

UNITED STATES DEPARTMENT OF AGRICULTURE

PUBLIC MEETING TO RECEIVE)
COMMENTS ON FSIS REGULATORY)
PROPOSAL CONCERNING)
READY-TO-EAT MEAT AND)
POULTRY PRODUCTS)

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THE UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

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COMMENTS ON FSIS REGULATORY)
PROPOSAL CONCERNING)
READY-TO-EAT MEAT AND)
POULTRY PRODUCTS)

Federal Hall
The Washington Plaza Hotel
10 Thomas Circle, N.W.
Washington,

D.C.

Wednesday,
May 9, 2001
9 a.m. - 4 p.m.

PARTICIPANTS

From FSIS:

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Dr. Daniel Engeljohn, Director of Regulations and
Directives Development

Philip Derfler
Kaye Wachsmuth, Administrator

Commenters

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Jenny Scott, National Food Processors Association
Katie Hanigan, Farmland Foods
Kim Rice, The American Food Institute
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Caroline Smith DeWaal, Center for Science in the Public
Interest

Charlotte Christin, Center for Science in the Public
Interest

P R O C E E D I N G S

(9:08 a.m.)

1
2
3 MS. GLAVIN: Thank you all for coming and getting
4 to your seats so quickly. My name is Margaret Glavin and
5 I'm going to the moderator today. I appreciate the fact
6 that you all are here and ready to participate.

7 We wanted to have this public meeting in order to
8 provide an opportunity for later communication and
9 understanding and particularly to gather comments on the
10 proposed regulation that we have out for comment on
11 performance standards for the production of processed meat
12 and poultry products.

13 Yesterday many of you were able to be here for the
14 technical meeting and that was very interesting and I think
15 will help to inform some of the discussion today. This
16 meeting is consistent with an approach we've taken over the
17 last several years and also with Secretary Veneman's pledge
18 to ensure that our food safety policymaking process
19 continues to be transparent and that the public continues to
20 have the opportunity to provide input and to be fully
21 involved.

22 As you know, the proposed rule for ready-to-eat
23 meat and poultry products was published on February 27th and
24 that was after the new Administration had an opportunity to
25 review that rule and make a decision that it should be put

1 out for public comment.

2 The proposed rule is intended to ensure that all
3 categories of ready-to-eat meat and poultry products are
4 covered by a safety performance standard and also to give
5 establishments the incentive and flexibility to adopt
6 innovative science-based food safety processing procedures
7 and controls and provide objective measurable standards that
8 FSIS can verify.

9 These standards are part of our effort to reform
10 our regulatory system for meat and poultry safety. Science-
11 based processors with proven effectiveness developed by
12 establishments and subject to Agency oversight will improve
13 food safety and make better use of government resources.

14 Many of you were here yesterday and will today
15 speak on the importance of using sound science to establish
16 our food safety priorities and to guide our program and
17 policy decisions. I'd like to reiterate our belief that
18 sound science must underpin all of our food safety efforts.

19 Pathogen reduction performance standards play a
20 key role in our science-based food safety efforts. Pathogen
21 reduction performance standards have proven to be effective
22 in reducing the prevalence of pathogens on meat and poultry
23 products and ultimately food-borne illness.

24 Our most recent data for the salmonella
25 performance standards show significant reductions in the

1 prevalence of this pathogen across all meat and poultry
2 product categories. The Centers for Disease Control and
3 Prevention are reporting continued reductions in foodborne
4 illness associated with meat and poultry products.

5 We must continue to build on these successes and
6 the proposed rule on the performance standards for processed
7 meat and poultry products is a step in that direction.

8 At the time we developed the proposed rule we used
9 the best data available to us. However, we recognize that
10 additional data is needed and we're hoping to gather
11 information that we can use to review and improve upon our
12 approach to improving the safety of processed meat and
13 poultry products.

14 I'd like to briefly mention the data needs we've
15 identified in the Federal Register -- . Specifically we're
16 seeking information on appropriate environmental testing
17 specifically through contact surface testing which we
18 believe is effective in reducing the risk of post lethality
19 contamination by Lm and data on the potential growth of Lm
20 in the product after the product leaves the Federally
21 inspected establishment.

22 Before I review the agenda I'd like to emphasize
23 that this public meeting -- and I said this a little bit
24 yesterday for those of you who were here. This public
25 meeting is to receive comments.

1 We have set it up that individuals from the staff
2 will make presentations on particular aspects of the
3 proposed rule and then we will ask -- you will have a brief
4 opportunity for any clarifying questions to clarify what the
5 presenter has put forth and then we will ask for comments.
6 And if any of you have signed up to make comments and we'll
7 go through that list -- through that assignment list and if
8 there are any additional comments either from people who
9 didn't sign up or because additional comments are raised by
10 the earlier speakers we'll go through those.

11 So this is an opportunity for you to give us your
12 comments but it's more particularly an opportunity for us to
13 hear your feedback and to gather additional data and
14 information related to the proposal. We are still
15 collecting data and other comments through the written
16 comment process and we weigh all of the information before
17 deciding how to proceed.

18 I'd also like to note that we've extended the
19 comment period for the proposed rule. The new comment
20 closure date is June 28th and that was to ensure that
21 everyone has ample time to prepare comments based on the
22 discussions at this public meeting. The original comment
23 date came very soon after this meeting and you felt it
24 wouldn't provide an opportunity for things that are raised
25 in that meeting can be reflected in your comments. So we've

1 extended it to June 28th.

2 We found that we really wanted to get this meeting
3 scheduled. Every date we had, someone else had something on
4 the books. So it took us a little longer than we had
5 originally anticipated.

6 So now let me briefly review the agenda for --
7 actually for the two days. First of all, Dr. Daniel
8 Engeljohn who is the Director of our Regulations and
9 Directives Development staff will introduce the morning
10 session on lethality and stabilization performance standards
11 and that ought to wake everybody up.

12 Following the morning session we'll break for
13 lunch at about 12:30 and return about 1:30 to introduce the
14 subject of requirements for the control of Listeria
15 monocytogenes. We anticipate ending by no later than 5:00
16 this afternoon.

17 Tomorrow we will start again at 9:00 with a
18 session on revisions to the regulation governing the
19 elimination of Trichina from pork products and governing
20 commercially stored canned products.

21 Paul Uhler and Dr. Mimi Sharar and the Office of
22 Policy Program Development and Evaluation will lead this
23 session. We'll break again for lunch at about 12:30 and
24 will begin in the afternoon with a session led by Dr. Felix
25 Spinelli, an Economist with our Regulation and Directives

1 Development staff, on the economic impact of the proposed
2 regulations and cost benefit data needs. Again we will plan
3 to wrap up by about 5:00.

4 On both days we will have breaks and I get to run
5 the breaks, so depending on how good you're being we'll have
6 more or fewer breaks. So are there any questions or
7 concerns about the agenda before we get started?

8 (No response.)

9 Okay. When people have either questions or
10 comments it's real important that you come up to one of the
11 microphones and that you state your name so that the
12 reporter can both hear what you're saying and know who is
13 saying it.

14 For those people who are making comments I would
15 particularly urge you to come up and sit at the table.
16 There are a lot of places with microphones. I think that
17 will make it easier. If it's just a question, you're more
18 than welcome to sit at the table but you could also just
19 come up and use the microphone briefly and then go back if
20 that's more appropriate for you. So with that, since you
21 all have the agenda and understand the agenda I'm going to
22 ask Dr. Engeljohn to proceed.

23 DR. ENGELJOHN: Thank you. Can everybody hear me?

24 I have two microphones on. Oh, now you can hear, okay,
25 great. Thank you very much. I'm glad to have the

1 opportunity to walk you through the lethality and
2 stabilization performance standards of meat poultry
3 products.

4 As Maggie mentioned, I'd like to remind you that
5 this is a -- this session this morning is associated with a
6 public docket that we have on record in the docket room with
7 FSIS. That room is available to you, the public, Monday
8 through Friday 8:30 to 4:30. If there are copies of
9 documents that you need we do have a process you can go
10 through that we can make that available to you through our
11 Freedom of Information activities.

12 I'd also point out that all the presentations made
13 at these meetings, and my comments included, are intended to
14 be posted on the FSIS webpage as quickly as we can get them
15 there. So for copies of what I say this morning as well as
16 other presenters that have prepared remarks, our intention
17 is to make them available as quickly as we can. That should
18 be within a matter of days.

19 This is Docket No. 97-013P, the performance
20 standards for the production of processed meat and poultry
21 products. It is a proposed rule. I've given the Federal
22 Register citation and as was stated earlier, the comment
23 period was extended through June 28th.

24 I've had several questions already this morning
25 about how comments can be submitted for the official record

1 and within the document itself, if you have access to it, it
2 explains that. Otherwise, please see me or someone else
3 from FSIS and we'll be glad to try to help you get the
4 information you need to submit your comments.

5 With regard to lethality, I'm going to walk you
6 through the specific components of the proposed regulation
7 that I think -- and you just need to be reminded of and
8 maybe will trigger some thought or some comment that you
9 want clarification on.

10 We're proposing to add a new section to nine coded
11 Federal Regulations, this would be Section 430. For those
12 of you familiar with how they're doing our regulations now,
13 all regulations that are combined requirements for meat and
14 for poultry are now in our new Section 400.

15 Because these lethality performance standards are
16 crosscutting between meat and poultry, we're adding them to
17 this new section. So what that means is that the old
18 Section 9 CFR 318-17 for roast beef, as an example, or 9 CFR
19 318-23 for cooked meat patties or 9 CFR 381-150 for cooked
20 poultry, will no longer be contained in those sections of
21 the regulations but will be removed from there and put into
22 the new Section 430, and that would be once we issue a final
23 regulation.

24 We began the new section with a definition section
25 to provide some clarity as to what we mean by fermented

1 product, ready-to-eat product and worst case product. The
2 fermented products are made ready-to-eat by bacteria enzymes
3 acting to lower pH and microbial inhibition.

4 Also contained within the definition section are
5 other definitions that will be discussed tomorrow that are
6 applicable to canned thermally processed product. There,
7 for an example, we have an acidified product which is
8 different than fermented products. So for purposes of the
9 lethality performance standards, fermented product is
10 defined very specifically.

11 For ready-to-eat product we are putting in a new
12 definition within the regulations that make it specific to
13 ready-to-eat meat and poultry which means that this product
14 is safe to consume without further cooking or application of
15 some other lethality treatment to destroy pathogens.

16 In worst case products for purposes of developing
17 the lethality performance standard are very specifically
18 defined within the new Section 430.2(a)(1) for meat and
19 poultry. For beef, this would be a fermented beef product,
20 430.2(b)(1) and that would relate to the e-coli standard.

21 I would also like to point out for those of you
22 who need a little more background, within the preamble
23 section of the proposed rule, and this would be on pages
24 12592 through 12601, where there's specific discussion about
25 how we derived the definition for a worse case to establish

1 lethality.

2 I would just point out that for worse case raw
3 poultry that would contain 6.7 logs of salmonella in any 143
4 gram sample. This was based on our national baseline study.

5 For worse case for raw meat products the level for
6 salmonella was determined to be 6.2 in any 143 gram sample.

7 We then, as I will explain later, went on to derive a
8 lethality performance standard for the finished ready-to-eat
9 product that takes this raw number and converts it for
10 ready-to-eat product.

11 In the new Section 8 CFR 430.2(a) we're proposing
12 for lethality that you either achieve a probability of
13 survival, meaning that there would be no greater than a
14 specified salmonella -- level of salmonella organisms in any
15 100 gram of finished product. That's assuming that the end
16 product in the meat product is worse case. Again, I just
17 gave you the numbers for the raw numbers. We added a safety
18 margin to that raw number to derive the finished lethality
19 performance standard.

20 For those of you who aren't familiar with the
21 lethality performance standards, in this case we are
22 identifying that for the meat products this would be a
23 survival of greater than zero organisms in any given product
24 of 39.4 percent, greater than one organism of 9.06 percent,
25 greater than two of 1.45 and so on. But we have made

1 available the probabilities that we believe are necessary
2 for establishing the safety of the ready-to-eat product if
3 the processor chose not to use the log reduction mandatory
4 requirement.

5 So you're given an either/or situation. So you
6 can either determine a probability of survival based on the
7 worst case in your product or you can base it on the worst
8 case that FSIS has given you that we made our assumptions
9 for this proposed rule. Or you can do a log reduction.
10 In this case it's given that for meat products that would be
11 a 6.5 log reduction for salmonella and for poultry products
12 that would be a 7.0 log reduction for salmonella.

13 In addition, the lethality performance standards
14 specifies that there can be no detectible viable salmonella
15 organisms in the ready-to-eat product, otherwise it would be
16 determined to be adulterated. So although we're giving you
17 a probability of survival or we're giving you a lethality
18 log reduction, you still have to achieve no viable
19 detectible salmonella in the finished ready-to-eat product
20 in order to determine that that product is not adulterated.

21 Salmonella was determined to be our target
22 organism in this case because of their relatively high
23 numbers and we believe that there is sufficient data to
24 establish lethality for it, and that it can be used as an
25 indicator that other organisms, likewise, will be reduced if

1 you reduce the levels of salmonella.

2 For Section 9 CFR 430.2(b) we note specific
3 requirements for ready-to-eat beef products that are
4 fermented. This would be any product containing beef that
5 is fermented. It can be a poultry product with a minimal
6 amount of beef in it that if that's product's fermented then
7 in addition you have to meet the additional performance
8 standard for lethality.

9 For E.coli 0157:H7, it can be no greater than a
10 given number of organisms in 100 grams of finished product
11 or a log reduction of five. This is consistent with the
12 current policy that the Agency has had since 1994 on
13 fermented beef products with regard to a five log reduction
14 for e-coli.

15 But for the ready-to-eat products today if you
16 have -- we're proposing that if you have fermented -- a
17 fermented process with beef that now you would have a
18 regulatory requirement to meet, an additional E.coli 0157
19 requirement as opposed to just the salmonella requirement.
20 We also are giving -- to the proposed rule. The level of
21 surviving organisms for that probability statement and for
22 0157 greater than zero organisms there's 22.2 percent and
23 greater than one organism would be 2.67 percent.

24 In addition, any detectable viable E.coli 0157 in
25 the finished product would adulterate that product, so you

1 would also have to ensure that it is taken care of at that
2 level.

3 For proposed Section 9 CFR 430.2(c) we go on to
4 state that in addition to the target organisms that we've
5 identified, that means salmonella and E.coli 0157, reduction
6 of other pathogens and endotoxins or toxic metabolites also
7 have to be dealt with and validated to prevent product
8 adulteration.

9 In new Section 9 CFR 430.2(d) we're proposing that
10 the lethality performance standard needs to be maintained
11 throughout the product shelf life and that it should be
12 validated under the conditions to which the feed is stored,
13 distributed and held.

14 I'd like to give you a little more background
15 about the determination of worse case levels. In the
16 absence of a specific risk assessment to help derive how we
17 establish the lethality performance standards we have
18 constructed a worse case approach, which is what we used in
19 the raw beef and poultry rules that went into effect in
20 March of 1999.

21 In general, the Agency did baseline nationwide
22 studies for the various species and classes of products. We
23 used the highest most probable number results from those
24 surveys. I point out that those survey samples were frozen
25 and the samples were also the companion to those that were

1 used to test for salmonella as a qualitative test for the
2 performance standard determination.

3 We also made conservative assumptions in
4 determining our worse case levels. Some of those
5 assumptions are, again we adjusted the most probable numbers
6 for recovery. We used the upper 97.5 percent confidence --
7 for statistical majors and we assumed that the levels of the
8 organisms were uniformly distributed throughout the 143
9 grams of raw product. We also assumed a 70 percent yield
10 going from the raw product to the finished product.

11 This is an example of the data that were collected
12 in the nationwide baseline. This happens to be for the
13 levels of organisms in ground poultry. As an example, for
14 poultry products the most probably number, the highest
15 number, was 2,300 per gram, this is actually for ground
16 poultry products. For red meat it was actually 720, the
17 most probable number per gram.

18 FSIS pulled the sample results for this species.
19 So for the ground beef and the beef carcass data from the
20 nationwide survey, we pulled the data from those two sets in
21 order to determine a worse case level and the same holds
22 true for poultry.

23 I mentioned that we added a safety margin onto the
24 worse case level that we had derived from the raw products,
25 the .3 log for each of those levels resulting in the

1 performance for poultry at 7 and for red meat at 6.5.
2 Again, the probability -- if you were to use that approach
3 the probably of any viable surviving cells that is greater
4 than zero is 39.4.

5 For 0157 we went through the same process, also
6 adding a safety margin. Instead of a safety margin of .3 as
7 we added for the salmonella performance standards, we added
8 a safety margin of .6 for E.coli 0157:H7 in fermented beef
9 products.

10 I'll move on to stabilization. Stabilization as
11 we define it for ready-to-eat meat and poultry products is
12 actually the same as cooling. We chose to use the term
13 "stabilization." It's the same term we used in 1999. We're
14 certainly open to comments on that particular term, but as
15 we refer to it, stabilization means cooling and it generally
16 implies cooling from the thermal process, from the cooking.

17 In our new Section 9 CFR 440.3(a) we're proposing
18 that the processing methods such for ready-to-eat meat and
19 poultry products that prevent the multiplication of toxigen
20 microorganisms, the organisms that we've identified include
21 C. botulimon and C. perfringens. We allow no multiplication
22 for C. botulimon. We did have specific questions in the
23 Preamble asking for information about how much
24 multiplication could occur before toxin formation would
25 occur. And we're certainly open to assess the way we've

1 written this performance standard, if we can have more
2 informed information about the development of toxin which is
3 actually what we're trying to prevent from occurring in
4 ready-to-eat products. For perfringens, we have kept the
5 same performance standard that we issued for cooked roast
6 beef and for cooked poultry, which is that there can be no
7 more than one log growth of C. perfringens.

8 In new Section 9 CFR 430.3(b) we're proposing that
9 the processing of all heat treated not ready-to-eat meat and
10 poultry products also must meet these performance standards
11 for toxin and for C. botulimon. So we know we have
12 partially heat treated products out there. There seems to
13 be our indication the cooked meat patty regulation which
14 specifically has partially cooked meat patties as a
15 component and we have some specific revisions for partially
16 cooked poultry with any additional performance standard
17 first stabilization for the partially heat treated products.

18 New Section 9 CFR 340.3(c) then goes on to say
19 that processing of products are applicable to this Section A
20 and B. They must be validated to maintain the stabilization
21 performance standards throughout the product shelf life
22 under the conditions in which the product is stored,
23 distributed and held. This is an example of the baseline
24 data that we pulled together to establish the performance
25 standard for stabilization. This represents the levels of

1 perfringens in whole red meat products.

2 For determination of the worse case levels for C.
3 perfringens, again we used the baseline data. We had no
4 values greater than -- a fifth per gram. The worse case is
5 it seemed to be -- C. perfringens per gram. That could
6 become heat shocked, germinate and after a live period,
7 multiply as vegetative cells.

8 I'll point out that in ground beef out of 1,687
9 samples only one sample result was greater than 10 to the
10 fourth. In chicken, the level was at 11,000 per gram. We
11 also have the data for raw meat carcasses, but we did, in
12 fact, pull these samples.

13 Then finally, I want to point out that we have
14 made available on our website draft compliance guidance for
15 ready-to-eat meat and poultry products. We'll be happy to
16 answer questions on that today if you've had an opportunity
17 to review them. We announce them through the constituent
18 update on Friday. They're available at our website. I have
19 made two copies available out on the display table. I
20 didn't bring enough copies for everyone, it's 59 pages long.

21 I would encourage you to take a look at them. If we can
22 answer questions on them, that's what we want to be able to
23 do as well as to provide you with some clarity as to your
24 concerns.

25 The guidelines themselves include new information

1 related to the specific processes of cooked, fermented,
2 salt-cured and dried meat and poultry products. We also add
3 for the first time, time and temperature combinations for
4 cooked poultry. For those of you who are familiar with the
5 cooked poultry current regulation 381-150, we've provided
6 only the 160 degrees as being sufficient for safety. We've
7 now provided, based on data soon to be published, in a peer
8 review journal article, time temperatures for common meat
9 and poultry products, that means from one percent fat up to
10 12 percent fat. We would welcome your comment on those time
11 temperature performance standards that are included there,
12 as well.

13 That concludes my prepared remarks and I'll be
14 glad to answer any questions or give clarity at this time.

15 MS. GLAVIN: Are there questions for Dan on what
16 he's presented, or in the areas where you'd like a little
17 further explanation before we move on?

18 A PARTICIPANT: -- .

19 MS. GLAVIN: Can you come up to the mike, please?

20 JOHN DROZD: Doctor, you said that this
21 incorporated 381.150 -- the regulation stated that the
22 cooking of poultry was at 160 but there is another part of
23 it, 381.150, that allowed the cooking of poultry to 155 with
24 the addition of nitrites. Now is that also going to be
25 included into this or had that changed?

1 DR. ENGELJOHN: I would say, yes, that it is
2 included in this proposed rule. Just so you know, we have
3 removed the specific requirement that 381.150 currently has
4 with regard to the 160 and 155. We now have it as a
5 performance standard and have the 155 for cured poultry
6 products or 160 for ready-to-eat poultry products in our
7 compliance guidance. So that is something that you can
8 continue to do. This proposal would not change those
9 provisions.

10 MS. GLAVIN: Could I just ask you to give your
11 name for the reporter?

12 JOHN DROZD: John Drozd.

13 MS. GLAVIN: Thank you.

14 JENNY SCOTT: Jenny Scott from National Food
15 Processors Association. Dan, would you elaborate a little
16 bit. You said that manufacturers could meet the
17 probabilities of the performance standards by looking at
18 their own worst case product and developing a -- what type
19 of information would satisfy you in terms of establishing
20 worse case that is different from the worse case in the
21 baseline?

22 DR. ENGELJOHN: Okay. As is provided in the
23 current cooked poultry regulations as an example, this
24 proposal does not change the intent, which was we wanted to
25 provide flexibility to industry so you didn't have to meet a

1 flat lethality requirement. That you should be able to use
2 innovative lethality or control the number of organisms on
3 your source materials such that the profile of those
4 organisms, the levels and types of organisms may, in fact,
5 be lower than those that FSIS has assumed for the baseline.

6 If that's the case, then you should be able to in
7 your procedures of how you would document your control over
8 the level of incoming perfringens, how you've established
9 the microbial level in profiles of that and maintain that,
10 and establish your own worse case. That information would
11 be made part of your documentation for your hazard analysis
12 that you would ultimately use for your HACCP plan.

13 So that the intent of the proposal is clearly to
14 allow you the flexibility to achieve different levels of
15 cooking and lethality, in fact, but still achieve the same
16 probability of survival so that we have a level playing
17 field for the objective outcome. But you can achieve it in
18 whatever manner you are able to document as being
19 equivalent. That would be something we would expect you to
20 have on file on file as part of your hazard analysis
21 documentation.

22 We have not prepared a great deal of guidance at
23 this time on what we would believe to be the absolute
24 components of that type of documentation other than what's
25 presented in the technical paper that was made available as

1 part of this proposed rule, which described how the Agency
2 determined its worse case. It has a great deal of
3 mathematical modeling in there.

4 That was how we determined our worst case. We
5 believe we built in the flexibility that you should be able
6 to establish your own methodology for that and verify and
7 validate that that, in fact, is sufficient. If we need to
8 provide more information on development of that type of
9 guidance that would be the type of thing we would want you
10 to incorporate into your comments.

11 MS. GLAVIN: Katie?

12 MS. HANIGAN: Katie Hanigan from Farmland Foods.
13 I have a question on heat treated products. My question is
14 if a processor would decide to process a product that is
15 normally considered heat treated, that they had processed it
16 to a temperature that basically makes it a ready-to-eat
17 product based on lethality performance standards from a
18 regulatory standpoint, do I now have a fully cooked product
19 as far as the HACCP program is concerned or is this still --
20 can it still be called heat treated, not shelf stable for a
21 HACCP program? How do all of these regulations come into
22 effect here, or proposed regulations?

23 DR. ENGELJOHN: I don't recall that we had a
24 discussion about the issue of designating products ready-to-
25 eat or not ready-to-eat in the proposal. There was

1 certainly some -- a limited discussion about that.

2 The intent of this proposed rule was not to define
3 what products are ready-to-eat and which ones are not ready-
4 to-eat. That would be a different rulemaking that the
5 Agency would choose to pursue at some later date. There are
6 certain products that the Agency believes that it has
7 defined in the same identity or composition as being ready-
8 to-eat and there would be no opportunity to review those --
9 to modify that.

10 As an example, a hot dog. We consider that under
11 the standard of identity and composition to be a cooked
12 sausage and, therefore, a ready-to-eat product. That is
13 within the Agency's policy on that.

14 This particular rulemaking was not intended to
15 define which products were ready-to-eat or were not. To
16 answer your question or to give you some guidance -- and I
17 encourage you to also write that down and put it into a
18 comment so that we are sure to address it -- that you as the
19 industry should have the opportunity to determine through
20 your hazard analysis what category of products you believe
21 your process should be in.

22 Depending on how you choose to label that product,
23 if there are no other limitations for you in terms of if
24 there is no standard of identity or composition that would
25 limit you as to what that product should be, then if you

1 chose to identify that as heat treated not ready-to-eat
2 product or a heat treated, not shelf stable, I think that
3 should be a determination you have. As far as how the
4 Agency implements that, that's an issue that we need to be
5 made aware of so that we can also address that in how we
6 implement our ready-to-eat sampling program.

7 But right now, if you choose to apply a lethality
8 to a product that's greater, you've chosen to do that for a
9 variety of reasons but are choosing to label that product as
10 a not ready-to-eat product. We don't have a regulation that
11 would prohibit you from doing that and marketing that
12 product as a non ready-to-eat product.

13 We do have concerns, however, about how the
14 consumer interprets the information contained on that label
15 and how they handle it. But again, as I said, that would be
16 another issue we would choose to pursue in another
17 rulemaking. I encourage you to put that question forward in
18 your comments.

