

P R O C E E D I N G S

(8:40 a.m.)

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2
3 DR. PRUCHA: Good morning, my name is John Prucha,
4 I'm the Assistant Deputy Administrator for Program
5 Coordination and Evaluation, Food Safety and Inspection
6 Service, and welcome to our public meeting.

7 The purpose of today's meeting is to introduce a
8 new Food Safety and Inspection Service Meat and Poultry
9 Port-of-Entry Reinspection System, which is currently under
10 development by the Agency. The new system will be an
11 important part of our program for the future. This new
12 system does not, at this time, extend to aid products. I
13 will be chairing today's meeting. I am joined at the table
14 today my key members of my office who will present a
15 description of the new port-of-entry reinspection system we
16 are developing. I will introduce these persons to you in
17 just a moment.

18 First, however, it give me great pleasure to
19 introduce the administrator of the Food Safety and
20 Inspection, Mr. Thomas Billy who has some opening remarks
21 for today's meeting.

22 MR. BILLY: Thank you very much, John, and I to
23 would like to wish all of you a good morning. And to
24 welcome you to today's public meeting on import
25 reinspection.

1 We're here today to present changes that FSIS is
2 planning to make to it's import inspection program, relating
3 to port-of-entry reinspection of meat and poultry entering
4 the U.S., and to provide the public, all of you and others
5 as well that may provide comment through writing, the
6 opportunity for input. FSIS is continually assessing both
7 its domestic and import inspection programs to identify
8 changes that will improve the safety, wholesomeness, and
9 labeling of meat, poultry, and egg products.

10 We are particularly focusing on steps to reduce
11 the incidence of food-borne illness attributed to these
12 products. American consumers deserve the same level of
13 protection for all meat and poultry products consumed in the
14 country, whether these foods are produced domestically or
15 abroad.

16 I'll start with some background on the
17 requirements for importing meat and poultry products into
18 the U.S. and then discuss the changes we are proposing to
19 the import inspection program. After my introductory
20 remarks the staff, as John indicated, will go into much more
21 detail in terms of what we are planning to do.

22 U.S. law requires FSIS to insure that any meat and
23 poultry products imported into the U.S. are produced under
24 conditions that achieve the same level of consumer
25 protection as domestically produced meat and poultry. In

1 other words, we require a foreign country's meat and poultry
2 inspection system to be equivalent to the U.S. system,
3 consistent with our international trade obligations. Food
4 Safety Equivalence Evaluations are based on provisions in
5 the agreement on the application of sanitary and phido-
6 sanitary measures, commonly referred to as the SBS
7 agreement. This agreement requires World Trade
8 Organization, or WTO members to accept as equivalent the
9 food regulatory system of another country if it demonstrates
10 the same level of public health protection as provided by
11 their own systems.

12 Before a country can become eligible to export
13 meat and poultry products to the United States, we first
14 conduct a rigorous paper review of their laws, regulations,
15 and other requirements, followed by an onsite review
16 process. If the result of this process is that the
17 country's meat and poultry inspection system is equivalent
18 to the U.S. system, then that country is eligible to export
19 meat and poultry products to the U.S. We continuously
20 insure that each country maintains equivalency by selecting
21 certain meat and poultry shipments for reinspection as the
22 enter the United States, and by conducting periodic reviews,
23 these reviews are in-country. We call it reinspection
24 because the product was previously inspected and passed by
25 the foreign country's inspection system that was determined

1 to be equivalent to the U.S. inspection system.

2 The automated import information system, or the
3 AIIS system, is the computer based approach or system we use
4 to select shipments for reinspection, and that selection is
5 currently based on foreign establishments that produced it,
6 and the type of product that is involved.

7 Now, the 1996 pathogen and HACCP final rule had a
8 profound effect on countries exporting meat and poultry
9 products to the U.S. When the final rule became effective,
10 countries eligible to export to the U.S. were required to
11 implement equivalent pathogen reduction and HACCP measures.
12 Given the impact that this rule had on both the U.S.
13 domestic and import inspection programs, in 1996 FSIS
14 reorganized the programs within the Agency to allow for more
15 integration. Prior to this the domestic and import
16 inspection programs were located in completely separate
17 areas within the Agency, and operated independently of one
18 another. Integration of these programs allowed for cross-
19 utilization of inspectors as well as improved correlation of
20 procedures and standards between domestic and imported
21 products.

22 While we believe our current system of
23 reinspection is good, we think that we can make it better.
24 We are proposing to change the way we select meat and
25 poultry product shipments for reinspection in two ways.

1 First, we want to base shipment selections to permit ongoing
2 verification of the foreign country inspection systems,
3 rather than evaluating the foreign establishments. Since
4 equivalence determinations are made on a foreign country's
5 meat and poultry inspection system, this will provide a
6 better measure for evaluating the ongoing equivalence of the
7 foreign country's inspection system. Second, we are
8 proposing to replace the product codes and AIIS system with
9 the eight HACCP process categories used in our domestic
10 inspection program. This will more closely align our
11 domestic and import inspection programs, and allow us to
12 quickly and easily adopt any changes made in our domestic
13 program to our import program as well. As we learn new
14 information through risk assessments, scientific studies, or
15 other information, we can then apply this information to
16 both programs.

17 Finally, FSIS does not plan to change the
18 standards used to judge the acceptability of meat and
19 poultry products reinspected at ports-of-entry. And when a
20 shipment fails reinspection, product from the exporting
21 establishment will be subject to extra follow-up
22 reinspections, in addition to the overall planned number of
23 reinspections, to evaluate the export country's inspection
24 system overall.

25 Now in closing, the FSIS believes these changes

1 will strengthen the basis for judging the continued
2 equivalence of inspection systems maintained by foreign
3 countries exporting meat and poultry products to the U.S.
4 And that they will enhance the level of production in place
5 today. It is also important to note that these changes are
6 consistent with recommendations made by the U. S. Department
7 of Agriculture's Office of Inspector General, in their June
8 2000 Audit Report, that focused on foreign country
9 equivalency.

10 I hope that you gain a better understanding of
11 these planned revisions as we explain them in more depth at
12 today's meeting. I encourage your continued participation
13 as the Agency works to improve this important part of our
14 food safety strategy. Now it is my pleasure to turn the
15 meeting back over to Dr. John Prucha.

16 DR. PRUCHA: Thank you, Mr. Billy. Let us turn
17 now to the agenda for today's public meeting. As you came
18 into the room you should have picked up a copy of the agenda
19 and other hand-out materials. I will now walk you through
20 today's schedule.

21 The first agenda item will be presented by Ms.
22 Mary Stanley, the senior food technologist on our
23 international policy staff. May will describe the current
24 important inspection system and explain briefly how it is
25 driven by the automated import information system, and

1 inspection scheduling, and data collection, computer program
2 called the AIIS.

3 The second agenda item will be presented by Ms.
4 Karen Stuck, acting director of the international policy
5 staff. Karen will describe our current thinking on the new
6 port-of-entry reinspection system now under development, and
7 summarize changes we think should be made in the AIIS.

8 The third agenda item will be presented by Mr.
9 Loren Lange, assistant deputy administrator for policy
10 analysis and formulation. Loren will describe in more
11 detail how our AIIS might be revised to implement a new
12 port-of-entry reinspection system, and will explain some of
13 the statistical thinking behind those revisions which are
14 being contemplated.

15 And finally, Karen Stuck will return to the
16 microphone and speak to our future plans for import
17 reinspection.

18 After the formal presentations have been made, Mr.
19 Billy and I will facilitate a discussion session with
20 questions and answers about the topics we have covered here
21 today. At the end of our proceedings today, Mr. Walter
22 Menz, from our field automation and information management
23 division, will provide a demonstration of how the new AIIS
24 program would look to FSIS import inspectors. This
25 demonstration is especially for the computer techies here

1 today, but the merely curious are welcome as well.

2 I would like to also recognize several persons on
3 the staff who have contributed to today's program. I would
4 like to first recognize, if these folks could just raise
5 their hands as I mention their names, I'd first like to
6 recognize Mr. Jim Holt who is running our Powerpoint
7 presentation equipment today, Ms. Anita Manka who has done
8 much of the organizing work and preparation for today's
9 meeting, Mr. Ken Lee who did the data research necessary for
10 our presentations. Ms. Ida Gambrell who is back by the
11 door, our planning office represent who handled the myriad
12 of logistical details that go into setting up a public
13 meeting. I would also like to thank our field automation
14 and information management computer programming group, I
15 mentioned Bud's name, Bud Menz, and also Daniel Pogosan,
16 Tony Chung, Anne Dong, and Muhammad Ben Abdi. And I would
17 be remiss if I didn't recognize Mr. Clark Danford, if Clark
18 could raise his hand, who serves as my special assistant.
19 Clark is a key player on my staff and his thinking is
20 reflected in many of the policy issues we will be discussing
21 with you today.

22 As you can see from the agenda, we have a lot of
23 material to cover and only a half day to do it. We plan to
24 move quickly through these formal presentations, each
25 speaker will provide about five minutes at the end of his or

1 her session in order to answer questions. These short
2 question and answer periods are intended to clarify the
3 material you just heard. The last formal presentation by
4 Karen, will include a summary and tieing together of all
5 previous presentations, following that summary we will open
6 the floor to hear from interested parties with comments or
7 questions on the topics we have presented here today.

8 As I said earlier, hand-outs are available for
9 each of today's presentations, and you will need them at
10 certain points to follow along with some of what is being
11 said. Extra hand-outs are on the table near the door you
12 came in through.

13 Now by way of further introduction, before we
14 begin this scheduled presentations, I would like to
15 highlight several key points of the information that will be
16 presented to you this morning by Mary, Karen, and Loren, and
17 reemphasize some of the points that Tom made.

18 First I would like to call your attention to the
19 title of today's public meeting, and once again, highlight
20 the word reinspection. It is important for you to
21 understand that all meat and poultry products that enter the
22 United States originate from countries with food regulatory
23 systems that are equivalent to the U.S. system. Every pound
24 of imported product has been inspected and passed by the
25 foreign food inspection service before it is shipped to this

1 country. In addition, the competent authority of the
2 foreign government issues a certificate that accompanies the
3 product. This certificate guarantees in writing that the
4 product has been produced in full compliance with all FSIS
5 import requirements.

6 At port-of-entry, FSIS conducts a reinspection of
7 this product as part of its ongoing verification of
8 continuing foreign country equivalence. After the product
9 passes reinspection, it can then move into U.S. commercial
10 channels. Those of you who regularly attend FSIS public
11 meetings may remember the one we held in April 1999 to
12 explain the FSIS process for evaluating the equivalence of
13 foreign meat and poultry food regulatory systems. The main
14 message of that meeting was to explain what we call the
15 triad components of equivalence. They are document
16 analysis, which is an examination of the official issuances
17 of a foreign food regulatory system, and in particular the
18 documents that set forth its sanitary measures. Onsite
19 audit, in which emphasized visits to foreign country and
20 verifies that it is delivering the program described in its
21 official issuances, and port-of-entry reinspection during
22 which FSIS re-examines meat and poultry products from each
23 country that exports to the United States.

24 The first two components document analysis and
25 onsite audit are used to determine the equivalence of a

1 country when it initially applies for eligibility to export
2 meat or poultry products to the United States. Thereafter,
3 FSIS adds the port-of-entry reinspection component to
4 complete its equivalence triad. It is interesting to note
5 the recurrence of these components.

6 A major document analysis is performed when a
7 country first applies for an equivalence determination.
8 Thereafter, it occurs as necessary when new sanitary
9 measures are applied, either on the initiative of a foreign
10 country or in response to a new FSIS import requirement. In
11 other words, it is an as needed event.

