So I'm going to introduce Mr. Michael
5 Kowalcyk. He was the Chairperson of Subcommittee 1,
6 and if you wanted to sit right there, Michael, and
7 take us through the report.

8 MR. KOWALCYK: Okay. Thank you, Robert.
9 First, I'd like to thank Ellen from FSIS for helping
10 us keeping our notes on track, Dr. James and
11 Ms. White, for their assistance in answering
12 questions we had as well as folks in the public, our
13 friends from New Zealand and Australia who provided
14 good input as well.

15 Our Committee was charged with answering
16 the following question: What recommendations does
17 the Committee have regarding FSIS triad of
18 protections, these being equivalence, audits and
19 reinspection of protection for imported meat,
20 poultry and egg products?

21 The first part was should each element of
22 the triad be retained or some element dropped?

1 The Subcommittee felt based on the
2 background information we had and our experiences,
3 that all elements should be retained, although some
4 modifications should be considered based on risk and
5 historical country compliance.

6 This is very general guidance, and as we go
7 through our report in more detail, there are certain
8 elements of the triads that we would recommend
9 focusing additional resources to or attention to.

10 With respect to, should elements be added?
11 If added, identify the elements.

12 We felt that there should be additional
13 collaboration with CODEX concerning new work in the
14 CCFICS on guidance concerning on-site audits. We
15 also requested that this Committee receive the draft
16 guidance on on-site audits resulting from the
17 workshop in July that was held in Brussels, as well
18 as the document, the Law on Food Safety and Our
19 Reference Point, again to provide this Committee
20 with additional information so that we can further
21 provide input to the Agency as needed. We felt this
22 would be informative.

1 Another element that should be added to the
2 triad or recommended is looking at EIAO
3 methodologies used in domestic programs. An example
4 of a defined methodology to assess the food safety
5 system. This approach may be a good approach to
6 further define and implement in imported product.

7 Then we looked at each element of the triad
8 and identified areas related to each element that we
9 felt could use further refinement.

10 Before I get into each specific triad,
11 would anybody else from the Subcommittee like to add
12 anything to our comments to now?

13 (No response.)

14 MR. KOWALCYK: Okay. Equivalency. Initial
15 equivalency should include a formal risk assessment
16 of the products or product category and the process
17 in order to help determine initial equivalence of
18 the country's food safety system. Again getting to
19 the spirit of outcome based rather than process
20 based, we felt that this would be a good place to
21 start. Risk assessments should be added for
22 product and country as part of the equivalence.

1 Also the requirement of information being
2 collected in a consistent manner and this
3 information should be in such a structure where it
4 can be cross-referenced. Again this is part of a
5 process where the Agency is collecting data
6 regarding exporting countries as well as potential
7 facilities, and as the Agency moves to a more data-
8 driven management system, we felt that this was an
9 important component, making sure that the current
10 system is constructed in such a way or adapted so
11 that the capture of that data is manageable.

12 An additional component with respect to
13 equivalence is training foreign country in the USDA
14 systems needs to be strengthened to ensure
15 equivalency. Again, this is speaking to the
16 collaboration with our trading partners, working
17 with them, so that they understand the USDA's
18 processes and systems so that they can either model
19 theirs like the U.S. system or, you know, provide
20 information to the USDA, if there's ways that it can
21 be done better.

22 With respect to audit, we discussed that

1 there have been times when countries have been
2 suspended. Our recommendation was the Agency needs
3 to be more proactive in their audit process with
4 respect to risk.

5 Okay. Currently audits are done on a
6 periodic basis and that's interpreted as annual.
7 The Subcommittee felt that more attention should be
8 paid to risk, either of the product or of the
9 country in guiding their audit processes and the
10 timing of the audits as well as the focus of the
11 audits.

12 Length of time between audits can be based
13 more on risk and compliance history in a foreign
14 country, again related to point 1.

15 USDA audits need to report on elements
16 passed as well as elements failed to ensure that the
17 audit is adequately assessing the program. An
18 important observation was made that the audits in
19 their current form, in the example we had earlier of
20 an audit checklist, is only the deficiencies were
21 noted in the audit. Our recommendation was to
22 include all information in the audit. So if the

1 auditor looked at 100 elements, the facility passed
2 on 95 of those elements, and only failed on 5,
3 instead of just identifying the failures, should
4 also identify where the facility is passing, and
5 this would help guide potential audits in the
6 future, maybe to be more focused on parts of the
7 process that are more vulnerable to risk, as well as
8 guiding other parts of the triad with respect to
9 equivalence or reinspection.

10 The final point with respect to
11 reinspection, we felt that reinspection should be
12 directed to high risk product and high risk imports.

13 We also recommended that FSIS needs to
14 develop a protocol for enforcing compliance and to
15 ensure that the Agency has the proper enforcement
16 authority to follow through on findings, either in
17 audits or in this case reinspection.

18 And again recommended open communication
19 with all involved in the import process, not only
20 the importing and exporting countries, but as well
21 as the other agencies that are conducting activities
22 at ports-of-entry. An example would be customs.

1 And those are our responses to question 1.
2 I'd invite anybody from the Subcommittee to add to
3 it, and then I'll open up the floor to the full
4 Committee for comments.

5 (No response.)

6 MR. KOWALCYK: Okay. On question 1 we can
7 take questions and then we'll go into question 2.

8 MR. TYNAN: Dr. Harris, we'll start with
9 you.

10 DR. HARRIS: Okay. Thanks. Several times
11 or two or three times in there you used the term
12 risk assessment. Could you explain in a little more
13 detail what you envision as a risk assessment? You
14 know, we've seen several risk assessments conducted
15 by both FSIS and FDA over the years, and these are
16 big major undertakings that take long periods of
17 time and generate really big reports. Is that what
18 the Subcommittee was envisioning or something less
19 than that?

20 MR. KOWALCYK: Well, I would like to invite
21 others from the Subcommittee because we did have
22 quite a bit of a discussion on that, but I think it

1 really went to, you know, risk from two sides. One,
2 the risk of the product. I think there's been
3 studies done in the past over certain products are
4 more risky than others and, you know, that
5 definitely should be considered. However,
6 countries, you know, risk related to a country, an
7 exporting country, should also be considered. It's
8 just a fact that certain countries are much more
9 advanced in their agricultural systems with respect
10 to meat and poultry processing or slaughter. Those
11 I would imagine would be treated a bit differently
12 than countries that so to speak are in their infancy
13 and participating in these markets.

14 I'd invite others in the Subcommittee to
15 add to that, but that I think is the general intent
16 of that recommendation.

17 MR. COVINGTON: This is Brian Covington. I
18 would agree with Michael. We did not get into the
19 depth or width of the risk assessment. We just felt
20 that a risk assessment would aid in determining the
21 risk of a product category in relation to potential
22 hazards or potential things of concern as it relates

1 to the equivalence with the food safety system.

2 DR. HARRIS: The other question I had dealt
3 with developing a protocol for enforcing compliance,
4 ensure that we have the proper enforcement
5 authority. Did you envision something beyond de-
6 listing the country or the facility? What other
7 enforcement capacity did the Subcommittee envision?

8 MR. KOWALCYK: Well, I think -- in the
9 Subcommittee, I think other than those two items, I
10 think if there were other actions that the Agency
11 could take, that would be appropriate, we felt
12 should be explored, and as far as clarity and what
13 the actions are, going to happen, it doesn't seem to
14 me that there's a clear roadmap as for, you know,
15 importers consistently failing on reinspection or an
16 audit finds egregious problems within a food safety
17 system. What are the logical next steps? And, what
18 authority does the Agency have? So they're broad
19 recommendations, we understand that, but I don't
20 think we had the time to really delve into the
21 specifics of actual cases.

22 MR. TYNAN: Does that help, Dr. Harris?

1 Mr. Corbo.

2 MR. CORBO: Just as an extension of what Joe
3 just asked, does that also include the continued
4 equivalency determination of the country in terms of
5 any steps that could be taken? What would trigger
6 removing a country from the list of approved
7 countries to export to the United States?

8 MR. KOWALCYK: Tony, we didn't get into
9 specifics as far as, you know, if Company X from
10 Country A had this problem, what we would recommend
11 the Agency to do. We didn't get into the specifics.
12 I think, you know, this is under reinspection but
13 others on the Subcommittee can correct me if I'm
14 wrong, but I think we all felt if any of those
15 processes, either the ongoing equivalence evaluation
16 or the ongoing country audits, if any of those found
17 something that would raise a flag with respect to
18 the system in a given country or certain producers
19 within that country, there needs to be a clear set
20 of action steps that would be taken. So although
21 it's in the reinspection part of our answer, you
22 know, that's an area that we could probably put in a

1 broad, general sense that the Agency needs to
2 develop a protocol and communicate that protocol as
3 far as what would occur, you know, given audits are
4 continually failing at a certain level. I mean
5 right now we don't -- I don't know. There's
6 probably enough information to develop a baseline
7 for, you know, a given country, how many audits were
8 done and out of those audits, you know, where are
9 they failing? How many failures are there? What
10 defines a failure so to speak? You've got 200
11 items. If you miss on 10 out of 200, is that really
12 a failure or is that just cause for communication
13 with government to government as well as to that
14 establishment to address those issues. So we didn't
15 get into those specifics but it should be general
16 across all the elements of the triad.