19 MS. HANIGAN: Just for further clarification and
20 I'm not trying to put anyone on the spot, but let me make
21 sure I understand what you've just told me. If I use the
22 neckbones as an example, are you saying that they would not
23 be -- they should not be sampled then by FSIS for listeria
24 because they -- under the Agency definition, they are not
25 considered a ready-to-eat product regardless of what our

1 lethality process is? Is that what -- was that partially
2 what you just said to me?

3 DR. ENGELJOHN: That's partially what I said.
4 Again, I think this is an issue of clarity on how we
5 implement the policy to date versus the proposed rule. So I
6 think if we can address this in another format then we
7 certainly will take this back into consideration. I know we
8 get questions about how the Agency institutes it's sampling
9 program but we are dependent in part on what the
10 establishments do for labeling of that product and how
11 they've defined it in their master plan.

12 We have established criteria that we use for how
13 we direct our sampling program. Again I think the Agency is
14 interested in information on that issue and we'll do what we
15 can to try to clarify it, but I think that's separate at the
16 moment from this proposal.

17 MS. HANIGAN: Okay. Thank you.

18 MS. GLAVIN: Back here?

19 A PARTICIPANT: -- from Mcdonalds. I have a
20 question. Normally if you're going to establish an
21 equivalent lethality to -- a certain log reduction as you
22 indicated. That's dependent I think on a D value or a Z
23 value for the specific organism that you're measuring the
24 lethality against. Is somewhere there that you consider to
25 be a representative D value or Z value for the different

1 organisms as someone who was working through the lethality
2 calculations to see whether or not their process meets the
3 log reduction or is that up to the company to, you know, do
4 their research and pick a number?

5 DR. ENGELJOHN: I would say on that, again, that
6 would be an issue that we as an Agency I believe had
7 intended to provide the greatest amount of flexibility to
8 the industry to use their data that they believe to be valid
9 information to support their processes.

10 We have provided our compliance guidance based on
11 published literature as well as information that we have
12 available to us. Where possible we've tried to make that
13 part of or cite that information within the compliance
14 guidance themselves, so that you know what information we
15 used to derive our performance standards in what D values
16 and Z values.

17 An example would be with the cultured ones that we
18 have included in the labor compliance guide. The
19 information that's soon to be published is not yet
20 available. It was conducted by the Agriculture Research
21 Service as a submitted publication. It represents, we
22 believe for the first time published data on poultry that
23 hasn't been available before. But if you have your own data
24 and that's what you use as your documentation for your
25 facility then that should be sufficient for you to use.

1 A PARTICIPANT: Thank you.

2 MS. GLAVIN: Can you speak into a microphone
3 please.

4 A PARTICIPANT: I'm -- from the -- Research
5 Center. Dr. Engeljohn had mentioned about the kind of --
6 contamination and -- is going to be published in the
7 International Journal of Food Microbiology, hopefully in a
8 month. But I do have at this time a draft copy of it. I'd
9 be willing to give you a copy of that.

10 DR. ENGELJOHN: Thank you.

11 MS. GLAVIN: Thank you very much. That's a very
12 generous offer. Jenny?

13 A PARTICIPANT: I have a follow-up question. Once
14 you publish D values for salmonella in poultry for food
15 safety, I haven't looked at DJ's (phonetic) work yet. I
16 don't know if our D values are comparable but let's assume
17 that there is a difference, and companies see a difference,
18 and the R values are supposed to be greater, vice versa and
19 they happen to be lower, what is the the Agency's position
20 going to be if they published data that may not be the same?

21 DR. ENGELJOHN: It's a valid point that needs
22 considering the development of the compliance guide that we
23 put together. Where possible we try to take all of the
24 available information and if we've made assumptions in terms
25 of deriving our outcome of what we actually put in there, we

1 try to make it known as to how we have either summarized the
2 two data points or whether or not we've chosen the more
3 conservative.

4 Where possible we try to -- we will change --
5 update the data in the compliance guidance as frequently as
6 we possible can, make them available to our inspection field
7 force but, most importantly, to the small businesses who
8 really will have a great value derived from them.

9 So as the information becomes available and there
10 are differences, I would guess that our technical staff
11 would try to look at them, try to resolve differences
12 between the two or explain which ones you use and the
13 limitations of them. If they can provide both of them and
14 believe them both to be adequate in terms of the -- then
15 there's no reason why we wouldn't publish both of them in
16 our guidance.

17 A PARTICIPANT: Excuse me. I'd like to make a
18 comment. Two weeks ago in the Journal of Food Science, we
19 published a paper in which we screened more than 50 strains
20 of salmonella. That -- different -- species and the CDC and
21 we have industries from all over the US and after that paper
22 was published we selected several types of salmonella that
23 we had decided to use as a -- we decided to use in our
24 studies with -- and -- ..

25 The paper that is going to appear -- was and that

1 was -- those issues that -- talking about isolated --
2 species as -- were used. Currently we are working on
3 developing a different model also by -- also -- for
4 salmonella and, of course, -- that we had -- what strains to
5 use. So that was the result of this paper which was
6 published in the Journal of Food Science.

7 MS. GLAVIN: Thank you. Are there other
8 questions? Kim? Could I ask you all to let me know if
9 someone behind me would like to speak?

10 MS. RICE: Sure.

11 MS. GLAVIN: Thank you.

12 (Laughter.)

13 MS. RICE: I'm Kim Rice with the American
14 Institute for Food. I want to go back to Katie's question
15 on the definition of a non ready-to-eat versus a ready-to-
16 eat product. I think it's important that the Agency do that
17 at the same time or in conjunction with this rule because
18 that has been the biggest issue, as you all know, because
19 you get more phone calls than probably anybody else on that
20 specific issue as it relates to the directive and what
21 products are considered ready-to-eat and not-ready-to-eat,
22 especially when it comes to the small and very small
23 facilities and whether they're going to meet these
24 requirements or not.

25 So I think you really need to think about doing

1 that at the same time, not separate, after, or later.

2 DR. ENGELJOHN: Just let me get some clarity on
3 that Kim, you're asking that we define which products are
4 ready-to-eat versus which ones are not or make clear of the
5 conditions under which we're going to sample a ready-to-eat
6 product?

7 MS. RICE: I think --

8 DR. ENGELJOHN: Which is the issue?

9 MS. RICE: Both. Who and what these requirements
10 apply to and don't apply to.

11 MS. GLAVIN: It seems -- one moment, it seems to
12 me that that comment would -- written comments would be
13 extremely helpful if you provided some proposed definitions.

14 MS. RICE: Okay.

15 MS. GLAVIN: It would be more helpful than 'just
16 do it.'

17 MS. RICE: We intend to.

18 MS. GLAVIN: Yes, okay. Thank you. I'm going to
19 go to Bernie. He's had his hand up for a while and then
20 Katie.

21 MR. SHIRES: Bernie Shires, American Association
22 of Meat Processors. Basically I just wanted to reinforce
23 what Kim just said. This is a big issue for us. We've
24 gotten loads of calls about this, as well. We are planning
25 to provide some examples and some possible suggestions.

1 But this -- again this is going back to the
2 directive. It's a major problem and it seems that this
3 would be a good -- it seems to us that this would be a good
4 place to do this in the rule if that's -- you know, because
5 if the rule comes to be that's, you know, basically to
6 replace the directive I think anyway, the way it stands. So
7 it just makes sense, common sense, to do it.

8 MS. GLAVIN: Phil?

9 MR. DERFLER: I would encourage people to speak
10 your comments to the rule, but if there are problems with
11 the directive now, speak right to me, okay. I mean you try
12 -- you try -- I don't know if we're getting closer or
13 further away, but I mean if there are problems, let us know.

14 MS. GLAVIN: Okay. I've got Katie lined up next.
15 Katie?

16 MS. HANIGAN: Just as a follow-up on that, Dan. I
17 think the confusion that we felt accompanies that statement
18 that comes in on the partially cooked. I don't mean to keep
19 beating this thing to death, but that statement that comes
20 in or does it appear to be fairly cooked by the consumer?

21 I mean there comes a point in time when the
22 consumer needs to read the label and see if it says it's
23 fully cooked or not. I think that's where part of the
24 confusion comes in with some of this partially cooked, fully
25 cooked and does appear to be partially cooked. I thought

1 maybe you could just make a note on that and I will comment
2 on that, as well.

3 DR. ENGELJOHN: Okay.

4 MS. GLAVIN: Thank you.

5 MS. SWANSON: Katie Swanson from Pillsbury
6 Company. One of the definitions that should be considered
7 for ready-to-eat for harmonization purposes might be in the
8 food code. That would help manufacturers that are subject
9 to both USDA and FDA regulations in the same processing
10 facility.

11 Work with one definition in addition to
12 harmonizing across state and local agencies throughout the
13 country. That is something the Agency needs to be working
14 on at this point because people need a common system.

15 DR. ENGELJOHN: Thank you for bringing that up. I
16 would ask though that if you do in fact submit those in
17 written comment, could give us a specific issue as to why
18 they aren't comparable? Okay.

19 MS. GLAVIN: Again, my understanding is that we're
20 dealing with two connected but different issues. One is the
21 definition for the purposes of this regulation and to what
22 it applies, and the other one is the question of our
23 sampling program.

24 MR. BERNARD: Dave Bernard. I'd like a couple of
25 clarifications, if I may. See if my notes were correct.

1 Dan, were you saying that you're proposing a different
2 performance standard for fermented beef items than for
3 cooked beef items?

4 DR. ENGELJOHN: For fermented beef items, any
5 product that contains any meat and fermented beef, meaning a
6 poultry product that is fermented and has some beef in it.

7 In addition to the salmonella -- standard, we also
8 would have to address E.coli 0157:H7. So for fermented
9 products containing beef and that are fermented will have an
10 additional performance standard -- than just salmonella.
11 All ready-to-eat products would have to address salmonella,
12 but those products containing fermented beef would also have
13 to address E.coli 0157:H7.

14 MR. BERNARD: If I were to make an all beef summer
15 sausage would I have the same performance criteria to meet
16 as if I were cooking a hamburger patty?

17 DR. ENGELJOHN: If you were making an all beef
18 fermented sausage, if that was your question, versus an all
19 beef cooked patty?

20 MR. BERNARD: Yes.

21 DR. ENGELJOHN: For an all beef fermented product
22 you would also have to also address 0157:H7 specifically as
23 a performance standard. You would not address specifically
24 as a performance standard 0157 for a beef patty.

25 MR. BERNARD: We're going to have to address

1 salmonella for the summer sausage?

2 DR. ENGELJOHN: Yes. All ready-to-eat meat and
3 poultry products address salmonella. Both containing
4 fermented beef would also address 0157.

5 MR. BERNARD: Okay. Regarding the stabilization
6 standard, you're proposing that the stabilization standard
7 be continued throughout the transportation shelf life of the
8 product?

9 DR. ENGELJOHN: Yes. If I could just go over that
10 slide just so that you'll see. Could I have this slide
11 turned on for a second?

12 MS. GLAVIN: Okay.

13 (Pause.)

14 DR. ENGELJOHN: For stabilization, the performance
15 standards must be validated to maintain the requirements
16 throughout its shelf life under the conditions in which the
17 food is stored, distributed and held.

18 To get a -- in part we have been made aware since
19 we've issued the previous final rule, situations where
20 ready-to-eat cooked and cooled cooked products have been
21 sliced and then reheated either nominally or completely. So
22 the issue was then to address the performance standard, if
23 you're in that situation where you have control over both of
24 them, to address whether or not you're meeting the one log
25 growth of perfringen rule combination process.

1 MR. BERNARD: I'm trying to understand and I thank
2 you for that clarification. If I am a processor, for
3 example, I'm going to pick a species -- let's see, it's a
4 whole muscle piece that is to be sold to a distributor for
5 further distribution. Where does my burden as the primary
6 processor end, with regard to this performance standard?

7 DR. ENGELJOHN: While you have control over the
8 product -- operation and you're applying the heat treatment
9 or in some fashion having to deal with the stability
10 performance standard so that you cool that product properly.
11 While it's under your control, you would have the
12 obligation to meet these performance standards.

13 So once you -- as an example, once you heated it,
14 cooled it and then when you open it out of the package and
15 slice it and then pour gravy on it and then repackage it and
16 then cool it, you would deal with that as an entire process
17 and ensure that you are meeting this performance standard.

18 Once you've cooled it down sufficiently so that
19 microorganism then becomes an issue, then the intent would
20 be that that goes on into distribution and wherever the next
21 point is, whoever has control over it at that point would
22 deal with the performance standard at that point.

23 MR. BERNARD: Okay. And as a final question, do
24 we have any information regarding -- that would lead us to
25 believe that products produced in current convention in

1 terms of performance standards or whatever the current
2 convention is. If the product is properly cooked according
3 to current convention, have we had health problems due to
4 survivors?

5 DR. ENGELJOHN: Did you mean for the organism
6 stabilization or for the lethality, as well?

7 MR. BERNARD: For the lethality? For example,
8 using the current, I believe it's five log inactivation for
9 fully cooked patties? If someone has met that, does that
10 result in any problems?

11 DR. ENGELJOHN: The Agency, before the proposal,
12 we had a discussion about the modification or the proposed
13 modification to the cooked meat patty requirements. For
14 those of you not familiar with cooked meat patties, we
15 presently have a prescriptive requirement for cooked meat
16 patties for in that they have to meet a very specific
17 time/temperature combination to make them ready to eat and
18 that we believe to be a five log reduction for salmonella.

19 This proposed rule would change that and make it a
20 -- we're proposing a six and a half log reduction for cooked
21 meat patties. We do not have evidence or reason to believe
22 that the current processes are inadequate but the proposal
23 goes through the discussion, and I would encourage you to
24 specifically look at the discussion in the Preamble, that
25 identifies that in order to establish our worst case, which

1 we are using the national baselines for raw beef, the same
2 materials used to make the roast beef products or other
3 roasted or cooked beef products are also used to make the
4 cooked meat patty products.

5 Because we've established the worse case on the
6 highest, most probable number we have then determined that
7 the roast beef category and the cooked meat category should
8 have the same performance standard, which is a six and a
9 half log reduction instead of a five. The Agency is
10 specifically looking for comment on that issue and whether
11 or not the assumptions that the source materials are the
12 same and should be derived differently.

13 I did mention that in order to determine the worst
14 case for the meat products for lethality we pooled the
15 results from the ground beef baseline surveys and the
16 carcass surveys and made them into one sample set. If for
17 your analysis and your belief that they should be maintained
18 separately, that is what the Agency is seeking comment on,
19 so that we can make the determination that there may need to
20 be different performance standards for different categories
21 of product.

22 MR. BERNARD: Thank you.

23 MS. GLAVIN: Stan Emerling.

24 STAN: Stan Emerling representing the American
25 Meat Processing Association. I guess for clarification in

1 listening to the requests of definitions of what we're
2 talking about; are you considering going in the direction of
3 putting things that are cooked, fully cooked, ready-to-eat
4 into different categories for each one of those? I remember
5 back from years ago, there was a big confusion as to what
6 beef products -- .

7 DR. ENGELJOHN: I would -- just so that you
8 formulate your comments on that issue. The Agency doesn't
9 specifically -- was not specifically looking for comments on
10 how we should define products as what's ready-to-eat and
11 what's not ready-to-eat in terms of what goes in the product
12 label.

13 Although that certainly can be a comment that you
14 register for this rule, since definitions as to what they
15 apply to for the lethality standard versus what they apply
16 to for consumer distinction. And I would encourage you to
17 continue to think about those issues.

18 I will say that the Agency through the Listeria
19 reassessment that we had years ago and had the issues on --
20 relating to not ready-to-eat versus ready-to-eat -- we did
21 provide guidance in the directive that we issued to our
22 employees as to some of the criteria that can be used to
23 make some distinctions of when a product is ready-to-eat and
24 when it's not. Some of that relates to how the product was
25 labeled and whether or not that's distinctive enough for the

1 consumer to be able to discern whether or not they need to
2 handle this product differently if it's not a ready-to-eat
3 product.

4 MS. GLAVIN: Katie and then Bruce.

5 A PARTICIPANT: Katie -- from the National Food
6 Processors Association. I have a stabilization question for
7 you. In your guidance document you indicate that several
8 steps can be done to demonstrate that someone's meeting the
9 performance standards for cooling is going to get cool --
10 and you indicated -- you said that -- that was because it
11 grows faster than C. botulimon and -- yet in the Preamble
12 the suggestion that under certain circumstances there may be
13 -- . Can you clarify this?

14 DR. ENGELJOHN: I would say that the Agency --
15 that the Agency made some assumptions in the Preamble on the
16 issue of stabilization that C. perfringens generally grows
17 faster than botulimon and that under most circumstances
18 there are other inhibitors there that could be addressing
19 botulimon. Through your validation studies it may not be
20 necessary to do so.

21 What we would look for is if you as a company were
22 to address this issue would be to assume if this were to be
23 a final rule, or if you're making the poultry products and
24 the roast beef products today that you would still need to
25 address the issue of botulimon because they are regulatory

1 performance standards.

2 So in your hazard analysis of what areas that
3 you're doing you would still need to address that particular
4 organism or any other -- that may, in fact, be there as part
5 of the toxins or toxin compatibytes that could grow out.

6 But specifically for stabilization, perfringens is
7 the one that we were most concerned about because of the
8 inhibitors that we're aware of for botulimon. We would
9 expect you to have that type of documentation on file as
10 part of your HACCP program.

11 MS. GLAVIN: Katie.

12 MS. SWANSON: I'm Katie Swanson with the Pillsbury
13 Company. I have a related question. I'm not aware of --
14 I'd like the Agency's comments on the types of methods or
15 validation that they would expect to have with respect to
16 botulimon growth because the technology in that area really
17 isn't available. I mean how do we do it?

18 (Laughter.)

19 DR. ENGELJOHN: I have no help.

20 (Laughter.)

21 I'm sorry. In terms of the question you're
22 asking, if you were an industry member and you wanted to do
23 your own validating studies to address those services the
24 stabilization performance standards --

25 MS. SWANSON: Mm-hmm.

1 DR. ENGELJOHN: And you're asking for guidance. I
2 haven't indicated it today but I will make it -- I do know
3 that people that work on our technical compliance guidance
4 are here and we'll get together and we will, in fact, take
5 up that issue specifically in terms of the compliance
6 studies that we put together.

7 I'm hearing that we need to provide more guidance
8 on doing validating studies and I can tell you that within
9 the Agency, validation determinations are something that we
10 are actively working on as a separate issue.

11 But in terms of the compliance guidance, I clearly
12 will make a note of that. I do believe that we can and
13 should be making more information available to you. We'll
14 be seeking from you, the industry and academia, assistance
15 or guidance and input as to what would constitute
16 sufficiency for those issues.

17 MS. SWANSON: Okay.

18 A PARTICIPANT: Excuse me, I'd like to make a
19 comment. C.botulimon, if you recall about 10 years ago, Dr.
20 Weingarten (phonetic) published a paper regarding the
21 requirements or the guidelines for -- studies in
22 C.botulimon.

23 Traditionally -- toxin production that has always
24 been a concern and all the publications in the past have
25 been related to that kind of toxin production. And of

1 course, as Dr. Engeljohn mentioned, there is nothing
2 available as far as the minimum number of what -- cells of
3 C.botulimon or the extent of growth that is required to
4 produce a particular level of the toxin, and this is
5 documented in the research on the kind or the germination of
6 C.botulimon cells.

7 MS. GLAVIN: Bruce and then Joe.

8 MR. TOMPKIN: If I may --

9 MS. GLAVIN: First can you introduce --

10 MR. TOMPKIN: My name is Bruce Tompkin and I'm
11 from ConAgra. First I'd like to know, at this point in the
12 deliberations we are just asking questions for clarification
13 of what was just presented, correct?

14 MS. GLAVIN: Yes.

15 MR. TOMPKIN: Okay. With regard to C.botulimon we
16 have had an extensive botulimon challenge testing program in
17 place and companies for which I have worked, going from
18 about 1955 through '85 and we are no longer in that
19 business. Quite frankly, the policies with regard to having
20 mice in facilities is very strictly controlled.

21 The number of laboratories available in the United
22 States for conducting botulimon research is very small, and
23 historically I'm hard pressed to come up with an example of
24 a meat or poultry product that has been implicated in
25 botulism -- was produced under Federal inspection and that

1 goes back through decades.

2 So I think we're lacking epidemiology -- concern
3 for the pathogen and suggest that we delete it from
4 consideration in this proposal and that we focus on the
5 target organism of concern and that is C.perfringens.
6 My third -- if I can switch to the third topic --

7 MS. GLAVIN: Sure.

8 MR. TOMPKIN: -- it relates to an entirely
9 different thing and I don't know that you can -- anyone can
10 give us the answer today but I would like to see the Agency
11 pursue the answer to this question.

12 In the baseline studies the data are presented in
13 terms of number samples and number samples positive and for
14 those samples that were positive, quantitative measurements
15 were made. The values were recorded as log mean and
16 geometric mean.

17 A footnote states, "Estimates, these estimates for
18 log mean and geometric mean" -- estimates, they're estimates
19 -- "and they are weighted by weekly production with an
20 adjustment for the non-responders and non producers."

21 I don't know what that means but it almost sounds
22 like they biased the data or slanted the data based on
23 weekly production in the facility and that was a single
24 sample. So I'd like to know whether that was true or not
25 and what that did to the data?

1 DR. ENGELJOHN: That would be something that need
2 to address in our analysis of comments that come in. If we
3 can do something ahead of that time if there is another
4 opportunity for us to have a follow-up in any case in a
5 public way then we'll be -- we'll try to have an appropriate
6 response for that, as well.

7 MS. GLAVIN: Joe?

8 JOE: Good morning, Maggie. Thank you. Dan, I
9 want to revisit the citation that you have up right now.
10 They raise some questions at least in my mind when you were
11 talking about it.

12 It was clear enough that if you have a one log
13 target during chilling or cooling with the stabilization of
14 the product and if you heat it again you have to you have to
15 hit at that target again. But the way this reads, it says
16 that, I cook my product, I stabilize it, I meet the target
17 and then I put it into distribution, my warehouse. If I
18 have a 16 week shelf life product. If this goes out during
19 that 16 weeks I fail. Is that the intention?

20 DR. ENGELJOHN: Part of the way the performance
21 standard for this particular issue is written is that in the
22 identification of your hazard analysis and your HACCP
23 planning, you would be developing your program to address
24 the expected handling practices of your product. If, in
25 fact, you're going to -- if you have identified that this is

1 going to have a long distribution or it's going to be held
2 under fluctuating temperatures, our expectation is, it's
3 written that would address those in the way you've address
4 your survey --

5 JOE: Part of the discussion that's come up during
6 listeria, shelf life and outgrowth and what not, but as this
7 was originally proposed I understood it to give a different
8 type of target, a process control target here and it seems
9 to imply something different now.

10 DR. ENGELJOHN: At least the way it's worded.

11 JOE: Excuse me?

12 DR. ENGELJOHN: I would just -- if you could just
13 in your written comments, if you could just make it real
14 clear as to the differences of how you think it's being
15 interpreted now versus what you thought it was before.

16 JOE: Well, I can do that real quick. On your
17 conditions in which food is stored, distributed and held
18 your prior discussion with Dane was clear enough, if it
19 changes hands, it's no longer my problem, it's somebody
20 else's.

21 But I'm holding it in my warehouse and it's
22 already met the target temperature, stabilization
23 temperature, without allowing one log outgrowth of
24 C.botulimon which is specified.

25 But the way this is written right now it's open-

1 ended so that if outgrowth were to occur even though I've
2 hit all of your defined targets, your standards, I can still
3 fail.

4 DR. ENGELJOHN: Okay. We will reassess this
5 language and see if we can make it more clear.

6 JOE: Okay. Thank you.

7 DR. ENGELJOHN: Thank you.

8 MS. GLAVIN: Yes?

9 MS. RICE: That same language I believe appears in
10 the lethality section, as well.

11 DR. ENGELJOHN: Yes. The language is exactly the
12 same in lethality. I can tell you on the lethality in part
13 it's -- the issue here is that it's maintaining. The
14 lethality is in part to prevent recontamination while it's
15 under your control. So in part, that's what this deals
16 with. But clearly we will look for whatever input that you
17 give us on this and we certainly will take this under
18 advisement for clarity.

19 MS. GLAVIN: I'd like to suggest if people are
20 amenable that we take a brief 10 minute break for people to
21 collect their thoughts. There has been alot of good
22 discussion.

23 (Off the record at 10:20 a.m.)

24 (On the record at 10:40 a.m.)

25 MR. DERFLER: Does anybody have any remaining

1 questions? Does anybody have any remaining questions about
2 the presentation this morning? Come right up Stan.

3 MR. EMERLING: I'm Stan Emerling. I'm having a
4 serious problem with how plausible some of the issues that
5 were brought up are, concerning how far do we go in
6 checking? I can't even see how a distributor who takes a
7 fully cooked product is responsible for maintaining the
8 parameters, if you say. First of all, I'm not sure how the
9 -- first are vilified.

10 You would have to guess under a HACCP plan, you
11 could decide whether it's even further distributed -- which
12 would be a compliance issue. But then I'm having trouble
13 because if it goes down one way it's written, whether it's
14 in the refrigerator of the consumer at home, and let it rise
15 above what -- you can go in and check their fork -- this is
16 just out of the top of my head, but I'm having trouble with
17 the way it's written, if that's the way it could be
18 interpreted but also how would you identify it -- ? Thank
19 you.

20 DR. ENGELJOHN: I thank you for your comments and
21 I think we got the message that the language may need some
22 tweaking just to make clear that while this product is under
23 the control of an establishment they have certain
24 responsibilities for it. Once it leaves their control that
25 responsibility changes somewhat.

1 Although, if you don't have a "keep refrigerated"
2 statement on there, you don't have the types of controls in
3 place that give the purchaser of that product some
4 indication of how to properly handle it, then that is a
5 concern. This was not intended the way it was written to
6 change the current practices that are in place. It was just
7 intended to make clear the obligations in meeting the
8 performance standards.