12 Similarly, an extensive onsite team audit is
13 performed before a determination of initial equivalence is
14 made. Thereafter audits are conducted, at least annually,
15 in each country that exports meat or poultry products to the
16 United States. Thus audits are for the most part annual
17 events.

18 Port-of-entry reinspection, by comparison of frequency,
19 is conducted each and every day at dozens of foreign entry
20 points all along the parameter of the United States. So
21 reinspection, you see, is a continuous daily activity.
22 Today as this meeting is conducted, FSIS import inspectors
23 are drawing assignments from the AIIS and conducting
24 verification reinspections on some part of the nearly four
25 billion pounds of meat and poultry products that are

1 imported annually.

2 Another key point I would like to make is the way
3 reinspection is conducted today. And contrast it to how we
4 are considering reinspection will be conducted under the new
5 port-of-entry reinspection system.

6 Today every shipment is checked to insure that the
7 paperwork is complete, including the health certificate
8 which is essentially a government to government letter of
9 guarantee that the product has been produced in full
10 compliance with all FSIS requirements. Every shipments is
11 also examined for obvious transportation damage or overt
12 signs of spoilage. Under the current system, certain
13 shipments are randomly selected and these shipments may then
14 be subjected to a certain type of inspection, what we call a
15 TOI. For example, one shipment of boneless beef may be
16 selected to be thawed out and examined for blood clots.
17 Another shipment may be sampled for analysis for certain
18 chemical residues. Another shipment might be examined to
19 make sure the labeling is truthful and accurate. Under the
20 new system we would continue to exam the paperwork
21 accompanying every shipment as well as check for
22 transportation damage, and general signs of spoilage.
23 However, a key difference would be that when a shipment is
24 selected for a more thorough inspection, we would perform
25 all applicable types of inspection, not just one or two as

1 is the current practice.

2 I would like to emphasize that the current FSIS
3 import inspection system is a good one. It has served
4 American consumers well since 1978, but a better one is on
5 the way. For example, as an equivalence component, port-of-
6 entry reinspection now differs in character from document
7 analysis and onsite audit, if you remember the triad, in
8 that reinspection is establishment based and the others are
9 system based. You will hear more about that difference in
10 later presentations, but a key characteristic of the new
11 import reinspection system is that it will be more system
12 based.

13 A reinspection program based upon foreign
14 inspection system performance, rather than foreign
15 establishment compliance, will provide a better measure of
16 equivalence. This is true, because equivalence is a
17 government to government matter, and is not specific to
18 particular food processing facilities which regularly enter
19 and depart the export business as market conditions dictate.
20 System performance is the best public health indicator as
21 well. An equivalent foreign food regulatory system is one
22 that provides the same level of public health protection
23 achieved under our domestic system of meat and poultry
24 regulation. And the systems approach to equivalence holds
25 foreign governments accountable for their food regulatory

1 program and provides a basis for FSIS to trust the health
2 certifications they make for every shipment of meat and
3 poultry products exported to the United States.

4 As you will hear later this morning, the shift in
5 emphasis to a systems model for import reinspection will be
6 achieved through a powerful, highly representative,
7 statistical sampling methodology.

8 Another key point, and an important characteristic
9 of the new port-of-entry reinspection system is its
10 relationship to domestic inspection. In particular, as Tom
11 mentioned, the new statistical sampling methodology will be
12 organized around the same eight HACCP process categories
13 used domestically. The significance of this correlation is
14 that FSIS import inspectors will be able to more closely
15 apply standards to imported product that equal those placed
16 on domestic products. This will become increasingly
17 important as FSIS moves domestically to an enhanced, risk-
18 based inspection approach as was discussed in yesterday's
19 public meeting on the FSIS public health approach to
20 processing inspection.

21 Our new port-of-entry reinspection system will
22 also have an important feedback element. That is, it will
23 provide more accurate data about the performance of a
24 foreign food regulatory system. These data will be used in
25 two ways. The first is through direct communications with

1 foreign governments to provide periodic notification of
2 reinspection results and highlight any trends that may
3 indicate problems. FSIS managers will monitor these trends
4 for evidence of continuing system equivalence. And the
5 second way port-of-entry reinspection data will be used for
6 feedback is in audit-planning to target any foreign
7 establishment or class of products on a country by country
8 basis, that exhibits significant deficiencies. By that I
9 mean, FSIS auditors will zero in on foreign establishments
10 and processes that may not be performing at a level that
11 meets our public health standards.

12 We also think that our new AIIS will be a much
13 better management control tool in many respects. One
14 important feature is that the new system will share data
15 with other systems, such as the Agency's database of
16 laboratory test results. This will provide managers prompt
17 notification of microbiological failures in imported
18 products. Several other management control features will be
19 added as well, and these will be explained further in the
20 formal presentations. Many of these AIIS changes
21 specifically address concerns, as Tom mentioned, raised by
22 the USDA's Inspector General, in his June 2000 report on the
23 FSIS import of meat and poultry inspection process.

24 There is just one other point that I would like to
25 make. And please keep it in mind as you listen to this

1 morning's presentations. Our new port-of-entry reinspection
2 system is a work in progress. Our new port-of-entry
3 reinspection system is a work in progress. We hope to
4 complete the developmental work on this project by year's
5 end, and bring the new system online in 2002. The reason
6 for this meeting at this time is to bring all interested
7 parties up-to-date with our progress, and to seek your
8 input.

9 In my opening remarks I have presented an overview
10 of the information we plan to discuss further, and in much
11 more detail at our meeting today. Again, I welcome you. We
12 look forward to this opportunity for open, transparent
13 discussion, and we very much want your comments and advice
14 on how we might proceed to update and improve the important
15 port-of-entry reinspection function. Thank you very much.

16 I am pleased now to introduce Ms. Mary Stanley,
17 who will present an overview of our current import
18 reinspection system.

19 MS. STANLEY: Loren's prompting me to thank you,
20 John. I was waiting for the slides.

21 DR. PRUCHA: If all else fails we have hand-outs.

22 MS. STANLEY: There you go. I've been asked to
23 review the current port-of-entry reinspection procedures and
24 some of the features of the current automated import
25 information system, the AIIS, that enables FSIS to

1 uniformly evaluate meat and poultry products for foreign
2 countries.

3 And as previously discussed, and to re-emphasis,
4 FSIS relies on its initial determination of a foreign
5 country's eligibility coupled with the ongoing audits to
6 provide the assurances that products shipped to the U.S. are
7 safe, wholesome, and properly labeled and packaged. The
8 port-of-entry reinspection supplements the assessment of the
9 effectiveness of the foreign inspection systems by
10 continuously verifying that the foreign inspection system
11 functions in an equivalent manner.

12 In 2000, the U.S. imported approximately 3.7
13 billion pounds of meat and poultry from 32 eligible
14 countries. I think that is an error, there -- 31 countries
15 actually shipped product to us, and of this volume about 86
16 percent of the product was fresh meat, which includes
17 manufacturing meat carcasses and cuts; two percent of the
18 product was fresh poultry, and 12 percent was processed meat
19 and poultry.

20 Three countries are responsible for almost 85
21 percent of all the meat and poultry products that are
22 imported. Canada accounts for 48 percent, while Australia
23 exports 23 percent, and New Zealand 14 percent. The
24 remaining 15 percent are imported from all the remaining
25 countries.

1 All merchandise, including meat and poultry
2 products entering the United States must clear U.S. Customs
3 Service first, and is subject to a Customs duty. Clearance
4 involves a number of steps: entry, inspection,
5 appraisement, classification, as well as liquidation.

6 Entry includes filing the appropriate documents by
7 the importer or the customs broker who serves as an agent
8 for the importer. These documents may include the bill of
9 lading -- or will include the bill of lading, commercial
10 invoice, manifest, and the packing list. Meat and poultry
11 shipments are considered restricted merchandise, so prior to
12 release into commerce, U.S. Customs Service releases the
13 shipments to the Animal and Plant Health Inspection Service
14 to verify the eligibility regarding the animal health
15 concerns. Once APHIS had confirmed this eligibility, the
16 shipments are then presented to FSIS for reinspection.

17 FSIS reinspects meat and poultry products at the
18 port-of-entry before they are allowed into commerce. The
19 term reinspect as you've heard numerous times already today,
20 is used because the products have already been inspected and
21 passed in the originating country. Each shipment is
22 accompanied by a health certificate which is issued by the
23 foreign inspection service and certifies the wholesomeness
24 of this product.

25 We have about 75 FSIS inspectors that are

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1 dedicated to import reinspection activities. And district
2 offices utilize inspection personnel from the domestic
3 program as well to perform import reinspection duties as
4 needed. All shipments must be presented to FSIS for
5 reinspection at one of approximately 150 import
6 establishments, and these establishments operate under a
7 grant to federal inspection from FSIS, and are required to
8 have adequate facilities to perform the reinspection tasks
9 required by the type of product that is presented to our
10 Agency.

11 As illustrated in this slide, import
12 establishments are located in close proximity to the
13 parameter of the country, clustered around the major ports-
14 of-entry, such as Long Beach, Seattle, Tacoma, the Canadian
15 Border, New York, New Jersey, Philadelphia, Baltimore,
16 Miami, New Orlean, Houston, and El Paso. In order to manage
17 this reinspection activities, all shipments and inspection
18 results are entered into a central database which is called
19 the AIIS. And this database links all ports-of-entry, so
20 that any action taken by the inspector at one port, is
21 immediately considered when an inspector draws an assignment
22 at another port-of-entry for the same type of product from
23 the same foreign establishment.

24 This level of communication also enables FSIS to
25 be more efficient and effective in identifying the status of

1 the product in the United States. Such as whether it has
2 been entered, reinspected and released -- the AIIS went into
3 operation in 1979 and continues to provide compliance
4 histories on each establishment in every foreign country
5 eligible to export meat and poultry to the United States.
6 The AIIS receives and stores reinspection results, then uses
7 this information to select subsequent shipments for
8 reinspection, assigning the scope and intensity of the
9 reinspection. The AIIS system has the ability to develop a
10 complete compliance history for each country and
11 establishment exporting to the United States. The AIIS also
12 is to develop comprehensive product histories of the
13 establishment, and the system also have the ability to
14 increase and decrease reinspection of products by country or
15 establishment.

16 The reporting features of this system are
17 currently limited. These reports are used in numerous ways,
18 including as trend data to prepare for audits of the foreign
19 inspection system as well as to provide direct feedback to
20 the foreign country regarding their performance.

21 Currently FSIS has two approaches to assigning
22 reinspection tasks. One, which is applied to all countries
23 except for Canada, schedules reinspection tasks based on the
24 individual establishment's performance. Canada, on the
25 other hand, has approximately 3000 lots reinspected each

1 year, which are randomly assigned across all products
2 presented from all eligible establishments certified by the
3 Canadian Food Inspection Agency.

4 For all countries except Canada, the reinspection
5 activities are performance based by the foreign
6 establishment, in that the better performing foreign
7 establishments have their products reinspected less
8 frequently. With the exception of products from Canada,
9 every shipment is staged for reinspection, currently. The
10 inspector is able to walk around each pallet, checking for
11 general condition of the shipment, appropriate labeling on
12 the cartons, evidence of transportation damage, and proper
13 box count. The inspector also insures that the health
14 certificate manages the shipment that is being presented.