17 Any other comments?

18 MR. TYNAN: There being none, Michael, why
19 don't you go ahead and do number 2 please.

20 MR. KOWALCYK: Okay. For each of the three
21 elements of the triad of protection for imported
22 meat, poultry and egg products, sub-elements have

1 been identified. What recommendations does the
2 Committee have regarding the sub-elements?

3 Part A, should each sub-element be retained
4 or some sub-elements dropped. If dropped, identify
5 the elements.

6 Again, our recommendation is that each sub-
7 element should be retained. However, the
8 Subcommittee recommends additional review of each
9 sub-element within the triad. So again like our
10 answer to question 1, we felt that given the
11 information we had at hand, we were not comfortable
12 with making a recommendation to drop anything
13 outright, although we do have some recommendations
14 with respect to specific areas the Agency can delve
15 deeper into determining what's a more effective way
16 to manage this process.

17 Okay. The first part we talked about was
18 equivalency. Initial as well as continuing
19 equivalency, we felt that these both should be
20 retained.

21 Initial equivalence is critical in
22 determining a baseline for the trading country. So

1 again, we feel this is a critical step for getting
2 things started with an importing country again, you
3 know, first impressions mean a lot. So we felt that
4 this was certainly an essential step to the process.

5 Ongoing equivalence would be reevaluated
6 based on changes within the importing country's
7 processes or historical compliance or FSIS audits
8 and inspection outcomes. So again I think this
9 addresses some of the concerns I've heard from the
10 Committee about, one, a country will change an
11 intervention or something else in their process.
12 Within their industry, they will typically
13 communicate to the USDA. That would be a prompt for
14 continuing reevaluation of that country's
15 equivalence. As far as history of compliance, if a
16 country had compliance failures that were deemed
17 unacceptable, we did not get into specific
18 thresholds, but that would also be cause for
19 reevaluation. So the mechanism of ongoing
20 reevaluation would be important as well as audits
21 and reinspection outcomes again tying the whole
22 system together. If things are found consistently

1 from a given country or establishments within a
2 country, that would be cause for reevaluating that
3 country's equivalence.

4 Also regular documentation should include
5 how equivalence is monitored and enforced. The
6 Agency should review the process and develop
7 guidelines concerning ongoing monitoring procedures
8 used to ensure conformity with the initial
9 equivalence document, and when the judgment of an
10 equivalency measure may be suspended. So again this
11 is managing that -- ongoing equivalency should be
12 more of a continuous process, looking at outcomes.
13 Basically the outcome here is product delivered from
14 the country. So what are things in that country
15 that are changing? Are they conforming to the
16 original requirements with respect to their initial
17 equivalency review?

18 Again, we reiterate ongoing equivalence
19 measures should address historical compliance.
20 Again that's addressed earlier. So this could
21 probably be removed as redundant, but again we feel
22 that that's an important component of this. It's

1 been pointed out, you know, certain countries have a
2 long history of exporting product to the United
3 States, versus countries that don't have a very long
4 history or have a history where the compliance has
5 been sketchy.

6 Finally, a procedure for translating
7 equivalency documents needs to be looked at in order
8 to improve the process. There were discussions
9 about non-English speaking countries and
10 documentation in English and that can create
11 inefficiencies in the process as far as just the
12 time and resource to get those translated as well as
13 the potential for miscommunication, just how things
14 are taken out of context. So that should also be
15 revisited.

16 With respect to the audit process,
17 historical evaluation of trading country audit
18 outcomes is important. Again, we feel that
19 historical compliance is a key component of this.

20 The audit process needs to be strengthened.
21 While periodic audits should continue, ongoing
22 audits should be based on risk for all equivalency

1 programs. Timing should be based on risk, and
2 elements of the audit process should be based on
3 risk.

4 I think what we mean to say here is
5 currently the Agency periodically audits countries,
6 and that's interpreted as an annual audit. We felt
7 that that's important in at least establishing a
8 baseline but again additional audits should be based
9 on risk. So compliance history, reinspection
10 findings, problems with equivalency should be
11 indications for maybe stepping up the audit process
12 in certain countries. Someone on the Subcommittee
13 felt that you can't audit safety in, and I would
14 agree. You know, audit by itself isn't going to
15 make products safer. However, it is a mechanism to
16 find out what is going on and, you know, any
17 recommendations with respect to frequency, I think
18 we want to shy away from that at this point because
19 of the information we currently have as a
20 Subcommittee.

21 Reinspection, the key question here is, are
22 we adequately using Agency resources to do routine

1 reinspection?

2 Many products are going to further
3 processing with HACCP plans. Reinspection should
4 focus on for cause and directed. We should look at
5 the system to reduce redundancy and focus on food
6 safety rather than non-food safety elements such as
7 counting boxes.

8 We had a pretty good discussion about the
9 reinspection process and where's our opportunity to
10 better allocate limited resources. I think in the
11 presentation from yesterday, there were 70 FSIS
12 employees dedicated to 140 points-of-entry. You
13 know, the mathematics there indicates that you have
14 resources stretched really thin. So it's important
15 to allocate those resources in a manner that's going
16 to best protect public health.

17 Our recommendation is thoroughly evaluate
18 the current reinspection process and correlate
19 activities among all involved agencies. That would
20 include APHIS, Customs, FSIS as well as other Agency
21 such as Homeland Security, to see where there are
22 redundant steps in the process that can be better

1 streamlined, so that Agency personnel can spend more
2 time on either countries that are failing audits and
3 -- or have other compliance issues where you can
4 direct your resources more efficiently.

5 Secondly, and this would be part of the
6 evaluation process, is to identify elements of the
7 routine reinspection that need to be retained by
8 FSIS. There may be some elements that FSIS still
9 needs to be involved with. It might not be seen as
10 directly food safety related but those activities
11 and findings with respect to certain elements of
12 that reinspection activity might be highly
13 correlated with food safety issues. Again, this
14 would be based on the evaluation of the current
15 process.

16 Random reinspection needs to continue at
17 the point-of-entry in order to understand ongoing
18 risk and emerging trends. While we would like to
19 direct resources on a risk basis, we feel that
20 random reinspection is an important component to
21 understand. What is the baseline? What is actually
22 happening? Are there emerging trends that are out

1 there?

2 Another recommendation is expanding the
3 electronic certification system would help give the
4 Agency a lead time to determine whether reinspection
5 is necessary or not, and we'll be able to share
6 data. Again, this is expanding your capacities in
7 sharing information, we felt is critical.

8 Data collection and management
9 processes/capacities need to be evaluated. There
10 should be an agreement among participating agencies
11 as to who would own and manage the information.
12 Again, multiple agencies are working at ports-of-
13 entry to scrutinize product coming into the United
14 States. We felt that coordination among the
15 agencies would be important so that things don't
16 fall through the cracks.

17 Again, resources need to be allocated to
18 properly use and analyze the data. This may mean
19 different types of resources that the Agency
20 typically does not employ. So this is also an
21 important consideration.

22 Again, the final point there really, we

1 could probably reword that a little bit, is risk-
2 based sampling procedures would also need to be in
3 place.

4 Section B, should other sub-elements be
5 added? We felt that at this point there was nothing
6 we would recommend adding other than these
7 additional modification or further investigation in
8 the current process.

9 Again, I'd invite others from the
10 Subcommittee to add their comments from what we come
11 up with, and then I'll open it up to the full
12 Committee.

13 (No response.)

14 MR. TYNAN: There's no comments from the
15 Subcommittee. Are there comments from the other
16 members of the Committee?

17 (No response.)

18 MR. TYNAN: There being none, I'm going to
19 pass -- oh, I'm sorry. Dr. Dickson.

20 DR. DICKSON: Just a quick question. You
21 have in there on audits, periodic audits. Are you
22 referring to what USDA is currently doing or are you

1 suggesting something different than what USDA is
2 currently doing?

3 MR. KOWALCYK: With respect to periodic,
4 and we did have some clarification from the Agency,
5 that their interpretation is that it's annual.
6 We're not recommending any changes to that, but what
7 we are recommending is that based on analysis of
8 risk, can the audit process be improved by, you
9 know, maybe not a full audit but maybe a focused
10 audit on certain aspects of a process could be
11 investigated. We didn't feel that adjusting that
12 time window at this point, we didn't feel
13 comfortable with the information we have to make any
14 recommendations on either lengthening it a two or
15 three window or shortening it. We stayed away from
16 that. So we're going with an annual period audit as
17 our definition.