9 So if it still is confusing to you I would
10 encourage you to make more clear your concern about this in
11 your written comments.

12 A PARTICIPANT: Okay.

13 MR. DERFLER: Any other remaining concerns about
14 the presentation you heard today?

15 MS. SCOTT: Jenny Scott, National Food Processors
16 Association. Dan, I'd like you to clarify something with
17 regard to cooked product that is subsequently reheated.
18 Where there's language in there that suggests that two
19 cooling steps combined should yield no more than one log
20 growth of C.perfringens.

21 But if you're receiving a fully cooked item from
22 another manufacturer and then heat it yourself and cool it
23 down, are you expected to go back to that manufacturer and
24 get data on whether you've got one-half of log growth of
25 perfringen -- so that you can adjust your cooling? Is that

1 the intention?

2 DR. ENGELJOHN: There's a certain way that it's
3 written up in terms of the premium on the discussion on this
4 performance standard, was that we waived the issue of
5 multiple processing status. And that we really didn't get
6 from industry and academia on the issues related to how we
7 applied this performance standard.

8 I would say that the way that it's written there
9 would be in part that you have the obligation to look at it
10 in a cumulative manner. We brought up that discussion in
11 the Preamble so that we could get comment on that, but it
12 was also intended to raise the issue of could this
13 performance standard for stabilization be more clearly
14 written, written in a manner to provide you some greater
15 flexibility. You don't have flexibility with it right now,
16 it's a flat one involving growth and -- we have received
17 suggestions before and we are expecting to receive written
18 supportable comments on the issue of maybe making the
19 performance standard more flexible.

20 MR. HARRIS: I'm Joe Harris with Southwest Meat
21 Association. I have a question about the -- on the
22 stabilization performance standards. In your presentation
23 today on the proposed rule, cured products really didn't
24 specifically address relative to the stabilization and the
25 potential growth of particular *C.perfringens*.

1 In some of your previous rulemaking, there was a
2 provision for a delayed chilling, a slower chilling process
3 with cured products. I guess my question is do you remember
4 similar provisions being provided? Secondly, how does the
5 Agency go about determining that?

6 I'm really not aware of any process -- problem
7 with outgrowth of perfringens on cured product. Almost --
8 chilling or lack of chilling conditions. So I guess I'm
9 just interested in how the Agency is approaching that.

10 DR. ENGELJOHN: I would suggest that when you have
11 the opportunity, look through the rule and if you can --
12 also look at the compliance guidance that's sitting out on
13 the table in the lobby.

14 We haven't changed our provisions with regard to
15 stabilization for the ready-to-eat products, those that have
16 been cooked and that contain cure, and that in the Appendix
17 B to the final law on roast beef and cooked poultry, we did
18 include additional guidance for ready-to-eat products that
19 have been cooked and then cooled, but contain a minimum
20 level of nitrites to control those C.botulimon and to
21 control the perfringens.

22 So the current -- compliance guide, Appendix B,
23 does contain some examples of sufficient cooling procedures
24 or stabilization procedures for cured products but they're
25 also dependent upon a minimum level of nitrite.

1 The Agency is open to additional new data or
2 information that would support additional or alternative
3 cooling for cured products. If you make that information
4 available to us and it would necessitate a modification of
5 the compliance guidance, that would be what we would want to
6 do. So I would encourage you to provide that.

7 The Agency has made the determination though that
8 all ready-to-eat products, in this proposed rule anyway,
9 will need to address the performance standard for
10 stabilization whether or not they're cured.

11 MR. HARRIS: Okay.

12 MR. DERFLER: Go ahead.

13 MS. SCOTT: Jenny Scott, National Food Processors
14 Association. With regard to the lethality performance
15 standard, this is proposed for meat and poultry products.
16 But if you're starting with a fully cooked item where the
17 meat or poultry product has already met the performance
18 standard, is it the Agency's expectation that when you
19 combine this with other -- you need to give it the same
20 lethality step again, or could an alternative be designed
21 based on what you feel might be necessary with the
22 ingredients that you are adding to the product?

23 DR. ENGELJOHN: Again, there was a very limited
24 discussion about this issue of entrees and application to
25 this lethality performance standard.

1 If you're simply assembling products, that's one
2 issue for which the Agency is seeking comment as to how the
3 Agency should apply the performance standards to products
4 that are just simply formulated as opposed to processed, in
5 which the lethality is -- or is necessitated. So I would
6 say that we are looking for input on that issue.

7 We do see a distinction between formulating or
8 just assembling versus actually applying an additional
9 process that would impart some type of lethality. In any
10 case, we believe that the alternative probability that's
11 provided there, should provide the flexibility to address
12 that issue.

13 MR. DERFLER: Anybody else with questions for
14 clarification?

15 A PARTICIPANT: On the -- on the cured meat
16 product, we have just completed -- in my lab we have just
17 completed the studies regarding the fate of C.perfringens in
18 the cooling of cured meat products, and the conclusion was
19 that C.perfringens is not -- of one fifty-six parts -- types
20 and all the cured beef, pork and poultry and -- .
21 The study will be submitted in a few months and once it is
22 published in the journal we will share the data with you.
23 Thank you.

24 DR. ENGELJOHN: Thank you.

25 MR. DERFLER: Are there any other questions?

1 (No response.)

2 Okay. Okay. Now we're going to shift to the
3 second part of the meeting, the second part of this phase of
4 the meeting anyway, which is to get your comments on the
5 proposed rule. There is an opportunity to sign up although
6 there will be plenty of opportunity to volunteer. We've
7 only got one name on the sign up list. Dr. Tompkin, the
8 floor if yours.

9 DR. TOMPKIN: It's a critical distinction to be
10 the only one. My name is Bruce Tompkin. I am with ConAgra
11 Refrigerated and Prepared Foods. I will be submitting
12 comments in writing when I have that opportunity to get
13 those together.

14 This proposed rule has significant implications
15 internationally. For example, I'm only going to discuss a
16 cooling phase in the regulation, proposed regulation. I
17 know that Australia has -- the UK both have adopted some
18 requirements specific to food. We compared them to see if
19 they illicit our experience or not.

20 What I have to say will be a result of some work
21 from Martin Kowenoski, Peter Bodner, Jennifer Smelder
22 (phonetic), and now Peyton Pruitt to some degree. But Robin
23 will be presenting information in the poster session at the
24 IAFFP. So some of this will appear at that meeting.

25 I will be addressing solely the stabilization

1 portion, which is -- cooling. As we all know, C.perfringens
2 certainly is a public health concern and one that we all
3 have to be addressing. It's most commonly associated with
4 cooked meat and poultry products and stews and a variety of
5 products in which meat and poultry are added.

6 To help me out, Caroline Smith DeWaal gave me this
7 last night, and I was able to then go through and pull out
8 the information relative to outbreaks that have occurred
9 since 1990 and there are some miscellaneous ones but
10 relative, and actually they are primarily meat and poultry
11 products, as history would tell us.

12 Mexican food -- there were only 39 outbreaks,
13 reported outbreaks that is, in the booklet since 1990. Of
14 course, it doesn't have complete information for the last
15 few years. We're still waiting for the CDC for that.
16 But there's just isolated cases of dairy products, tuna
17 salad. Mexican food is 11 out of the 39; beef, 13; corned
18 beef, which is cured, two; chicken and turkey products,
19 seven; and pork, three. So really it is a meat and poultry
20 issue, but we must not think only in terms of roasts or
21 whole turkeys. We're talking about Chicken a la King,
22 etcetera. So there's -- the reporting is not clear as to
23 the specific foods.

24 So we certainly do recognize this pathogen as
25 being a public health concern but the question is, as has

1 been puzzling me; has an outbreak ever been traced back to a
2 cooling defect in any state or Federally inspected facility?
3 I don't recall that any of these were associated with that,
4 just as I remember. Normally if we hear that some of us had
5 a problem, we would know about it. And the thing is, to go
6 back to maybe a handful that -- that may have occurred.
7 Historically, if I may, I've been in the business for 37
8 years and I have never been associated with a cooling defect
9 that led to a *C. perfringens* problem. I can assure you that
10 power outages did not start in 1995.

11 (Laughter.)

12 So there was a tremendous amount of product being
13 produced over these years and this never did really surface.

14 Certainly that doesn't mean that we can't be cautious and
15 concerned about this possibility.

16 But I am concerned as to why FSIS has become
17 increasingly concerned about the rate of chilling in cooked
18 meats and poultry products. I think it really comes back to
19 the use of challenge tests and the resulting predictive
20 models. Now please do not misread what I'm saying. I am
21 not against the use of challenge tests in predictive models
22 because I recognize the value they can provide. I've used
23 the predictive models and they have great value to us. I
24 don't think that's really where the issue lies, however.

25 Now I began -- for example, that this pathogen

1 multiplies very rapidly in the range of 90 to 120 degrees
2 fahrenheit and, yes, sodium nitrite does have -- has
3 virtually no effect on that rate of growth based on the
4 studies that we have done, also, in cooked poultry to do
5 that. So essentially our challenge studies verify what has
6 just been mentioned just a while ago. They're quite in
7 agreement with ARS.

8 The FSIS estimates derived from the baseline study
9 do lead to a worst case scenario of 10 and one-fourth per
10 gram of *C. perfringens* in raw meat -- . So for that reason
11 after cooking there is a one log increase and some of the
12 product would exceed 10 to the fifth.

13 In fact, it's stated, and this is a quote, "What
14 the amount of product that would exceed 10 to the sixth
15 would not be significant." Well, if you get a two log
16 increase instead of a one log increase, there's clearly a
17 deviation. In the worst case scenario, we would have people
18 sick because -- is generally considered the value with the
19 associated risk of *C. perfringen* illness.

20 So certainly the conclusion that FSIS reached,
21 that cook products under Federal inspection could be as high
22 as 10 to the fifth per gram and nearly 10 to the sixth under
23 normal conditions, is really a scary thought. That's why I
24 was wondering why the Agency has created the guidelines and
25 the recommendations to the industry, particularly in the

1 last five or six years. Under that scenario we could not
2 tolerate larger than a one log increase.

3 So again based on experience over the years and
4 knowing that cooling deviations have occurred historically
5 in the past and we haven't really seen a problem, the
6 question then is why haven't we been experiencing actually
7 numerous outbreaks from this pathogen with products produced
8 in Federally inspected facilities? Certainly history shows
9 this is not true. The question then is why? Why haven't we
10 experienced outbreaks of this nature? That's a question
11 that I think the Agency would have asked itself before
12 issuing it's cooling guideline requirements.

13 As a little side note, I really -- question -- I
14 really wonder how much money has been spent in the past five
15 years knowing what we've done in our own case to meet the
16 tighter requirements because they have become -- are
17 becoming increasingly tighter. I'm certain that large
18 quantities of food has been destroyed because the chill rate
19 was beyond the one log increase predicted by the model.
20 That is reality, also.

21 I also suspect that the impact has been greatest
22 among smaller producers who have lacked the technical
23 support to challenge the Agency's determinations as to
24 whether a lot is or is not safe.

25 Well, to get back to the science. Our lab has

1 been conducting studies to determine why these products from
2 these plants have not been or have been rarely implicated in
3 illness as a result of -- cooling. I'd like to summarize
4 and go through some things on what we have learned. First
5 I'd like to start with the baseline data. The baseline
6 studies conducted by the Agency did not look for the number
7 of C. perfringen scores. And that's a very important factor
8 because the real issue is what is a store population of raw
9 meat going into the cook step because it's that population
10 which will survive, germinate and then multiply.

11 The Agency assumed that the C. perfringen counts
12 reported in the baseline studies for raw meat and poultry,
13 also would apply after cooking. The analysis does not
14 include confirmation for C.perfringens. So the numbers
15 presented were not really confirmed as C.perfringens and
16 certainly it was not known whether they were spores.
17 Essentially all white colonies surrounded by a 2.4 -- were
18 assumed to be C.perfringens and counted. So, to summarize,
19 in the baseline data that were used to reach the worst case
20 scenario, really are not valid and have no true meaning in
21 terms of arriving at an acceptable or safe cooling
22 guideline.

23 So what is the actual spore level in meat and
24 poultry? Well, I'd just like to give you one example. In
25 cases of baseline study for raw and ground turkey, there

1 were 296 samples analyzed with 28.1 percent being positive
2 with a standard error of 3.3. The seven -- positive samples
3 were then subjected to a quantitative analysis and there are
4 done at the same time. I'm not sure how that was done. But
5 they came up with a large mean value of 2.08, something over
6 100 per gram.

7 So we've been doing studies over a number -- the
8 last few years, anyway. We produce ground turkey meat in
9 three plants and so we have had samples come in to us and we
10 have examined 154 of those. We're talking about samples
11 coming in over a period of months, if not years, certainly
12 months. What we did was to take the ground product and
13 place it into a bag and heat it to 160 fahrenheit just as
14 you would the product you would produce and then analyze it
15 for C.perfringens assuming that anything we would detect
16 would certainly be spores. All 154 samples were non-
17 detectible and at a less than three spore per gram count.

18 To take you back a little bit in history, in 1964
19 or '65 we did a year-long survey for the true effects of
20 anabolic spores in raw meat, poultry and chicken. This had
21 to do with a -- contract to determine the baseline level for
22 pH spores to see if they could arrive at radiation
23 treatments for food that would ensure their safety. This
24 was focused towards C.botulimon but the data and the
25 analysis would also have mentioned the presence of

1 C.perfringens.

2 It was slanted in a way that the samples were from
3 the bloody neck area of hogs and beef carcasses. What we
4 took from chicken I don't remember. But out of the 22,358
5 samples 77 percent had three or fewer spores per gram and
6 the remaining, 2.8 spores per gram. We too, have had some
7 deviations which were 180, I think you mentioned other than
8 that unfortunately, but we represent a variety of producers,
9 but we had 53 that we've examined over the last -- I don't
10 know -- four or five years past. We had been looking for
11 the prevalence and number of C. perfringens.

12 Initially we were analyzing for any -- plate count
13 and -- plate count, thinking that an -- plate count would be
14 adequate. I wanted to know is the product safe or not? But
15 the Agency had difficulty dealing with the manner of plate
16 count and they wanted a perfringens count. So we've now
17 started doing that, too.

18 We have growth on anaerobic plate count of 582
19 analysis across those lots. 425 were less than 100 and 55
20 showed some growth between 100 and 10,000 per gram. Then we
21 did have two that were in the range of 10,000 to 20,000.
22 But that's just anaerobic growth. They could also have
23 picked up lactics and anything else that survived the
24 process and then multiply.

25 Specifically, C. perfringens they analyzed 340

1 samples and 336 were negative and two were in the range of
2 11 to 100 and two had greater than 100 per gram and those
3 were 110 and 140 per gram. So it would appear that at least
4 they're not selective in terms of -- deviation. There were
5 deviations outside the guideline and we wanted to know what
6 is the acceptability of this product and what should we do
7 with it?

8 Well, another thing that we found, this is what
9 Peter Bodner found. That is not perhaps the sole answer, so
10 in his studies and the Chairman's study is do we inoculate
11 cooked ground turkey, essentially it's a turkey breast
12 formulation to which perfringen spores have been added prior
13 to being cooked and then subjected to different cooling
14 temperatures, 90, 100, 120, and so on.

15 We essentially followed the rate of both and
16 matched what we've been hearing. Then we put some packages
17 into the refrigerator and analyze them over time. After one
18 -- after a 24 hour hold in the refrigerator, there was a one
19 log reduction. After seven days in the refrigerator there
20 was a two log reduction. It didn't matter whether they were
21 held at 33, 40 or 50 degrees fahrenheit, the rate of death
22 was comparable in all three temperatures. So essentially we
23 have an unexpected, perhaps -- but it's in the literature --
24 we shouldn't be surprised at this, but it was an unexpected
25 benefit that Clostridium perfringens does die. So without

1 extensive growth, we have, perhaps that could help to
2 explain why there has been no issues.

3 So I'm going to go through a few conclusions and
4 then a few recommendations. The conclusions are that the
5 guideline, the cooling requirements, are really not based on
6 your solid scientific basis and that is important for us to
7 deal with. The wording within the FSIS material with regard
8 to cooling is not warranted. It's quite scary and --in a
9 way, you know, as I read it and it certainly communicates
10 concern for this one log increase, to the one log increase.

11 In essence, it's certainly understandable considering the
12 data that they had -- I'd like to also suggest that -- this
13 is kind of a bold statement -- that *C. perfringens* is not a
14 hazard that is reasonably likely to occur. Now I don't know
15 that I'm going to go that far, but I said it.

16 (Laughter.)

17 So that raises the question do you really need a CCP for
18 cooling? Of course. I would suggest that the majority of
19 *Clostridium perfringens* outbreaks actually occur at food
20 service and at home where the product is heated and held at
21 wrong temperatures and then consumed while a high population
22 is still present. Perhaps in the past where we have had
23 *perfringens* growth in some products, perhaps some die off
24 over the time between production and when the product is
25 actually prepared for serving or consumed that, in fact, the

1 population may have been low enough -- and this is
2 speculation, of course -- that the product was not
3 hazardous.

4 So then we can come to some recommendations. It's
5 one thing to say what I've just said and then stop, but I
6 think we need to address the potential for a public health
7 issue. Certainly the no more than one log increase is not
8 appropriate, but what would be? The Agency had assumed 10
9 to the fourth was the worst case so it would almost suggest
10 that we have up to 10 of the four to work with but I don't
11 know that we'll go that far.

12 That should be considered, whether it's a three
13 log increase or not is one possibility. Another way of
14 looking at this is that the performance standards should be
15 such that product will not have greater than 500 per gram at
16 the time that the product is released for shipment.

17 At the current time the Agency is of the opinion
18 that the risk of illness is best controlled through
19 processes that are based on challenge tests and predictive
20 modeling. Those two tools are very important to us but I
21 would suggest also that more is needed, and that is a
22 reality check that is based on historical commercial
23 experience and critical review of the epidemiological
24 experience data. Where do these outbreaks occur and why do
25 they occur?

1 I would also propose that in the event of a
2 deviation the product could be sampled. I know that the
3 guidelines discourage that. We have been doing it for quite
4 some time because we find it very helpful. Incidentally, we
5 have found lots that we have destroyed. We have found lots
6 where we just say, "Don't bother sampling." You know, there
7 is a point in time. It's not our intent to save every count
8 -- our intent is to produce and make sure that the products
9 that are released and shipped are in fact, safe poultry. So
10 this is not a means to avoid that responsibility.

11 I would suggest that a sampling plan and criteria
12 could be 10 samples and this is going to be working from --
13 approach and would equal 10. Little "c" would equal three
14 "m" 100 per gram and large "M" 500 per gram. These values
15 would be based on the current methods as currently used in
16 the compendium of methods and in the microbiology laboratory
17 guidebook. So in the event of a deviation, our sampling
18 plan should be an acceptable sampling considering the
19 pathogen and it's relative severity.

20 So, finally, there's one other part and there have
21 been questions here this morning that dealt with that; is
22 what do we do with these products that are cooked, chilled
23 and then reheated? For example, for smoking, browning,
24 caramelizing, searing and charring and in some cases post-
25 pasteurizing? Which is of course intended to address

1 listeria. But the Agency is almost saying we have to add
2 those times and temperatures to our calculations. I would
3 suggest that historically these also have not been
4 associated with microbiological issues of a public health
5 nature, anyway, and that they should be permitted to proceed
6 as traditionally has been done. Thank you.

7 MS. GLAVIN: Thank you. I'm sorry I missed the
8 beginning, but that was very thoughtful of you.

9 DR. TOMPKIN: That's what I did last night.

10 (Laughter.)

11 MS. GLAVIN: I would assume that there are
12 questions and comments for Dr. Tompkin. Anybody either at
13 this table or in --

14 MS. HANIGAN: Kim Hanigan, FarmLand Foods, just
15 going back to the question that Katie from Pillsbury asked
16 that also ties in with Bruce's presentation. FarmLand did
17 contract to have a large challenge study done in cooling,
18 very costly, very -- to what Bruce said. Companies have to
19 make a lot of changes here when these chilling requirements
20 kept tightening down. Particularly in our large volume
21 areas, and we've spent significant dollars having our
22 processes replicated and an outside commercial lab for C.
23 bot. and C. perfringens and the findings from the outside
24 laboratory that we contracted with support everything that
25 Bruce's work showed here today.

1 I think also that probably helps Katie over at
2 Pillsbury as to how you do these studies. We did not do
3 these studies in-house. To get someone in to replicate your
4 process, and move that to a different lab, and to get your
5 product over to the lab, and have it inoculated is extremely
6 costly to the company to have that done.

7 DR. ENGELJOHN: I would suggest that if possible
8 that that information should be made available as part of
9 the public process it would greatly help us inform our
10 office how to move forward as well as how to redevelop
11 performance guidance.

12 MS. WACHSMUTH: Bruce, did you anticipate --did
13 you expect anything to be any different with botulimon?

14 DR. TOMPKIN: OK, the question is whether or not I
15 run tests that may indicate different with regard to
16 Clostridium botulimon. Our experience here of course, we
17 really did work with the effectiveness of sodium nitrate and
18 Clostridium botulimon. But as was pointed out earlier, our
19 endpoint was time swelled, we did not look for rate of
20 growth as I recall. I have to go back two months, I'm
21 trying to recall a lot of data over a lot of years, and I
22 mean I don't recall that we really followed growth rates,
23 germination and growth rates.

24 But I would -- one thing, sodium nitrates effect,
25 according to the work done some time ago by Mike Forrester,

1 was that it actually interferes with germination. So it has
2 an early effect on the public health risk potential. Then
3 once its germination starts to multiply, other factors enter
4 in such as salt concentration and so on. So with the
5 presence of the amount of iron, there's a whole host of
6 factors that enter in.

7 But I would think that with regard to Clostridium
8 botulimon we do have a margin of -- in looking for
9 Clostridium botulimon in a variety of foods when that was of
10 interest. The prevalence rate was quite low for raw meat
11 and poultry.

12 DR. ENGELJOHN: This is Engeljohn. If I could
13 add, while you're thinking about it in your comments and
14 looking back at your data, one of the issues for which would
15 help us particularly would be if there is any new
16 information, any specific information, that identifies the
17 specific level of nitrite needed to eliminate germination
18 and new growth. I think that is some information that, as
19 we moved into ready-to-eat type products, we now have to be
20 concerned about what the minimum level of effectiveness is?

21 For nitrite, along with the other safety factors that
22 control things after germination, of course, would be --

23 DR. TOMPKIN: If I could add one thought about
24 Clostridium perfringens, Robin is now contributing to pursue
25 this idea. We want to better understand the effect of salt,

1 100 percent salt, on Clostridium perfringens. So we're
2 looking at different formulations and different salt levels,
3 mainly at 110 fahrenheit because we get a pretty good
4 probe there. So we're looking at different formulations, in
5 the case that it is product specific.

6 In the case of Cotto salami, for example, we got
7 no growth. I don't exactly know why that is, yet we'll try
8 to figure it out, because I think what we're going to get to
9 is there may be some -- out there in terms of relative risk
10 depending on the type of product. A lot of the early work
11 was done with a turkey product because it's high moisture
12 and low salt and certainly ideal for perfringens growth, and
13 turkey has been in the literature in terms of being
14 implicated in cases. So we know that bacteria grows rapidly
15 there, but as you go through the spectrum of a wide variety
16 of processed meat and poultry products, if you have
17 increasing levels of salt and other factors that could
18 interact, it could have an impact. So I think we want to
19 pursue that.

20 It would suggest also that Mexican foods and the
21 -- seems to place those in a little different category. I
22 don't know why we haven't found in our case, C. perfringens
23 in those samples. The epidemiology does suggest that
24 Mexican foods, whether it's the spicing and other things
25 that are inherent in the product, whether those have any

1 effect on the level that's in the food.

2 MS. GLAVIN: Is there a question here?

3 MR. KOBAYASHI: My name is John Kobayashi,
4 Washington State Health Department. I just have some
5 comments with regards to reporting of Clostridium
6 perfringens food poisoning.

7 I definitely appreciate the importance of having
8 documentation. The problem before regulations with regards
9 to the particular issue of -- . One warning that I would
10 have with regards to the absence of certain types of
11 C. perfringens outbreaks is that at least in my opinion
12 there might be different types of foodborne outbreaks that
13 we have. C. perfringens outbreaks are a little more
14 difficult to document and are documented less frequently
15 than many others such as 0157 listeriosis and so forth. You
16 don't have that sort of stuff with C. perfringens.

17 While it's possible to have a very severe illness
18 with C. perfringens and colitis, at least what we see in the
19 United States, it's something that's right on the lines of
20 viral gastroenteritis. When you have diarrhea of relatively
21 short duration, it's very difficult to convince people and
22 the department investigators that it's worthwhile to collect
23 the necessary source specimens to document that
24 C. perfringens has occurred.

25 I completely agree with Dr. Tompkin's assessment

1 that the type of outbreaks that we've found involving local
2 outbreaks, at least with the ones I've seen, didn't have the
3 flagrant, you know, temperature and cooling abuses -- on the
4 other hand, I'm not sure that I could say that widespread
5 outbreaks have never occurred. It may be that they've
6 occurred in the same way the listeriosis outbreaks have
7 occurred, but we just didn't have the tools to identify them
8 at this time. It might be a good idea to get some input
9 from the CDC folks as to how confident they are with regards
10 to the absence of widespread outbreaks of listeriosis and
11 C. perfringens.

12 Having said that, I think that it seems to me that
13 the big problem is not on the regulatory side, but it's, I
14 think, the academic epidemiologists who -- the tools that we
15 have with regard to C. perfringens investigations.

16 MS. GLAVIN: Thank you.

17 DR. TOMPKIN: This might be a good one to give to
18 the National Advisory Committee.

19 MS. GLAVIN: Well I think the members are here.

20 (Laughter.)