15 In addition, there are additional types of
16 inspections which we term TOIs that are performed depending
17 on the type of product being presented. Examples of types
18 of inspection include an examination for product defects,
19 laboratory analysis for food chemistry, microbes or
20 residues, net-weight checks, or condition of container for
21 canned products. When the shipment arrives the inspector
22 enters information into the AIIS. An assignment will not be
23 generated unless the foreign country, the establishment, and
24 the type of product is eligible to export to the U.S.
25 Import categories have been established to address the

1 various restrictions related to animal health as well as to
2 enable FSIS to track the type of product. These include
3 canned product for the various species, pork, beef, sheep,
4 goat, poultry, and combination products; and for fresh
5 product, pork, beef, sheep, goat, poultry, and combination.

6 This system's import categories also include
7 cooked product for the species indicated, for cured product
8 for the species indicated, and for horse. The AIIS
9 determines the reinspection assignment based on the
10 compliance history of the country and the foreign
11 establishment, and the type of product. Currently there are
12 over 325 specific products codes established in the current
13 system. TOIs must be individually programmed for each
14 product code based on the type of product so that the
15 appropriate type of inspection will be assigned at port-of-
16 entry.

17 The inspector follows procedures that are outlined
18 in the import manual of procedures for the type of product
19 assigned. And upon completion of the reinspection, all
20 inspection results are entered into the AIIS. Once products
21 pass reinspection, they are stamped with the official mark
22 of inspection and are allowed to move freely in the U.S.
23 commerce. Products not meeting the U.S. requirements are
24 stamped refused entry, and the importer has 45 days to
25 export the product, destroy the product, or convert the

1 product to animal food. Conversion to animal food requires
2 permission from the Food and Drug Administration. FSIS
3 maintains controls over these products until disposal is
4 achieved. Also, if the product is re-exported to a country
5 other than the country of origin, FSIS will provide third-
6 party notification to the country of destination.

7 There are four levels of sampling frequency for
8 reinspection that identify the extent to which product
9 offered for import is reinspected. These include normal,
10 skip one level, skip two level, and tighten and hold. A
11 foreign establishment is not limited to a single level of
12 inspection, rather the level of inspection is set for each
13 type of inspection on the product. For example, a shipment
14 of hams maybe on skip one for net weights, but under normal
15 for lab analysis. Normal level is -- all lots are
16 reinspected. Skip one is one out of every four lots are
17 reinspected, this means there is a one in four chance that
18 each lot presented under S1 will be reinspected. Skip two
19 is that one out of every 12 lots are reinspected. And what
20 this means is that each lot has one in 12 chances of being
21 selected. Within the time period that shipments are in S1
22 and S2, sampling occurs with no predictability. For tighten
23 and hold, shipments are held by FSIS pending the results of
24 test that is being done.

25 Movement between levels of inspection is governed

1 by several switching rules. A switching rule specifies the
2 condition for transition between the levels of the sampling
3 frequency. For example, the first ten shipments are
4 reinspected at normal or 100 percent; after ten consecutive
5 passes within 180 days, the sampling shifts to S1. After
6 ten more consecutive passes then it shifts to S2. If a lot
7 fails or if an establishment does not ship product for 180
8 days then the sampling returns to normal.

9 Residue controls are a major feature of an
10 inspection system that must be judged equivalent to the U.S.
11 system before the country becomes eligible. In addition to
12 receiving an annual update to the testing performed in the
13 foreign countries and auditing the foreign countries' system
14 to insure adequate controls are in place for chemical
15 residue analysis, FSIS also samples product at the port-of-
16 entry.

17 On an annual basis, FSIS determines the compounds
18 to be analyzed for, as well as the frequency of sampling.
19 And the initial rate is based on the volume of product that
20 is imported into the United States for the previous year.
21 Violative positive reports of test results are based on U.S.
22 tolerances or actions levels for the compound in question.
23 In addition, FSIS randomly samples specific imported
24 products at port-of-entry for microbiological testing.
25 These modeled after the domestic program, ground beef and

1 veal are tested for ecoli 0157H7; ready-to-eat further
2 processed products are sampled for listeria,
3 monosytongensis, and salmonella; and the dry, semi-dry
4 fermented sausages are sampled for ecoli 0157H7, listeria,
5 salmonella, and staph inert toxins.

6 Sampling frequencies are monitored to assure
7 consistency with domestic program sampling for the
8 microbiological controls. Any laboratory result that is
9 reported as a pass/fail, such as in the residue or micro is
10 scheduled according to the specified frequency unless a lot
11 fails an analysis. This triggers tighten and hold level of
12 sampling. For residue or microbiological samples, the next
13 15 consecutive shipments are sampled, and samples are held
14 at port-of-entry pending acceptable results from the
15 laboratory. After 15 shipments the establishment returns to
16 normal level or 100 percent of the shipments are sampled.
17 The product will not be held by FSIS pending the results.

18 Since 1989 FSIS has approached port-of-entry
19 reinspection differently for Canadian product. This change
20 was intended as a prototype and it proved successful, and if
21 proved successful it would eventually be extended to the
22 rest of the world. The most significant changes was that
23 sample frequency for product reinspection was no longer
24 based on the performance of the individual establishment,
25 but rather on the performance of the country as a whole. On

1 an annual basis, a predetermined number of lots that were
2 presented for reinspection received an inspection
3 assignment. Rather than each TOI being assigned
4 independently, the lot is reinspected for all applicable
5 types of inspection. For Canada this number was originally
6 set at 3000 lots, which at that time was approximately ten
7 percent of the shipments being presented. This level of
8 monitoring has continued due to the similarities between the
9 two inspection systems and the fact that the inspection
10 procedures, as well as the frequency, was harmonized with
11 agriculture in Canada, which is now CFIA for the U.S.
12 exports as well.

13 It is important to keep in mind that the 3000 lots
14 that are being reinspected are for monitoring purposes only.
15 If a product fails reinspection for any reason, then the
16 establishment is then placed on intensified inspection,
17 which is under the same criteria as the rest of the world.

18 In addition to changing the way inspection
19 assignments are made, there were some other changes made as
20 well. Canadian shipments are controlled by the application
21 of a unique number that must be applied on the shipping
22 cartons. CFIA has opted to use the health certificate
23 number for this identification. The application of this
24 number is important because Canadian product is not stamped
25 with the official mark of inspection when it passes FSIS

1 inspection. The health certificate that is presented with
2 the shipment and maintained on file by the FSIS import
3 inspector is stamped inspected and passed.

4 However, Canadian product not meeting U.S.
5 requirements is currently stamped as refused entry, and the
6 importer has the same options available, to destroy the
7 product within 45 days. Canadian reinspection activities
8 are managed through the AIIS as well, though entry into the
9 system is slightly different. Rather than using the 325
10 product codes that are described previously, the importer
11 identifies products grouped by generic product codes which
12 include fresh and processed categories for each species or
13 combination of species. The specific type of product are
14 used to identify the sublots that will be selected for a
15 reinspection assignment. So this is just an example of the
16 processed and the other generic categories.

17 Once the product arrives at the import
18 establishment along the Canadian border, and assignment is
19 requested through the AIIS. When a skip assignment is
20 received for Canadian product, a cursory check is made at
21 the rear of the vehicle to evaluate transportation damage,
22 general condition of the shipment, labelling compliance on
23 the pallet that is at the rear of the vehicle, as well as
24 proper certification. The shipment is released into
25 commerce without off-loading the product. If an inspection

1 assignment is given, the entire generic lot containing the
2 subplot that received the assignment for inspection is staged
3 for the inspector to view. All applicable types of
4 inspection will be performed on the subplot following
5 procedures that are outlined in the import manual of
6 procedures. Upon completion of this reinspection, the
7 inspection results are entered into the AIIS, and once
8 products are passed, the health certificate is stamped
9 inspected and passed and the product is released into
10 commerce. If a subplot fails, then the entire generic lot is
11 refused entry and subsequent shipments from that
12 establishment are subject to test and hold procedures.

13 In conclusion, the data stored in the AIIS
14 provides a record of the effectiveness of the foreign
15 inspection system. These data enable FSIS to shift
16 resources to the port-of-entry and in audits performed in
17 the foreign countries, to focus on the foreign inspection
18 systems that may have potential health risks. However,
19 status quo is no longer an option. There are immediate
20 needs to have the AIIS re-programmed, and the Agency
21 realizes this is an opportunity to modernize the port-of-
22 entry inspection procedures.

23 At this time I'll take the time to clarify any
24 questions about what I've presented here.

25 DR. PRUCHA: I have a question.

1 MS. STANLEY: Okay.

2 DR. PRUCHA: I have a question from the audience.
3 What is FRATS?

4 MS. STANLEY: Fresh ratites.

5 DR. PRUCHA: You might have seen that up there as
6 a code. We might have to change that to fresh ostrich or
7 fresh emu or something like that --

8 MS. STANLEY: We put a lot of thought into that,
9 John, we like FRATS.

10 DR. PRUCHA: Are there any additional questions
11 before we move on the next presentation? That was very
12 technical but I think it is important to have that
13 background to understand the changes we are thinking about
14 making to the that basic system.

15 I'm pleased now to introduce Ms. Karen Stuck, who
16 will review with you the basic design of the new port-of-
17 entry reinspection system that we are considering, and the
18 status of our work to develop this system. Karen?

19 MS. STUCK: Thank you.

20 The description of our current port-of-entry
21 program provides the basis for explaining import
22 reinspection in the future. As you have heard, regulation
23 of imported meat and poultry includes a number of
24 activities, including determining initial equivalence,
25 auditing inspection systems in eligible countries, and port-

1 of-entry reinspection, today's public meeting focuses on the
2 port-of-entry activity.

3 I want to re-emphasize as we've already heard
4 several times, that FSIS conducts reinspection at the port-
5 of-entry. That term is appropriate because all product is
6 previously inspected and passed by the foreign countries'
7 inspection system that has been determined to be equivalent
8 to the U.S. inspection system. Furthermore, the great
9 majority of imported meat enters federal establishments for
10 further processing under FSIS inspection. Thus, an
11 important objective of port-of-entry reinspection is to gain
12 information about the performance of the exporting
13 countries' inspection system. Information that will be used
14 to inform our decisions about the continued equivalence of
15 that system.

16 So far you have heard about how FSIS employs a
17 systems approach to audit activities, and how we have used a
18 systems approach in port-of-entry reinspection of Canadian
19 shipments, which represent almost one half of total meat and
20 poultry imports to the United States. Our intent now is to
21 extend that port-of-entry systems approach, which we have
22 used for over 20 years, to all countries.

23 The key elements of change that will be described
24 today are, first, to redirect sampling to monitor a foreign
25 country's inspection system rather than individual plants,

1 and second, to re-program the automated import information
2 system, the AIIS.

3 Before I describe our plans, I want to explain
4 what is driving the change. FSIS is in the process of
5 upgrading its computer hardware and operating systems. And
6 as a result the AIIS needs to be re-programmed to run in the
7 new environment. This provides the opportunity to adjust
8 and modernize a system that has served as well since the
9 late 1970s, but is suffering under the strain of age. As
10 you have heard from previous speakers, FSIS has shifted to a
11 systems approach in determining equivalence on an ongoing
12 basis. And we use the systems approach in monitoring
13 Canadian shipments. The next step is to re-direct sampling
14 for all countries to a systems approach. And the re-
15 organization of FSIS in 1996 brought domestic and import
16 inspectors under the same organizational unit in the Agency,
17 a move that facilitates cross-utilization of inspectors and
18 more efficient use of inspection resources.

19 In my presentation, I'm going to explain our plans
20 for re-programming the AIIS to incorporate the systems
21 approach and to make other enhancements. The next
22 presentation by Loren Lange will go into detail on our
23 thinking about sampling.