18 DR. DICKSON: Okay. Thank you.

19 MR. TYNAN: Ms. Conti, you had a comment
20 you wanted to make?

21 MS. CONTI: I guess I was surprised to see
22 that wording periodic, and I discussed it with Mark,

1 and I actually didn't think periodic meant annual
2 the way we worded it because we were talking about
3 the length of time can vary according to compliance
4 history. So I guess I'm surprised to hear that
5 interpretation.

6 MR. KOWALCYK: Okay. Yeah, I mean the
7 current, currently, at least the Agency indicated to
8 us during our meeting that their interpretation is
9 annual. I guess the language in there, we can clean
10 it up a little bit is the periodic audit, leaving it
11 open to adjustments to that based on risk. So we
12 might need to clean that up a little bit but we
13 didn't want to come out, or at least I'm not
14 comfortable with coming out with a recommendation
15 that it should be, you know, six months, it should
16 be three years. I don't think we have enough data
17 to support that.

18 MR. TYNAN: Ms. Conti, though your
19 recollection of how that was, was sort of based on
20 compliance history of the country involved, so as
21 opposed to a fixed timeframe.

22 Mr. Painter, you had a comment or a

1 question? Oh, I'm sorry.

2 MR. SCHAD: Yeah, I was just going to try
3 to clarify that part of the report there.

4 MR. TYNAN: Mr. Schad, please do.

5 MR. SCHAD: At first we were talking about
6 have audits based on risk, and then the concern was,
7 well, maybe there were some countries that were
8 considered low risk or had low risk products, and
9 then there was concern, well, maybe those would
10 never be audited and we did not want it to get to
11 that point. So we left the word periodic in there,
12 and that was my recollection, not to interpret
13 periodic as annual, as it is now. We just didn't
14 want to, like I said, we didn't want to get to the
15 point where a country was never audited. So the
16 rest of the Subcommittee maybe can tell me if I'm
17 incorrect in that interpretation.

18 MR. TYNAN: That's okay. It sounds like
19 that's fairly consistent with the conversation.

20 Mr. Painter.

21 MR. PAINTER: I have a question. Stan
22 Painter with the NJC. I have a question regarding

1 your use of the work risk and risk based. I noticed
2 in your report you've used the word risk four times
3 and risk based three times. Are you referring to
4 the level of risk in transit, once the product
5 leaves the country, the likelihood of it being
6 adulterated or contaminated?

7 MR. KOWALCYK: I think our use of risk is
8 in the broadest sense. I mean obviously food safety
9 is the top priority. So obviously that risk is a
10 key component of it. Risk in transit, that's also
11 an important consideration. We did not distinguish
12 between the two. We're just all encompassing risk
13 and I guess that would beg the need for additional
14 work by the Agency to evaluate those risks and, you
15 know, what's more likely to occur? Is there
16 problems during transit as far as improper
17 temperatures, you know, in the storage containers,
18 you know, in conjunction with typical food safety
19 risks or if your temperatures are incorrect, you
20 know, bacteria will grow out at an unacceptable
21 rate. So, you know, our use of risk was in the most
22 general sense.

1 MR. PAINTER: Is the Committee using risk
2 based in the sense, the Agency used risk based
3 recently in regards to risk-based inspection?

4 MR. KOWALCYK: Again, I don't think we
5 specifically looked at it as part of that
6 initiative, although there would be ramifications
7 long term, but again we did not address that.

8 MR. PAINTER: What ramifications long term?

9 MR. KOWALCYK: Well, if the inspection
10 system is modified, going forward, based on -- using
11 a risk-based model, that would have implications for
12 what is going on and how we handle imports. I would
13 think those two would have to be handled in a
14 consistent manner. So that's where I think the
15 ramifications would occur. Again, that's just my
16 opinion, but the Subcommittee, we did not address
17 the risk-based initiatives that the Agency is
18 undertaking domestically.

19 MR. TYNAN: Mr. Busch?

20 MR. BUSCH: Yeah, under the equivalency,
21 you have information collected in a consistent
22 manner and able to be cross-referenced. To my

1 knowledge I think each country is given the same
2 five audit questionnaires and each auditor is also
3 going by the same checklist and given the same
4 information. So I was wondering if the Subcommittee
5 felt that the information wasn't being collected
6 consistently the way they're doing them now?

7 MR. KOWALCYK: Again, I think as far as
8 consistency is, you know, obviously if the Agency's
9 using the same format, same forms are being
10 required, also how that data is used and stored
11 historically, would also need to be consistent over
12 time. Again, that's related to any changes. So
13 maybe we can clarify that more. I think maybe as a
14 Committee we were unaware of some of the
15 standardized documents when we deliberated this.

16 MR. TYNAN: Follow up? Okay. Any other
17 questions on Subcommittee 1's report? Comments?

18 (No response.)

19 MR. TYNAN: Okay. Then I'm going to turn
20 it over to Dr. Harris to report out on Subcommittee
21 Number 2.

22 DR. HARRIS: Thanks, Robert. Much as

1 Michael said, we really appreciated the
2 participation of everyone that we had. We had
3 several Agency personnel in there with us helping
4 answer questions for us about procedures and process
5 and guiding us along the way. Josh, in particular,
6 was responsible for trying to get some of this on
7 paper. We appreciated having I guess all three of
8 the bargaining units in the room with us, and we
9 appreciated their input as well, and most definitely
10 I've got to thank the Subcommittee members for
11 staying on task and keeping us going, finishing on
12 time. We got our work done.

13 We did not go quite to the level of detail
14 as Subcommittee 1, but as I listened to the
15 recommendations from the first Subcommittee, I think
16 that a lot of what you'll hear in the second report
17 is pretty closely related. We may use some
18 different terminology but I think when you really
19 compare, the two are pretty much in line in terms of
20 recommendations.

21 So to start off, the Subcommittee generally
22 supports the Agency's current triad of import

1 oversight activities. The Subcommittee further
2 strongly recommends or strongly encourages
3 additional and continuous improvements to the FSIS
4 implementation of its domestic and import programs
5 and recommends that the Agency work very diligently
6 with exporting countries to encourage their
7 continuous improvement relative to compliance, data
8 sharing and transparency. It's just kind of a
9 general recommendation there.

10 The specific questions, in terms of
11 recommendations regarding the objective evaluation
12 of outcomes and specifically, what objective
13 outcomes are most appropriate to evaluate?

14 We thought we should say right up front
15 that the most basic objective outcome that the
16 system is striving for is the import of safe, clean,
17 wholesome, unadulterated and properly labeled
18 products.

19 Now, in terms of getting to that outcome,
20 we felt like that there were some objective outcomes
21 that should be considered. Particularly, when
22 looking at an exporting country, consideration of

1 whether they have in place effective hazard control
2 measures that address the three main hazard
3 categories, physical, chemical and biological; that
4 they have programs in place that ensure sanitary
5 facilities and operations of those facilities; that
6 the country has in place testing and verification
7 programs; effective government oversight along with
8 enforcement provisions; that programs -- this next
9 to last bullet here, I don't remember seeing that
10 one, for programs established to prevent adulterated
11 products, okay. We'll leave that there for now.
12 That one, I don't remember seeing that one, but
13 maybe I just proofread it ineffectively here.
14 (Laughter.)

15 And finally, a demonstrated commitment to a
16 science-based approach that takes into account risk
17 in its application.

18 Then what means are most appropriate for
19 evaluating these objective outcomes? One in
20 addition to the triad of things that are already
21 being done, the Subcommittee saw as a potential
22 would be self-assessments. So that the exporting

1 country would have an opportunity to conduct at some
2 frequently a self-assessment of its programs against
3 the standards established by FSIS.

4 Specifically the question presented to us
5 asked about the idea of third-party audits, and the
6 Subcommittee definitely sees a potential
7 supplementary role for third-party audits as an
8 enhancement to the current system, not as a
9 substitute. Also pointed out that third-party audit
10 is not necessarily private but could be a government
11 audit as well depending on the specific situation.

12 That's question 1. Do you want to stop
13 there for comments or questions?

14 MR. TYNAN: Please, let's do that. Did
15 your Subcommittee have other comments on -- to
16 elaborate?

17 (No response.)

18 MR. TYNAN: Any questions from the
19 Committee as a whole on question number 1?

20 (No response.)

21 MR. TYNAN: Masterful, Joe.

22 DR. HARRIS: Not the term that I would have

1 used there, but, you know, I kind of surprised
2 myself. (Laughter.)

3 The second question deals with variation
4 between countries with regard to information-sharing
5 capabilities and compliance history in terms of
6 demonstrating equivalence, and the recommendations
7 around that.