21 Question up here?

22 MR. SPERBER: I'm Bill Sperber with Cargill. I
23 didn't have the time to prepare a formal comment, but I will
24 organize some of our data and put some of it in writing.
25 I certainly would like commend Bruce for his formal comment

1 that reinforces my opinion and that of my colleagues that --
2 -- leading foodsafety microbiologists on the planet.

3 Incredible!

4 (Laughter.)

5 MR. SPERBER: But I would just like to say, as a
6 way of reinforcing his comments, though I don't have all of
7 our data on this; in our own cooked turkey operations, in
8 order to comply with stabilization requirements of 1999, we
9 have looked at thousands of samples of cooked turkey and
10 never found *C. perfringens*. All of the samples were less
11 than 10 per gram.

12 In the cooked beef side of things, we were
13 concerned about the remote potential of *C. botulimon* growth
14 during extended -- and in an effort to comply with the food
15 growth regulations; and this supports Katie Swanson's
16 request to harmonize according to and across the agencies.

17 We did an incidence study of *C. botulimon* in
18 cooked meat products. The actual incidents in terms of
19 percentages was very low. I don't remember the number,
20 whether it was less than one percent. The spores per gram
21 in positive samples was very low, talking in terms from a
22 barely detectible amount which is generally around 3 spores
23 per 100 grams. We did further characterization of those and
24 found that all of the -- *botulimon* which claim to be unable
25 to grow below 50 degrees fahrenheit and we in fact confirmed

1 that.

2 The concern of C. botulimon in a lot of -- in the
3 refrigerated areas is the potential for non -- strains to be
4 able to grow during the extended refrigerated shelf life.
5 But there never has been a reported case of botulimon from
6 non -- C. bot. in such products, and our data so far have
7 confirmed that. We don't even find alot of spores, quite
8 likely because they are quite heat sensitive and we kill
9 them in the normal cooking process. Thank you.

10 MS. GLAVIN: Thank you.

11 DR. TOMPKIN: That sounds fine. In the challenge
12 studies that we did do with clostridium botulimon, and there
13 are many. Using a canned ham model, we added salt and so
14 on, essentially formulating a canned ham, canned minced ham,
15 and we had zero, 50, 100 and 150 parts per million of
16 nitrite. Even in the cans to which nitrite was not added,
17 as I recall, it took from 100 spores per gram and it took
18 about two weeks for them to multiply to such a level for the
19 can to swell and become toxic.

20 All of that data is readily available still,
21 despite not being on the Internet, but all of that data are
22 available on clarifying any concerns relative to clostridium
23 botulimon outgrowth, and that was in -- that was in the
24 absence of nitrite.

25 MS. GLAVIN: Other questions or comments on this

1 presentation? Dane?

2 MR. BERNARD: Thank you. It's a difficult problem
3 in the plants for the food microbiologists and I certainly
4 echo their sentiments there. Two observations though if I
5 may. I heard one of our former colleagues once say, that a
6 microbiologist would rather use someone's else's toothbrush
7 than their methods.

8 In the discussion regarding D values and Z values,
9 echoes essentially that comment. I prefer seeing that when
10 we get into -- not really so much substantially, but could
11 significantly bog down the process here. I can assure that
12 if one goes through the literature and searches for D values
13 and Z values and salmonella in various products, you're
14 going to end up with quite a range of differences in those
15 numbers. Many of those differences will be related to the
16 methodology used at the time. I personally have my favorite
17 in terms of the methodology to be used, but that is
18 something we can -- we can share.

19 But I just caution and bring up the note that we
20 are going to find a lot of differences in the published
21 nature of what people may submit. I'm not sure that
22 focusing greatly on those differences is going to be very
23 fruitful because there are ways to get around that, and that
24 deals with verification and validation and information
25 generally which kind of brings me to my second point.

1 When I asked Dan earlier whether we had any
2 indication that current cooking practices were, in fact,
3 leading to public health problems, specifically that
4 question is, first all we have is survivors of pathogens
5 based on current cooks. And echoing John Kobayashi's
6 comment, maybe we don't know. I recognize that our data
7 simply isn't accurate for us to be able to tell when we have
8 a widespread outbreak, but to the best of my knowledge
9 having been a food processing authority for much of my
10 career, I do not recall a single incident where a well-
11 established, implemented and accurately executed food
12 processes proved to be the problem.

13 If one looks at the outbreaks that we have and
14 then John can echo this, the one outbreak I think that
15 stands out in people's minds is a restaurant-associated
16 outbreak where undercooking was the problem. We had gross
17 undercooking. The problem was not missing our target 155
18 versus 158. We're talking about temperatures of 120 to 130
19 versus 158.

20 So in my estimation, rather than focus greatly on
21 if the target is the right target, our money and time would
22 be better spent in focusing on how we achieve the targets.
23 How we implement, how we design and how we verify that we're
24 achieving the targets should be more beneficial than
25 reexamining the targets themselves. Just some observations.

1 Thanks.

2 MS. GLAVIN: Thank you, Dane. Other questions or
3 comments? Are there other people -- as you know, Dr.
4 Tompkin was the only one who was brave enough to sign up to
5 make a comment.

6 (Laughter.)

7 But are there other people who would like to comment on this
8 section of the program? That is the -- the presentations on
9 lethality and stabilization?

10 (No response.)

11 Okay. Then what I would suggest is that we ask
12 Dr. Engeljohn and his colleagues, I gather on the second
13 one, to walk us through -- they're not here yet? Do we need
14 them? Because we can take an early lunch and come back.

15 DR. ENGELJOHN: We can go.

16 MS. GLAVIN: You can go? All right.

17 DR. ENGELJOHN: Yes.

18 MS. GLAVIN: Dan's -- Dan's ready to go ahead.
19 This is requirements for the control of listeria.

20 DR. ENGELJOHN: I just need some help here with
21 the computer first, I locked it up somehow.

22 MS. GLAVIN: If you'll hold for just a few minutes
23 while we get our computer working.

24 (Pause.)

25 DR. ENGELJOHN: Okay. I'm going to walk you

1 through the portion of the proposed rule that deals -- deals
2 with the *Listeria monocytogenes* and the *Listeria* species
3 testing requirements. I'll remind everyone that this is
4 Docket No. 97-013P. You have the opportunity to submit
5 written comments and we'd be more than happy to help you if
6 you have questions about how to do that as an individual or
7 as an organization. The actual references in the Federal
8 Register which published on February 27th -- and again the
9 comment closing date has been extended now to June 28th.

10 In the new -- in the proposed rule, Section 9 CFR
11 433.4(a) we identify the controls for proposed testing for
12 *Listeria* species. This is an either/or condition with
13 regard to the requirement. Either control is through HACCP
14 systems of preventive controls, which would identify
15 *Listeria monocytogenes* as a hazard reasonably likened to
16 occur after lethality treatments but before final packaging.

17 This control for *Listeria monocytogenes* is non --
18 HACCP system, then it needs to be controlled by *Listeria*
19 species for testing of the food contact surfaces. So the
20 requirement would be that you would test food contact
21 surfaces using the sanitation standard operating procedures
22 for *Listeria* species. There's a mandatory requirement for
23 the SSOP verification activity for *Listeria* species. For
24 large plants there would be a minimum of four tests per line
25 per month. For small plants it would be two tests per line

1 per month and very small plants will be one test per line
2 per month.

3 For those of you not familiar with the size
4 requirements, a large plant would be an establishment with
5 more than 500 employees, 500 or more. A small one would be
6 499 or less or fewer employees, but more than 10, and a very
7 small plant would have 10 or fewer, or less than \$2.5
8 million in annual sales.

9 Sanitation SOP testing requirements for listeria
10 species, in Section 9 CFR 430.4(b) results of listeria
11 testing would be used to verify sanitation SOPs. This would
12 be for preventing direct product contamination or
13 adulteration of the product and the results must be made
14 available to FSIS for review. This is the regulatory
15 language contained within the proposal. In Section 9 CFR
16 440.4(b) this is a positive listeria species result.
17 Establishment must take corrective actions under 9 CFR
18 416.15(a) and (b), this is the sanitation SOP section of the
19 regulations, to determine and demonstrate that the effective
20 lot or lots are not adulterated with *Listeria monocytogenes*.
21 You do this to determine which lot or lots are effected.
22 The establishment would hold sample and test products for
23 *Listeria monocytogenes* and would have procedures in place for
24 disposal of effected product. That's the listeria testing
25 requirement section.

1 MS. GLAVIN: All right. Any questions or comments
2 on this section? Perhaps, any food microbiologists from the
3 plant?

4 DR. TOMPKIN: Well, I'd prefer to wait until after
5 lunch, whatever I am.

6 (Laughter.)

7 The Agency has assumed that relevant to plant size that the
8 larger facilities would certainly have greater impact with
9 regard to the amount of exposure and the number of
10 individuals affected and that's not questionable.

11 However, the majority of listeriosis in the US and
12 elsewhere, is really associated in isolated cases. If we
13 think through, what does that mean? One of the cases that -
14 - just had recently was franks of 101 cases, and yet we're
15 thinking in terms of approximately 2,500 per year. What
16 really counts for the rest? If they are isolated cases, I'm
17 not certain. While the focus for this Agency in our
18 discussions is on, of course, meat and poultry products, I
19 think we should think in terms of foods in general. But I'm
20 not certain that we could really reach a conclusion that
21 size of the establishment really has a relationship to rate
22 of exposure in these isolated cases.

23 MS. GLAVIN: Thank you. Other -- Kaye? I think
24 Kaye had her hand up. Go ahead.

25 MS. WASHSMUTH: I just have a comment on Bruce's

1 comment. If we have a smaller population, a susceptible
2 population, that would be -- that could develop listeriosis,
3 then exposure would be in relation to the amount of
4 contaminated product in the market. If something happened,
5 if we had a catastrophe at a large plant, than the
6 consequences could be much worse.

7 DR. TOMPKIN: That's certainly correct.

8 MS. GLAVIN: Katie?

9 MS. HANIGAN: Katie Hanigan, Farmland. One
10 concern I have when I see the portion under listeria control
11 via an SSOP program. I have walked through in my mind what
12 this would do to one of Farmland's plants. Just to keep the
13 numbers simple, if you will. If you're a plant that has 20
14 packaging lines and you have four different lots of product
15 going down it each day, because we are under listeria going
16 from clean up to clean up, we no longer have this two hour
17 window of military coding (phonetic), and I know we're all
18 up to date on that. But you could literally have four lots
19 of product go over each one of those lines. So on any -- if
20 you've got 20 lines and you've got four lots of product
21 coming off of each line, already your at 80 lots of product
22 and now we're going to do this four times a month, each line
23 is going to be sampled four times a month. I'm making the
24 assumption here, I'm a large plant. I have 320 lots of
25 products that I would want to hold in the event that my

1 product contact surface was positive for listeria species
2 positive.

3 The concern I have is we physically don't have the
4 capacity to hold that type of product in-house at the plant.

5 We don't have the storage room. We wouldn't have enough
6 trailers to put it on to keep them on the premises. So then
7 if you'll try to ship it off-site to a public warehouse,
8 then pretty soon I'm going to be in violation of the 1996
9 Pathogen Reduction Act because I shipped it off-site. I've
10 now put it into commerce by the definition that we're now
11 using of going into commerce.

12 So now I have an invalid I would assume, HACCP
13 program, or an inadequate HACCP program, if I ship this
14 product to a public warehouse to store it while I'm trying
15 to hold on and wait for my environmental results. I'm just
16 wondering if the Agency has considered how companies are
17 going to implement this? If you look at a company that has
18 multiple plants like myself, I have 11 plants. When we
19 start tagging up all this product all over, from all these
20 plants, I don't think there's enough refrigeration capacity
21 in the United States in warehousing to hold all this.

22 Of course, I don't think a company would be
23 willing to send the product out into the marketplace and run
24 the risk of getting a positive environmental on product
25 contact, and then try to take corrective action to prove the

1 product coming off of that line is negative. I mean you
2 just couldn't run that risk.

3 DR. ENGELJOHN: Thank you for the comment that
4 you've described. I say that it really is important for you
5 to address that in your written comments, particularly the
6 economic impact issues of that. The Agency did consider the
7 issue of storage and holding the product while testing does
8 occur.

9 I do want to just make one clarification statement
10 that you did say that if you were to ship this product into
11 a warehouse -- you would not be allowed to do that. I just
12 need to clarify that the Agency has provided some clarity in
13 the past in parts of the regulation directive that we did
14 issue, that the definitions of shipping and produced may
15 have different connotations. You can still have control
16 over the product and you haven't completed the shipment in
17 your records. So that you still have control of that
18 product and have not completed the shipment records, and you
19 want to store it in a warehouse off-site while you're
20 getting the results -- that way, that's perfectly
21 acceptable. If that does appear to be a problem with how
22 it's being addressed, then that's something that we need to
23 know to make sure that we are communicating that informally
24 today.

25 So I just want to clarify that one issue. Did you

1 mean that you had completed your shipment reviews when you
2 shipped it out, or you had not completed them?

3 MS. HANIGAN: I meant that we have all the CCPs
4 which were applicable to this product would be within the
5 establishment. My understanding, Dr. Engeljohn, of what you
6 just said was that only applies if I have a CCP located at
7 this warehouse and that would not be the case. I'm saying
8 for us all our CCPs would be located within the
9 establishment. Are you saying that even though they've all
10 -- they're all located within the Farmland establishment,
11 you can still ship that product without doing record review?

12 I don't think that's the current interpretation. I think
13 the last CCP would have to be at the warehouse. So if
14 you're talking about a warehouse located 200 miles from you,
15 going over to look at this CCP and do a record review, that
16 in itself presents a whole other facet to this.

17 DR. ENGELJOHN: We'll make a special point of
18 looking into the issue to see how we are implying this. I
19 would say that it is not our intent to have you to do a CCP
20 elsewhere. If you still have control of the product,
21 similar to your own status in which you can pull that
22 product back, that was again the consideration that the
23 Agency had, but we will certainly follow up on that issue.

24 MS. HANIGAN: And you want me to comment on that,
25 as well, as to what the definition of in transit -- into

1 commerce means? You want that included in the comments?

2 DR. ENGELJOHN: Well, yes we would like that as
3 part of the record of what you're going to submit, but we
4 can -- I will look into this other issue as well meanwhile.

5 The Agency did make clear that we are looking for
6 economic impact data, particularly with regard to what the
7 plants do with present practices and what alternatives or
8 suggestions that you would have for how to deal with the
9 issue of listeria species positives and the handling of that
10 product.

11 If we are presented with sampling plants that are
12 based on science with regard to how such a program should be
13 devised, that's the type of information also that we're
14 looking for.

15 MS. HANIGAN: Katie Hanigan still at -- still
16 with Farmland. One other thing that I think would be
17 helpful, if the Agency could provide some guidance material
18 as to really what is a scientifically or statistically-based
19 sampling program, because those questions continue to come
20 up more and more for those of us out in the field.

21 Once you look at if you do have a generic positive
22 for listeria species, if you get into a sampling plan that's
23 involving thousands of cases of product how much testing is
24 enough?

25 DR. ENGELJOHN: It's a very good point. When you

1 recognize that the guidance available to the industry, in
2 particular small businesses, it's critical. We do want that
3 kind of information. We did not have access to such
4 information when this rule was pulled together.

5 I do want to just make it clear because I know
6 there may be some misunderstanding of the intention of the
7 proposed requirements for listeria species testing. FSIS
8 has proposed the minimum testing requirements that we deem
9 necessary to have documented within the control programs
10 that you have for verification of SSOPs. Those -- the level
11 or frequency of -- was not determined to be based on
12 scientific efficacy of an appropriate SSOP. So that was the
13 piece that we did not have and that we made -- we tried to
14 make clear in the Preamble that we were seeking information.

15 If we had that information, as quickly as we have it, we
16 can make it available today for comment and guidance as part
17 of our compliance information. It also would inform us on
18 how we should proceed with -- completion on this issue.

19 A PARTICIPANT: Charles from -- I guess I'm a
20 little bit confused because I'm looking at this document
21 that not everybody has seen yet. But to Katie's point, if
22 the samples surface, and we get a positive, and hopefully
23 that product's in the warehouse. But this document here
24 says, "Results and follow-up based on product contact
25 surfaces."

1 It says, "Once the product contact surfaces found is
2 positive for the number of samples indicated in the HACCP
3 plant for listeria species, the next modified -- sample and
4 test -- ." So that indicates to me that if my HACCP plants
5 tests -- positive twice in a row, for example, then maybe
6 I'm testing -- I'll have to test the next lot. But now what
7 you were saying is that if I find any positive at all, I've
8 got to go back and test the lot.

9 Basically in the conversation yesterday I think we
10 resolved that there is no really a true coloration of
11 listeria species. There was in some cases and in some cases
12 not. So I just look for some clarification on exactly where
13 we're going with this?

14 DR. ENGELJOHN: Again, part of where the Agency
15 was coming from that the issue here is to be able to make a
16 determination that product that potentially is effected by
17 the listeria species positive on a product contact surface
18 already the product is not adulterated. The issue is to
19 make a determination from the justifications and the type of
20 reasoning that you as an establishment would have to
21 determine why your product would not be adulterated. You
22 can look for guidance of whatever it is you want to see in
23 the compliance guide and programs that we put together as to
24 what would be helpful.

25 MS. RICE: Kim Rice with the American Food

1 Institute and Dan you may want to answer this question after
2 lunch when your other colleagues get here. There were a lot
3 of -- and you indicated in answering some of these questions
4 -- a lot of requests for data in this session. And the
5 Agency was up front that they didn't have data to justify a
6 lot of what they were proposing. It would be helpful to us
7 in preparing our comments if the Agency could at least
8 review this afternoon, and perhaps later provide us with
9 exactly how they need that data to make a decision, because
10 we've been down this road where you ask for data and we give
11 you data that's not exactly how you may have wanted. So
12 we've got to go and redo the data oftentimes.

13 So I would just ask that if you want to handle
14 that right now, we can do that or if you want to wait until
15 after lunch that would be very helpful for those of us who
16 are trying to pull information together from our members and
17 for those companies that are doing it on their own, as well,
18 to know exactly how the Agency wants it and what they're
19 going to need to make those decisions to justify what you're
20 planning to do.

21 DR. ENGELJOHN: I think we can try to come up with
22 some thoughts on what we think would be -- can you tell me
23 what issue you're addressing though? Are there specific
24 issues that you are referring to?

25 MS. RICE: I'm talking about this particular

1 section of the rule.

2 DR. ENGELJOHN: Right.

3 MR. DERFLER: Are there any more questions?

4 MS. HANIGAN: I have one more.

5 MR. DERFLER: Oh, I'm sorry. Go ahead.

6 MS. HANIGAN: Perhaps you could answer this this
7 afternoon. But as I understand it -- SSOP program that
8 there was, if you will, the way it was proposed, there was
9 no option at the first listeria species positive on the
10 product contact surface meant I had to, if you will, prove
11 the product coming off the line was not adulterated. This
12 is where I get confused. I thought if I had it in my HACCP
13 program based on what these compliance guidelines are
14 written, that if my HACCP program says I'm going to look for
15 a trend on the product contact surface that we would take
16 action based on what my HACCP program is saying. Is that --
17 is that not correct?

18 DR. ENGELJOHN: I'll just make some clarity there.
19 There is a slide that I showed you that gave an either/or
20 situation. You control *Listeria monocytogenes* through your
21 HACCP plan as a exposure for ready-to-eat meat product post
22 lethality treatment -- control it that way how you deem
23 necessary in your HACCP plan. And you follow up through
24 your HACCP plan as to how you're going to propose your
25 corrective and follow-up action and how you're going to deal

1 with a listeria positive result as part of your HACCP
2 ongoing verification.

3 If you don't address *Listeria monocytogenes* in the
4 HACCP plan, but it's used to deal with the sanitation SSOPs,
5 we would have to follow the requirements that are listed
6 here, meaning that we would sample at the frequency --
7 listeria species. If you get a positive result, the
8 establishment has to take corrective action to determine and
9 demonstrate that the effected lot or lots of product are not
10 adulterated with *Listeria monocytogenes*. So if I answered
11 your question correctly, if you have a HACCP plan
12 controlling *Listeria monocytogenes*, you would identify in
13 your HACCP plan what you wanted to do with regard to -- with
14 regard to listeria species and so forth. That's true, that
15 was our intention when we wrote this rule.

16 If you chose not to deal with it in the HACCP plan
17 but through the SSOP, you have to follow these requirements
18 as a minimum. Our expectation would be that your sanitation
19 SSOP would have more complete procedures for your daily
20 ongoing procedures, but at a minimum you would have to have
21 this level of testing and have this follow-up action if you
22 have a positive result, but that's if you address it solely
23 through the SSOP and not to HACCP. Did I clarify that?

24 MS. HANIGAN: Very well. Thank you.

25 MR. EMERLING: Stan Emerling. The concern I think

1 I have having listened yesterday -- and probably I should
2 first disqualify myself as a science-based person because I
3 am not. I haven't had that type of training but I listen to
4 what I hear here. There seems to be no consensus whatsoever
5 of any correlation between listeria species and Lm

6 And I'm wondering if we support strongly food
7 safety measures, I mean because it's in our best interest
8 that what we put out is safe for consumers. But I'm
9 wondering if whether we're not putting alot of people's
10 lives, because I think it's even affecting lives -- with all
11 the species testing that is the requirement from you that
12 actually may be of no use. Because if there is not a
13 correlation between that and Lm, then why are we doing it as
14 I heard yesterday, we have all kind of different serotypes,
15 sometimes even the ones that have been damaging to public
16 health. Other times that serotype is not.

17 And so I'm wondering whether we're just putting
18 layer upon layer of regulatory performance standards on top
19 of the industry when we're not affecting the public health.

20 I would really suggest that some parameters for it would be
21 better served -- these types of programs would be more
22 appropriate -- performance standard and particularly with
23 the species applications that you're asking for.

24 DR. ENGELJOHN: Thank you for your comments. It
25 would be very helpful to the Agency if you could identify

1 what some of those alternatives would be to a regulatory
2 proposed requirement and that would help us inform our
3 decisionmaking.

4 As pointed out in the Preamble, the Agency has
5 made the determination that there is a lack of control for
6 *Listeria monocytogenes* in ready-to-eat meat and poultry
7 products. For that reason the Agency identified a number of
8 reasons as to why we deemed it necessary to address either
9 through the SSOP or through the HACCP programs.

10 We did have a discussion in both the front part of
11 the Preamble as well as the economic impact analysis before
12 we discuss tomorrow afternoon with regard to the impact on
13 very small, small and large establishments. And what we
14 believe to be the level of control of listeria species types
15 of programs in place in the various types of establishments.
16 We recognize that there is an economic impact, but we also
17 believe that it's necessary as we propose to put in place
18 some mandatory requirements that also require records to be
19 made available to the Agency to be able to verify what the
20 establishments are doing.

21 MS. GLAVIN: Kaye and then Bernie.

22 MS. WACHSMUTH: I'll begin by saying I am not a
23 food microbiologist.

24 (Laughter.)

25 But we have quite a few knowledgeable people in the room and

1 what I'd like to do is just present my understanding of why
2 species is a way that we should go and see if the food
3 microbiologists disagree with this.

4 There's no direct one-to-one correlation which was
5 provided in the data yesterday. But the fact that you found
6 species when you had very low numbers of moncytogenes would
7 seem to me that it might be a more sensitive indication that
8 you could have a moncytogenes problem that you might even
9 miss just going from one moncytogenes.

10 I was also under the impression that species
11 testing would be a result that you could get faster and
12 cheaper than going from moncytogenes. So I would -- I would
13 have thought that these would have been advantages to
14 species testing. We're not talking about drains, we're
15 talking about product contact surfaces. Is this notion
16 wrong?

17 MS. GLAVIN: Bruce, Bernie, we're going to hold
18 just a second on yours if you don't mind.

19 A PARTICIPANT: That's okay. I'm --

20 MS. GLAVIN: Okay.

21 A PARTICIPANT: -- I think I'll stand.

22 MS. GLAVIN: Okay.

23 DR. TOMPKIN: I'm sorry, Bernie. This is Bruce
24 Tompkin from ConAgra. There are a number of reasons why we
25 are in the situation of testing for listeria-like or

1 listeria species, but we do that and in the case of cost,
2 for example, and timeliness you can do an analysis for
3 listeria-like and essentially in the second day looking for
4 black tubes (phonetic) as the first clue.

5 The first day is enrichment and the second day is
6 for black tubes and then the third day, whether you have
7 listeria-like on the plates. So, essentially two days or
8 three days here you're working with something. We've been
9 doing that on environmental samples and the cost is about
10 \$4.00 per sample.

11 Now the key to this using listeria-like or
12 listeria species is what do you do with the data? I know
13 that we have stated that, "Well, it's an indicator or an
14 index or whatever it's called." So it gives us some
15 indication as to whether we have control or not on that
16 particular line and that gives us the information we need to
17 make a judgment to bring about control, fix something. So
18 it's a rapid, relatively cheap way to go. The key thing,
19 however, is there's been a misunderstanding of what to do
20 when you have a positive listeria species. Do not ignore
21 it. If you ignore it, you can, in fact, be jeopardizing
22 consumer health because some of those species may, in fact,
23 be Lm and lead to food-borne illness. So the key is, we
24 have an indicator that's cheap, but you must respond to
25 every positive. If you don't respond that's when the

1 problems really arise. Does that help?

2 MS. GLAVIN: Yes, thank you. Bernie, thank you
3 for your patience.

4 MR. SHIRES: Bernie Shires, American Association
5 of Meat Processors. I had a question for Dan, really a
6 clarification question I guess, in what you're talking about
7 there as a response by the plant to a positive test result
8 for listeria species, is that right? Where you get into the
9 fact, when we get to talking about making a determination as
10 to whether there's an adulteration with Lm or not. How, for
11 example, do you envision a small plant, a very small plant,
12 taking that positive result from Lm and then determining the
13 lot or lots that would be affected and how much would have
14 to be held and sampled for Lm?