24 To review, the current AIIS programming under
25 which assignments are made for each shipment presented to

1 FSIS operates around 325 plus product codes. The inspector
2 enters information about each shipment into the AIIS,
3 including the product code. For all countries except
4 Canada, each shipment is classified in the code -- for
5 Canadian shipments we have the broader classification, the
6 generic code. All shipments are entered into one of those
7 generic codes. The current 325 plus product codes will be
8 replaced by eight HACCP process categories which are the
9 same as those used in the domestic inspection program. The
10 first four are and their code numbers, I won't read their
11 code numbers, but the title of the classification is raw
12 ground products, raw not ground products, thermally
13 processed shelf stable products, not heat treated shelf
14 stable products, heat treated shelf stable products, fully
15 cooked not shelf stable products, heat treated not fully
16 cooked not shelf stable, and products with secondary
17 inhibitors not shelf stable. And all products will fit into
18 one of those categories.

19 Using the HACCP process categories improves the
20 AIIS in several ways. First, this simplifies the
21 categorization of products by eliminating the 325 product
22 codes, and the process categories are familiar to all
23 inspectors, including those who are cross-utilized from the
24 domestic program to conduct import reinspection. Second,
25 when changes are made in the domestic program that are

1 linked to process categories, it will be very easy to adjust
2 the AIIS accordingly. Finally, and most significantly,
3 samples will be allocated for each country by species and
4 process category based on the annual volume of shipments
5 from the country. This more precise targeting will result
6 in a stronger statistical basis for drawing conclusions
7 about the performance of a country's inspection system. And
8 you will hear more about this in the next presentation.

9 The first data entry by the inspector for every
10 shipment under the new planned AIIS will be the name of the
11 exporting country, the foreign establishment, the species,
12 and the process category. Based on these items of
13 information the system will confirm the eligibility of the
14 country, the plant, and the specific product from both the
15 public health and the animal health standpoint. Each
16 shipment is required to be marked with a unique shipping
17 mark which will be captured in the AIIS. This will
18 facilitate trace-back in the event a problem arises after
19 the shipment enters the United States or in the event we
20 need to check the status of an imported shipment at some
21 location in the country.

22 Canada and the United States both apply export
23 certificate numbers on shipping containers, and countries
24 can use that number or another unique alpha numeric
25 designation. The AIIS will be able to capture production

1 dates and certification dates when that information is
2 needed to trace shipments or to confirm the eligibility of a
3 particular shipment. Each shipment that is randomly
4 selected by the AIIS for reinspection will be subject to all
5 applicable types of physical inspections, as is currently
6 done with shipments from Canada. These can include a
7 product examination, checking the condition of the
8 container, incubation of canned product, and checking net
9 weight. As a result every shipment will receive an in-depth
10 examination providing a more complete picture of the
11 performance of a country's inspection system.

12 We do not plan changes in the laboratory sampling,
13 port-of-entry residue sampling will continue to be part of
14 the National Residue Program which sets the frequency of
15 sampling. The frequency of microbiological sampling will
16 continue to mirror the domestic program. We also don't
17 intend to change action taken when a shipment fails
18 reinspection. The AIIS will direct follow-up sampling of
19 products from the same process category and foreign
20 establishment, for non-laboratory failures, the next ten
21 shipments will be checked, for laboratory failures the next
22 15 shipments will be checked.

23 In the end, we believe the initiative to redesign
24 the AIIS and the import reinspection program offers
25 important benefits. The new program will provide truly

1 random statistical sampling of a country's performance for
2 use in verifying on a continuing basis that the original
3 decision on equivalence remains valid. The use of HACCP
4 process categories facilities correlation with the domestic
5 program, and positions the port-of-entry program to take
6 advantage of FSIS risk based approach to inspection. A
7 modernized AIIS will have enhanced reporting capabilities
8 assuring that agency managers can receive timely reports
9 that inform audit plans and equivalence decisions. Reports
10 will also be provided to exporting countries. Increased
11 data collection and a user-friendly system will improve the
12 Agency's ability to track and recall imported products after
13 they have entered the country. The in-depth examination of
14 each selected shipment, rather than spreading out types of
15 inspections individually over more shipments, will reduce
16 product handling and the potential for temperature abuse,
17 and is more efficient use of inspection resources.

18 The status of this initiative is that the changes
19 are in the planning and development stages. The revised
20 sampling strategy will be embodied in the reprogramming of
21 the AIIS. We anticipate being able to pilot test the new
22 AIIS during 2001, and implementation is scheduled for
23 January 2002. This completes the description of the
24 overview of the plans for re-programming the AIIS.

25 Are there any questions needing clarification?

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1 DR. PRUCHA: Okay. Well let's just move right
2 along to the next presentation by Mr. Loren Lange. Loren is
3 going to review with you the new strategy that we are
4 considering for randomly selecting certain shipments of
5 imported meat and poultry for reinspection. So Loren let me
6 turn the microphone over to you.

7 MR. LANGE: Thank you, John. Before I begin my
8 formal presentation, I just wanted to remind everybody of
9 what John said earlier, if you have a hand-out for this
10 presentation it may be more useful, because there's a couple
11 slides that have a lot of numbers, and I'm not sure how the
12 numbers are going to show up in the back. So if you have
13 the presentation -- I sort of remember we were debating the
14 other day whether you could say import-shipments or imported
15 shipments, I guess we decided neither was appropriate, and
16 we import shipments -- but, you know -- one or the other.
17 And one last comment, I would like to acknowledge the work
18 of Bill Kelley and Pat Saunders in helping me prepare this
19 presentation. And Bill and Pat are both statisticians in
20 our policy office -- I know Bill is in the back of the room
21 -- I don't think Pat is here, but I really appreciated there
22 help. (PowerPoint Presentation)

23 I will be presenting the Agency's current thinking
24 with respect to the overall strategy for randomly selecting
25 lots of imported product for reinspection. My presentation

1 applies only to the types of inspection, that is TOIs, that
2 are carried out at the port-of-entry. The sampling plans, I
3 will discuss, do not apply to the collection of product
4 samples for analysis at Agency laboratories. Examples, as
5 both Karen and Mary have mentioned of types of inspections,
6 are examination of product for defects, the review of
7 certain label claims, net weight checks, and for canned
8 product incubation check.

9 As both Karen and Mary have discussed, FSIS view
10 port-of-entry reinspection as a procedure to verify on a
11 continuing basis that the original decision concerning the
12 equivalence of a foreign country's inspection program
13 remains valid. With the focus on system verification, the
14 Agency needs a procedure for determining the number of lots
15 of imported product to randomly select for examination by
16 inspection program personnel at the ports.

17 In thinking about this need then for a procedure,
18 an initial question might be, what is our overall strategy
19 for selecting lots for reinspection. Reinspection is a
20 process where there are two possible outcomes, either the
21 lots is conforming or non-conforming in terms of existing
22 regulatory requirements. For sampling situations with two
23 possible outcomes, it is possible to design a probability
24 based sampling program that will provide a specified level
25 of confidence that the sample results are reflective of the

1 country's program.

2 My next three slides will illustrate, at a 95
3 percent confidence level, three alternative levels of
4 detection that could be used when sampling a population of
5 imported product. Now the 95 percent level of confidence we
6 selected is a fairly standard level used for many of the
7 Agency's sampling programs. For example, historically the
8 95 percent level of confidence was used for sampling species
9 chemical compound combinations and the domestic residue
10 program. The Agency considers this a high level confidence
11 considering the types of problems detected at port-of-entry
12 reinspection. One might think of -- besides sort of
13 obviously from 95 percent confidence one could go up to 99
14 percent, I think if we were sort of inspections for nuclear
15 reactors, I would think that they would be at 99 or even
16 higher -- but when we just -- there is a judgment in there,
17 but we've selected this as sort of when we consider the
18 types of problems we think it is a high level and an
19 appropriate level.

20 Let's take a look at these three levels of
21 detection then, that we could use. The first, when sampling
22 two outcomes from a large population of lots, such as we
23 have here, reinspecting 300 sample lots provides a 95
24 percent level of confidence of detecting an unacceptable
25 outcome in at least one lot, if that unacceptable outcome is

1 present in 1 percent of the imported lots from a foreign
2 country system. Similarly, you could increase the sampling
3 size to 600 sample lots and you get a 95 percent level of
4 confidence of detecting an unacceptable outcome in one lot
5 if it is present in only one half of one percent. Or we
6 could go the other direction and decrease sampling. We
7 could reinspect 150 lots and still get the same 95 percent
8 confidence level of detecting in at least one lot an
9 unacceptable outcome that was present in approximately two
10 percent. So the three sort of detection levels that we sort
11 of considered in our thinking here was a 95 percent level of
12 confidence of detecting a problem of half a percent, one
13 percent, and two percent.

14 The next question of course is, what is our
15 population to sample? As Karen has described, FSIS plans to
16 sample imported lots based on the processes identified in
17 our HACCP regulations, and within each HACCP process we will
18 also sample by type of livestock or poultry, thus a
19 population for sampling could be raw ground beef, which is a
20 process and a type of livestock or poultry, or species, or
21 it could be fully cooked not shelf stable pork from a
22 particular country. This species type of livestock or
23 poultry -- we have some purists in the policy office that
24 always points out that chickens and beef are not species and
25 stuff, so I may flip back and forth from saying types of

1 livestock or poultry, because technically I guess people
2 point out, species means something very specific in the
3 biological sciences, I guess, so there is both terms I use -
4 - I mean the same thing.

5 Now if the expected number of lots from each
6 country by HACCP process was approximately the same then we
7 could pick a single sample size, 300, 600, or 150, or the
8 corresponding detection level one percent, half a percent,
9 two percent, and apply it evenly across the board. Life
10 would have been simple if we could do that. But that is not
11 the case. In calendar year 2000, 31 countries presented
12 168,737 lots, but 18 of the 30 countries presented fewer
13 than 600 lots, so the idea of picking 600 across the board
14 was not possible. So then when we further subdivide this
15 168,730 lots by the species within HACCP processes we found
16 that we had a range from a single lot to over 34,000 lots,
17 thus using any sort of constant sample size, such as 600,
18 300, or even 150, was not an appropriate way to proceed.

19 As a preliminary strategy we have developed the
20 sampling plan that is illustrated on the following slide.
21 And people may want to at this time -- I'm just going to
22 pause -- I think I will before I have my remarks, I'll just
23 sort of try this clicker and talk about what is really on
24 this sampling plan, because this really is the crux of our
25 thinking of how to proceed in the future. The first column

1 is, when I talk about what is our population, it really
2 means from a specific country how many expected lots of a
3 HACCP process bi-species would we expect to find, so if for
4 Country X would we get 6000 or more, would we get from 3000
5 to 6000, or 1000 to 299. So I am looking down this first
6 column. And what I mean by the end is, for a particular
7 HACCP process and species combination the last row would be
8 if we got 13 or less. You will notice in the second column
9 was the sample size we talked about earlier, 600, 300, 150
10 were the ones I mentioned, and the half of a percent
11 detection, one percent, and approximately two percent that
12 corresponded with these. And then we have different sample
13 sizes as we go down. It obviously changes then the sort of
14 probability of detecting one lot that was non-conformance.