8 Specifically, the first one, Part A, dealt
9 with the in-country audits and should they be
10 adjusted in terms of scope or frequency based on the
11 capability of a country to share useful information
12 and its compliance history. If yes, how should it
13 be adjusted.

14 The first answer was yes, the Subcommittee
15 felt that there should be some adjustment to the
16 scope or frequency of audits based on consideration
17 of those things. In particular, how transparent is
18 the exporting country's food safety system and
19 outcomes; the exporting country's ongoing ability
20 and willingness to share data about their system and
21 the quality of the data shared and, of course, the
22 compliance history of the country in question.

1 The Subcommittee further suggest that
2 possibly a three-tiered system would be appropriate
3 in terms of three levels of frequency and/or scope
4 and that the standardized application of the audit
5 criteria would be important for that type of program
6 to succeed. The idea behind that, maybe a little
7 further explanation is that by having a tiered
8 approach, an incentive for countries to try to move
9 up on that tiered approach in terms of how
10 frequently they were having to deal with audits.

11 Part B is the same question only dealing
12 with directed reinspection instead of audits.
13 Again, similar to Part A, the Subcommittee agreed
14 that there should be some adjustment made to the
15 frequency of those reinspection activities based on
16 the factors that were outlined in the Part A, as
17 well as one that we really didn't deal with in Part
18 A, that being the specific characteristic or process
19 category of the product involved would probably come
20 into consideration relative to frequency of
21 reinspection.

22 And that is our report.

1 MR. TYNAN: Comments from the Subcommittee
2 to supplement what Joe just said?

3 (No response.)

4 MR. TYNAN: How about questions or comments
5 from the full Committee? Mr. Schad.

6 MR. SCHAD: Yeah, this is Mark Schad. The
7 question came up this morning about should we
8 emphasize the, you know, answer the question about
9 process versus the outcome and as I'm just reading
10 your report, what did you guys come up with or
11 what's the answer to that authority?

12 DR. HARRIS: We did not -- we answered the
13 questions that were given. We didn't take on the
14 question of should the equivalency system be
15 processed based or product based.

16 MR. TYNAN: I'm sorry. I didn't quite pay
17 attention. Did you get your question answered?

18 MR. SCHAD: No, I guess not really.

19 MR. TYNAN: I heard that much. I could
20 tell --

21 MR. SCHAD: I was trying to get the
22 question to the --

1 MR. TYNAN: Outcome versus process.

2 MR. SCHAD: -- whether it was process based
3 or product based --

4 MR. TYNAN: Right.

5 MR. SCHAD: -- and he said they did not get
6 into that. So they did not answer that question.

7 DR. HARRIS: Let me add to that. This is
8 Joe Harris again. The questions themselves I think
9 were leading us towards a product or -- when I say
10 product based and outcome based, I guess I'm
11 interchanging those terms. But that was the
12 direction the questions led us rather than a
13 process-based approach.

14 MR. TYNAN: Okay. Mr. Covington.

15 MR. COVINGTON: Thank you, Dr. Harris. The
16 Subcommittee talked about one of the factors in
17 consideration should be the transparency of the
18 exporting country's system and then the outcomes.
19 Did you guys in the Subcommittee have any
20 discussions around that and what that may contain or
21 look like? Maybe some examples of some things that
22 are going on today?

1 DR. HARRIS: We did, and I'll invite any of
2 the other Subcommittee members to weigh in on that.
3 As part of that discussion, we were getting a lot of
4 input on how things are going on out there in terms
5 of international trade, and some countries we
6 learned today are very far advanced in the level of,
7 you know, if USDA or any interested party wanted to
8 take a look at how their program works, how
9 establishments are performing within that program,
10 all of those things are available at some level or
11 another, and apparently in some countries, very far
12 advanced.

13 Anybody want to add to that, feel free.

14 MR. CORBO: Yeah, I think we were fortunate
15 to have Dr. Jolly participate in our Subcommittee
16 and it seems that some countries, including his own,
17 has -- it's getting to the point where they can
18 quantify and easily transmit data, you know, at a
19 moment's notice if FSIS wanted to take a look at it.
20 And so I think that was where we were going as a
21 Subcommittee is that if a country, you know, has the
22 capability of transmitting information very quickly

1 and, you know, if you even wanted to take a look at
2 their version of noncompliance reports, that would
3 be very helpful in terms of moving the process
4 along.

5 MR. TYNAN: Mr. Kowalcyk.

6 MR. KOWALCYK: Thank you. Dr. Harris, when
7 your Subcommittee talked about a three-tiered
8 system, what country specific attributes did you
9 discuss, if any, regarding to how the tiers would be
10 determined? Can you elaborate on that a little
11 more?

12 DR. HARRIS: Yeah, and it was the factors
13 there that we were just talking about in terms of
14 how, how willing and able is that country to share
15 data, the frequency of the sharing of that data.
16 The point was made this morning about, I'll get the
17 terminology wrong, but like a 365-day audit kind of
18 thing. So that there's ongoing communication
19 between the exporting country and the U.S. That
20 country's compliance history relative to both the
21 on-site and offsite audits and reinspection, all of
22 the information that's being generated from the

1 existing triad would come into play there in terms
2 of determining the scope and frequency of those.
3 And so basically you would have three tiers that
4 would be really, really frequent, not quite as
5 frequent and less frequent. I mean, we didn't
6 define what the three tiers specifically would be.

7 Much like, the Agency has a recent history
8 of doing a lot of three-tiered things relative to
9 its testing programs and things like that, where
10 you're either, you know, in the frequency that you
11 get sampled is based on your performance history, a
12 similar type approach.

13 MR. KOWALCYK: Okay. Was there any
14 discussion regarding volume of product being
15 exported?

16 DR. HARRIS: We did not touch on the
17 volume. We talked some about the specific
18 characteristics of the product, and whether or not
19 it was, you know, a higher risk product versus --
20 the examples we talked about, we talked some about
21 canned products versus fresh products versus fully
22 cooked dried products like a jerky or something like

1 that. We did not talk about volume actually.

2 MR. TYNAN: Other questions or comments
3 from the Committee at this point?

4 (No response.)

5 MR. TYNAN: Okay. There being none, I
6 think we passed over very quickly Michael's report
7 and Joe's report without really making any
8 modifications on the part of the Committee. I think
9 when I introduced the topic, I think the concern we
10 had this morning was there were places where there
11 might be overlap that we needed to consolidate.

12 So I think our first question is, do the
13 two reports, are they sufficiently dissimilar so
14 that we can leave them as is and maybe go back and
15 do a little modification on each, or do we have to
16 do some combining. I'm not advocating combining but
17 I'm just suggesting it because I know you had the
18 concern this morning about the overlap.

19 MR. COVINGTON: Robert, this is Brian
20 Covington. Based on the questions, particularly the
21 questions asked to Subcommittee 2, I would suggest
22 that they stay separate.

1 MR. TYNAN: Does everybody agree with the
2 idea of separate reports?

3 (No response.)

4 MR. TYNAN: Okay. Then if we can, if we
5 could go back and maybe look at Mr. Kowalczyk's
6 report again, Subcommittee Number 1, there were a
7 couple of places that I heard and there maybe others
8 that you captured, but I know there was some issue
9 regarding the periodic. So I think we need to
10 perhaps do a little bit of better definition on
11 that. I think there was some discussion of risk and
12 what risk essentially meant. So perhaps we need to
13 elaborate a little bit on that. So if Ellen can get
14 that other report for us. Ah, there we go. Okay.

15 How should we deal with periodic? I think
16 Ms. Conti, you had some --

17 MS. CONTI: Yeah, I thought in our
18 Committee we agreed that periodic should not mean
19 annual. I hope I'm correct in saying that for the
20 Committee members. That the frame could --
21 timeframe could vary depending on compliance history
22 and risk.

1 MR. TYNAN: Based on risk.

2 MS. CONTI: And compliance history.

3 MR. TYNAN: Okay. Could you suggest some
4 language to put up there so the Committee can --

5 MS. CONTI: Oh, goodness. Is there another
6 word we could substitute for periodic?

7 MR. TYNAN: Mr. Elfering, you usually have
8 alternate language that you like to suggest. Can we
9 simply say periodic, not annual?

10 MS. CONTI: Uh-huh.

11 MR. ELFERING: Again I think what --

12 MR. TYNAN: Mr. Elfering.

13 MR. ELFERING: Yes, thank you. I think one
14 of the issues that we had is first of all, it just
15 says that there's going to be an audit, and the
16 Agency subject-matter experts that were with us said
17 that that has been interpreted to be an annual
18 audit.