15 DR. ENGELJOHN: Bernie, I think the issues that
16 you raised are issues for which the Agency really would like
17 an informed scientific reason for how to develop guidance
18 from the very smallest establishments.

19 The number of samples necessary to take and which
20 products and how frequently to do that, all those issues are
21 things for which we do need information that we can then
22 pull together to make available to small businesses. Had we
23 had that information on how much sampling and at what
24 frequency and at what locations we would have made that
25 available as part of the document to be commented on for the

1 rulemaking process. That is specifically what we're asking
2 the scientific community to come forward with, with their
3 best expert judgment or guidance maybe from the
4 International community that would help us put together
5 guidance for plants.

6 MR. SHIRES: Okay. Because many -- the reason I
7 raise it is part of the reasons that many -- for many of us
8 who run very small plants, as you know, we're making a
9 multitude of products, anyway. That's another issue that I
10 was going to raise and question that maybe this is something
11 -- maybe this is something we need to comment on as well.
12 There's large numbers of products that they're making
13 compared to lines how many -- how many tests will we end up
14 having to do? That's a -- that's a question we have as
15 well.

16 DR. ENGELJOHN: To just simply state, if you're
17 doing the SSOPs, then it would be four production lines from
18 where the meat product had contact, those lines if you're a
19 large plant, two tests if you're small and one if you're
20 very small.

21 The details as to the specifics of how you ration
22 that out across product lines, that's what we would be
23 seeking comment for or have you ask questions for clarity in
24 the comments that you submit to us.

25 MR. SHIRES: Okay.

1 MS. GLAVIN: Yes?

2 A PARTICIPANT: If a plant decides to go ahead and
3 put this in their HACCP program or as an SSOP I mean --
4 excuse me -- as a CCP, will we have an opportunity to have
5 it reviewed by the Tech Center or will we be at the mercy of
6 an inspector at the plant?

7 DR. ENGELJOHN: I would -- could we get your name
8 for the record?

9 A PARTICIPANT: Sure, my name is Bill Gates.

10 (Laughter.)

11 DR. ENGELJOHN: I didn't mean that. So I'd
12 follow-up with you.

13 (Laughter.)

14 A PARTICIPANT: I've been around for a long time,
15 too. I don't bruise that easily.

16 (Laughter.)

17 DR. ENGELJOHN: The Agency has received prior to
18 us publishing this proposed rule, various proposed processes
19 for which establishments are looking into doing just to get
20 feedback from the Agency. The Technical Service Center does
21 have a group of experts that are there to provide you
22 guidance.

23 We are not going to be looking at a renewal to
24 give you an approval or acceptance of that procedure but we
25 certainly can give you guidance on what we think is things

1 to be concerned about and to think about, but we have done
2 that on a case-by-case basis. We really are looking for as
3 much information on this issue as possible so that we can
4 where possible, condense the data and put it into the final
5 compliance guidance that we can make available as quickly as
6 possible so that industry can use it. So as we have
7 information that comes forward that establishments or
8 institutions are willing to share, that would be the kind of
9 information we would -- if we look at it and we think it is
10 sounds reasonable, that would be the kind of information we
11 would want to put in our compliance guides.

12 MS. GLAVIN: Katie?

13 MS. SWANSON: Katie Swanson, Pillsbury Company.
14 Yesterday during the scientific presentations that were
15 made, there were several speakers talking about intervention
16 strategies to prevent listeria growth through preservation
17 -- preservatives and that kind of thing.

18 The risk assessment that was -- the draft risk
19 assessment that was just published suggests that growth of
20 the organism is a risk factor that -- or it magnifies
21 potential risk. As I'm reading this, however, I just want
22 clarity. This requirement does not seem to have an
23 alternate approach for preservatives, for example, that
24 would be added probably before cooking or, you know,
25 inventions like freezing that would prevent growth after

1 packaging to provide a different approach on this listeria
2 monocytogenes. Would that be something that would be or
3 should be entertained?

4 DR. ENGELJOHN: I think the Agency would welcome
5 input and any clear examples of what it is that you're
6 expecting or thinking about doing. If you're going through
7 the HACCP program, as the proposal is written, if you're
8 addressing that issue through HACCP you have considerably
9 more flexibility there than you do if you're solely going to
10 address it through the sanitation SOP.

11 The sanitation SOP does not give you the
12 flexibility to look at other than listeria species. For
13 instance, if there's something else you want to use as an
14 indicator, the SSOP, as proposed, does not give you that
15 flexibility. We need to ponder on the appropriateness of
16 that requirement.

17 But in the HACCP plan, we did recognize that there
18 are situations where interventions may be available,
19 available today and then how the language to the proposal
20 should be treated to allow for that flexibility. So that if
21 you can document that you have this pathogen controlled,
22 then you should be allowed to address that through your
23 HACCP plan. So we would be looking for specific examples
24 that would be very helpful to us.

25 MS. SWANSON: Okay.

1 MS. GLAVIN: Dennis? And I think I have two
2 people back here, is that right? You both? Okay. Let's
3 go, Dennis, and you two can fight it out as to who's next.

4 MR. JOHNSON: Dennis Johnson. I'm probably the
5 world's worst microbiologist --

6 (Laughter.)

7 -- but I am a lawyer.

8 (Laughter.)

9 I do have a question. Dan, what I've heard today
10 is very encouraging. I like the words you've been using.
11 The HACCP plan addresses *Listeria monocytogenes* and I
12 understand that you can't flip back to a slide earlier, but
13 one of the slides, that the alternatives are, you have
14 determined that a food safety hazard isn't likely to occur
15 or are you doing it under the SSOPs?

16 If you read the regs, once you have determined
17 that a food safety hazard isn't likely to occur you have to
18 have a CCP. CCP's are a lot different than address, you can
19 address for verification, you can address through hazard
20 analysis. So I'm kind of curious if you're -- that language
21 would mandate a CCP but if we're supposed to have the
22 flexibility to handle this and put it on our plans how we
23 deem best, which is it? Is it the language which gives you
24 the mandatory CCP which you guys don't mandate, right?

25 (Laughter.)

1 Or are we saying we have to address it, which is really what
2 I think you were gunning for?

3 DR. ENGELJOHN: This is the actual language
4 contained in the proposal which makes it very, very specific
5 that you have to address it as a hazard. If you've
6 identified it as a hazard reason not to occur, that would
7 result in a CCP as the regulation is currently written and
8 as the language here would propose. The Agency is seeking
9 input on how to treat this language or to address it
10 differently if you see that to be appropriate. I mentioned
11 the issue about maybe other ways to control Listeria
12 monocytogenes that we believe are valid and so this is the
13 language proposed. We're open to input as to how we can
14 make it more flexible or to maybe change the tone or
15 direction of it.

16 MR. JOHNSON: Okay. Just was trying to see
17 whether or not -- because there's a bit of a dichotomy
18 between control and CCP.

19 DR. ENGELJOHN: As we --

20 MR. JOHNSON: -- and the CCP.

21 DR. ENGELJOHN: -- we made the determination that
22 for ready-to-eat products that are handled post-lethality
23 prior to final packaging, that it's reasonable that there
24 would be a hazard -- that's the determination we made. But
25 we did go one step further to say, "However, you may be able

1 to address that, some environmental issues in the sanitation
2 SOP's also." So we did provide the flexibility with regard
3 to HACCP and SSOP's. If you have other alternatives you
4 want the Agency to consider we are clearly open to that
5 through the comment phase.

6 MR. JOHNSON: Thank you.

7 MS. GLAVIN: I think we're next here.

8 A PARTICIPANT: I think he made my point, I won't
9 have to.

10 MS. GLAVIN: All right.

11 MR. BEUCHAT: Thank you. Larry Beuchat,
12 University of Georgia. A comment on the discussion relative
13 to non-Listeria monocytogenes species versus monocytogenes.
14 There is data that you shared with us today, I think largely
15 if not entirely were from samples taken from locations in
16 plants other than the surfaces themselves, the food contact
17 surfaces. The ecology, the environment, in the drains and
18 the floors are quite different than it would be from the
19 contact -- food contact surface and could therefore result
20 in different results and the predominance of different
21 species, could. That I think we need to consider.

22 The question I have in trying to better understand
23 the rationale for the mandatory frequency, the differences
24 large, small and very small. If, for example, a very small
25 plant has the very same line as does a large plant and that

1 very small plant is running at 100 percent capacity, but the
2 large plant the same line runs at 50 percent capacity, would
3 it -- would the results that would come out of the testing
4 at these frequencies really exceed the degree of confidence
5 relative to the risk of the product per consumer consumed by
6 the public?

7 I'm trying to understand the rationale in terms of
8 establishing a level or degree of risk, if you will, if the
9 frequency of testing the lines and that being whether the
10 plant is large, small or very small?

11 DR. ENGELJOHN: Thank you, Larry, for bringing
12 that up. I just at this point, just to provide some more
13 information and maybe trigger some thoughts for comment.
14 On the first issue with regard to, again the listeria
15 species in product contact surface versus just environmental
16 sampling, for the SSOP requirement as listed here in the
17 proposed rule the plant may, in fact, be doing environmental
18 testing and choose to do environmental testing. But if
19 they're addressing listeria species through the SSOP in lieu
20 of HACCP, as contained in this proposal, it would have to be
21 food contact surfaces.

22 So this does not give flexibility to environmental
23 sampling. That may be something that you -- that the plant
24 is doing and that we would expect to be doing, but as far as
25 the requirements of the proposal the requirement is that we

1 have to at a minimum have evidence that you're testing for
2 verification of SSOP on the food contact surface.

3 With regard to the distinction between the large,
4 small and very small in the product sampling frequencies,
5 there was not intended to be some level of confidence
6 associated with that degree of sampling and the risks that
7 would be associated with it. The issue here was that there
8 would be -- if handled through the SSOP there would be a
9 minimum level of testing that had to occur for which the
10 records would be available and we just made the distinction
11 between large, small and very small because of the economy
12 of size within the plant and that it gave some economic
13 relief with regard to the amount of testing that had to
14 occur. It was not intended to imply that there would be a
15 greater degree of confidence that if listeria was there, it
16 would be found.

17 Had we had that kind of information to base the
18 rulemaking that would have been formulated as part of the
19 proposal. That is the type of information we're seeking.
20 We did make the public health judgment that large plants
21 produce more product, you bring up the point that they only
22 produce a quarter of capacity or 50 percent capacity. But
23 we just need the distinction so that there would be some
24 economy of cost here with regard to the amount of mandatory
25 testing, not intended to imply some verification of

1 confidencing risk. If we -- that's the type of information
2 we truly would like to have. It may not be made part of the
3 regulation, but certainly could be made part of compliance
4 guidance for how to meet an appropriate or approving and
5 SSOP and HACCP program.

6 MR. DERFLER: This is Phil Derfler. There's
7 something I'd like to add to that. I mean we've said that
8 what we're trying to do is make our regulations as
9 consistent as possible with sound science and common sense.
10 There's also other statutory mandates that we work under
11 including the SBEFA, which is the Small Business Economic --
12 I don't know -- Fairness Act, which essentially says that we
13 have to take into consideration in doing rulemaking the size
14 of plants and the economic impact on them and stuff like
15 that. In the absence of what we felt was adequate data, we
16 developed this in consideration of trying to minimize the
17 burden on small and very small plants and yet at the same
18 time try and accomplish what we -- what we were trying to
19 accomplish.

20 If there is scientific data that will help us do
21 that in a more effective way we really welcome it. I mean
22 that was a question I asked of Dr. Wiedmann yesterday and he
23 kind of blew me off. So I mean we need --

24 (Laughter.)

25 -- we need that kind of data. Thank you.

1 MS. GLAVIN: Thank you. Ah, you got up to the
2 front of the line.

3 (Laughter.)

4 MR. GROSS: Sort of reorganized.

5 (Laughter.)

6 John Gross. Dr. Engeljohn, there's -- there's
7 something I just don't understand and probably everybody
8 else in the room does understand it, but if somebody could
9 take just a minute to explain it to me. If you identify
10 *Listeria monocytogenes* as a hazard likely to occur in your
11 HACCP plan you've done a risk assessment and you say, "Okay.
12 It's probably going to happen."

13 Regulations of the SSOP 416(a) says, "All food
14 contact surfaces including food contact surfaces of utensils
15 and equipment must be clean and sanitized as frequently as
16 necessary to prevent the creation of unsanitary conditions
17 and the adulteration of product. If you identify for your
18 HACCP plan *Listeria monocytogenes* as likely to occur, aren't
19 you saying that the SSOP doesn't work?"

20 DR. ENGELJOHN: Now I would just clarify that.
21 With regard to this proposed rule and with regard to the way
22 the HACCP regulations are written, you have identified
23 *Listeria monocytogenes* in this case, as a hazard reasonably
24 likely to occur from which you can have in place at a
25 critical control point, some treatment or measure that will

1 control by reducing it or eliminating it, or preventing it
2 from occurring.

3 The SSOP requirements are a bit different in that
4 you're dealing with direct product contamination and the
5 sanitary operation of the plant. We view the SSOP, in
6 essence, as a prerequisite program. It's something that
7 should occur with regard to daily sanitation and operation
8 of the facility.

9 In the case of ready-to-eat products that have a
10 post-lethality -- prior to the packaging the consideration
11 that has to be given is, is there opportunity there for a
12 pathogen to be introduced to that product such that it's
13 critical that we can reduce, eliminate it or control it? In
14 this case, the establishment would need to make that
15 decision as to, is there the potential that on handling my
16 ready-to-eat product post-lethality, prior to packaging,
17 such that I need to control *Listeria monocytogenes*?

18 If so, then our expectation would be that not only
19 are you addressing it in some fashion in the environment
20 through the SSOP but you have your HACCP plan specifically
21 addressing at the control point how you're dealing with this
22 particular hazard. Does that help clarify the issue?

23 MR. GROSS: I -- I --

24 DR. ENGELJOHN: We -- let me just put it this way,
25 with *Listeria monocytogenes*, we recognize the fact that it

1 is a -- it is truly an environmental contaminant that is
2 ubiquitous throughout the environment inside and outside of
3 the plant. It's different than the -- pathogens that come
4 in on the product, for the most part. This means airborne.

5 It frequently can be there and just simply flying in the
6 air on things, or on the floor and the water. It presents a
7 different situation.

8 For those products that are going to be handled
9 after lethality treatment before packaging our issue is you
10 need to make special consideration as to does that present a
11 hazard reasonably likely to occur, so it would need to be
12 addressed in HACCP. If not, then if you're handling ready-
13 to-eat product that meets the criteria of this proposed
14 rule, then you at a minimum would have to address your
15 minimum sampling components in your SSOP; so handling this
16 particular pathogen in HACCP differently than most other
17 pathogens that we have out there. The other pathogens that
18 we are aware of at the moment that we consider to be
19 appropriate to be handled either in the SSOP or in the HACCP
20 plan.

21 MR. GROSS: Okay. Thank you.

22 MR. SPERBER: Thank you. I'm Bill Sperber from
23 Cargill. I mean no irreverence on this first comment, but I
24 have an atheist friend who says, "Nothing fails like
25 prayer." In the context of food safety I would say when it

1 comes to assuring food safety nothing fails like product
2 testing. In this case of the sanitation SOP, if you find
3 listeria species and your corrective action drives you to
4 product testing, you're eventually testing for -- you really
5 don't have a prayer of a chance of finding it in the
6 finished product because of the statistics of the
7 saturation. It would be an unusually grossly, heavily
8 contaminated product to have an incidence of listeria of one
9 percent of finished packaged product, but even at that very
10 high incidence you would have to analyze 300 samples to have
11 a 95 percent chance of finding one positive.

12 So what does that do for small and very small
13 plants? That would be an enormous burden for a large plant
14 but what about the smaller plants who are producing a dozen
15 products? They can't sample hundreds of finished products
16 to be able to find a positive.

17 In the last couple of years there have been two
18 large foodborne outbreaks of listeria attributable to
19 hotdogs and to cooked turkey products. In each case it was
20 extremely difficult to find Lm in those finished products.
21 So if you're going to try to manage this in the second
22 section by sanitation SOP's you really don't have a prayer
23 of a chance of controlling the Lm hazard by that.

24 If you have products that are potentially
25 hazardous because they can support the growth of Listeria

1 moncytogenes during refrigerator shelf life, you're going to
2 have to rely on process control and not product testing. If
3 you extrapolate that to your proposed rule you will for most
4 products need to have a CCP in your HACCP plan and not rest
5 your case or try to base your strengths on sanitation
6 sampling.

7 DR. ENGELJOHN: Thank you. I would really
8 encourage you to write that down and give some more
9 description as to the appropriateness of, if the issue is
10 that SSOP's are not an appropriate alternative for this
11 proposed rulemaking, then I think that's something that you
12 truly need to put in writing and submit as your comment.

13 MR. SHIRES: Bernie Shires. The question I wanted
14 to raise with you, Dan, basically had to do with CCP's.
15 From the discussions and the presentations that were made
16 yesterday and from talking to scientists at universities and
17 other sources, basically all the plants have these two
18 choices that you've outlined for us this morning.

19 The critical control point, if you're going to say
20 that it's a hazard reasonably likely to occur and so it has
21 to be handled through a HACCP plan, for small and very small
22 plants, the CCP's that they would have to come up with to
23 make this part of the HACCP plan seem to be few and far
24 between. I just wonder if there is some kind of -- if the
25 small or very small plants are not going to have the same

1 opportunity because of cost and other economic factors, to
2 come up with critical control points that -- that the larger
3 firms would have? This is something I think -- what one of
4 my comments is about. I think this is something the Agency
5 needs to consider especially in looking at your economic
6 factors.

7 The other point I wanted to make is that in terms
8 of -- another person raised it here kind of -- the numbers
9 that you came up with for testing. I mean I can think of
10 plants, small plants, that would maybe doing -- small and
11 very small plants that might do one hundredth or one two
12 hundredth or one five hundredth of the product. For
13 example, let's say a large facility might do. So how do the
14 numbers 402 and one come out? Did you shake some dice or --

15 (Laughter.)

16 -- I'm sure that's not the case, but what was the
17 -- what was the justification for those particular numbers?
18 Because you're really not going to necessarily get the same
19 correlation here.

20 DR. ENGELJOHN: Again as we explained in the
21 Preamble to the proposed rule, the numbers were devised
22 simply to give some flexibility in terms of economy of scale
23 or the burden on large versus small versus very, very small.
24 They are not based on determination of efficacy or on
25 prevention of risk or confidence.

1 If you have other suggested sample frequencies
2 that would be more appropriate such as one test per order,
3 or whatever, we would welcome that. We'd also like some
4 justification that you would have as to why you think that
5 would be more appropriate than the numbers that we're
6 proposing?

7 We're truly looking for a more scientific basis
8 for having the numbers there. Right now they're simply as
9 minimum levels for verification of the SSOP. Our
10 expectation is that the plant would be doing many other
11 things on a daily basis, on a hourly basis, with regard to
12 control of pathogens in their products. At a minimum this
13 is what we are proposing to require as having documentation
14 available to FSIS.

15 MS. GLAVIN: We have someone at the table here?

16 MR. TOURJE: Yes. Tom Tourje. Just one comment.

17 Several times you've mentioned -- after lethality, before
18 packaging; and issues have come up there. In operations
19 where that's not the case, where the product was packed at
20 lethality, it doesn't look like there's any option to
21 address that. It just looks like we're being forced to pick
22 as a CCP just out of -- you know, the easiest way out but,
23 in essence, the product being packed at lethality should not
24 be required to be picked as a CCP nor should it be required
25 to have an elaborate testing program.

1 DR. ENGELJOHN: I will say that the way that the
2 rule is written again that the issue here is -- oh, I've
3 punched the wrong thing --

4 (Laughter.)

5 -- I have to stop pressing these buttons.

6 (Laughter.)

7 I would say the issue is the Agency was concerned
8 about product that are manipulated. They may be cooked in a
9 bag and then removed from the bag and exposed to the
10 environment and then repackaged. Those products that --
11 canned products, for instance, which are in a container for
12 which there is no opportunity for external contamination the
13 Agency identified that as -- as an issue and wanted comment
14 on how we could tweak the language or make sure that we
15 address the language so that this part for which lethality
16 is sufficient and there's no opportunity for a re-
17 contamination or post-process contamination then we're
18 looking for comment on -- as to what we should do about this
19 proposed rule in either addressing them or not addressing
20 them.

21 We agree that if you have produced a product in a
22 bag for which it's not going to be contaminated after --
23 after it has been cooked that there probably should be some
24 different considerations given. So we would welcome input
25 on that.

1 A PARTICIPANT: Thank you.

2 MS. GLAVIN: Yes, sir?

3 MR. HABTEMARIAM: Thank you. It's not by design
4 that I ask the question --

5 MS. GLAVIN: Okay. Can you give your name?

6 MR. HABTEMARIAM: Yes. Tsegaye Habtemariam from
7 Tuskegee University. I wanted to comment on Dr. Swanson's
8 comment earlier which I did think is very important. It's a
9 very important premise and rationale and I'm glad
10 Dr. Swanson is back, too. There's a point that she made
11 that listeria species is literally -- if I use the word
12 intentionally, an indicator for *Listeria monocytogenes* and
13 if listeria species cannot be that representative within the
14 same series (phonetic), I can't imagine what other organism
15 could come close to that.

16 The other point is about the cheap and easy --
17 which could be done. It sounded to me, very rational. I'm
18 not a microbiologist but an epidemiologist. It made a lot
19 of sense.

20 The problem, the fundamental problem, that we saw
21 yesterday and based on Dr. Weidmann's report, if you
22 remember the results that listeria species do not correlate
23 with *Listeria monocytogenes*; you find one and correct it.
24 But it was based on pilot studies. There are several pilot
25 studies out here reporting. Now pilot studies, if they're

1 conceptual, can provide very useful data, -- test but really
2 not conclusive, definitely not powerful to make inferences
3 that are significant, such as in this case. I think what
4 would really be useful, especially to look at listeria
5 species on product as well as *Listeria monocytogenes*. If
6 you really have an appropriate sample size, a larger sample
7 size and, in fact, then do a correlation analysis and then
8 you see the correlation -- that would have been I think,
9 more substantive and more conclusive in my opinion.

10 But I think this is clearly -- to really end up
11 with this very significant and very important conclusion
12 that the species is not indicated for the other *Listeria*
13 *monocytogenes* maybe to me, is a little premature, but I
14 think it is a very important rationale in terms of what
15 you're proposing to do, in my opinion anyway.

16 MS. GLAVIN: Other comments or questions?

17 (No response.)

18 Let me get a sense of the group. We are scheduled
19 to return after lunch and I would like to know are there
20 people who want to, have comments to make and have
21 additional questions to make on the two subjects we have
22 covered so far? The answer is one?

23 A PARTICIPANT: Yes. Behind you.

24 MS. GLAVIN: Okay. Then -- then my suggestion is
25 that we take a lunch break and return at 1:30. Okay. Thank

1 you.

2 (Lunch break at 12:33 p.m.)

3 (Meeting resumed at 1:44 p.m.)

4 MS. GLAVIN: Good afternoon. Thank you for coming
5 back so timely. Before we broke for lunch we were still on
6 the requirements for the control of listeria and then a
7 number of you indicated that -- that you had further
8 questions or discussion or comment. So I don't know who is
9 ready to go first.

10 MS. GLAVIN: Dan tells me he's prepared to answer
11 a question that arose this morning. So why don't we let him
12 do that.

13 DR. ENGELJOHN: Dan Engeljohn with USDA. The
14 question was asked about the format for submittal of data
15 particularly related to listeria type of data. So I have
16 Walter and Victor Cook prepared to answer questions about
17 their needs in terms of looking at it from a microbiological
18 standpoint and then Warren Lang is going to speak to the
19 issue of the statistical types of information that we would
20 be looking for.

21 A PARTICIPANT: Thanks, Dan. It makes sense to me
22 that any materials that you submit to us would be more or
23 less in a draft form.

24 A PARTICIPANT: We can't hear you.

25 A PARTICIPANT: I'm sorry.

1 A PARTICIPANT: I can't hear you right here.

2 A PARTICIPANT: It seems to make sense to me that
3 any information that's submitted to FSIS as far as
4 scientific findings is concerned, would be in a form of a
5 draft in the format somewhat similar to what you would
6 submit to a scientific journal for publication, that is, it
7 would have materials in different sections and
8 interpretation of data and -- interpretations of data and
9 some conclusions and any additional reference materials that
10 you'd like to include as well. And I think that there was
11 also some talk about the actual -- data solution.

12 A PARTICIPANT: When I think of data, I think of
13 certainly -- submitted or one of the things about --- and
14 that's to sort of focus on what question, you know, what is
15 really the answer. If the issue is, as what was discussed
16 this morning, what is the correlation between listeria
17 species and Lm and if that -- if that would be an important
18 issue, then it's certainly -- sort of have information that
19 sort of -- and that relationship and that is the HACCP
20 process, specific products that were -- you know, the size
21 of the establishment and other things that people think
22 might -- might be available that would -- that could
23 possibly have caused in one establishment, you know, for
24 that relationship to be different than others.

25 I mean -- things like environment -- or not or was

1 that -- maybe these characteristics -- the extent to which
2 the product had been exposed to the environment the time or
3 something. You know, it's really hard to -- now that's a
4 specific question and trying to get an answer. Is that
5 relationship -- I mean other than that -- devices, that
6 you're presented with would even -- this -- this information
7 helps answer this specific question and why. I mean, it is
8 hard to know without really knowing what -- what question
9 you're trying to answer, it's -- how far is someone involved
10 in the data analysis. Until you really get to folks on what
11 question you're trying to answer. It's really hard to get
12 more specific answers than you are. Which data variables do
13 we think could be effecting the relationship of trying to
14 measure -- and answer the question right?

15 MS. RICE: Well -- this is Kim Rice with AMI.
16 Since I'm the one who asked the question -- with the
17 variations between the establishment-- my membership and
18 some of the other food associations that are -- I assume
19 will be trying to answer some of these questions and
20 collecting them.