15 We applied two sort of general principles in
16 developing this proposed sampling plan. The first
17 principles was sort of a risk management principle based on
18 the exposure component of risk analysis. Thus we decided we
19 wanted a very high level of detection which means we have a
20 95 percent probability of detecting a problem if it only
21 occurs in one half of one percent. We wanted a high level
22 of detection where the annual expected number of lots was
23 the greatest, thus in cases where we were over 6000, if you
24 go to the first column, we would randomly select 600 lots
25 for reinspection. As we have discussed already, this gives

1 us 95 percent level of confidence of detecting the problem
2 if it occurs in only one half of one percent. Now remember
3 that a population is the imports of a single species for a
4 single HACCP process. And similarly we decided that if we
5 were in a lower level of expected lots, that 300 samples
6 would be an appropriate number in the range of from 3000 to
7 5999. Again, that was based on our sort of risk management
8 principles, but still where we had a little lower level of
9 potential exposure.

10 The second principle we applied was sort of a
11 common sense approach to setting the maximum percentage of
12 lots examined while still maintaining a relatively high
13 degree of detection probability for non-conforming lots,
14 thus, as we sort of look at the table, the decision to
15 sample in the middle 60 right there, to sample 60 lots, when
16 the anticipated range was 300 to 999 was really sort of a
17 common sense decision to sample from 6 to 20 percent of the
18 imported lots in that range. Following down lower there,
19 the sample of 30, if the expected number of incoming lots
20 was 60 to 299, is a decision to sample from 10 to 50
21 percent. If there was actually 60 anticipated, the system
22 would sample 30, which was actually 50 percent or the 299,
23 approximately 10 percent.

24 Now, these sampling frequencies that we've sort of
25 used with this second judgment principle can be compared

1 with the assignment frequency of approximately eight percent
2 on skip lot two, one in 12; or it is sort of equivalent, you
3 can compare them with sort of the early thinking when the
4 Canadian system was put in place, of approximately 10
5 percent, so we sort of considered what happens at skip lot
6 two, we considered the Canadian system, so we sort of used
7 this sort of judgment of how to decide when the population
8 was really small.

9 There was one other consideration in deciding to
10 keep the sampling rate relatively high at the lower end of
11 anticipated lots, down here in less than 300, where we get
12 the higher sampling rates. Generally, we expect to see more
13 retail products and more ready-to-eat products in cases
14 where there are relatively few total lots. The Agency
15 believes it is prudent to examine a higher proportion of
16 imports and move directly to retail outlets and especially
17 ready-to-eat products.

18 Next I will discuss how our proposed sampling plan
19 would effect the number of imported lots that are assigned
20 for reinspection. And I will use Canada, France, and
21 Australia to illustrate some of the changes that could be
22 expected. The next slide, has a lot of numbers on it again,
23 so you might want to look at this in the hand-out. The next
24 slide illustrates the existing calendar year 2000
25 reinspection assignments and the projected randomly

1 reinspection assignments for Canada under the plan revision
2 or the sampling we've discussed. So the three columns -- or
3 four columns, are the HACCP process over on the left, then
4 the Calendar year 2000 actual lots that were presented from
5 Canada, the number that were assigned in 2000 under the old
6 system, and our proposed sampling under the new system.

7 We can first note, down at the bottom of this
8 slide, that the overall number of assignments goes up from
9 3422 to 3979. Why? Well we think this occurs because
10 Canada ships product across seven different HACCP processes,
11 each representing several different types of livestock or
12 poultry or species. Next, I want to point out where the
13 largest total increase was, and that was for HACCP process
14 O3D -- canned product or thermally processed commercially
15 sterile, it actually jumped from 399 with an increase to
16 949. In this case the projected assignment rate actually
17 increases from around 4 percent to over 2 percent. Now this
18 may be exactly what the Agency wants. As I said earlier, we
19 believe that the rates should be higher for ready-to-eat
20 products and products that are generally moving directly to
21 retail. However, and this is sort of something that we
22 think is really important, if the Agency decided that
23 thermally processed commercially sterile products do not
24 warrant that level of assignment, the new system will have
25 the flexibility to adjust sampling within a HACCP process or

1 even with a particular species within a HACCP process, so
2 there is a lot of flexibility within any of these HACCP
3 processes, we could actually change the sampling frequency
4 if, based on risk analysis or risk assessment we decided
5 that we really wanted to lower the frequency for a
6 particular HACCP process.

7 We can also see that under our proposed plan the
8 number of Canadian inspections increases for all the three
9 ready-to-eat categories, and that is O3E, O3F, and O3G.
10 Those are three categories that are mostly ready-to-eat
11 products. And that increases, and that is consistent with
12 what we also wanted to do.

13 The one process where a decrease in assigned lots
14 occurs is in raw not ground, which includes both carcasses
15 and parts of carcasses. This slide now shows this process
16 by individual type of livestock or poultry. Note that while
17 assigned reinspections would decrease substantially for raw
18 beef and pork, and that is the first two rows in here
19 showing assignments for beef would go from 1107 down to 600,
20 our sampling size, giving us a 95 percent confidence of
21 detecting one half of one percent; and pork goes from 1006
22 down to 600. The other types of livestock or poultry
23 actually increase, but those two, one could say, they
24 decrease substantially. So let's look at those, I mean, we
25 have 1107 lots in 2000 and we go down to 600. And the

1 question we really should be asking is what would we be
2 achieving by keeping our sampling level up at 1107? We know
3 that reinspecting 600 lots gives us a 95 percent confidence
4 of detecting a problem that it was in half of one percent;
5 if we upped to 1107 we really get that 95 percent confidence
6 of detecting .3 percent, you know, if the problem -- so you
7 really get two-tenths of one percent increase in detection
8 capability. You know, what we've sort of concluded that
9 that is not much gain in detection capability on a system
10 basis when you consider the added cost of almost doubling
11 the sampling.

12 The next slide I'll show is similar information
13 for France. As we can see in this slide the sort of same
14 pattern of change exists even though France was under a
15 different sampling approach from Canada. The total number
16 of lots go up, actually from 226 to 247. The total number
17 of lots for the canned product go up. And the number of
18 lots for the raw product actually decreased a little bit,
19 raw not ground would go down. The same pattern of change
20 that we saw in Canada.

21 My next slide shows the same comparison for
22 Australia. As we can see the total number of assigned lots
23 drops considerably here, from 6992 to 1659, now the main
24 reason is that over 73 percent of Australia's 47,028
25 calendar year 2000 shipments were in a single process

1 species combination. The HACCP process of raw not ground
2 and the species beef. Raw not ground lamb accounted for
3 another 16 percent. In contrast when we look back Canadian
4 imports were spread more evenly across more HACCP processes
5 and more types of livestock or poultry.

6 These types of comparisons between our current
7 level of assigned reinspection and the proposed sampling
8 plan for random assignments must be done cautiously. The
9 numbers for calendar year 2000 assigned reinspection, that
10 was the 6992 for Australia, include all the follow-up
11 reinspections that are now assigned automatically by AIIS.
12 Our plan revision, as Karen has talked about, will also
13 include follow-up samples, follow-up assignments, but these
14 are not included in the tables I presented today. Thus
15 under the proposed system, there would be more than 1659
16 lots from Australia assigned for reinspection. The other
17 thing to remember, as has been mentioned before, is under
18 the plan system when a lot is randomly selected, all
19 applicable TOIs will be performed. Today that is only true
20 for the Canadian system.

21 In closing, I just sort of noted that the
22 Australian example that we've seen is somewhat analogous to
23 a large domestic beef slaughter establishment that ships out
24 high volumes of boxed beef that doesn't even produce ground
25 beef. Under our domestic inspection system this type of

1 establishment would be scheduled for an average of six HACCP
2 verification procedures per week. In contrast, a very small
3 domestic establishment that had seven to eight HACCP process
4 categories would now be scheduled for 21 to 24 HACCP
5 verification procedures per week. So when we look at our
6 domestic system we, the frequency and the amount of
7 verification we do is really highly dependent upon the
8 number of unique HACCP process categories we look at.

9 And finally, we note that our domestic HACCP
10 verifications are driven more by the number of unique HACCP
11 processes than by volume of production. Similarly, as
12 import reinspection moves to a more system verification
13 approach, we will see that the numbers of reinspections are
14 more influenced by the diversity of imports, rather than by
15 a simple count of the number of lots. Thank you.

16 DR. PRUCHA: Loren, are you going to take any
17 questions for clarity?

18 MR. LANGE: I can. I realize in presenting that
19 it is a lot of material. I tried to --

20 DR. PRUCHA: I have one question. Can we throw up
21 the slide, Jeff, on Australia? I don't know if this is a
22 typo. If you look over at the right-hand column, proposed
23 sampling, I thought the max was going to be 600.

24 MR. LANGE: Well, what happens right here, is --
25 thanks for asking a question I can answer. If you look at

1 the first bullet here and what's coming in is beef and veal,
2 there were 600, you know, because of the beef, and 60
3 because of the veal, so it added to 660.

4 DR. PRUCHA: Okay.

5 MR. LANGE: We have two different -- we treated
6 veal as a separate type of livestock or poultry than beef.
7 So these combinations here are not the same. The only slide
8 that actually had the actual numbers that relate to the
9 sampling program was the one where we went into Canada and
10 actually had the raw not ground, those numbers would all
11 have been -- the 600, the 300, the 150 that is on the
12 sampling plan.

13 DR. PRUCHA: Okay. Excellent. Mike, would you
14 state your name and organization because we are recording
15 all of this meeting.

16 MR. TISDALE: My name is Mike Tisdale, I own U.S.
17 Import Meat Inspection in Sweetgrass, Montana, we inspect
18 Canadian meat. I'm also a member of USCBIA, the U.S.
19 Canadian order inspection association. And my question has
20 to do with the 95 percent accuracy. Am I understanding this
21 correctly, that by sampling 600 of 6000 lots we would
22 achieve a 95 percent accuracy rate?

23 MR. LANGE: Not exactly. When you sample 600
24 samples from the incoming population, what that says is,
25 you're 95 percent confident, or you have a 95 percent

1 assurance that if that HACCP process species combination had
2 an actual non-conforming defect level of one half of one
3 percent, then you are 95 percent confident you are going to
4 find it, you're going to find it in at least one lot.

5 MR. TISDALE: And would the entire lot have to be
6 inspected to gain that accuracy?

7 MR. LANGE: No, it is just if you -- remember the
8 600 assigned inspections, randomly assigned inspections, all
9 TOIs are conducted, and it is really a statement that if the
10 non-conformance exists at that very low level of one half of
11 one percent, over the year you will have a 95 percent
12 confidence that you are going to find that one or more
13 times. You are at least going to find it once. And from a
14 systems verification that is what we really want to do, we
15 want to make sure that if there is a problem with any HACCP
16 process category for any subdivision by type of livestock or
17 poultry or species, that we want this level of assurance
18 that if there is an ongoing system problem we are going to
19 find it, and that is sort of the thinking behind this.

20 MR. TISDALE: Currently, the inspection process
21 taking a very small portion of a lot, for example I know at
22 my station it amounts to -- our inspections in relation to
23 the amount of meat moved through the station are
24 approximately two hundredths of one percent of the meat that
25 is actually looked at, actually examined by FSIS inspector.

1 Looking at this small a portion, are we saying that we still
2 maintain this 95 percent accuracy?

3 MR. LANGE: Yes, because what you are really doing
4 is taking -- you are still taking 600 samples from the
5 system-wide production.

6 MR. TISDALE: But not inspecting the full sample
7 lot, only inspecting a small portion of that sample lot.
8 Would we not have to inspect the full sample lot to gain the
9 accuracy we are talking about?

10 MR. LANGE: I really would defer on that. I'll
11 call on my statistician, I identified earlier. My guess is
12 not, but Bill can you address that question?