19 And I guess what we're trying to get at is
20 that probably is a place to start, but based on,
21 based on compliance history, based on many other
22 factors, maybe it should be volume. There's other

1 things that can be put into a system where you could
2 say, okay, they've not had any compliance problems,
3 let's back off this inspection from an annual audit
4 to every two years. And then if that compliance
5 history changes, you may want to go back to one
6 year, but I think we're kind of hung up with the
7 annual that is kind of almost set in FSIS' mind
8 right now. That should probably be changed to based
9 on the products that are produced and the compliance
10 history and it doesn't have to necessarily be always
11 that it's going to be monitored. Sometimes there
12 would be more. You know, if you have a really
13 concerned situation with a particular country, you
14 would maybe be going back more often than annually.

15 So I don't know how we would say that other
16 than -- I don't know what word you would put in
17 there to change it.

18 MR. TYNAN: If I understand it, I think
19 this is Ms. Conti's concern that we're saying it
20 should -- it isn't necessarily cast in stone that
21 it's annual.

22 MS. CONTI: Right.

1 MR. TYNAN: That there's some other
2 frequency that is built in, right?

3 MR. ELFERING: Exactly. You know, maybe we
4 just want to just strike periodic, just put audits
5 should continue and not use a time period and you
6 know, something that really can't be defined very
7 well.

8 MS. CONTI: Right. I agree.

9 MR. TYNAN: Okay. Ms. Conti, are you okay
10 with that?

11 MS. CONTI: Yes.

12 MR. TYNAN: Okay. Periodic is out.
13 Mr. Stromberg, did you have an alternate way of
14 approaching that?

15 DR. STROMBERG: Not really.

16 MR. TYNAN: Okay. Okay. Mr. Kowalcyk.
17 Oh, I'm sorry.

18 MR. COVINGTON: I'm not sure --

19 MR. TYNAN: We're going to Mr. Covington.

20 MR. COVINGTON: Sorry. Brian Covington.
21 I'm not sure that in our discussions we -- our
22 discussions related to this point weren't actually

1 answered by Subcommittee Number 2 in their question
2 2(a), and maybe the question needs to be asked does
3 this need to be part of our report or Subcommittee
4 Number 2's report when we talk about the timeframe
5 around the in-country audit schedule.

6 MR. TYNAN: And do you have a position on
7 that? Where should it be? Yours or 1?

8 MR. COVINGTON: Well, I think our
9 discussions were merely if you determined
10 equivalency based on product category, compliance
11 history and all of the factors, that an annual audit
12 may not be a necessary item. It may be that every
13 two years may get you the same confidence level that
14 the equivalent food safety system of that country is
15 working but on the flip side, if you do see
16 compliance issues, maybe a more frequent visit than
17 on once a year or an annual basis was necessary and
18 that was my recollection of our conversations
19 relative to the periodic and annual conversation.

20 MR. TYNAN: You were suggesting before,
21 Brian, if I understood you correctly, that that
22 perhaps is something that more appropriately goes in

1 Joe's report?

2 MR. COVINGTON: And maybe I'm --

3 MR. TYNAN: Or Subcommittee 2.

4 MR. COVINGTON: -- reading it incorrectly,
5 but as I read question 2(a) for the Subcommittee
6 Number 2, it says should in-country audits be
7 adjusted by scope and frequency based on the
8 capability of a country to share useful information
9 and its compliance history.

10 And my recollection of our conversations,
11 we kind of delved into that question without looking
12 at their questions based on the conversations we had
13 which was relative to product category, risk,
14 compliance history, data sharing, et cetera.

15 MR. TYNAN: 1, 2, 1? We've addressed it a
16 little bit in Joe's, I think in Subcommittee Number
17 2. So if we take the periodic out of number 1, are
18 we good to go?

19 MR. KOWALCYK: Yeah, if we're not specific
20 on periodic, I think that gets us there and they
21 Subcommittee 2 gets more to the specifics of how
22 that frequency would be determined. That's part of

1 the question. So maybe just, you know, audits
2 would, you know, continue based, you know, based on
3 risk for all equivalency programs and leave the rest
4 there and, you know, let the answer to Subcommittee
5 2 get to more specifics because again, we were
6 unsure as to whether or not what could we determine
7 the frequency. I mean, you know, the current
8 understanding, in the Agency, the current practices,
9 it's annual. So do we have enough to change that?
10 So maybe if we just back that language out, that
11 would probably be okay.

12 MR. TYNAN: Mr. Schad, I think I cut you
13 off there. I apologize.

14 MR. SCHAD: Oh, not, that's fine. It's
15 logical that it would fit more in Subcommittee
16 Number 2. I think the bottom line is, as long as it
17 gets communicated to the agency well enough, that's
18 fine. So I think it would be more logical with
19 Number 2.

20 MR. TYNAN: The simple answer works in this
21 particular case. Thank you.

22 Mr. Painter, I think you were next and then

1 I'll come over to Mr. Corbo. You always like to
2 have the last word, Mr. Painter.

3 MR. PAINTER: No, no.

4 MR. TYNAN: No, no. Okay.

5 MR. PAINTER: Stan Painter, National Joint
6 Council. You may put your finger on that mute
7 button over there, Robert.

8 MR. TYNAN: No, I have the priority. I'm
9 ready.

10 MR. PAINTER: Oh, okay.

11 MR. TYNAN: I can cut you off at any time,
12 Stan.

13 MR. PAINTER: And you have before. So it
14 wouldn't be the first. I just want to say one thing
15 about the Committee's report, that bothers me. And
16 it's the use of the Agency's catch word or catch
17 phrase, risk based. You better be careful what you
18 ask for. You may get it, and I know a number of the
19 people on the Committees were opposed to the
20 Agency's risk-based inspection. And buying onto
21 those catch words and catch phrases, the next thing
22 you know it's going to turn around and then the

1 Agency's going to say the Committee has adopted
2 risk-based inspection, and then there you have it.

3 So then you're trying to deal with what you
4 thought and the Agency's saying that it was adopted.
5 So I would just like to caution the Committee on the
6 use of risk based and those catch phrases. Thank
7 you.

8 MR. TYNAN: Before I go to you, Tony, I
9 think that was one of the questions I think we were
10 trying to better define risk because I think I heard
11 in the initial discussion, there were some concerns
12 about what risk meant and what risk was. So did you
13 have some suggestions, Mr. Painter, on how we might
14 fix the report?

15 MR. PAINTER: Stan Painter again with the
16 National Joint Council. You know, the group that I
17 was in, this very thing came up and as the people in
18 the group can tell you, you know, I opposed the use
19 of the words risk and risk based. I think, you
20 know, what we were looking at is something that was
21 a likelihood to make people sick, whether it was
22 through adulterated or contaminated product, whether

1 it was microbial or whether it was through some kind
2 of chemical residue, that could make people sick,
3 and maybe I'm wrong with what I'm reading into what
4 the group's saying. I think that may be what
5 they're trying to say, and I'm not trying to put
6 words in their mouth, but I felt comfortable with
7 some language along those lines versus the catch
8 phrase.

9 MR. TYNAN: Okay. Mr. Corbo.

10 MR. CORBO: You know, I just wanted to get
11 back to the issue of periodic. The Agency, well,
12 from a historical standpoint, the Agency at one
13 point used to do quarterly visits abroad, and over
14 the years that's been scaled back and we have this
15 annual system now. But if the Agency does find some
16 systemic problems with a country's food safety
17 system, they do enforcement audits or at least
18 that's what's supposed to happen. Sometimes it
19 doesn't happen because of political considerations
20 but that's what's supposed to happen, and if you'll
21 look at the Agency's website where they list the
22 audits that have occurred, there's some countries

1 where you visit them three times a year in order to
2 deal with their issues. So the Agency does that
3 now. So the word periodic doesn't bother me that
4 much.

5 MR. TYNAN: I think we've beaten periodic
6 to death. But we do have the risk issue --

7 DR. RAYMOND: We could always raise it
8 again periodically. (Laughter.)

9 MR. TYNAN: Periodically. Thank you,
10 Dr. Raymond, for your input.

11 DR. RAYMOND: That's why I'm here.

12 MR. TYNAN: But we do have the risk issue.
13 Is there something -- I'm sorry. Mr. Elfering.

14 MR. ELFERING: Yes, Kevin Elfering. I
15 think -- I'm going to discuss the risk issue and
16 number 1, it's not a catch phrase. Risk-based
17 inspection is a very tried and true method of doing
18 efficient inspections, and it had been used a lot
19 longer than before FSIS ever came up with the
20 terminology. It had been used by agencies for
21 years, and I don't know a person out there that
22 would disagree that risk-based inspections are not a

1 good way of doing things because they are. You want
2 to make sure that you're focusing your efforts on
3 what is the riskiest product that is out there, the
4 riskiest processes. Law enforcement uses it all the
5 time. They have for years. They've dedicated their
6 resources to what is the riskiest things that
7 happen.