21 The facilities themselves have so many different
22 variables and on top of that the frequencies at which they
23 test, how they test, the methods they use, etcetera. All of
24 those things are going to be there so I would ask if you
25 don't answer it today, I would ask that you provide some

1 direction on how we can take current data that may or may
2 not exist and basically reconcile it to help you answer the
3 questions that you've asked.

4 Maybe the members who are microbiologists will be
5 able to help me do that, but unless we're all going to go
6 out and just do like some huge investigational protocol to
7 go find the data to answer your questions, you know, we need
8 some direction on how to reconcile all of those different
9 issues. So I'd just ask that if anyone would like to, you
10 know, work that out, get some direction.

11 MS. WACHSMUTH: I was thinking that Dan and Walter
12 and some of the people who know the data and the needs,
13 might be able to come up with some data-needs document to go
14 through the proposal --

15 MS. RICE: I think we know -- Kim Rice again. I
16 think we know what the questions are and how I would answer
17 them. But because I would provide the information one way
18 that doesn't necessarily mean that that is the information
19 you want. I'm asking for that before we go out and do that
20 I'd like some direction on exactly what it is you need and
21 how you need to see it? You asked a lot of questions asking
22 for -- and you asked for a lot of data so before we go out
23 and compile the data --

24 DR. ENGELJOHN: I would say -- this is Dan
25 Engeljohn. we will put some thought into that and see if we

1 can come up with a document or come up with a format and
2 make that available on the website to say, "Here's what it
3 is that we're looking for" and we'll specifically try to
4 share that with you just so we can effectively get back the
5 information.

6 MS. GLAVIN: Katie?

7 MS. HANIGAN: Katie Hanigan with Farmland. Going
8 back to one of the points raised this morning which was the
9 division of small, very small and large plants, the sampling
10 came through well under the SSOP. I refer to my written
11 comments and I think you need to go back and consider not
12 the size of the establishment but how many lines the
13 establishment has. The reason I think you need to go back
14 and look at that is some of these very large facilities, and
15 we have five within Farmland, we have the majority of those
16 employees -- these are the plants with over 500 employees --
17 those facilities are located on -- and boning operations.
18 Those large plants of ours -- we have two ready-to-eat
19 slicing lines or packaging lines, if you will.

20 When you go back to what I call a medium-size
21 plant, those with 10 to 499 employees, we can use seven and
22 eight packaging lines in those and they're in that smaller
23 group of plants because they don't have a slaughter facility
24 attached to it. When you start looking at which plants turn
25 out more product, etcetera, it's the medium-size. So I

1 think you may want to go back and say, "The sampling scheme
2 needs to be based on how many lines are in the plant." The
3 other thing is regarding the very small folks, if you get in
4 an industrial engineer, basically the staffing that it takes
5 to run a packaging line is very similar.

6 I mean it comes with recommendations from the
7 company how many staff people you need to run this line,
8 etcetera, so I don't see that as being a big issue between a
9 very small plant, a medium sized plant and a large plant.

10 DR. ENGELJOHN: I appreciate the comment. I would
11 say related to that, Katie, and one issue that the Agency
12 struggled with was production data in terms of the amount of
13 product produced, and that would be very helpful in that
14 decision process. So again, in terms of you evaluating the
15 information that you have access to, if that could be a
16 component in this issue regarding the amount of production,
17 and the trade associations have access to a variety of
18 establishments, that's helpful.

19 We made a slight public health decision that the
20 size of the plant had some reasoning for why we would have a
21 different sampling from them. In this case it was based on
22 burden and not on an efficacy issue. If, in fact,
23 production volume has an impact on risk, that's an issue for
24 which we would look for science to help support that as
25 well.

1 MS. GLAVIN: Bernie?

2 MR. SHIRES: Bernie Shires. I guess I'm pushing
3 to -- to get an answer to a question raised earlier before
4 lunch. We were talking a little bit about the -- testing
5 requirements or the number of lines. I guess if you're
6 talking about facilities that have a lot of different
7 products, whether they were made from the same species or
8 varied species, various types of seasonings, for example,
9 and what -- what you would consider -- what the Agency is
10 considering to be a line in that instance?

11 DR. ENGELJOHN: Bernie, I would follow-up on that.
12 We didn't define line within the Preamble itself and
13 clearly that would be something we were hoping to get input
14 on as to how you would define that.

15 MR. SHIRES: Okay.

16 DR. ENGELJOHN: -- to define that specifically,
17 but you raised the issue and we can certainly consider that.

18 MR. SHIRES: Okay.

19 MS. GLAVIN: Yes?

20 MS. VOOGD: Erika Voogd, OSE Industries, In
21 keeping with the same type of question that Bernie just
22 asked about, what is a line? When Katie was talking earlier
23 this morning and she was talking about performing a number
24 of tests I'm not sure -- I have not had a chance to read the
25 guidance material that just came out, but I'm a little

1 unclear. When I first read this proposal and it said,
2 "Number of tests" I'm thinking like a test of sponge, so
3 four tests means four sponges for one line in a large plant.
4 I'm thinking, okay, does that mean one sponge per week for
5 four weeks? Does that mean four sponges today and nothing
6 the rest of the month? So I don't know if there's any --
7 any information available. If that is in the guidance,
8 perhaps you can tell me that. What is a test or, you know,
9 or is a test also possibly, anything I test today is
10 Test No. 1?

11 DR. ENGELJOHN: Again on that issue in particular,
12 the Agency did have a limited amount of discussion in the
13 Preamble. We did not define what a test was. We knew that
14 was five composites making up the tests or just one test or
15 that that was one sponge once a day for four days. We did
16 not define that and was looking for input on that. Again,
17 the issue was that we did not base the sampling frequency on
18 the efficacy or on a specific risk reduction or a confidence
19 level. Had we had the science behind that to establish
20 that, then we would have been able to give more descriptive
21 information.

22 We are looking from the science community
23 information about what would be appropriate and effective
24 sampling programs. That would then help inform us as to how
25 we go forward with the proposal, the final as well as with

1 the compliance guidance.

2 MS. VOOGD: Okay. Clarifying that would be very
3 important to us. Again, our interpretation was entirely
4 different just that quickly. In going forward and trying to
5 decide how we would test, that clarification is very, very
6 critical to understanding what it is that is expected of us.

7 MS. GLAVIN: Caroline.

8 MS. SMITH-DeWAAL: Thank you. I'm sorry, at this
9 morning's presentation I was following your agenda that had
10 this whole discussion starting after lunch so I'm sorry if I
11 repeat questions that other people asked this morning.

12 What is the level of confidence that you expect to
13 achieve with the four tests a month requirement? We had
14 petitioned the Agency for a statistically valid sampling
15 program. It's unclear from the Preamble that we've got one
16 and so I'd really like to know what -- how you came up with
17 the four tests -- four tests a month? I know the question
18 immediately before me went to this issue as well as, what do
19 you really mean by that? But I also want to go into kind of
20 what -- what does it mean statistically?

21 DR. ENGELJOHN: On that particular issue with
22 regard to the sampling frequency specific to the sanitation
23 SOP's, the Agency did not establish a confidence around
24 those -- they're meant to be minimum testing requirements
25 based on plant size if the plant is doing product contact

1 testing through SSOP's in lieu of the HACCP plan. So there
2 is not a confidence associated with it or a determination
3 that a reduction of risk would be achieved or a certain
4 effectiveness would be -- result in a -- program if
5 the plant followed that testing regime. It was strictly
6 mandatory minimum testing that had to be available for
7 review by the Agency. The Agency's expectation would be
8 that the plants would have ongoing sanitation programs that
9 address its entire environmental program that may be -- but
10 at a minimum this is the information that --

11 MS. DeWAAL: Well -- highly problematic. As you
12 can see, there are industry lawyers as well as industry
13 scientists sitting here. I'm sure they're already working
14 on their briefs to shoot this as not being, you know,
15 statistically meaningful to the plants. I think in the
16 final rule we do need something that provides some level of
17 assurance that the conditions for which you're testing,
18 which is that listeria subspecies is in the environment and,
19 therefore, could survive -- that *Listeria monocytogenes* could
20 survive in that environment which is, in fact, what you're,
21 I think trying to prove with this testing program.

22 That -- that you have some level of confidence
23 that if -- if it's in the environment on that surface that
24 you are, in fact, finding it and I think four tests a month
25 isn't going to provide us much in terms of assurance that if

1 it is there, you're finding it.

2 DR. ENGELJOHN: I will just follow up with that by
3 saying that is the charge that we have to the scientific
4 community. That we don't believe that information was
5 available to us to be able to come up with that type of
6 criteria for the proposed rule and, therefore, did not
7 establish those sampling statistics based on reduction risk
8 or effectiveness, but based on the minimum testing
9 requirement that we thought had to be available to us.

10 MS. DeWAAL: So do you mind if I follow-up on
11 this?

12 DR. ENGELJOHN: No. Go ahead.

13 MS. DeWAAL: So are you saying that the -- your
14 expectation is that in the final rule you will have gathered
15 this additional data and you will have a testing frequency
16 should plants choose not to go the HACCP route that will --
17 that will be more solidly based in statistics?

18 DR. ENGELJOHN: I would say that if you were -- if
19 the Agency were to receive scientific data and information
20 from expert panelists on what would be appropriate
21 sanitation procedures? That that would inform our
22 decisionmaking as to how we would go forward with modifying
23 the final rule if we were to go forward with the final rule.
24 How we would -- how we may revise the regulatory
25 requirements in terms of making a different standard and

1 make it a more general standard and provide that specific
2 sampling data that was important for the plants in the form
3 of compliance guidance, that this would be the prudent way
4 to do it.

5 Again, the lack of information at this time caused
6 us to put it in the rule the way that we did and then ask
7 for the scientific community to come up with a more science-
8 based approach that would inform how we would go through --

9 MS. DeWAAL: I get nervous though that, you know,
10 all the science in the hands of the industry -- and they may
11 not necessarily want to give it to you for whatever reason,
12 maybe like they haven't been properly told the format or
13 something, but they may not want to just give it to you.
14 So I think you need to think beyond that. I think it's not
15 only what the scientists bring to it, which is, you know,
16 which will give you some information but also to know what
17 is the best in the industry doing? What is the industry
18 already accomplishing? How much testing's going on?

19 Based on the public hearing on this topic was it
20 two years ago now? A year and a half ago? We -- I mean it
21 seemed clear that industry was doing more testing as a
22 general rule than what is being required in this proposal.
23 So I think you need to -- to provide yourself another
24 vehicle to get to that result, that if you can't get the
25 exact scientific things that you need that you were using

1 information that was already in your hands. And I thought
2 that -- this proposal, that it represents industry --
3 current industry practice?

4 DR. ENGELJOHN: If I could just follow-up there.
5 We will take into account all the information available to
6 us. Our true goal here is to have an impact on public
7 health and to put the motivations where they need to be,
8 that are most effective and that, in fact, have some
9 qualifiable determinants on the impact on the size of the
10 establishment, which is an issue that you have to account
11 for in the rulemaking process. So we do believe that we
12 will get information to help us move forward.

13 MS. GLAVIN: Katie?

14 MS. HANIGAN: I'm just going to keep asking until
15 I'm clear. This is Katie with Farmland, Katie Hanigan with
16 Farmland. Can we just talk about listeria now for those who
17 opt to put it in the CCP? Well, I'll try to keep this short
18 and not to confuse myself.

19 Yesterday we saw many, many outstanding
20 presentations. The one thing we never did see yesterday was
21 the cost of this intervention would be, whatever, \$25,000
22 and you would need one of these units for each one of your
23 packaging lines. You know, that's one thing that nobody
24 ever talked to the industry or to the Agency about
25 yesterday. Or, if you want to formulate this compound into

1 this item it's going to be X number of cents per pound and
2 then the labeling is going to come in, etcetera. So we
3 still have that whole unknown.

4 So I'm sitting here today thinking to myself,
5 okay, so now let's -- we put that in the SSOP and let's look
6 at it from a CCP point. Everybody knows that the Tech
7 Service Center in Omaha is going to be hounded with calls
8 of, "So what is the CCP that belongs here after the
9 lethality study?" And they know pretty well that the Agency
10 came out and said, "You need to have a CCP at the final
11 round on the slaughter floor for fecal."

12 You know the same question is going to come, so
13 what is the CCP you're wanting after lethality? Because we
14 all sat through this meeting yesterday and nobody agreed to
15 anything, which is right and which is wrong, there are a lot
16 of opportunities out there. I think you need to be prepared
17 to address just what is the CCP that's going to be
18 acceptable.

19 The other questions I have is, for instance, if a
20 company would do something like put their CCP's in personal
21 hygiene, and I'm not recommending anybody does that, but if
22 somebody would do that and all of a sudden you have a
23 positive product -- and understand this is a CCP now -- and
24 I've got a positive product, whether it's in the field, not
25 in the field, however you want to look at it.

1 Have I just taken down the entire fully cooked,
2 not shelf stable processing category under the HACCP rule or
3 what have I just done to myself as a company? Have I just
4 created an inadequate HACCP system for that entire
5 processing category, or have I just affected only the
6 bologna line where this employee was seen not following
7 personal hygiene procedures? Just what happened here?
8 I think we need to have a dialogue as to what did just
9 happen, because I don't think anyone in the room knows.

10 MS. GLAVIN: Are there contributions to this?

11 DR. TOMPKIN: This is Bruce Tompkin from ConAgra.

12 Actually this is one of the comments that I wish to make
13 relative to that is that the proposal does indicate that
14 guidance documents for the establishment of CCP's and
15 sampling procedures and the corrective actions would be
16 provided with a final action on the rule. So your answer I
17 believe will be forthcoming and the final rule provided by
18 the Agency and so I don't know that there is an answer right
19 now.

20 DR. ENGELJOHN: I would just follow-up with that
21 and say we clearly will provide the guidance within the
22 final action but our goal at the moment is as the
23 information becomes available to us, that we believe is of
24 the quality that should have public input or at least have
25 some dialogue on the content of the guidance that we put

1 together, we will make that available and announce it to the
2 constituent update and any other type of format that we can,
3 which is what we did last Friday with the compliance
4 guidance which came out in draft form. We're looking for
5 input to modify it and we will continue to modify it and
6 update it as we get more information that comes in that we
7 need to provide.

8 So I wouldn't say that we're only going to provide
9 -- that's -- that can be some time away. Our goal is to
10 make available information that is at least of enough
11 quality in terms of -- and listeria testing behind it, that
12 it would be supportable to put out there for the public to
13 comment on.

14 MS. GLAVIN: Yes?

15 DR. TOMPKIN: Bruce Tompkin from ConAgra. I think
16 that the guidance documents are very important in terms of
17 our ability to understand how this rule will be applied.
18 With that information not being available for review during
19 the comment period essentially we're -- we're being asked to
20 buy into a new direction and we don't know how we're going
21 to be -- how the rules are going to be put in place. It's
22 difficult for us to assess the true impact of those rules
23 for that reason.

24 MS. GLAVIN: Caroline?

25 MS. SMITH-DeWAAL: May I just comment as well? I

1 mean Katie raised the issue of the cost of the HACCP -- of
2 implementing one of the HACCP CCP's, whether it be the clean
3 room technology or the steam technology, whatever you wanted
4 to do. If you're dealing with a sampling program that is so
5 -- I wasn't here this morning but I heard a rumor that the
6 estimate of cost per test is what? Four dollars?

7 A PARTICIPANT: Yes.

8 MS. DeWAAL: What? I mean --

9 A PARTICIPANT: That's what it costs --

10 MS. DeWAAL: I mean I think that's in-house
11 tasking but potentially a fairly minimal cost for the
12 testing. You need to have -- you need to have some
13 relationship between the costs of these various programs.
14 If you have a very inexpensive program that the expense of
15 which is borne by either a food-borne illness outbreak or a
16 recall when it doesn't work I mean that's not -- that's not
17 tremendously valuable to the industry, either. I think it
18 would be -- because the costs are all borne -- borne at the
19 back end rather than then at the front end.

20 So if you're driving people towards adopting this
21 in a HACCP system, you need to make the testing system also
22 reflective of the cost. We know, although we're not
23 covering this until tomorrow, that the economic costs of
24 illness and death are very high in this -- what this rule is
25 supposed to cover and, therefore, the cost of the regulation

1 can be somewhat higher than what you had put in at least in
2 the testing portion.

3 MS. GLAVIN: Dane?

4 MR. BERNARD: My question is one that Katie asked
5 first about CCP's, but just for clarification -- and the CCP
6 if you decide that you want to put this in your HACCP
7 program, is the language specific to -- lethality treatment
8 in packaging. I mean if that -- and if that is so, would
9 that preclude the flow technology that we discussed
10 yesterday --

11 DR. ENGELJOHN: Let me clarify. The language in
12 the proposed rule was that you had to address in the HACCP
13 plan, that your process involved post-lethality handling of
14 the product prior to the final packaging. So to the degree
15 that the product is going to be manipulated after lethality,
16 and it's going to get packaged. It doesn't say where that
17 where that CCP has to be, but that is the portion of the
18 process that we believe needs to be addressed in the HACCP
19 critical control point.

20 So I would venture to say that the flow technology
21 that we heard about yesterday which is the packaged --
22 product, would be an appropriate way for us to address that
23 issue.

24 MR. BERNARD: Dane Bernard. If I were to look at
25 that technology, would I have to meet a lethality

1 performance standard, or could I just say that this is a
2 listeria control CCP and leave it at that?

3 DR. ENGELJOHN: I think that would be the type of
4 thing we would want you to address in your comments to say,
5 "I think this should be addressed in the regulatory
6 language."

7 MS. GLAVIN: Yes?

8 MS. HANIGAN: Can I make a comment just for
9 clarification? At this time, Dr. Engeljohn, you're not --
10 you're not able to answer my question as to if it is a CCP
11 -- I just want to make sure I understand this, if it is a
12 CCP, at this time we're not sure if that would take down
13 that entire processing category as described under the 1996
14 packaging, the entire fully cooked, not shelf stable? I
15 mean we don't know what that would do yet?

16 DR. ENGELJOHN: I'm not -- I'm not answering that
17 portion of the question in the sense that I think that is
18 what we would expect you to have addressed in your HACCP, in
19 your hazard analysis as to how you've designed your critical
20 control point and what that has as an impact in terms of the
21 product and the processing.

22 I believe that the way the HACCP regulation is
23 written is that you have some ability to be able to define
24 what is affected when you have a loss of control in the CCP.
25 So I think that is an issue that you need to come up --

1 come to terms with. In the course of your comments, if you
2 want to lay out some scenarios of this is how -- these are
3 some of the options of how you think this may be handled
4 either by yourself or by the Agency and then a
5 recommendation for what you think it should be based on
6 HACCP principles. That would be a good way to get this
7 issue on the table.

8 MS. HANIGAN: Thank you.

9 MS. GLAVIN: Okay. Any other questions along this
10 line of inquiry? There are a number of people who have
11 signed up for comments and I'll just go in the order in
12 which they've signed up.

13 MS. SCOTT: Thank you. I'd like to present this
14 comment on behalf of the members of the National Food
15 Processors Association. We produce ready-to-eat meat
16 products that are subject to listeria testing. We did have
17 a couple of comments to submit.

18 The food industry has a strong interest in
19 programs that will assure the continued safety of our food
20 products. We will support government efforts to develop and
21 implement science-based food safety strategies. We believe
22 in sound science. We need innovative solutions to be able
23 to respond to food safety challenges.

24 First, we believe that the Agency should take into
25 account the fine rules of the FDA and the FSIS Listeria

1 monocytoenes Risk Assessment in this rulemaking initiative.
2 Specifically, the key finding that not only do the food
3 products present the same level of risk to the consuming
4 public. There is also risk assessment that clearly shows
5 that those products that do not prevent the growth of
6 *Listeria moncytoenes* and the attendant conditions of -- do
7 not present the level of risk associated with products that
8 do.

9 The primary goal of the *Listeria moncytoenes* Risk
10 Assessment was to identify those products for which
11 additional industry and regulatory measures might yield the
12 greatest public health benefit. Based on the findings of
13 the Lm Risk Assessment, we believe that foods containing
14 inhibitors to growth presume a low risk. Products that are
15 intended to be heated or cooked present less risk than those
16 intended to be consumed without further preparation. Foods
17 that are frozen so that there's no Lm growth, and then
18 thawed or heated and eaten, present low risk.

19 We believe that control measures for such products
20 presenting low risk can differ from control measures for
21 other products, rather than a one-size-fits-all approach.
22 For example, we believe that environmental sampling programs
23 can be structured differently for products in which *Listeria*
24 *monocytoenes* cannot grow.

25 We believe that testing of food products based on

1 a single finding of listeria species on the food contact
2 surface may not be warranted. Sporadic contamination of the
3 environment, including food contact surfaces, may occur and
4 have little or no impact on product. You heard that from
5 Dr. Weidmann yesterday.

6 The real problem occurs when *Listeria monocytogenes*
7 finds -- contamination of the product, the persistence that
8 Dr. Weidmann was talking about. Our leading food safety
9 microbiologists on the planet will concur with that.

10 (Laughter.)

11 Only through rigorous testing of the environment
12 that such harbor sites can be discovered. Thus we don't
13 feel that it would be appropriate to require product testing
14 based on a single positive listeria species on a food
15 contact surface. Investigation of any positive on food
16 contact surfaces should be done. Additional testing that
17 may include product testing, should be limited to additional
18 positives on the same surface or in the same area. This
19 appears to be the approach that the Agency has outlined in
20 the recently released guidance document on performance
21 standards. The industry would support this position.

22 The proposed rule would not require food contact
23 surface testing in establishments that identified *Listeria*
24 *monocytogenes* as a hazard reasonably likely to occur, and
25 consequently established more and more critical control

1 points or a HACCP plan after the lethality treatment.

2 However, industry and academic experts will tell
3 you that with so many products, it's impossible to identify
4 one or two scientifically sound critical control points if
5 you have a big *Listeria monocytogenes* contamination.

6 Dr. Marsden provided some examples yesterday for
7 some procedures for which scientifically sound critical
8 control points can be developed. However, these procedures
9 are not applicable to all ready-to-eat products.

10 Since listeria is the cause of -- the industry's
11 done quite a bit of work in developing and implementing
12 effective listeria control measures. Keep in mind that
13 there's no silver bullet for processing steps that can be
14 applied at the end of the line, to go to zero tolerance for
15 *Listeria monocytogenes* in all ready-to-eat products.

16 As Dr. Weidmann pointed out, keeping listeria out
17 of food processing areas requires constant vigilance,
18 because the microorganism is commonly found in ingredients
19 such as raw meat and other products, -- water and shoes and
20 clothes, -- nooks and crannies in the plant. Therefore,
21 industry combines a number of different control tools to
22 keep *Listeria monocytogenes* from getting into processed
23 foods.

24 For example, today's processors focus on the
25 importance of designing and maintaining equipment so it can

1 be cleaned effectively. Designing production facilities so
2 that employees who run the equipment do not spread bacteria
3 from room to room. Teaching employees to use good
4 manufacturing practices without exception. Using sensitive
5 detection programs to monitor the effectiveness of the
6 processor's control systems in reassessing detection and
7 control programs based on actual results -- involving
8 science. We know from experience that effective food safety
9 systems must be tailored to each processors work practices,
10 manufactural situations, and final product attributes.

11 As has been noted time and again, as Bill Sperber
12 so eloquently pointed out, finished product testing has
13 significant limitations. The most obvious -- packaged the
14 product. Finding pathogens in products where contamination
15 levels are low and organisms are not -- distributed requires
16 extensive sampling and he gave you some numbers related to
17 that.

18 Industry's experience has led us to conclude that
19 testing processing areas and equipment is both more
20 sensitive and more efficient. We feel that with the
21 proposed testing requirements, existing environmental
22 monitoring programs have been modified in ways that would
23 make them less effective. As a result of the regulation
24 establishments are likely to feel compelled to hold products
25 inside if a food contact surface is tested and

1 establishments may also feel compelled to hold other
2 products produced in other lines that day because of the
3 potential for the test results to be applied to these
4 products. You've already heard Katie Hanigan talk about the
5 potential costs involved with something like that.

6 Therefore, some establishments will elect to do
7 the minimum level of food contact surface testing because of
8 the expense of the proposed test programs. The aggressive
9 environmental testing programs that many establishments
10 employ today to effectively reduce *Listeria monocytogenes*
11 contamination, may actually be scaled back with a likely
12 negative impact on public health.

13 If FSIS requires food contact surface testing as a
14 final rule we urge the Agency to create alternative options
15 that recognize the efforts of firms that do more than
16 minimal testing. As an example, FSIS microbiological
17 sampling directive, currently has issued some proposed rules
18 referring to specific environmental end-of-product testing
19 to be subject to reduced -- product. This could be one
20 alternative, and other alternatives should be explored.

21 In summary, what you administer is key to
22 protecting public health with respect to listeriosis is
23 emphasized in the need for manufacturers to develop and
24 implement listeria control programs. The Essential
25 Component Control Program is aggressive environmental

1 testing with a disciplined root cause analysis collective
2 action program to address the results of the monitoring
3 program. We believe that such programs are best promoted by
4 regulatory policies that encourages rather than discourages
5 firms to test for foreign -- for the growth of pathogens.
6 Manufacturers should also note possible design products that
7 inhibit the growth of *Listeria monocytogenes*. Ultimately,
8 improvements in food safety must be designed into food
9 processing systems.

10 As a practical matter it's not possible to test
11 every single product defect of the food supply. That's why
12 a regulatory system that encourages intensive -- and self-
13 audits that protects the confidentiality of the associated
14 records is so important for Lm control. Thank you.