13 MR. KELLY: Bill Kelly with FSIS. Yes, the 600 is
14 from an infinite population. Even if you were to take
15 micro-samples and took 600 micro-samples and only looked at
16 600 pounds or 625 grams, the 600 sample will give you the
17 same probability of detecting a bad product or non-
18 conformant product. So that 600 is sufficient for detecting
19 bad product at one half of one percent -- detecting at least
20 one defective, or detecting in this case micro-sample, if
21 you were to take 600 micro-samples.

22 MR. TISDALE: Thank you.

23 DR. JOLLY: Dr. Bill Jolly, New Zealand Embassy.
24 Loren can you just clarify the definition of lot, whether it
25 is defined as a kind of symmetry, you might have bone in

1 beef, boneless beef, is two lots, would they be regarded as
2 two lots in your system or would it just be the whole
3 consignment which would be a lot?

4 MR. LANGE: I'll have to refer to our import
5 experts on that.

6 MS. STOCK: The lot would be presented or
7 determined by the importer, but it would be a single process
8 category species in order to be entered.

9 DR. JOLLY: Okay. The other comment I had to make
10 is, if we're moving from a situation where you are doing an
11 inspection but you are only looking at one TOI category to
12 doing the inspection and looking at five or six, then the
13 whole statistical basis has sort of changed, if you like,
14 because you are no longer looking at an individual category,
15 you're looking at a possibility of finding in one out of six
16 categories, I wonder if you'd done the statistics to
17 actually compare the degree of confidence of each of those
18 individual categories, and whether there is any ranking
19 between those categories.

20 MR. LANGE: When you take the 600 randomly
21 selected lots for reinspection and when you conduct each
22 TOI, then what the probability statement is you have that 95
23 percent level of confidence of detecting a problem that
24 exists at whether it is at one half or one or two percent in
25 the product defect area, or the same, since you've taken the

1 600 samples, or in the labeling claim area; so your level of
2 confidence of detecting the problem is there for all the
3 different types of inspection, for all the different defects
4 or non-conformances you are looking for.

5 DR. JOLLY: To that effect, my understanding of
6 statistics is that if you move from a single criterion to a
7 multiple criterion then the constant interval is actually,
8 of taking one or more of those criteria, actually is the
9 sum of the, like if you use the 600, is the sum and you look
10 for six criterion it would be six times point five percent,
11 in other words three percent of the -- one or more of those.
12 The other comment I had was, for certain hazards which are
13 not distributed evenly throughout a lot and are not
14 potentially representative of that lot, such as a non-farm
15 criteria, such as a residue deposit within an individual
16 animal as opposed to a process type issues such as a
17 microbiological contamination, have you looked at how the
18 statistics deal with those situations, and is it the same as
19 it is for process type defects such as contamination?

20 MR. LANGE: As I said at the beginning, this
21 sampling approach is only applicable to the types of
22 inspection we are going to be conducting at ports-of-entry.
23 The residue sampling and micro-sampling are sort of
24 patterned after our domestic program. And the domestic
25 residue program is sort of based on a similar type of

1 confidence level. Our micro-sampling is not based on a --
2 it is sort of a frequency type --

3 DR. JOLLY: Your domestic program for residues,
4 your lot is an individual animal and not a whole 700 cartons
5 of product, first of all. And the other comment I quickly
6 had was with respect to these confidence intervals and what
7 is acceptable and what is not, we all know that nothing
8 coming through a meat processing plant is sterile. There is
9 always going to be a few problems. And when is the process
10 out of control? When you reinspect product of course you
11 are actually adding to your assurance as far as a high
12 sensitivity to picking up a problem. Has there been some
13 comparison done to reinspect an American product to see what
14 sort of confidence you had with American produced product?
15 Just to give you a start-up, we heard about the RTI's
16 findings and quantifying the performance of U.S. inspected
17 product, and we weren't talking about, you know, a sort of
18 95 percent confidence of being able to detect a point five
19 percent, we're talking about problems with much higher
20 percentages than that. So, again, I know the statistics,
21 but as far as what is the acceptable level, understanding
22 that there is always going to be some coming through, is
23 that correlated back to U.S. domestic performance?

24 DR. PRUCHA: What I'd like to do -- we laid out a
25 lot of technical information, and I would just like to have

1 the questions at this stage of the program be directed for
2 clarity, and then we're going to take comments, and we need
3 to take comments, but we need to get through all the
4 material and make sure everybody at least understands what
5 we have presented. And then I'd like to come back and take
6 question and comments and we can have a full-blown
7 discussion at that point in time, if that would be okay with
8 you, Bill? Okay. Let's just do that, we've been at this
9 for quite a long time now this morning. The agenda calls
10 for a break, let me just ask if there are any more questions
11 as pertains to the clarity of the presentations, and if
12 there are we will be happy to address those right now, if
13 not let's take a quick break and we'll take that question
14 and just table it for the time being, Dr. Jolly, and we'll
15 come back to that if we can. Are there anymore questions
16 just to understand, so you all understand what Mary, and
17 Karen, and Loren laid out for you this morning? I don't see
18 anybody's hands, so let's just take a break. Let's take at
19 least 20 minutes. Thank you very much.

20 (Pause.)

21 MR. PRUCHA: Okay, we're going to go ahead and get
22 started. We're just about on schedule. Karen is going to
23 make a very brief presentation on some of our thinking for
24 future changes in regards to import reinspection. And then
25 following the program, we will then turn to some prepared

1 presentations. We have four persons that have signalled to
2 us that they wish to make a prepared statement, which we are
3 happy to accommodate. Those will be no more than five
4 minutes in accordance with the procedure. And if any of
5 those individuals or if any other persons would like to
6 submit additional written statements, we will be happy to
7 accept those and I'll make that comment again, we'll be
8 happy to accept those, but we would like you to do that
9 quickly, I would say in the next two or three or four weeks
10 would be a good time-line.

11 I would like to note that we have been joined at
12 the table by Mr. Phil Derfler, who is the Deputy
13 Administrator for the Office of Policy Program Development
14 and Evaluation; and Mr. John Hogan also joined us but he had
15 to step out to take a phone call. He'll be sitting right
16 next to Phil when he returns. He is the Acting
17 Undersecretary for Food Safety in the U.S. Department of
18 Agriculture.

19 So with that brief introduction, Karen could you
20 share with the audience our thinking on possible additional
21 changes that might be looming in the future with regards to
22 import reinspection.

23 MS. STUCK: Thank you. Before I go into that, I
24 just want to summarize what we've heard up to this point.
25 First, FSIS is reprogramming the AIIS and revising the port-

1 of-entry reinspection program. Our plans to use HACCP
2 process categories will allow the Agency to take advantage
3 of decisions on risk involving the categories. Our plans to
4 adopt a systems approach for assigning port-of-entry
5 reinspection --

6 MR. PRUCHA: My mistake, we need to turn on the
7 microphone for Karen. I don't think we had your microphone
8 on. I'll ask Karen to just start again.

9 MR. STUCK: Okay. I was just mentioning that
10 prior to going through some of the initiatives for the
11 future, I want to summarize what we've heard up to this
12 point. First, FSIS is reprogramming the AIIS and revising
13 port-of-entry reinspection program. Our plans to use HACCP
14 process categories will allow the Agency to take advantage
15 of decisions on risk involving the categories. Our plans to
16 adopt a systems approach for assigning port-of-entry
17 reinspections will strengthen the statistical basis of the
18 data used to make ongoing decisions about the continued
19 equivalence of a country exporting meat and poultry to the
20 United States. And the new AIIS will have enhanced
21 reporting capabilities serving program managers, audit
22 planners, and exporting countries. Planning and developing
23 those initiatives remain the focus for this year. We will
24 conclude today's formal presentations by outlining our
25 thinking for initiatives beyond this year. These plans

1 build on some of the current initiatives, our experience
2 with import from Canada, and new technology. I want to
3 emphasize that these initiatives are still in the
4 preliminary thinking stage, some will require regulatory
5 change so they will be proposed and subject to public
6 comment.

7 The first area I want to discuss related to import
8 inspection facilities, commonly referred to as I-Houses. I-
9 Houses are cold stores and warehouse facilities that operate
10 under a federal grant of import inspection. They are not
11 subject to the HACCP pathogen reduction regulations, but
12 they are subject to sanitation standard operating
13 procedures. An FSIS import inspector may be assigned to one
14 or several I-Houses. Just as in the domestic program, we
15 are considering the proper role of import inspectors. We
16 believe that some activities that are now carried out by
17 import inspectors may be appropriately handled by I-Houses.
18 Such activities may include verifying counts, sorting
19 transportation damaged boxes, and controlling refused entry
20 product.

21 With regard to the handling of shipments presented
22 for import reinspection, FSIS currently has two approaches.
23 For shipments from countries other than Canada, the product
24 is staged on pallets for presentation to the FSIS inspector.
25 For shipments from Canada it is not necessary to unload the

1 truck and stage the shipment at the I-House if a physical or
2 laboratory examination has not been ordered. As you heard
3 in the first presentation on our current program, the FSIS
4 inspector checks the documents and views the Canadian
5 shipments while they are on the truck. This permits the
6 shipment to proceed directly to its final destination
7 without having to be unloaded at the I-House and subjected
8 to extra handling. We intend to explore implementing this
9 same approach for shipments from all countries, and
10 eliminating the requirement to unload and stage every
11 shipment for FSIS unless the shipment is selected by the
12 AIIS for a reinspection assignment. If that change were
13 made, the FSIS inspector could view a shipment either on the
14 truck or at a storage location within the I-House and check
15 documentation, labeling, and condition.

16 If we were to eliminated the staging requirement,
17 the way would be paved to eliminate the requirement to stamp
18 imported shipping containers with the U.S. inspected and
19 passed import mark of inspection. For the last ten years we
20 have not stamped shipments from Canada, U.S. inspected and
21 passed. One reason for this is that we can trace the status
22 of any Canadian shipment by the unique shipping mark on the
23 containers, as I noted earlier, the reprogrammed AIIS will
24 capture the unique identifier marks for shipments from all
25 countries. As a result, we plan to explore the possibility

1 of discontinuing stamping the shipping containers of all
2 imported products with the U.S. inspected and passed mark.
3 Of course, any shipment or part of a shipment that is
4 refused entry to the United States will be stamped U.S.
5 refused entry, and we don't intend any change in that
6 policy.

7 These changes offer benefits to consumers and to
8 I-Houses. They facilitate product movement, reduce the
9 amount of product handling required and the potential for
10 temperature abuse, and in the end increase product safety.
11 The changes also offer I-Houses flexibility in their
12 operations. We also intend to consider changing how follow-
13 up sampling is conducted for laboratory failures. At
14 present for all countries except Canada, when a laboratory
15 failure occurs for chemical residues, microbiological
16 contamination, or species, the next 15 shipments of similar
17 product from the originating foreign establishment are
18 subject to testing at the port-of-entry, and the shipment is
19 held at the import inspection facility until the laboratory
20 results are received. For the last ten years, we have
21 followed an alternative procedure for Canada that we believe
22 could be extended to all countries. When a laboratory
23 failure occurs in a Canadian shipment, the required follow-
24 up sampling is conducted in Canada prior to the shipment
25 entering the United States. Inspectors with the Canadian

1 Food Inspection Agency sample the next 15 shipments and the
2 analysis are conducted in a government or government-
3 certified laboratory. The laboratory sampling results must
4 be submitted to FSIS with the Canadian export certificate
5 that accompanies the shipment.