8 And to call it a catch phrase is not right
9 because it's very scientifically based. And again,
10 it's about time that FSIS get into the 21st Century
11 and start using some of these systems that are
12 focused on not redundancies that are doing
13 absolutely nothing and focusing on things that are
14 getting people sick.

15 MR. TYNAN: Okay. The question is on the
16 table. Do we have to do anymore --

17 MR. PAINTER: May I respond?

18 MR. TYNAN: I'm sorry. Mr. Painter, I'll
19 let you have your --

20 MR. PAINTER: Stan Painter, NJC. Yeah, I
21 just wanted to respond, and I respectfully disagree
22 because, you know, I've worked with this Agency now

1 almost 23 years, and what may seem to be a common
2 sense approach in some cases don't always end up
3 that way, and you take the HIMP program for
4 instance. It's supposed to be a more scientific
5 method of inspection, and a company person looking
6 into the product or looking at the product is more
7 science based according to the Agency. So it's all
8 according to the interpretation and the beauty being
9 in the eye of the beholder, and sometimes the
10 beholder don't interpret things the way that you
11 would like for them to. Thank you.

12 MR. TYNAN: Thank you, Mr. Painter.
13 Dr. Negron.

14 DR. NEGRON-BRAVO: I just want to say a
15 couple of things. I think that what she was trying
16 to tell about periodic was that the interpretation
17 of being annual, it was not straightforward. So
18 periodic could be there as long as it's not meant
19 annual because --

20 MR. TYNAN: Right.

21 DR. NEGRON-BRAVO: The other thing would be
22 about the risk. I thought when we discussed it, it

1 was one of the factors that would direct our
2 thinking but not that it was the only factor because
3 that's what we were talking, that if it was just
4 based only on risk, maybe a company or -- be audit
5 if it was just based on risk. So it will just be
6 one of the factors in determining where the efforts
7 are going more directly but not the only factor, if
8 the Committee, that's our discussion.

9 MR. TYNAN: Thank you, Edna. Mr. Kowalcyk.

10 MR. KOWALCYK: Yeah, I think to get back to
11 our Subcommittee's answer and the use of risk based,
12 in looking at the last bullet point in Question
13 2(a), the sampling procedures, I would propose we
14 rephrase that to statistically sound sampling
15 procedures and get away from risk based because that
16 speaks to being part of another, you know, it's
17 perceived as being part of another initiative. I
18 would change it to, employ -- get rid of port-of-
19 entry ensure, and just put employ statistically
20 sound sampling procedures at ports-of-entry.

21 MR. TYNAN: Is everybody in agreement on
22 that? The one other issue, I had a note here, had

1 to do with risk assessments, and I think there was a
2 question. I don't remember if we resolved that at
3 the beginning but I think the question was what
4 constituted the risk assessments that we were
5 talking about. Do we need to clarify that or is it
6 as good as it is?

7 MR. KOWALCYK: I would defer to others on
8 the Subcommittee who brought it up.

9 MR. TYNAN: Mr. Covington.

10 MR. COVINGTON: This is Brian Covington.
11 Again, as my answer to Dr. Harris, we didn't have
12 the time or spend the time digging deep into what
13 that risk assessment would constitute other than
14 there needs to be some analysis of the product
15 category or products that are being imported into
16 the country. I think Dr. Harris used an example of
17 canned products which we obviously know have a
18 different microbiological profile than raw beef trim
19 or raw beef.

20 MR. TYNAN: But does the report have to be
21 clarified or is it fine as it is? Dr. Harris.

22 DR. HARRIS: Joe Harris. And I was the one

1 that asked the question originally, and I have no
2 problem with that language. I just wanted to make
3 sure that we were okay there, that the term risk
4 assessment didn't have too many strings attached to
5 it relative to what people expect when we use the
6 term risk assessment. If the expectation is that
7 we're suggesting a full blown, you know, the example
8 I used is the *Listeria* risk assessment that was done
9 what, a couple of years ago, you know, that was a
10 massive undertaking and I just want to make sure
11 that we don't imply we're suggesting that level of
12 kind of thing, and I don't know, I'll throw out a
13 suggestion. Can we use the term risk evaluation?
14 Just so we make sure we don't get any baggage
15 attached to it, to the word assessment.

16 MR. TYNAN: Mr. Kowalcyk.

17 MR. KOWALCYK: Thank you. Yeah, I think to
18 your point, Joe, if that term would have a lot
19 associated with it, if we changed that to risk
20 evaluation. You know, unless others on the
21 Committee feels that there should be that rigorous
22 of an analysis, we can discuss that but, you know,

1 risk evaluation, I think that's what we're
2 ultimately getting at, you know, where a country is
3 on its lifecycle with respect to the meat and
4 poultry products compared to other countries, things
5 of that nature. So maybe risk evaluation would be
6 more appropriate.

7 MR. TYNAN: Mr. Corbo, did you have a
8 final --

9 MR. CORBO: No, that's fine.

10 MR. TYNAN: Okay. I didn't have anything
11 else on my list. Are there any other comments
12 regarding Subcommittee Report Number 1?

13 (No response.)

14 MR. TYNAN: Are we all in agreement with
15 the report? Any -- I'm sorry. Ms. Conti.

16 MS. CONTI: I just wanted to clarify one
17 element. Where it says identify elements of the
18 routine reinspection, they need to be retained by
19 FSIS. I think we were speaking to the fact that
20 currently the routine inspection applies to 100
21 percent. Isn't that correct?

22 MR. TYNAN: I'm sorry. Can you point us to

1 where you are?

2 MS. CONTI: Okay.

3 UNIDENTIFIED SPEAKER: Top of page 3.

4 MR. TYNAN: Top of page 3, okay.

5 MS. CONTI: Routine reinspection currently
6 applies to 100 percent of product. Is that correct?
7 And we were basically saying that getting away from
8 the 100 percent routinely reinspected. Is that
9 correct? I don't know if we should put that in
10 there more specifically.

11 MR. TYNAN: Could you read it for us one
12 more time?

13 MS. CONTI: Okay. Identify elements of the
14 routine reinspection that need to be retained by
15 FSIS.

16 MR. TYNAN: That's the very first bullet on
17 the top of the page.

18 MS. CONTI: Right. So basically stating in
19 a sense that, you know, we're moving away from the
20 100 percent routinely reinspected which is the
21 current standards.

22 MR. TYNAN: Is that what the Committee

1 meant or do we need to clarify that?

2 MR. KOWALCYK: Yeah, I'm not sure, or at
3 least I don't think that's what we meant. I mean
4 100 percent, I'm thinking of 100 percent of
5 shipments, for 100 percent of the countries,
6 exporting to the United States. I think it's --
7 right now there's a routine process for
8 reinspection. It's those points within that
9 process, that was my understanding as to what we
10 were getting at is, you know, okay, routine
11 reinspection has 10 points. There might be three of
12 those points that can be sufficiently addressed by
13 Customs and I think that was our intent of having
14 that there.

15 MS. CONTI: Okay.

16 MR. KOWALCYK: Not, not scaling it back,
17 you know, share of countries coming into the United
18 States.

19 MS. CONTI: Okay. Maybe that could be
20 fleshed out a little bit more clearly in that
21 bullet.

22 MR. KOWALCYK: Yeah.

1 MR. TYNAN: Do you have a suggestion on how
2 we should do that?

3 MS. CONTI: No, I think Michael should put
4 that forth.

5 MR. TYNAN: Michael's the Chairperson.
6 We'll make him do the work.

7 MR. KOWALCYK: How about something like
8 identify steps within the current routine
9 reinspection process that need to be retained by
10 FSIS.

11 MR. TYNAN: Ellen, can you lift that up a
12 little bit higher for us so we can -- oops, a little
13 too high.

14 MS. BLUMBERG: Yeah.

15 MR. KOWALCYK: Identify steps within the
16 current routine reinspection process that need to be
17 retained by FSIS. Is that -- are folks more
18 comfortable with that wording.

19 MR. TYNAN: We're having a sidebar here.
20 Maybe Dr. Raymond has some more jokes for us at this
21 point while we --

22 DR. RAYMOND: Well, there was a guy that

1 bought a parrot.

2 MR. TYNAN: Ms. Conti, we have some
3 alternate language there on the first bullet. So if
4 we could attend to that for just a second and see if
5 we're okay with that, and then I think the report
6 sounds like it's done.

7 MR. KOWALCYK: I think we're having another
8 sidebar here. I think when we modified that last
9 bullet, through move risk based, we still wanted to
10 have something in here really with respect to the
11 for cause and directed reinspection.