15 MS. GLAVIN: I wanted to ask if in your written
16 comments you were able to -- you made a comment that -- part
17 of your comment was that the final rule should encourage
18 rather than discourage companies to look for an eliminate
19 pathogens in their plants. Are you able to include in your
20 written comments suggestions on specific changes or
21 alterations to the proposal that -- that would do that? I
22 mean it's pretty hard to argue --

23 MS. SCOTT: Yes.

24 MS. GLAVIN: -- that that's not a great idea.

25 MS. SCOTT: Right. We will do that.

1 MS. GLAVIN: Okay. Great. It would also be
2 useful to have some discussion of what it is in the proposal
3 that leads to a discouragement of that. So that would
4 hopefully help and not just for your comments, but because I
5 keep hearing not just here, but in other places, this
6 concern that in an attempt to improve things, a rule might
7 make things worse by discouraging plants from doing things
8 that they're already doing and causing them to scale back,
9 not scale up.

10 MS. SCOTT: Right.

11 MS. GLAVIN: Okay. Can you come to the mike?
12 Thank you?

13 A PARTICIPANT: John -- I think that question
14 almost answers itself. Anytime the government gets involved
15 -- as a plant manager, I'm more concerned about what my
16 product is for my customers than I am if I'm going to pass a
17 test for an inspector. But I've got inspection personnel
18 coming in and wanting to review my test records as -- as are
19 required by this proposal. What's FSIS -- what's FSIS going
20 to do with the information they get?

21 I've got an article from the newspaper that there
22 was a plant that probably had a recall. This paper was
23 dated March 23rd and the product was supposedly produced
24 March 19th. We heard yesterday that it takes 48 to 72 hours
25 to get even species test results, and yet the newspapers got

1 information for these several products that had been
2 produced that were being recalled.

3 The problem I think that everybody's concerned
4 about is that, yeah, we want to take care of our own
5 products. That, you know, being mandated by a government
6 agency to do it -- Dr. Weidmann said yesterday that he could
7 find listeria in this room. He could also not find listeria
8 in this room. If FSIS is going to come in and want to look
9 at my records, there's never going to be a positive for it.

10 But I will have positives for myself. I will check my own
11 records and make sure that my equipment and my product is
12 going to my customers safe. But I'm more worried about what
13 FSIS actions would take, if I came back with a negative
14 report.

15 We've got the finest minds in USDA sitting here
16 today and they have all kinds of questions. Dr. Engeljohn's
17 continually asking questions, "How do we do this? How do we
18 implement it? We need more information." This is your
19 proposal, this is your regulation. You're not sure how to
20 implement it. When it gets out to the field and finally
21 gets to inspection personnel, it's going to be implemented
22 subjectively. I don't know about everybody else in the room
23 but as a plant operator it bothers me. It worries me to no
24 end that one inspector will come in and do things one way
25 and another inspector will come in and do things another

1 way. One set of information is going to be read in one way
2 and one set of information will be read another way. And
3 the control that FSIS takes will be implemented differently,
4 just as much as everybody in this room has a different
5 opinion about the whole proposal. Thank you.

6 MS. GLAVIN: Thank you.

7 MS. HANIGAN: Can I make one --

8 MS. GLAVIN: Yes, please.

9 MS. HANIGAN: Katie Hanigan with Farmland. I was
10 sitting here just chicken scratching the CCPs I've got here,
11 just for example, so everybody understands the point I was
12 trying to drive home. I said "chicken" scratching.

13 (Laughter.)

14 Doodling. I should apologize to Jenny, doodling
15 during her presentation.

16 (Laughter.)

17 But I had to do this.

18 (Laughter.)

19 As a comparison, if you use the CCP that we have
20 for fecal and slaughter, if you get going along and all of a
21 sudden you have fecal on carcasses we're going to go back to
22 your last acceptable check, and you're actually going back
23 and looking at those carcasses for something that you can
24 see, which is fecal. For those sitting in the room that
25 have metal detection as a CCP -- not that I'm advocating

1 that, either --

2 (Laughter.)

3 -- but I'm just saying if you have metal detection
4 as a CCP and you get rolling along and all of a sudden your
5 metal detector's not working, the way it's supposed to be,
6 you've got your product and you fix the metal detector, you
7 recalibrate it or whatever you need to do. And you start
8 running the product back from the last acceptable check back
9 through and that's fine, that's good.

10 Now we get to this listeria CCP for those in the
11 room that opt to do this, and I just wrote down here
12 "application of sanitizer to the line" or whatever. I mean
13 I was just writing one of these down and I'm thinking, okay,
14 so you agree here that you're going to apply sanitizer to
15 the line at a level that is documented significant to
16 destroy listeria, so whatever. Say it's 150 parts per
17 million and I'm not saying it is, I'm just saying whatever.

18 (Laughter.)

19 You get to the end of first shift and you go to
20 verify the concentration of the sanitizer, which is coming
21 out of this unit you have mounted on the wall which is
22 guaranteed not to ever malfunction --

23 (Laughter.)

24 -- we all know how that works.

25 (Laughter.)

1 And all of a sudden, the sanitizer concentration
2 that's being delivered from this unit has dropped down to 75
3 parts per million and the last time we checked this was at
4 noon and it's now 4:00. All of a sudden we've got about
5 four hours worth of production that was packaged during this
6 timeframe when the sanitizer apparently sometime dropped
7 down to 75 parts per million.

8 If I have to go back to the last acceptable check
9 with this packaged product what am I doing? Going to reopen
10 all these packages? It's not like I'm going to see the
11 listeria. I mean I get -- sitting here saying, "So what's
12 my corrective action? I'm not going to see the listeria. I
13 mean I've got the product held because the level of
14 sanitizer here dropped off. What corrective action will be
15 taken on this product to make sure under the rules, it's not
16 hazardous to the health? I mean we're just going to run
17 ourselves in a circle.

18 Clearly if you would buy one of the interventions
19 that we saw yesterday, but as I said we don't know the cost
20 of those interventions and that cost is much more
21 significant than the \$4 attachment. I think it's two
22 totally different things. But it would be one thing if you
23 did have the intervention where you could run all the
24 packages back through it again. But I think nobody in this
25 room has got those interventions right now, and I don't

1 think anyone's going to have those interventions in the next
2 three to six months.

3 I mean, we're kind of at a stop. It's not like we
4 -- we want to do the right thing but we're kind of locked up
5 here. I recommend, the best of the best I'd say is at the
6 Omaha Technical Center. I think more scientists need to sit
7 down and say, "So just how do you lay out the CCP so that
8 when it fails, the corrective action goes back to the last
9 acceptable check and how do you do this because the product
10 is already packaged and you can't see the listeria?"
11 Because you sure don't want to go reopening all of that
12 stuff. And repackaging it again means a lot of issues with
13 cross-contamination if we start reopening packaging. Just
14 food for thought. I'll try to summarize that and put it in
15 written comments, as well.

16 MS. GLAVIN: Good. Thank you. Appreciate it.
17 Yes, Joe?

18 A PARTICIPANT: Dan, before you tell me to put in
19 my comments, I will.

20 (Laughter.)

21 We were talking about the cost of this thing, and
22 what it may or may not cost. I want to put this in
23 perspective and I didn't chicken scratch, I turkey scratched
24 this.

25 (Laughter.)

1 Roughly, if you would take a line and some may run
2 fast and some may run slower, but say you pack four cases
3 per minute. That's about 240 cases per hour and on an eight
4 hour shift, we've got 1,920 cases at 40 cases per pallet, so
5 we've got 48 pallets per line. Okay. Let's say you have
6 five to 10 lines in the plant. That's another 240 to 480
7 pallets per week. If you take those and store those in a
8 warehouse where you have eight slots, three deep and three
9 high. It would take 48 walls to store this in. That's
10 about 10 miles of warehouse space. At \$15 for handling per
11 pallet, one time charge hopefully, and \$1.50 storage per
12 month, you're talking about \$3250.00 per week, just because
13 you took a contact surface swab. That's what we're talking
14 about. That's significant. But that's what it comes down
15 to. And that's per week.

16 Now if you do that four times a week, you really
17 turn it every two weeks. You can always wait until you get
18 your results back. But you're roughly talking about \$16,500
19 per month of charge to comply. That's part of the problem,
20 to keep it in perspective. Thank you.

21 MS. GLAVIN: Yes?

22 MS. SWERBER: I'm Bill Swerber with Cargill. Just
23 to remind you on Katie's CCP. One easy way to think about
24 whether something should be a CCP or a JMP, is to determine
25 whether or not you can take action against the product when

1 a deviation occurs. A HACCP plan, if you have a deviation
2 on the CCP, you must control the product. Sanitation steps
3 are not good CCPs, so sanitizing your line really wouldn't
4 shouldn't be on a CCP.

5 So if you're looking to develop an example for a
6 CCP under this rule, there's -- or something like -- that
7 would be a good example and you would control that by
8 formulation controls. For some reason you don't have it,
9 then you go back to the affected product and it has to be
10 detained, reworked or destroyed. Other CCPs could be --
11 processing steps identifying the packaged product which
12 would be easily monitored by going through records or --

13 MS. GLAVIN: Thank you. Dane?

14 MR. BERNARD: Dane Bernard. Just to continue on
15 with what Bill said and to harken back to Jenny's remarks.
16 There's a significant value of product that's packed, that
17 is not amenable to the place to package further processing.
18 There's a great deal of products which are manufactured and
19 provided for other multiple uses. It simply is not amenable
20 to that sort of technology.

21 So there are challenges and when one thinks of the
22 problem products we've had -- and as a company I really
23 think we can post-package treat things and then incorporate
24 that with technology, but that's not the answer to
25 everything that this rule addresses.

1 MS. GLAVIN: Caroline, you signed up for -- do you
2 want to wait?

3 MS. DeWAAL: Yes. I'll wait.

4 MS. CHRISTIN: Hi, I'm Charlotte Christin. I'm
5 senior staff attorney at CSPI. It's been more than two
6 years since the Sara Lee outbreak sickened 101 people and
7 killed 21 others. Last year CSPI filed a petition to
8 require both environmental and product testing and labeling
9 requirements for ready-to-eat products because we were very
10 concerned about what happened in the Sara Lee outbreak.
11 We're glad at this point that we finally have a proposal,
12 but it has been more than two years. So it's taken us a
13 long time to get to this point and we need to continue to
14 work with expediency in getting a final rule going.

15 With regard to the issue of testing frequency, we
16 agree with Jenny. A lot of firms are doing a lot of -- a lot
17 more testing than what their proposal would require. A lot
18 of firms do have aggressive testing programs. We're
19 concerned that firms might scale back because they perceive
20 the proposal as some sort of a shield. While it may not
21 necessarily be legally a safe harbor, there certainly is an
22 issue of whether there would a ways to the bottom.

23 We also believe that more testing would save more
24 lives. There is a public health consequence to reducing
25 *Listeria monocytogenes* adulteration. We think that all

1 plants should sample all lines at a minimum of once a week.

2 We're also concerned because it appears that the proposal
3 would allow the bundling of testing.

4 The point was raised earlier about what the Agency
5 means by testing. The way I read the proposal, a large
6 plant presumably could perform all four of the -- tests
7 within a very short period of time and then not test and yet
8 still be in compliance with this proposal. We think the
9 regulation should be modified to change, for example, the
10 four times a month requirement for large plants to one time
11 a week, for example.

12 Finally, with regard to the issue of the listeria
13 species versus *Listeria monocytogenes* and what organism
14 should be tested for, we support the comments made earlier
15 by Kaye Wachsmuth and Bruce Tompkin regarding the value of
16 listeria species testing. One additional comment would be
17 that, for those of you who are concerned about the presence
18 of listeria species, in that it might not correlate to the
19 presence of *Listeria monocytogenes*, we have this alternative
20 -- test for *Listeria monocytogenes*. However, the
21 ramification of that, is that *Listeria monocytogenes* is an
22 adulterant.

23 I guess -- I'm sorry, one last comment, with
24 regards to the -- to the HACCP alternative to the SSOPs,
25 there's been a lot of discussion about that and there were a

1 lot of good questions -- questions raised by Katie and
2 others. I think that the proposal focuses a lot on the SSOP
3 alternative, however, I think a lot more needs to be fleshed
4 out with regard to the HACCP alternative. For example, the
5 language in the proposed regulation itself does not provide
6 any specifics about the required validation. Presumably the
7 Agency does intend that validation would be required but,
8 for example, nowhere in the section on listeria species
9 testing is there any mention of the validation for HACCP.
10 So I think that's a large gap that needs to be filled.
11 Thank you.

12 MS. GLAVIN: Okay. Other comments, questions,
13 discussion?

14 Bruce?

15 DR. TOMPKIN: I'm Bruce Tompkin from ConAgra. My
16 comments will eventually be submitted in writing so I'm
17 working from something that I wrote some time ago and I'm
18 trying to figure out where it's all going to go. But I
19 would like to remind us all as we head forward, at the
20 bottom line of all of this exercise is improved consumer
21 protection. There's a discrepancy as to what the actual
22 goal will be in terms of improved public health. The
23 discrepancy really falls within the Federal Register notice
24 where 167 cases are estimated to be attributed to ready-to-
25 eat meat and poultry products and yet the FDA/USDA draft

1 risk assessment sets this number at 1,660. So there's about
2 a 10-fold difference.

3 Well, there are probably a number of reasons why
4 that may be the case but, you know, it would be desirable to
5 have a better fix on what that number should be,
6 specifically, so that we know where we're going. What is
7 the estimated reduction in -- in food-borne listeriosis that
8 can be expected from this particular proposal, relative to
9 what we have in place today which is the directive. The
10 directive which was issued in December already does address
11 a number of the issues we've discussed, and it's a question
12 of what further reductions in illness would this provide?

13 I think that in reading through the document, we
14 do test aggressively in our company. We do test on a weekly
15 basis from every line. Cost, as I mentioned, was \$4 but
16 that does not include the sampling time and cost as well as
17 the shipping costs. So a few dollars is okay for us because
18 we're high volume.

19 We're looking very hard for this pathogen and
20 actually for an indicator of the pathogen and the conditions
21 under which we are operating. So we have been able to have
22 some economies of scale.

23 However, the way this proposal is set forth if you
24 do test product contact surfaces, and do detect a positive
25 for listeria whatever, species or the like, it will require

1 that we place the product, or actually go after the product
2 and test it. This is going to diminish our desire, I just
3 know it will, to do this. It's critically important for us
4 and for our level of confidence and our degree of control to
5 test as freely as possible.

6 The financial costs in terms of placing product on
7 hold has been described just a little bit ago and it's a
8 very real -- it's a very real factor. In addition to
9 placing product on hold, there is definitely a financial
10 cost associated with that. And also, we short customers,
11 and that's really not a very happy experience. So there are
12 a number of factors that enter into the mechanics and
13 whether or not this is really a practical thing.

14 As a matter of policy, our company says that any
15 time we sample a product for a pathogen, the product will be
16 placed on hold. That means that not only in the four weeks,
17 the four sampling times per month, but any other time that
18 we sample a product contact surface, we will place the
19 product on hold. And that's a negative feature.

20 The idea of incorporating one or more CCPs into
21 the HACCP plan for control of Lm between lethality and
22 packaging in lieu of testing, I think, is an easy way to do
23 it to avoid all this pain. But actually what that means is
24 that leads the industry to test less. And it places CCPs
25 which, quite frankly, I think there's a general consensus

1 that there is no such CCP between lethality and packaging.

2 Anything -- and we have done this before on other
3 issues, but there are no CCPs that we can put in place that
4 will ensure or control or prevent contamination with a
5 Listeria organism. That again really comes down to post-
6 packaging processing as the means to -- as we heard
7 yesterday, that would be a true, valid CCP.

8 The idea of adding additives has considerable
9 public health value, but it does not get around the issue of
10 a positive product. We would still be in violation even
11 though we feel that the product would be safe through the
12 shelf life and -- and until the product gets consumed.

13 There is a question, a number of questions, but I
14 think I added it up and there were 26 questions or more in
15 this proposed rule. Trying to respond to all of those
16 questions and all of this stuff and listeria risk assessment
17 from FDA/USDA all at one time is a bit much. But one of the
18 questions in there, was this relationship between listeria
19 species and Lm. I suggest that the Agency could actually go
20 into its product testing, look at the data and find out what
21 number of samples test positive or suspect, let's say, of a
22 listeria species state, a listeria-like organism -- such as
23 that, and then determine how many of those confirm --
24 confirm out as Lm? You could -- that would be one
25 indication for what that relationship might be, at least in

1 product, and that could be of interest to us.

2 The proposed rule does not address the issue of
3 risk of the product in terms of whether growth can or cannot
4 occur. I think that this is a feature that should be built
5 into it. I know the current policy states that, in fact,
6 the presence of Lm is an adulterant and it's -- and it's --
7 the product is subject to recall and destruction. However,
8 as we progress through the risk assessment process and
9 become more familiar with the public health issue, then
10 perhaps the future version of this could take into account,
11 growth versus no growth.

12 I would actually suggest that if you think in
13 terms of this whole process as we've gone through it since
14 1987, I believe, at least in the meat and poultry industry,
15 we've gone through a number of stages where it was thought
16 to be a concern, it was confirmed to be a concern with the -
17 -- franks situation. Then we had gone from a one gram
18 sample to 25 grams. A lot of things have been going on.
19 We've been changing and tightening up and that's -- that's
20 okay. That's not really the issue, but it's a matter of how
21 fast can we move this industry to an aggressive program as
22 defined in the proposed rule, in terms of sampling every
23 four weeks, you know, four weeks per month? Four times per
24 month has just been suggested.

25 I think that we've reached a point where the

1 directive that was issued in December of last year, as being
2 a very positive step forward and here now we're already
3 talking about leaving that behind and moving on to the next
4 one. I think that the directive that was issued is
5 practical, workable, and does increase the level of testing
6 that industry should be doing in terms of product testing in
7 particular. It does allow for environmental testing as an
8 alternative.

9 I think that that directive should be modified so
10 that when a product is sampled at whatever -- is used, the
11 product contact surfaces also be sampled. Through that
12 means, you would develop the data that your seeing in terms
13 of a relationship between product contact surface sample
14 results and the product. Also, we can also use that same
15 experience of data to address the question of listeria
16 species and its relationship to Lm. And we would take those
17 samples all the way to Lm.

18 DR. ENGELJOHN: Can I ask a follow-up question?
19 When you say if -- if you're talking about the FSIS coding
20 sample, the sample that we would take from listeria on the
21 ready-to-eat product?

22 DR. TOMPKIN: No, that's --

23 DR. ENGELJOHN: the same time --

24 (Multiple voices.)

25 DR. TOMPKIN: -- and I wasn't thinking of what you

1 folks were going to do. That's right. You can do that.

2 DR. ENGELJOHN: Okay.

3 DR. TOMPKIN: The product is going to on hold or
4 if it's positive it's going to be subject to recall, anyway,
5 so there's an opportunity from experience and information,
6 whereas in the other -- in our case where we sample once per
7 month per HACCP plan in each of our plants, we would
8 certainly, when our products are on hold, we could just as
9 easily sample the packaging lines at the same time. By
10 pulling that, data actually the data would add up rather
11 quickly.

12 As we've been hearing each other talk, I think
13 we're all concerned with testing as really the backbone of
14 our control program, in terms of assessing the level of
15 control, and then it's what we do after we find the
16 positive. That's another issue.

17 But there is a real problem, a real financial
18 problem and so on, with regard to smaller operators. They
19 do not have the resources and they do not have the financial
20 backing to enable them to be as aggressive as larger plants.

21 There has to be some consideration given to providing
22 education and help to those operators so that they
23 understand the problem, what they could be doing in terms of
24 minimizing this risk.

25 I think there should be a means by which -- I'm

1 getting into somebody else's area, but the private
2 laboratories that do the analyses, someone should be
3 negotiating with them for a better price. It can be done
4 cheaply. You don't have to know the final -- the final
5 number or answer. What you need to know is whether you have
6 listeria-like or listeria species. That is lower cost, and
7 that does provide the information that allows a processor to
8 direct their energy to a potential problem. Whether that's
9 done through them or it would be done through the Agency or
10 through some other mechanism, through land grant colleges
11 and so on, I think something should be done to enhance the
12 educational component of this whole package.

13 There is a parallel example that's gone on
14 recently with the FDA rule, it's a final rule now, for fresh
15 juice that really relates specifically to fresh citrus juice
16 where a processor can find an alternative procedure other
17 than food pasteurization or pasteurization; let's say for a
18 five year reduction. And they do have a program in place
19 for sampling for E.coli as an alternative to sampling for
20 the pathogen of concern. In the event they do find the
21 cause of E.coli it's all spelled out exactly what has to be
22 done with that, from a corrective action standpoint.

23 If it were in our case, testing for listeria
24 species, the product is not in jeopardy, just as in the case
25 for fresh juice, -- is not in jeopardy. However, it has to

1 go through the corrective actions and then I believe as you
2 resume sampling or producing, then you move on. If you have
3 in their case, a couple of positives, then you move toward
4 product testing. So we have the rule, it's a parallel to us
5 that offers I think some alternatives to where we are now.
6 Thanks.

7 MS. GLAVIN: Okay. Thank you.

8 MR. DERFLER: It's Phil Derfler. I have a
9 question.

10 MS. GLAVIN: All right.

11 MR. DERFLER: We have an aggressive testing
12 program but we're worried about, when you test for the
13 listeria species on food contact surfaces, but does not
14 necessarily lead you to test the product. I think that's
15 what you suggested earlier in your talk.

16 DR. TOMPKIN: Exactly, yes. We're sampling every
17 line every week, 230 something lines, plus we're running
18 over 60,000 samples per year. So I think, and what's in the
19 official program, we encourage our floor people in the plant
20 to go beyond that because we want them to find the problem
21 if there is one.

22 MR. DERFLER: Okay. Do you worry -- okay, you get
23 a food contact surface positive, do you worry that -- about
24 what that represents for the food?

25 DR. TOMPKIN: Well, that's a good question and

1 we've wrestled with it many times and -- well, we have also
2 looked at the data recently and we find that these are
3 isolated positives, and by a large number. I have the data
4 and we shared that a little bit a little while ago. But, by
5 and large, those are isolated positives, rather than
6 repetitive positives. It's the repetitive positives that we
7 heard yesterday where a niche is formed. And as Jenny had
8 discussed, that was the greatest concern and that leads to
9 the biggest issues.

10 MR. DERFLER: So if you had a repetitive positive
11 you might start doing --

12 DR. TOMPKIN: Oh, absolutely. That's -- that's a
13 real red flag. Now we have considered as a -- a product
14 contact surface sample holding the product and it's not
15 manageable. The impact to functioning, to the business, is
16 so tremendous. So to work on that -- on that scenario, is
17 very difficult and, essentially, it immediately has a direct
18 impact on your desire to go out and sample.

19 MR. DERFLER: Okay. Let -- Let me just ask one
20 more question.

21 DR. TOMPKIN: Sure.

22 MR. DERFLER: Then do you weigh that from a
23 product -- I mean do you think about the costs and benefits
24 from a product liability standpoint? I mean to a certain
25 extent you are taking a chance there.

1 DR. TOMPKIN: I recognize your legal background.

2 (Laughter.)

3 MR. DERFLER: Yes. Your answer will be --

4 DR. TOMPKIN: It's not -- I worry about it from a
5 consumer protection standpoint first. I also then worry
6 about the legal issue. If or whether we do have a problem,
7 that original data is just going to kill us in some ways.

8 Now the other way of looking at it is that we have
9 a very good story to tell in terms of that we have been
10 aggressive -- I don't know what the legal term is
11 but --

12 MR. DERFLER: Due diligence?

13 DR. TOMPKIN: Thank you.

14 (Laughter.)

15 If we have a problem, it won't be because we
16 haven't been trying to find it and cope with that. So
17 that's -- that's our defense from the legal standpoint is
18 that we're really trying to find -- I guess from the
19 Agency's standpoint that sort of indicates it's a very real
20 one. That's for sure.

21 MR. DERFLER: Thank you.

22 DR. TOMPKIN: It's where you try to get the
23 balance. It's really a matter of what can you do
24 practically and still achieve the public health.

25 MR. DERFLER: Through your experience, have you

1 ever developed like an odds ratio or something like that or
2 some sort of data that would suggest what the relationship
3 is between surface positives and consumer complaints or
4 anything like that that would give you some sort of long-
5 term handle as to how successful you've been --

6 A PARTICIPANT: Or how you define a spike or just
7 that random positive that you had? Do you have some
8 parameters for that?

9 DR. TOMPKIN: I mean we used to look at our data
10 closely and respond to those lines where we had two
11 consecutive positives or three in the last seven. We no
12 longer do that.

13 MS. WACHSMUTH: Do you ever do product testing
14 follow-up? I don't mean of the same product, just on the
15 day you took your sample?

16 DR. TOMPKIN: Okay. I can -- we do not on the
17 first -- on the first time. When we have a suspect -- we're
18 testing for listeria-like in our situation, and so if we
19 find a listeria-like, then we will essentially go through
20 our corrective actions and truly mark it Lm. Then we will
21 resume production and then if we -- then we will sample the
22 line two days in a row. We want to verify that, in fact, we
23 have had -- we have brought that condition under control.

24 So whereas we used to look for patterns and focus
25 on two consecutive or three out of the last seven, now we

1 treat every -- every positive as a concern and we go through
2 that step. If we find in the course of that event a series
3 of three another positive on the line then we will go
4 through the corrective actions, start up again, and continue
5 for the three consecutive negatives on the -- on the
6 packaging line. And in addition, the product is on "hold
7 and test" and we test the product.

8 We have had situations where we have had
9 definitive positives and definitive issues, the product is
10 placed on "hold and test, we've destroyed product as a
11 result of this program, on the basis of a listeria-like
12 finding without confirming to Lm when there's -- that's one
13 of the quirks of the current policy, because if you find Lm
14 that's a failure of the HACCP plan and that's not really
15 constructive.

16 Then we have to go through reevaluating the HACCP
17 plan. And we know with reality, that's not going to -- it's
18 not really addressing the issue, and so on. We're getting
19 into all these other things, but from a public health
20 standpoint, there is a program that can be put in place
21 that's manageable that would address those concerns. But it
22 is not taking action on the first positive product contact
23 surface.