6 The benefit of this approach is that it avoids the
7 need to hold product in import establishments awaiting
8 laboratory results, so product moves more freely. It also
9 reduces the burden on FSIS to conduct sampling. We
10 routinely verify the equivalence of foreign government
11 laboratories and their methodologies during onsite audits.

12 There are also technological changes on the
13 horizon that FSIS is looking at as potential enhancements of
14 the port-of-entry program. One of these is paperless entry,
15 or the electronic transfer of health certificate information
16 from one country to another, thereby reducing or eliminating
17 data entry by import inspectors. We are currently exploring
18 initiatives underway in Australia, New Zealand, Canada, and
19 Mexico, and hope to be able to pilot test one or more of
20 these during the year. We have also seen demonstrations of
21 bar-coding and believe this technology holds promise for
22 identifying product and transferring information about a
23 shipment.

24 At the present time, the industry has not adopted
25 a uniform international bar-code format, but should the

1 industry agree on and use a standard system internationally,
2 FSIS would be in a position to consider how the information
3 provided by the bar-code can be integrated into the Agency's
4 information systems. These technologies offer potential
5 benefits to FSIS in that they would integrate with the AIIS,
6 eliminating duplicate data entry and errors. They also have
7 the potential to improve the security of information
8 transfer.

9 As I indicated, many of these initiatives under
10 consideration require a regulatory change. FSIS plans to
11 revise import inspection regulations to combine the meat and
12 poultry sections when that occurs we will take the
13 opportunity to consider proposing other changes as
14 described. And that concludes my prepared remarks.

15 DR. PRUCHA: Okay, Karen, thanks very much. I h
16 think what I would like to do now is to move to the section
17 of the agenda where we now open up the floor and we hear
18 from all of you who have come to the meeting today; and hear
19 what you think about our presentations and our plans for
20 moving forward in regard to import reinspection.

21 In accordance with the procedure that we outlined
22 in our public notice, we invited persons that would wish to
23 make a formal public statement to let us know, and we would
24 put these persons on to the agenda. And we have four
25 persons that raised their hands. So what we will do right

1 now is ask these people to come to the microphone and to
2 make their statement for the record.

3 So the first person is Mr. Jeff Isenmann who is
4 the Director of the Meat Importers Council of America.

5 MR. ISENMANN: Thank you. Again, my name is Jeff
6 Isenmann, I'm a director for the Meat Importers Council of
7 America. And the Meat Importer's Council of America
8 welcomes the initiative of the United States Department of
9 Agriculture FSIS in proposing the modernization of port-of-
10 entry reinspection of meat and poultry food products, and
11 changes to the automated import information system. As
12 noted in the Federal Register notice for this meeting, the
13 federal Meat Inspection Act and the Poultry Products
14 Inspection Act require foreign countries that export meat
15 and poultry products to the United States to establish and
16 maintain inspection systems that are equivalent to the U.S.
17 inspection system. Countries undergo a rigorous review
18 process before they can become eligible to export meat or
19 poultry to the United States. Additionally, after a country
20 is granted eligibility, FSIS regularly audits inspection
21 programs to insure that it remains equivalent to the U.S.
22 system. Exports to the U.S. are then reinspected on a
23 sample basis as they enter the U.S., if they have already
24 been inspected and passed by the foreign country's
25 equivalent inspection system, consequently meat imported

1 from a foreign country undergoes a more rigorous inspection
2 regimen than does the domestic product.

3 For all countries except Canada, monitoring is
4 based on the compliance history of the foreign plant for
5 specific product being imported. Since 1989, FSIS has used
6 a random sampling approach for shipments from Canada. Once
7 selected a shipment is subject to a full range of
8 reinspection assignments applicable to the specific product,
9 by contrast the shipments selected for reinspection from all
10 other countries are subject to one or more reinspection
11 assignments. MICA welcomes the FSIS proposal to extend all
12 countries the systems approach that has been successful to
13 monitor Canada for more than ten years.

14 MR. PRUCHA: Thank you, Mr. Isenmann. The next
15 presenter that would like to make a statement is Mr. Mike
16 Tisdale, who is president of the U.S. Import Meat
17 Inspection. Is that an association?

18 MR. TISDALE: No, that is a station that inspects
19 meat in Sweetgrass, Montana.

20 Good morning, my name is Mike Tisdale, I own U.S.
21 Import Meat Inspection located in Sweetgrass, Montana. I
22 also represent the U.S. Canada Border Inspection
23 Association. Our members operate meat inspection stations
24 located along the Canadian border. We provide facilities
25 and service for unloading and preparing meat for inspection

1 by an FSIS meat inspector.

2 The reason I requested to speak today is our
3 concern for the future of import meat reinspection and that
4 system's effectiveness. The new system described to you
5 today used the current system for inspecting Canadian
6 imports as a model. We feel that the current Canadian
7 system is in need of some change before being applied for
8 the rest of the world importing meat to the U.S. For
9 example at my facility we receive shipments totally roughly
10 400 million pounds of meat last year, yet our FSIS inspector
11 was only instructed to examine approximately 100,000 pounds
12 or two hundredths of one percent. We feel this level of
13 inspection is far too low to provide a clear picture of a
14 foreign country's inspection program. Even with this low
15 level of inspection, two and a half million pounds of
16 Canadian meat was refused entry to the U.S. last year.

17 We could be inspecting much more product at no
18 additional cost to the government or the consumer. My
19 employees and the FSIS inspector have already been paid and
20 spend much time waiting for the one in twenty shipments that
21 are selected for inspection. We should be fully utilizing
22 these already paid for man-hours to inspect more meat. By
23 increasing efforts at our ports-of-entry we insure the
24 consumer the best defense by not allowing contaminated food
25 to enter the U.S. We also question the intention to reduce

1 inspection on meat destined for further processing. Much of
2 this meat is destined for processing at inspected plants,
3 but the remainder will enter our food supply through un-
4 inspected distribution. It makes sense to increase
5 inspection of this product at ports-of-entry as well as
6 processed items at the retail level.

7 Statistics show that increased inspections at
8 port-of-entry will result in the prevention of unwholesome
9 or contaminated meat from entering the U.S. We also feel
10 that reducing inspection of meat for further processing and
11 concentrating on process retail ready items may not be the
12 correct solution.

13 Have we done any risk assessment? Do we have data
14 to support this notion? Food safety principles tell us that
15 early detection is much more preventative than finding the
16 problem at the retail level. Meat should be inspected
17 before it is allowed to enter the U.S. not after it has
18 spent a week in transit and then sent back to the border.

19 We also feel it is important to insure that all
20 new systems are thoroughly tested in-house and in the field
21 prior to full implementation. Are we sure our computer
22 systems tracking data analysis and ability to communicate
23 with other Agencies and countries is sufficiently tested and
24 capable. Our Association members are ready and willing to
25 help FSIS implement a program of port-of-entry reinspection

1 for the future. This could include regional or onsite
2 laboratory testing, computer and manual tracking of
3 shipments to insure they have been inspected and enter our
4 country legally, as well as our ability to communicate with
5 other agencies located at border entry points, such as
6 Customs. We can become a very powerful line of defense for
7 our country's food supply. Thank you again for the
8 opportunity to speak today.

9 DR. PRUCHA: Thank you, Mr. Tisdale. The next
10 presenter is Mr. Walter Piatkowski from Piatkowski Meats,
11 and if Walter could raise your hand so we can turn the
12 microphone on? Thank you.

13 MR. PIATKOWSKI: Hi, I'm Walter Piatkowski from
14 Piatkowski Meats in Gasport, New York. I scheduled some
15 time for some statements for myself and Jim Mislowski
16 yesterday before the meeting. At this time, we're fairly
17 satisfied with the information that we have heard so far.
18 And we are encouraged by the effort that has been put in to
19 it. We do have some questions on the statistic evaluation
20 and risk assessment associated with the numbers of
21 inspections assigned to the different TOIs, or groups in the
22 HACCP outline. I think we would like to discuss that at the
23 open comment session. Thank you.

24 DR. PRUCHA: Did I understand that Jim was part of
25 your presentation? So we had down Mr. Jim Mislowski to make

1 a presentation but that is not -- you are declining
2 respectfully. Okay. That completes our formal statements
3 from interested persons.

4 Just to say again, there was a lot of information
5 presented this morning and we are going to be happy to
6 discuss that further in the remaining time this morning, but
7 I'll say again now and at the close of meeting, that there
8 was a lot of information and it is understandable how it
9 would take some time to digest that. So we encourage you to
10 think about what we've talked about today, and if you wish
11 to make any additional statements in writing, we would be
12 happy to receive those over the next couple or three weeks,
13 but we encourage you to do that and do it as quickly as you
14 can.

15 So now let's open it up to the floor to receive an
16 comments or additional questions that you all might have.
17 Maybe the best way to start, if I could, would be to pick-up
18 with Dr. Jolly. I kind of cut him off just a little bit
19 short because he was making a number of comments that were
20 sort of mixed up with comments as well as questions, and we
21 were just -- I had envisioned an extensive discussion
22 beginning. So between Dr. Jolly and Mr. Lange? Loren do
23 you have any comments? Or Bill would you like to revisit
24 the issues that you were beginning to discuss.

25 MR. LANGE: We had some hall conversations out

1 there, and I think the important thing to remember is we are
2 looking at a system verification. Now, we've said, you
3 know, it is based on the HACCP process and the species, and
4 one has to sort of think about, you know, the production,
5 the total product coming from another country within a HACCP
6 process. In the sampling that we talked about, it is the
7 units that people have to sort of think about, and that can
8 be a different thing. I could have a population of cans of
9 products, and I can actually count how many cans are coming
10 in, and if I have a label exam, and everyone of these have
11 an assumption that there is an equally likely probability of
12 finding a defect, if I look at the one can. And when one
13 takes a sample of 600 and if there is a sort of uniform
14 defect rate of one half of one percent, then I am, you know,
15 95 percent confident that I am going to find at least that
16 defect once. Now, my population may not be cans, it may be
17 boxes, it could be pounds but I'll have my statistician on
18 the staff correct me if I'm wrong, but once you've defined
19 what the unit is, and then if you under the assumption that
20 there is a uniformly distributed problem, once I've taken
21 600 samples of that unit, then I have that level of
22 confidence of finding a non-conformity or non-compliance
23 that is present in that HACCP process from that other
24 country. Maybe that helps, maybe it doesn't, but that is
25 one thing, that I sort of gathered in hall conversation is

1 when one thinks of the population, you have to decide what
2 is it, is it a total number of boxes for the year from that
3 country, is it a number of pounds, is it a number of cans,
4 so it is the units that are important because you are really
5 sampling from the units.

6 DR. JOLLY: Thanks Loren, before I begin with the
7 specifics, I'd just like to add that I think the changes
8 proposed are excellent and the staff have done a lot of
9 work, and they are more rational. It should be given a high
10 level of assurance and not a lesser level of assurance, and
11 it also should free-up the distribution of product. I made
12 a comment that when you sample for say six attributes
13 instead of one, the actual, you can multiply that .5 percent
14 by six, essentially you divide it by six. You actually have
15 a much higher level of assurance, so that might help answer
16 the question from the person on the Canadian border.

17 The question with respect to population and our
18 discussions in the hall really comes down to the situation
19 for non-processed defects. For processed defects you have
20 got a homogeneity of distribution, or should have, in that
21 consignment if it is from a single process day or single
22 process period. If it is from multiple process periods and
23 multiple process days assumptions start to go awry, but then
24 if you start talking about on-farm defects, then that is a
25 different situation as well. And so it is really just for

1 consideration and particularly in the residue side of
2 things, and particularly for small volume products, you can
3 actually get a much higher sampling rate for something which
4 is perhaps not justified on a risk basis. And it is
5 important to remember the whole agency, as we heard over the
6 last couple of days, is moving towards a much more risk
7 based system, so in a risk-based system and a system-based
8 system, you know, we are not trying to add on to what is
9 currently there, we are trying to replace it with a better
10 system delivering a high level of assurance, but which frees
11 up trade.