12 MR. TYNAN: I'm sorry. Say the first part
13 again. You wanted to have more in there about
14 the --

15 MR. KOWALCYK: The for cause and directed
16 reinspection.

17 MR. TYNAN: Uh-huh.

18 MR. KOWALCYK: Should be focused on, should
19 be focused on aspects related to public health.

20 MR. TYNAN: Michael, is that in the same
21 bullet that you're referring to? Or are we talking
22 about a different bullet now.

1 MR. KOWALCYK: No, this would be a
2 different bullet. So maybe on the end. Right. It
3 actually comes from our mention in the first
4 paragraph, before we get into the bullets on this
5 piece, reinspection should focus on for cause and
6 directed, say directed activities relating to public
7 health.

8 MR. TYNAN: Mr. Schad, you have a comment?

9 MR. SCHAD: I don't know whether this is
10 going to help or hurt. What we're getting at there
11 is FSIS, their reinspection activities should be on
12 the elements of for cause and directed and in our
13 meeting we were discussing like the routine
14 reinspection is already done by Customs. You know,
15 is it an eligible country? Is it eligible product?
16 And so that's what we were trying to use resources
17 the best so, you know, if Customs can do routine
18 reinspection, FSIS can put their resources on the
19 for cause and directed, and the Subcommittee can
20 tell if I'm correct in my understanding of that.

21 MR. KOWALCYK: I think you're correct and
22 that's why we had the recommendation to evaluate the

1 routine process to see where it can be streamlined
2 so to speak. I guess the other piece here that
3 they're focusing on parts where there's higher risk
4 to public health is where the primary focus of
5 resource allocation should be.

6 MR. TYNAN: Okay. With those, with those
7 additions and changes, are we okay with the first
8 report? Any dissension on that?

9 (No response.)

10 MR. TYNAN: So we have consensus. It's a
11 done deal. Number 1. Thank you very much for your
12 hard work on that thank you, Michael, for chairing
13 that Subcommittee.

14 We're going to flip over to Number 2 and
15 see if there's any comments or changes we wanted to
16 make on that one. I had a couple of just short
17 comments on the question number 2, that I took a
18 note on. We have the Subcommittee suggest a three-
19 tiered system, and I think there was a little
20 discussion about the levels. Do we need to clarify
21 or do anything with that?

22 (No response.)

1 MR. TYNAN: Apparently not. And I think
2 that was the only place I had a comment on Number 2.
3 Are there any other changes or issues we need to
4 make with Subcommittee 2? I'm not advocating. I'm
5 just asking.

6 (No response.)

7 MR. TYNAN: I think at the end of
8 Subcommittee 2, we have the issue of the -- that we
9 talked about earlier, Brian, you were saying that we
10 didn't address it in the periodic issue. It was
11 addressed better here. So we're done with periodic
12 at least for this meeting. Dr. Harris.

13

14 DR. HARRIS: This is Joe Harris. Relative,
15 and I asked this question before we broke out in
16 the Subcommittees, and I would like to ask it again
17 now that we've been through the deliberations.
18 Dr. Raymond, during his introductory comments
19 yesterday, talked about the transition from a
20 processed-based approach to a product or outcome-
21 based approach. And my question is, is that the
22 direction the Agency is committed to go or the

1 questions seem to lead me down the road of outcome
2 based instead of processed based, and I'd just like
3 to get a little clarification on the Agency's
4 thinking on that.

5 DR. RAYMOND: I'll give you Raymond's
6 thinking. I'm not sure I feel comfortable saying
7 I'm going to speak for the Agency because they'll be
8 here long after I'm off doing something else.

9 I don't think the number of inspectors in a
10 ground beef plant is as important as the purity and
11 quality and the wholesomeness of the ground beef
12 that comes out of that plant. And I would like to
13 see the USDA and the FSA go to a system to determine
14 equivalency that is based more on the protection of
15 the public health which I believe is done by having
16 a safe product, not the process of getting to a safe
17 product because there are many steps along the way
18 where one mistake can cause an unsafe product even
19 though you have a lot of inspection, you have a lot
20 of rules, you have a great HACCP plan. Mr. Painter
21 even mentioned in transport, when you're talking
22 about exports, you could have the best plant in the

1 world in New Zealand, but if that container gets too
2 warm on the boat coming over here, you've got a bad
3 problem. It's nothing due to inspectors in New
4 Zealand or their HACCP plans or anything else. It's
5 the step along the way, and that's what I really
6 think we need to be cognizant of. I think the
7 closer we get to the consumer, when we say that
8 product is good to eat, the safer the consumer will
9 be.

10 I don't know the right steps to get there
11 but that's one of the reasons we threw this out, to
12 get people to begin thinking about it, to listen how
13 other countries are doing it, and to get thoughts of
14 the whole Committee here.

15 MR. TYNAN: Number 2, any other comments?

16 (No response.)

17 MR. TYNAN: If there are none, I assume the
18 Committee is in concert with that one. There is
19 consensus that that report is acceptable as the full
20 Committee report?

21 (No response.)

22 MR. TYNAN: Okay. Then we have two reports

1 wrapped up at this point. So nice job, a lot of
2 work, a lot of effort put into that, and I
3 appreciate it very much.

4 The next item we have on our agenda is the
5 public comment period. And I only have two names on
6 the list right now. So we'll do those two
7 individuals first and then I will open it up to
8 other people who may have some comments they want to
9 share.

10 The first name I have is Mr. Steve Suppan.

11 DR. SUPPAN: My name is Steve Suppan. I --
12 (laughter.)

13 DR. RAYMOND: Would you care to comment
14 while you're there?

15 MR. TYNAN: Okay. The next name that I
16 have is Mr. Stan Painter. So I'm going to let
17 Mr. Painter make his comment, and he can do that
18 from where he's sitting.

19 MR. PAINTER: Stan Painter with NJC. First
20 of all, I want to say that I appreciate the Agency
21 inviting me and the Council to this meeting. I
22 always enjoy participating and I enjoy and

1 appreciate the ability to be here. And I think that
2 we've got a lot of folks that are behind the scenes
3 that need to be recognized.

4 The young ladies and the gentleman that
5 produce all the stuff that we work with, the tent
6 cards, the name tags, the books that take so many
7 hours and stuff to put together, that we appreciate
8 everyone, you know, for what they do behind the
9 scenes.

10 And the only thing that I would like to say
11 or recommend to the Agency and the Committee would
12 be the consideration that if you know ahead of time
13 what you're going to do for the next meeting, would
14 be to allot some time, say like for this meeting, to
15 have kind I guess you say a general open discussion
16 of what you're going to be dealing with at the next
17 meeting, and that way someone don't come in cold.
18 You've had a little bit of interaction with the
19 other people, a little bit of exchange, you kind of
20 know what other people may or may not be thinking,
21 and that may help the Committee to spark new ideas
22 or to, you know, come up with something because if

1 you're like me, when I go home, there's always
2 something that I think about that I didn't think
3 about at the time after I've had a little bit of
4 time to boil it over in my brain.

5 Thank you.

6 MR. TYNAN: Thank you, Stan. And I
7 appreciate the comments and I think the folks that
8 help put this meeting together would appreciate
9 that. So I'll pass that along, and I promise I
10 won't cut you off ever again because you did a good
11 job.

12 MR. PAINTER: That is on the record.

13 (Laughter.)

14 MR. TYNAN: But I think your comment having
15 some kind of a preliminary thing would be very
16 helpful, and I know we checked in with all of the
17 Committee members after our last meeting to see if
18 there were things that we could do better and
19 different -- we'll catch you in just a second -- to
20 do better and different, and one of the things was
21 to meet with the Chair people, and if there's some
22 way we can engineer something with the full

1 Committee as well as the employee organizations, we
2 will try and find a way to do that, to make this an
3 enhanced experience for both the Agency and for all
4 of you because I do know that you have other things
5 to do besides be Committee members.

6 In that regard, I would mention that we are
7 planning to have another meeting for this Committee.
8 We were looking at dates at the end of October but I
9 understand there are some conflicts with the week
10 that we were planning on. So if you allow me a
11 couple of days to try and find calendar dates that
12 would work best for everyone, I will do that.

13 The topic for that meeting that we're
14 tentatively considering goes back to our public
15 health risk-based inspection and the prompts that we
16 talked about at the last meeting. I think
17 Dr. Maczka, the Office of Food Defense and Emergency
18 Response has a tabletop exercise, and as I mentioned
19 to some of the Committee members, we'd like to do
20 that tabletop exercise with the Committee that would
21 then lead into some Subcommittee sessions around the
22 prompts. So I think it will be interesting and it

1 will be considerably different and it won't be a lot
2 of talking heads as they say for the next meeting.
3 So we'll try and isolate a date as quickly as we can
4 and we'll get back. So I hope that at least gives
5 you some preliminary thinking, Stan. So we would be
6 talking about the inspection prompts.