24 DR. ENGELJOHN: Let me see if I can follow-up.
25 When you sample the product is there an ICMF stratified

1 sampling scheme that you're using, or how are you
2 determining the product's sample size? Do you have a
3 comment for that?

4 DR. TOMPKIN: Yes, that could be done and -- but
5 at this point in time we have been simply using the USDA
6 sampling frame -- now we have had a situation where we
7 did -- we were concerned about -- we had a positive on the
8 product. And we went in and sampled that lot with an ICSS
9 sampling plan on 30 sets of five samples each by packages
10 and analyzed those. That's 30 separate analysis. They were
11 all negative. So that gives you some idea. There was one
12 positive and we had those 30 sets negative. We analyzed
13 those at the end of code date; again 30 sets and they were
14 all negative for Lm.

15 So it's not much data, but in terms of what is the
16 relationship between the product contact surface and the
17 product sample; I don't know that there's any data. We --
18 there was a time when we used to sample product every two
19 hours from every packaging line and record it and we used to
20 take those out certainly to listeria species at that time
21 and that's been discontinued because of all of the issues
22 that come up now.

23 So we really lost an opportunity. We've been
24 losing opportunities for generating the data that we all
25 need as a result of the adulteration issue and if we had

1 some -- some relaxation of that -- I know that's going to
2 make some people very nervous when I say that --

3 (Laughter.)

4 -- but there should be some way that we can arrive
5 at a mutually desirable way to -- to sample the equipment
6 where necessary and the product to verify HACCP and CCP and
7 the SSOP, and still allow for aggressive testing. It
8 doesn't matter how we get there. This proposal is -- is not
9 the answer.

10 A PARTICIPANT: After five years I didn't think I
11 was going to be sitting at this table again but I'm back
12 again on this topic. So you really asked two questions, and
13 the reason I came back up here was to try and give you some
14 comment as to what disincentive is and what used to be, and
15 what we found out when we could keep sampling.

16 We used to have a definition of a non-intact
17 sample as not being a sampling in which regulatory reaction
18 would take place. Industry had an opportunity to police
19 itself, at least it's own operations. And we did that, and
20 we sampled a lot. We'd sample contact surfaces and we'd
21 sample our product in a manner that gave us information to
22 improve our operations without shutting down the plant.
23 Pretty much -- didn't find much of a correlation from what I
24 recall, from the contact surface of the product.

25 But after the definitions changed as well, it's

1 kind of hard to say right now, we stopped taking those
2 samples. We don't have them any more. We can't afford to
3 take those types of samples that we did in the past. That's
4 a disincentive from the regulatory scheme of the past.

5 I have to agree with Bruce on this, the more that
6 you try to encourage with a strong arm, industry, into
7 taking sampling plans -- I don't know if we said it
8 yesterday, but I have to agree -- there are ways of sampling
9 and meeting regulatory requirements without looking and
10 finding nothing and that's not what you want, I don't
11 believe.

12 But to answer your question, as I recall there was
13 not -- there was no correlation between actual contact
14 surface positives product or product positives.

15 DR. ENGELJOHN: Just for the record, this is John
16 Engeljohn. John, you mentioned intact versus non-intact.
17 Because we dealt with the issue yesterday of intact versus
18 non-intact, but in a different context, just for the record,
19 what I believe you meant was, there was original
20 microbiological sampling program in which we'd find an
21 intact sample as one being inside an enclosed container, so
22 that is not exposed to the environment.

23 A PARTICIPANT: Yes, that's correct. Most of the
24 contact surface positives were subject to -- they're
25 outliers. Whenever we had repetitive issues, if we had a

1 repetitive issue it -- it didn't really correlate well with
2 the product at that time, but whenever we did get a positive
3 we could go back to a repetitive contact making more sense
4 in the long run. That's what we do now. As we move from
5 past experience. But just a single contact positive, no.

6 MS. DeWAAL: John, thank you. I think a lot of
7 good ideas have come out in this discussion. I do think
8 that USDA holds some of the key in its own hands, and that
9 is when you are taking food samples it would make sense to
10 have the government take some product contact samples at the
11 same time to give you some data on correlation.

12 I think what we've heard today are two different
13 approaches to the liability issues. I think Bruce has laid
14 out an excellent example of how a lot of people thought the
15 industry would respond in a responsible way to the zero
16 tolerance on listeria, which is we sample -- we may not
17 sample for Lm but we sample like crazy for listeria-like and
18 we take action even against product.

19 We're just -- you know, that's our defense. If
20 something happens, it's like we're really looking and that
21 is a responsible approach. Unfortunately, the industry
22 didn't do that. Because of legal advise given to the
23 industry that said, "Your best bet is not to know. Put your
24 blinders on and don't test this product." That is, in fact,
25 in a sense, why we're here today.

1 But I need to remind the audience, if not the
2 regulators, that the Bilmar plant did run samples. They did
3 find positives. They didn't know what to do. There wasn't
4 a mandate, their advice from lawyers had been scared. So
5 they -- instead of dealing with the product issues, they
6 just stopped sampling. They didn't want to know. They put
7 the blinders on, they listened to the lawyers and they
8 didn't do the responsible public health thing.

9 So we really need to move forward with regulations
10 in this area and I'm happy to see the government doing that.
11 But I think there are two approaches, and I think Bruce has
12 really outlined one very well. And I think the issue I'm
13 going to go home and think about is the issue of, we need
14 more than four tests a month, whether it's done once a week
15 or four tests in a month. That's not enough for a large
16 plant. That might be the minimum needed for a small plant,
17 which I think is what Charlotte was trying to say, but we
18 definitely think that more testing is required. The thing
19 that I'm going to go home and think about is what Bruce has
20 raised, the issue of what -- what happens after the first
21 positive?

22 I think the data that will be beneficial to the
23 Agency and I'd love to see it too, is what percentage of
24 random positives for Lm-like as opposed to repetitive
25 positives? Because that's -- that's an interesting new

1 concept that we should certainly think about. But at some
2 point, we do need to move on to look at the products and --
3 and you may need to move into the holding-test sampling
4 system. The bottom line is this isn't going to be a free --
5 the public -- the public health benefit here isn't going to
6 be -- there are some -- for the industry. This is going to
7 cost the industry something to improve their products.
8 Luckily, many of these meats are very inexpensive to
9 purchase, and they're produced in very high volume and so
10 the cost to the consumer, I think, from making these
11 improvements will probably be minimal, if even noticeable in
12 the family budget.

13 So I think it will cost the industry something to
14 comply. We need to make for compliance whether it's a
15 testing regime or a HACCP type regime. They need to be
16 related so there is some incentive to move to the HACCP type
17 system, you know. I just would urge the Agency to proceed
18 quickly, to work out these details and to move this forward.
19 Thank you.

20 MS. GLAVIN: Do people want to break or do you
21 want to keep going?

22 MR. JOHNSON: Well, can I just have the last word?
23 (Laughter.)

24 MS. GLAVIN: Go.

25 MR. JOHNSON: Dennis Johnson again. Sitting next

1 to Caroline, I noticed she mentioned lawyers. Without
2 naming names, I assume she was talking about lawyers other
3 than me.

4 (Laughter.)

5 -- and I appreciate that. I'm going to sort of
6 answer to the liability question, if I could. This is the
7 advice I've given publicly, this is the advice that I've
8 given to every one of my clients, and here it is. If you do
9 not control listeria in your plant, you're going to end up
10 with a problem. You're going to end up with harborage.
11 Your harborage is going to increase the amount of products
12 you have positive, which thereby exposes your risk
13 tremendously.

14 I've had clients who have had positive rates of up
15 to 30 percent, back when they hired me they had 30 percent.

16 Because it's long and short. If you don't look for it,
17 it's going to get you. It's what you don't know that will
18 get you in trouble. So in the case of listeria, you need a
19 very aggressive program recognizing that maybe, you might
20 have a liability, because maybe one time -- but I'd rather
21 eliminate the possibility of having widespread outbreaks,
22 where you have multiple Plaintiffs. The better way to go is
23 to eliminate it right in the bud. Therefore, from a
24 liability standpoint, I tell my clients not to worry about
25 an isolated incident, it's best to prevent the outbreak as

1 it goes along.

2 The question here -- and this is what Bruce has
3 raised and what I have also talked about -- is we don't want
4 to have an automatic, on thinking, regulatory reaction to a
5 single isolated positive. The regulatory issue should not
6 be, did you find it? The regulatory issue should be, what
7 are you going to do about it to make sure you don't find it
8 again? The one big bite of the apple -- the follow-up to
9 see what you do to handle it, as if it were a crisis from
10 the word go. That's where the Agency should be. That's
11 where I advise my clients to be from a product liability
12 standpoint. And if you have automatic, on thinking,
13 regulatory response to a single isolated positive you're
14 going to get people to go underground.

15 I've seen it and, notwithstanding, all my legal
16 advice, they're still going to do it because they're more
17 afraid. They have to be able to go ahead and find it. If
18 you discourage them from finding it by saying, "The first
19 time you find it, your HACCP plan's inadequate. We're going
20 to close you down." By the way, that is the answer, Katie.

21 They will close you down for an inadequate HACCP plan. I
22 make a good living on that.

23 (Laughter.)

24 But all kidding aside, we have to have that
25 encouragement, the cooperation of the Agency, "Okay. Go

1 ahead. Try to find it. We'll let you try to find it.
2 We're not going to punish you if you find it and take
3 action."

4 Now if I could extend my break time for just one
5 other second because I don't know when this is going to fit
6 in. On *Listeria monocytogenes* control, *Listeria* species is
7 not enough, *Listeria monocytogenes* is not enough any more.
8 If you find a positive Lm, you really need to know the
9 pattern, the ribotyping, the PFG, or whatever you want.
10 Dr. Weidmann yesterday, made that point real clear. I would
11 hope that the Agency has full access to all our records. I
12 mean my advice to clients when the FDA says, "Do you have
13 any PFG's? Can we see them?" My advice is, "They'll get a
14 subpoena and get it anyway, so you might as well share it."
15 But the Agency has data. The Agency runs the PFG's, from
16 the way I understand it, from all the positives. You have
17 full access to all our records, primarily. Maybe with a
18 subpoena -- oh I'm sure you're going to get them. But we
19 can't even get anything out of the Agency in terms of a PFG.
20 Maybe that's part of why I feel like this or maybe I'm --
21 maybe I'm uninformed.

22 MS. WACHSMUTH: Share the --

23 MR. JOHNSON: If we wanted to do ribotyping, could
24 you do ribotyping for us?

25 MS. GLAVIN: If you arrange it.

1 MR. JOHNSON: Okay. Well, then that solves that
2 problem.

3 (Laughter.)

4 Now who do I get the rest of it from?

5 (Laughter.)

6 Thank you very much, Maggie.

7 MR. DERFLER: I just want to ask one question and
8 nobody necessarily has to answer it right now, but I really
9 wish you'd address it in your comments and that is what is
10 the repetitive finding of Listeria monocytogenes on your food
11 content -- I mean a listeria species on your food content?
12 Is it listeria-like, is it two? Is it three? Is there --
13 is there a scientific basis in which we -- in which we could
14 reasonably draw that line? Because, otherwise, we're going
15 to wind up in the same spot where we are, because how many
16 times did we test for Lm? I'm not complaining. I'm merely
17 honestly asking for help.

18 If you're going to consider going down this or
19 consider going down this, I'd like to do it in a -- with a
20 rational basis in a defensible way and so that's why I
21 really would like comments.

22 MS. GLAVIN: And can I suggest that everyone
23 consider that question and go have a cookie --

24 (Laughter.)

25 -- and come back with an answer.

1 (Laughter.)

2 (Break at 3:22 p.m.)

3 (On the record at 3:45 p.m.)

4 A PARTICIPANT: We're down to the hard-core people
5 here.

6 A PARTICIPANT: As long as we have the leading
7 microbiologists on the planet, why not continue?

8 MS. GLAVIN: We anointed during this meeting --
9 what did we say? It was the leading --

10 A PARTICIPANT: The leading -- microbiologists on
11 the planet.

12 MS. GLAVIN: -- microbiologists on the planet and
13 someone referred to the greatest minds in the government.

14 (Laughter.)

15 (Multiple voices.)

16 Okay. We still left a question on the table in
17 terms of -- and I'm not sure that it really is one to answer
18 right now, but I do know that it will be given due
19 consideration, and some help given in the comment period.
20 And that had to do with what do you -- when you have your
21 company systems consider trends, what are some reasonable
22 parameters, or what are ways of thinking about that?

23 I was involved in a discussion just a minute ago
24 during the break, about a company that considers two a trend
25 and the inspector argued that it should be three. That two

1 is not a trend because it's not scientific.

2 (Laughter.)

3 So that would -- that isn't very helpful. But if
4 you do --

5 (Laughter.)

6 -- if you can share maybe not the specifics that
7 you use but your thought process. That might be helpful for
8 guidance material because I think it is real important to
9 think about the very wide range of plants and the wide range
10 of expertise we have with respect to some of these very
11 complex issues. So if guidance material can help you give
12 us a thought process, that's probably one of the most useful
13 things we can do. Comments, questions?

14 MR. HANIGAN: Yes.

15 MS. GLAVIN: Okay.

16 MS. HANIGAN: Katie Hanigan with Farmland. I
17 almost hate to make this comment with Caroline not here, but
18 she'll come in and then she'll want to talk about it. While
19 we're talking about things that need to occur, I know Dr.
20 Hulebak is working with ARS and is doing the component of
21 shelf life studies as it relates to listeria. So I hope you
22 don't mind if I bring this up, but it has to do with
23 listeria.

24 MS. GLAVIN: Mm-hmm.

25 MS. HANIGAN: I thought Bruce just did an

1 outstanding job of talking about some changes that need to
2 occur. One of the things I struggle with day in and day out
3 is, as a company, I have a tremendous amount of ready-to-eat
4 products on shelf life testing and then I am unable based on
5 the current guidelines, rules or whatever, to do any testing
6 on that product for listeria. I know the Agency needs the
7 information and I know the industry needs the information to
8 know whether or not listeria is growing during the course of
9 that shelf life. So when I have a product that's coded for
10 whatever, 60 or 70 days, there has to be some way that when
11 that product is past its shelf life date from whatever it
12 is, May 5th or May 15th or whatever, that if I have
13 packages, there's got to be a way to let me test that for
14 listeria so we can get the information we need because I
15 think the project ARS is doing is outstanding, I honestly
16 do.

17 But when it's all said and done I'm not sure what
18 it's going to tell us as an industry and as individual
19 companies and as individual plants, because I think
20 yesterday they said there was 12 plants that were involved
21 in that. Well, I have 11 plants and they're not all
22 involved in that but, you know, that's a small volume of
23 what's out there.

24 So when you're considering maybe ways that we need
25 to move things around, it would seem to me that allowing a

1 company to test a product that they're holding on shelf life
2 and part of the product is out in the field -- I want to
3 make sure you understand that -- part of this lot is shipped
4 out and I've kept X number of cases for my own testing. It
5 sure would be helpful if once the product is gone by its
6 code, it could be tested for listeria so we could gather the
7 information that everybody needs to have.

8 DR. ENGELJOHN: Katie, could I follow-up on that
9 just to get some clarity. When you're doing your shelf life
10 testing on your product, are you moving it at conditions
11 that you would think reflect what is going to occur in the
12 marketplace, or are you moving it ahead just regularly for
13 duration temperatures? Could you give me an idea of how
14 you've constructed that?

15 MS. HANIGAN: Mm-hmm. We try to hold ours at the
16 worst case scenario, and so most of ours is being held
17 before -- between temperatures of 38 to 42 degrees assuming
18 that there's no product storage at all between 28 and 34
19 degrees. I think that's probably incorrect because we do
20 have part of our product sitting in warehouses, but the
21 shelf life testing I'm doing now, I've got it under the
22 worst case scenario, 38 to 42 degrees the entire time.

23 DR. ENGELJOHN: I think there's an opportunity for
24 us maybe to sit and internally talk about this issue and try
25 to put together some thought process on how we could come to

1 grips with this issue. It was important for me to know what
2 temperatures you are holding that at, whether it's
3 refrigeration temperatures that you're recommending or are
4 those that are at temperatures above -- in this case above
5 42 degrees. So I think that's an opportunity for us to talk
6 internally to see what we may be able to do about that.

7 MS. HANIGAN: Okay. And I just -- just for
8 clarification. I do understand why if you're half way
9 through a product's code, testing at that time for listeria
10 and finding a positive would be extremely serious because
11 clearly you've got product out on the market that's only
12 half way through the shelf life, etcetera. I understand
13 that, but I did wonder what Bruce Tompkin's thoughts were on
14 this. I don't know how much testing, shelf life testing,
15 his company's doing. But I wonder, Bruce, what your
16 thoughts were on this?

17 DR. TOMPKIN: Thanks for that, Katie.

18 (Laughter.)

19 MS. HANIGAN: That's why they have chairs between
20 us.

21 (Laughter.)

22 DR. TOMPKIN: I'm Bruce Tompkin from ConAgra. We
23 did actually run analyses on shelf life samples some years
24 ago, that was something we did. We found the prevalence
25 rate to be very low. I don't remember exactly what it was,

1 but it is a source of information that could be generated
2 that could help each facility better understand its level of
3 control because that would be more reflective of what is in
4 the marketplace or what -- what may have been in the
5 marketplace. Whether you test it for listeria species or go
6 all the way to Lm and that kind of thing, is a question that
7 has to be sorted out.

8 MS. GLAVIN: Okay. Kim?

9 MS. RICE: I promised myself that -- Kim Rice with
10 AFI -- I promised myself and the members that I wouldn't
11 talk much but I do -- I think I need to say something.
12 It's unfortunate that the entire industry is getting painted
13 with the broad brush that no one is testing because that is
14 not true. We have a lot of members and we have a project
15 that we've undertaken that Randy Huffman described yesterday
16 with our listeria intervention and control workshop that we
17 have been conducting. It has been conducted by industry
18 people.

19 The foundation -- as a trade organization we
20 pulled the people together in a room -- the company members
21 -- they all came to the table with their best practices.
22 And we put together from start to finish, everything from
23 facility design to equipment sanitation practices, etcetera,
24 all the things you need to do to control listeria, including
25 how to put together a testing program, how to look at your

1 data, how to go about doing an investigation and corrective
2 action. We are teaching it on a regular basis and, in fact,
3 our next one is in June in Philadelphia. You know, stuff
4 like that.

5 But this is -- this is one of the first times in
6 my short experience in this industry that I've seen people
7 like Bruce and -- company and the -- and the Krafts and all
8 the other ones that are participating, come to the table and
9 share with their colleagues in the industry what it takes to
10 do this right.

11 One of the concerns I have when we do get people
12 who come, is that the way we start the course, or try to
13 start the course is, it doesn't matter what you folks on
14 that side of the table are going to do, that's not
15 important, it is but it's not, put that aside. What we're
16 going to teach you for the next two days is what's the most
17 important thing that you need to do. And the industry is
18 taking the rap. I think that that needs to be rewarded and
19 not just sort of passed over because not everybody's doing
20 everything they should be doing, because a lot of people are
21 out there doing what they should be doing.

22 MS. GLAVIN: Bruce, did you have a comment that we
23 missed, on something that what brought up earlier?

24 DR. TOMPKIN: I just thought I might respond to
25 Phil Derfler's question. I'm Bruce Tompkin from Conagra.

1 The question related to repetitive positives. I went
2 through our data not long ago for two years, 1998 and the
3 year 2000 to see what kind of tallies that we do have.
4 There were 7,000 in one case and 8,700 plus samplings in
5 each of those years.

6 Of course, you've got so many samples in each
7 sampling set, but what that could say is that 63 percent and
8 69 percent were single, isolated positives in 1998 and the
9 year 2000. There were two consecutive positives that were
10 20.5 percent and 16.4 percent in the two consecutive
11 positives only and then the rest, the other 15 percent, were
12 three or more consecutives. So, essentially, what that was
13 saying is that it's 84 to 85 percent roughly of the samples.
14 The product either was an isolated positive, or at worst
15 case two. Okay.

16 MS. GLAVIN: Okay. Thank you.

17 DR. TOMPKIN: Eventually with information and some
18 other things I'm doing will appear in a manuscript on
19 listeria control. And the idea that I mentioned and all
20 that sort of information that can be helpful to you in a
21 draft -- I'll give you a draft --

22 MS. GLAVIN: That would be terrific.

23 DR. TOMPKIN: -- of what we have.

24 MS. GLAVIN: That would be wonderful. Thank you.

25 We really appreciate that. Caroline?

1 MS. DeWAAL: Thank you. Caroline Smith-DeWaal,
2 CSPI. Bruce, I have lots of questions. When you say two
3 consecutive positives were you doing those tests on the same
4 day or what was the -- what was the time lag between tests?

5 DR. TOMPKIN: Well, it would have been no greater
6 than a week, but in the past year, in the year 2000, every
7 positive we had -- as soon as we had notification of a
8 positive, the plant went through a corrective action and
9 then it was resampled when it was started up.

10 MS. DeWAAL: So you would have one positive -- if
11 you had a single positive you would do a corrective action.
12 So for 100 percent of these you did corrective action?
13 Then if you found --

14 DR. TOMPKIN: -- positives.

15 MS. DeWAAL: And then when you found the second
16 positive is when you moved into the product --

17 DR. TOMPKIN: That's correct.

18 MS. DeWAAL: -- the holding test?

19 DR. TOMPKIN: That's correct. And this again is
20 still listeria-like.

21 MS. DeWAAL: Okay. And there would be -- you said
22 a week between each test? And was that one test --

23 DR. TOMPKIN: Well, I think --

24 MS. DeWAAL: -- or was it a -- it was a group of
25 five tests?

1 DR. TOMPKIN: It would be a minimum of -- I'd say
2 a minimum of three days you go through the -- you go through
3 the measurement, the second day measurement, then you -- and
4 all we're looking for is listeria-like, so you don't use
5 your super-sensitive method for Lm in this case. What we
6 were trying to find, is a listeria-like organism present?

7 MS. DeWAAL: And does -- I'm sorry to keep bugging
8 you, but that five -- it's five tests in a sample set. So
9 you would run five tests per week?

10 DR. TOMPKIN: On each line it's -- we use as a
11 rule of thumb five samples per line. However, that depends
12 on the complexity of the line. In some cases where it's
13 just a bulk packing station, all you have is a table and
14 somebody with gloves. So in those cases you may have two
15 samples.

16 MS. DeWAAL: Okay.

17 DR. TOMPKIN: But if it's a slicing line, it's
18 typically at least five.

19 MS. DeWAAL: Okay. Thank you.

20 DR. TOMPKIN: And those are analyzed as
21 individuals with the exception of a couple of plants where
22 the control level has reached a point where, you know, for
23 them to run all of those samples individually it's just --
24 the lab work would just be too great and they still
25 composite.

1 MS. DeWAAL: Okay. Okay.

2 MS. GLAVIN: Other questions or comments?

3 MS. HANIGAN: This is Katie Hanigan with Farmland.

4 I was just hoping to ask why is two consecutive positives a
5 trend and not one or three? So let me just -- for
6 clarification, if you're taking your samples on Monday and
7 if you don't have your labs on site, which we don't have all
8 our labs on site, some plants have them and some plants
9 don't. So some of the plants are shipping samples over to
10 other labs to get them analyzed. So those samples are not
11 starting until Tuesday morning, if you will. So by the time
12 those negatives, if you will, come back, or at the first
13 sign of a presumptive positive, you're already heading into
14 Wednesday and possibly Thursday. Well, by that time I've
15 already sampled my lines again, so I mean I'm already into
16 my second set of samples before the first set of results are
17 back. I mean it gets very difficult and complex to try to
18 explain this to inspectors.

19 I'm just wondering, also, if there shouldn't be
20 some consideration as to exactly who in your organization at
21 the establishment has access to these results and to the
22 interpretation of these results? Is it limited to the IIC?

23 Is this limited to the IIC and the inspector that's over
24 the processing end of the plant or, also, can you also have
25 your slaughter people asking to see them, too? If they want

1 to see them why do they need to see them?

2 You know, it really does get more complicated once
3 you get it out there and you start trying to figure all the
4 details of this out, because there's a big difference
5 between whether you're talking to your management staff or
6 your -- or the Agency's management staff. People who really
7 need to know what the data is versus people who just want to
8 know so that they have something to talk about, if you will.

9 We've limited our access within Farmland as to who
10 in our management team gets to see our data, and I think
11 there should be some consideration given from your Agency as
12 to who is considered an Agency official to look at this data
13 at the establishment. Because I don't think slaughter
14 inspectors should be looking at listeria data. I don't
15 understand the need for that or why they have to have that.

16 MS. GLAVIN: Okay. Thank you.

17 (Pause.)

18 Okay. Tomorrow's agenda will cover first of all,
19 the revisions governing trichina in pork products and the
20 revisions governing commercial sterile canned products.
21 Following that discussion, the economic impact of the
22 proposed regs and the cost benefit data needs.

23 Today we found that we moved through the morning
24 session somewhat ahead of schedule and we moved into the
25 afternoon session. So I will urge those people who are

1 particularly interested in the afternoon session to attend
2 at least in the late morning in case that happens again.
3 Obviously, we can't predict that, but if that's your
4 particular interest I would suggest you might -- might want
5 to be here before 1:30, before the lunch break, in case we
6 move into the second subject more quickly. Are there any
7 other things for today that you want to say?

8 (No response.)

9 Okay. Well, thank you for being very attentive
10 and very hardworking all day and for all of your good input.

11 (Whereupon, at 4:00 p.m., the hearing in the
12 above-entitled matter was adjourned.)

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CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

Public Meeting to Receive Comments on FSIS Regulatory
Proposal Concerning Ready-To-Eat Meat and Poultry Products
Name of Hearing or Event

N/A

Docket No.

Washington, D.C.

Place of Hearing

May 9, 2001

Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 1 through 186, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Marcia Logan, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

5/9/01

Date

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