12 To that effect the other comment I would like to
13 make is that current inspection procedures, physical
14 inspection procedures are causing a bit of a problem,
15 because rightly so the receiving companies who are receiving
16 this product, their HACCP plans are starting to exclude
17 product that has been physically inspected by -- this is the
18 actual specific product that has been physically inspected
19 by the Food Safety Inspection Service, because it has been
20 thawed, it has been cut, it has been manipulated, and it has
21 a lower health status, so I just wanted to make that comment
22 that inspection is not always about increasing the safety,
23 you actually can be adding hazards as well, especially when
24 we start dealing with high-value product, vacuum packed
25 product with modified atmosphere that is chilled --

1 alternative ways of looking at and inspecting that product
2 in the future would be appreciated. And the expert task
3 force, looking at what your veterinarians did in the next
4 millennium, had comments on that as well.

5 The other thing that I wanted to specifically
6 mention was that in a risk-based system looking at a
7 country's performance was still applying an accept/reject
8 criteria to a consignment and implications back to a
9 premises. Now that is appropriate for immediate hazards,
10 but a lot of hazards we are dealing with are not immediate
11 hazards, they are things where we know there is a level of
12 performance both domestically within the U.S. and
13 internationally, there are certain things you cannot totally
14 eliminate. And so, the ability to modify interpretation of
15 results depending on the level of risk posed by that hazard
16 to actually have a different type of criteria set up there
17 in the future, I think, and if you develop a full risk-based
18 system then that will justify it -- certain things you want
19 total rejection, other things you want more direct
20 communication with controlling authority because the
21 correction is going to come from the controlling authority.
22 And it is important to realize that in today's system, when
23 you reject a consignment you don't tell the controlling
24 authority directly. So what is being proposed is actually
25 an improvement. You are going to tell the controlling

1 authority directly. And as we move into an electronic age
2 we are going to know real-time and corrective actions can be
3 put in place, and with more inspection and more compliance
4 orders at the other end. Overall the system is a great
5 improvement. We want to move it more and more towards being
6 risk-based, and less consignment orientated, looking at
7 different hazard types, having different implications on a
8 country, this is a premises, especially with there are farm
9 hazards. And the statistical design has taken that into
10 account. Thank you.

11 DR. PRUCHA: Okay, thank you Dr. Jolly, and I
12 think I see Mr. Bryant's hand being raised? So if you could
13 again, state your name and any other information you want to
14 say about yourself before you make your comment?

15 MR. BRYANT: Yes, my name is Laurie Bryant, I'm
16 the Executive Director of the Meat Importer's Council of
17 America. I just have a question regarding the staging
18 requirements. Staging of meat, of imported meat in I-Houses
19 is an additional handling activity which increased the risk
20 of such things as carton damage et cetera. I am not sure
21 why the current proposals don't include moving fully to the
22 Canadian system whereby the staging of all product being
23 imported from other countries is not required when product
24 is not being inspected. If you could explain why that is
25 not being implemented at this stage? I was under the

1 impression that it was part of the changes being proposed.

2 Thank you.

3 DR. PRUCHA: I think we spoke to it very briefly
4 but went right past it. So Karen can speak to it again.

5 MS. STUCK: Some of the things that I talked about
6 do require regulatory change, and to the extent that -- I'm
7 not sure about that particular staging requirement. What my
8 comments were intended to say was these are the things that
9 we are thinking on about beyond the reprogramming of the
10 AIIS and the sampling plan, and they have different
11 timetables. And part of it would be tied to if we needed a
12 regulatory proposal. If we don't need a regulatory
13 proposal, which is true for some of the things that I was
14 talking about, then we can move as we go along with them.
15 But we are focusing right now on the programming of AIIS and
16 getting that going, and then we will start talking about
17 these other things.

18 MR. BRYANT: I understand that, and I applaud the
19 changes that are being made, I think they are a great move
20 forward. What I'd like to get an understanding of is are
21 there any reasons why staging would be necessary under this
22 changed circumstance, and I'm not suggesting that you can
23 implement it all on the same timetable if there is
24 regulatory change required, but is there a specific reason
25 that product that is not being sampled under the new system,

1 why it would actually need to be seen by the inspector?

2 MS. STUCK: I would have to look at the
3 regulations. The import regulations are fairly prescriptive
4 and they separate Canadian product from other countries. So
5 I would have to look at those. If there is not a regulatory
6 change required, then we can start considering that as soon
7 as we are -- in due time. But I would have to look
8 carefully at the regulations, and I don't recall if there is
9 something specific that talks about the way the product has
10 to be presented to the inspector.

11 MR. PRUCHA: Just a comment. We really haven't
12 had time to focus on the precise question that you're
13 asking, is there any reason not to do that or to do that,
14 but when you start getting folks together and looking
15 closely at the issue, you may come up with some good reasons
16 that we need to continue to do it in one form or the other.
17 For example, some product comes a long distance and there
18 could be a freezer breakdown and it could just be beginning
19 to be spoiled and that kind of stuff, and so, that is one of
20 the things that we look for when we do stage the product, to
21 see if there are any obvious signs of temperature breaks, so
22 that kind of stuff. I'm not saying that is or is not the
23 reason, I'm just saying there are issues that need to be
24 reviewed and considered before we eliminate that
25 requirement.

1 MR. STUCK: Let me just add, Mike Kelly from the
2 tech center pointed out to me, there is a requirement,
3 definitely a requirement in the regulation that products
4 have to be stamped inspected and passed from other
5 countries, and so if you are going to do that, that is
6 directly related to the staging requirements. Products have
7 to be staged in order to be stamped. And so that is one of
8 the factors that would effect that as well.

9 DR. PRUCHA: Do we have some more questions or
10 comments? And if you would go to the -- I'll take the first
11 person in the row there -- would you go to the microphone
12 and state your name? And then I'll come back to you, Mike.

13 MR. BRIGHTER: Thank you. My name is Jerry
14 Brighter. I am with the Western Hemisphere Association of
15 Meat Marketers. I have a question about the chart that you
16 gave here where it appears that there is a dramatic increase
17 in the sampling of the thermally processed and commercially
18 sterile products relative to fresh products and other
19 products. Can you give me a rationale why that increase has
20 taken place?

21 MR. LANGE: I would guess that the calendar year
22 2000 number of lots assigned for countries other than Canada
23 is, if they are lower, and increases that the types of
24 inspection were performed at points of entry today are not
25 finding problems. And when we apply the same criteria

1 across the different HACCP processes it goes up because it
2 gets the same frequency as others. So under that system of
3 normal, skip lot one, skip lot two, it is actually getting
4 assigned relatively infrequently today because a lot of it
5 is on skip lot two.

6 MR. PRUCHA: I'd just like to make a comment here
7 too. Loren, I thought you made a statement that that is
8 what the system would initially call for, but then it can be
9 over, the sampling scheme can be over-written if the
10 managers of the systems determine that that particular
11 product really doesn't pose a risk.

12 MR. LANGE: Yes, if anyone was at yesterday's
13 meeting for our domestic processing inspection, we at least
14 were raising the question now of should we have the same
15 verification frequencies across the different HACCP
16 processes? We didn't answer the question yesterday, but we
17 did raise it. So when I went through that Canadian example
18 and pointed out that that is where the maximum increase is,
19 I said, "The new system gives us a the flexibility to set
20 unique sampling frequencies by HACCP process, and those
21 decisions should presumably flow from the Agency's risk
22 management process."

23 MR. BRIGHTER: Again, Jerry Brighter from Western
24 Hemisphere Association of Meat Marketers. Canned products
25 are not under the HACCP system, at least not yet. So that

1 the sampling frequency shouldn't be based on an apples and
2 apples situation when we have apples and oranges. The
3 safety of products under the canned system would seem to me
4 to dictate the fact that this should be lower than anything
5 else -- just to put it on the same -- to try and get it on
6 an apples to apples basis doesn't make any sense.

7 MR. LANGE: Canned products are under the HACCP
8 system, they are not under the micro-sampling programs of
9 the domestic program.

10 MR. PRUCHA: Mr. Tisdale had his hand up, so we'll
11 turn the microphone to Mr. Tisdale.

12 MR. TISDALE: My question is somewhat similar. I
13 was interested whether there was any data to support the
14 reduced inspection of meat for processing carcasses and
15 wholesale products, to support the position that they may be
16 less of a risk and therefore require less inspection? Is
17 there any data to support that?

18 MR. LANGE: I'm not aware of any at this point,
19 but it is certainly something that the Agency could address
20 as we sort of think of for the domestic program, we think
21 of, sort of, risk analysis by HACCP process, I would think,
22 that what we gain from looking at our domestic processes we
23 then can apply to the same type of relative hazard ranking,
24 risk ranking stuff to the imported product. And the
25 question is if we decide that we want to do different

1 verification rates domestically, I would think we would want
2 to apply those same different rates to imported product.
3 But that is something we are looking at right now. But I am
4 not aware of any data -- I don't know -- Karen? Okay.

5 DR. JOLLY: Dr. Bill Jolly, New Zealand Embassy,
6 just an additional comment. The staging requirements are in
7 the federal regulations, and it has to go to an official
8 inspection facility, and what the facilities must have are
9 listed, so it is not something that can be done on the
10 wharf.

11 To that effect we've been looking at a review of
12 regulation 327, all the import requirements be they both in
13 the country of origin or the port-of-entry for a number of
14 years and every year it keeps getting bumped off the
15 regulatory agenda. So with the Acting Undersecretary here,
16 I'd like to make a plea to make substantial changes here.
17 We need regulation change. There are inconsistencies in the
18 regulations between the current domestic regulations and the
19 regulations required of exporting countries. There are
20 inefficiencies in those regulations which really restrict
21 the flexibility of applying a risk-based system at the port-
22 of-entry. We need that on the regulatory agenda. We need
23 it prioritized so that your staff can do there job and
24 provide a high level of assurance to the American public
25 while not unduly restricting trade. So if we can just make

1 that plea it will be well made. Thank you.

2 DR. PRUCHA: Thank you, Dr. Jolly. Mr. Hogan, I
3 introduced you to the audience in your absence, so that is
4 why he knew you were here.

5 Do we have any other comments or questions? Well
6 it appears that we don't have any other comments or
7 questions at this point in time. I'll say again that we
8 exposed you to a lot of technical information this morning.
9 We have every intent to be open and transparent and to
10 seriously consider your comments and your advice. And we
11 would welcome any additional information or statements that
12 you would like to submit to us in writing. We don't have a
13 precise deadline for accepting or not accepting such
14 information, but I would encourage you if you have some
15 thoughts, to send that to Karen Stuck or Anita Manka as soon
16 as you possibly can. And we will be happy to consider that,
17 and if you have any questions or would like to speak with us
18 over the telephone just give us a call and we would be happy
19 to discuss this subject further with you. I'll ask my
20 colleagues if there are any additional comments that any of
21 them would like to make? If not I would remind you that we
22 have organized a demonstration of this system on the
23 computer. So we'll take a break and if anyone is
24 interested, please hang around, and we will be happy to show
25 you what we developed to this point in time.

1 (Whereupon, at 11:27 a.m., the hearing in the
2 above-entitled matter was adjourned.)

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