7 So Mr. Suppan just came in. So I'm going
8 to allow him, he was on our list for making some
9 public comment.

10 We have a microphone way back there and
11 it's -- I'm told that it's on.

12 DR. SUPPAN: Hello. Is that working?

13 MR. TYNAN: It's government property you're
14 breaking.

15 DR. SUPPAN: Oh, well. So, first, thank
16 you for the opportunity to speak. I wanted to make
17 a couple of observations. I didn't know whether it
18 was allowed for the public to comment on the report,
19 but one thing I had noted, and I think has been
20 covered to some extent by qualifying formal risk
21 assessment as risk evaluation. I was just going to
22 suggest, you know, initial equivalency may include a

1 risk evaluation of the measure for which equivalence
2 is sought to try to better cover the wide range of
3 measure for which equivalence is sought.

4 But kind of more generally, one thing I
5 noted in Subcommittee 2 is that there was a need for
6 FSIS to supply the Committee with up-to-date
7 information about what is going on in CODEX with
8 regard to equivalence and perhaps one way of, in
9 addition to what I had suggested to Subcommittee 2,
10 one way that FSIS could help is in the next meeting,
11 have a presentation from the U.S. CODEX Office and
12 then also invite Committee members to submit
13 comments to the next meeting of the U.S. CODEX
14 Office that deals with the CCFICS agenda. If the
15 Committee members have not participated in a U.S.
16 CODEX call, it can be quite informative, quite
17 interesting, and that way you would get some sense
18 of where countries are headed as we enter into this
19 possible expansion of meat imports into the United
20 States, that's being planned from export platforms
21 in Brazil and Mexico and Argentina and Indonesia,
22 China, et cetera.

1 Okay. Thank you very much.

2 MR. TYNAN: Thank you, Steve. Before
3 you -- could you identify yourself and your
4 organization for the record.

5 DR. SUPPAN: I'm Steven Suppan, and I'm
6 with the Institute for Agriculture and Trade Policy.

7 MR. TYNAN: Okay. Thank you. We only had
8 two names on the list to register to speak, but I
9 will open it up to the audience, if there are some
10 other members of the public that want to make a
11 comment, this is the opportunity. And if you could
12 identify yourself when you get up there and your
13 affiliation, I would appreciate it very much.

14 MS. SMITH DeWAAL: Good afternoon. Thank
15 you. I'm Caroline Smith DeWaal, Director of Food
16 Safety for the Center for Science in the Public
17 Interest.

18 I just want to commend the Advisory
19 Committee on the work they've done. I think the
20 outcome and the reports are actually quite good and
21 forward thinking.

22 I did want to reiterate one concept, which

1 while I think it's in the second report, the concept
2 of a tiered approach to evaluating countries. I
3 think that's an excellent idea but I think it
4 also -- I want to remind the Agency of another
5 concept that was brought up yesterday, and that is
6 the concept of the peer review at the accreditation
7 stage that Jill Hollingsworth talked about. It is
8 critically important that national governments look
9 at best practices that are being done in all parts
10 of the world and engage in that peer process of
11 modernizing food safety systems really in parallel
12 and in tandem because it's not just about bringing
13 safe food into the U.S. but we have to be able to
14 ensure that we can export safe product, and we have
15 to really be aware that food safety needs to be
16 elevated for consumers in many, many parts of the
17 world.

18 So I hope that this concept of tiered
19 approaches is used bilaterally so that the U.S. is
20 also being evaluated on the effectiveness of their
21 system and will bring it up faster than their
22 history of modernizing their system. Thank you.

1 MR. TYNAN: Thank you, Ms. DeWaal. I
2 appreciate it.

3 Any other members of the public that would
4 like to make a comment at this time?

5 (No response.)

6 MR. TYNAN: Okay. There being none, I'm
7 going to turn it over to -- oh, I'm sorry.
8 Mr. Corbo.

9 MR. CORBO: Well, I wanted to thank the
10 Agency again for permitting me to sit in on the
11 Committee deliberations. Obviously Carol was much
12 more disruptive at the biotech meeting than I was
13 here because she emailed me late last night and
14 indicated that the Biotech Advisory Committee was
15 going to be meeting again today and she could not be
16 here, but I do want to thank you for permitting me
17 to participate.

18 You know, Dr. Murinda at one point, you
19 know, said to me, you know too much. This is an
20 issue that I've been working on for the last eight
21 years, and as I indicated earlier, my very first
22 FOIA was on equivalence and how this Agency does

1 equivalency. It is a very complicated issue. I
2 really commend the Committee members for, as usual,
3 doing an incredible amount of work and very steep
4 learning curve on this issue. And so you can rest
5 assured that I do not want to become a permanent
6 member of the Committee, but I did enjoy
7 participating in this session the last two days.
8 Thank you.

9 MR. TYNAN: Thank you, Tony. Let me look
10 around so I don't miss anybody else. With all the
11 public comment completed, the comments from the
12 group and the reports wrapped up, we're at the point
13 where we're going to do our wrap up and I've asked
14 Mr. Bryce Quick, our Deputy Administrator, to do the
15 wrap up for us.

16 MR. QUICK: Thank you, Robert. On behalf
17 of the Agency and Dr. Raymond and his office, we do
18 want to thank you because this is a very valuable
19 discussion that we've had over the last two days,
20 and I assure you that we will use the counsel you've
21 given us as we go forward and rethink the way we do
22 our equivalence policies and other things that we've

1 done in this room.

2 So we do want to thank you for taking it as
3 seriously as you have, and from what we've seen of
4 the reports, they will be helpful to us.

5 We wanted to do something a little different at
6 the end of this meeting, and I really appreciate
7 what Stanley, or Mr. Painter, I'm sorry, said about
8 our staff, and I want to echo what he said. There's
9 a lot of work that goes on behind the scenes that
10 we're not always aware of, and sometimes we think
11 these things just magically happen, and I want to
12 echo his statement about the staff that, you know,
13 make the name tags and put together the books and
14 research and get the meeting put together, but
15 there's one in particular that we want to recognize
16 today, and he's become the face of NACMPI and
17 Mr. Moderator to us. We think there's a relation
18 between the amount of hair he has on his head and
19 the number of times his face has almost exploded in
20 putting this meeting together. I think it's real
21 hair. I don't know, but anyway the staff put
22 together a top 10 list for Robert. Robert, you want

1 to come on up here so everybody can see you. I want
2 you all to watch Robert's face as I read these off.

3 MR. TYNAN: I would --

4 MR. QUICK: I'm seizing Robert's Rules of
5 Order. Anyway, the first 10, why Robert Tynan is
6 probably the perfect NACMPI moderator. Robert has
7 years and, Tony, I think this one, we thought of you
8 for some reason, Robert has years of parenting rowdy
9 teenage boys prepared him for this moderating NACMPI
10 position.

11 Number 2, he has become an expert at
12 setting up long distance teleconferences with tin
13 cans and strings.

14 He juggles meeting dates better than a
15 Ringling Brothers performer.

16 Four, he can redo an agenda, arrange for
17 printing, and have it posted on the website in less
18 than five minutes.

19 Five, Robert knows all the best bookies, I
20 mean binder makers.

21 Six, since I think he is older than Emily
22 Post, we think he taught her a few things about

1 setting up proper seating arrangements.

2 Seven, Robert puts the Robert in Robert's
3 Rules of Order, as we know, and he does it gently
4 but firmly.

5 Number 8, he handles the unexpected with
6 the patience he refined with the rest of the folks
7 in the Northeast waiting for the Red Sox to finally
8 win a World Series.

9 Nine, only rarely does he use his Irish
10 brawling skills to keep speakers in the allotted
11 time limits and to stay germane to the subject
12 matter at hand.

13 And, ten, Robert teaches us to respect each
14 other in our differing opinions by reminding us that
15 we're all striving for the same destination but
16 perhaps we're using different maps to get there.

17 So with that, would you just join me in
18 thanking Robert for all the work he's done over the
19 years for us.

20 (Applause.)

21 MR. QUICK: This says, to Robert, for
22 exceptional moderator skills and professionalism and

1 dedication in leading Agency preparation of and
2 coordination for the National Advisory Committee on
3 Meat and Poultry Inspection.

4 MR. TYNAN: Thank you, Bryce, very much.

5 MR. QUICK: With that, bon voyage, and
6 we'll see you again in several months.

7 (Applause.)

8 (Whereupon, at 2:30 p.m., the meeting was
9 concluded.)

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C E R T I F I C A T E

This is to certify that the attached
proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

INTERNATIONAL EQUIVALENCE

PLENARY SESSION

Washington, D.C.

August 28, 2008

were held as herein appears, and that this is the
original transcription thereof for the files of the
United States Department of Agriculture, Food Safety
and Inspection Service.

TIMOTHY J. ATKINSON, JR., Reporter
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