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MEETING	X	

VOLUME II OF V

STANDING SUB-COMMITTEE NUMBER 1

LISTERIA MONOCYTOGENES INTERIM FINAL RULE
AND FSIS' PRELIMINARY ASSESSMENT OF ITS EFFECTS

APPEARANCES:

DR. JAMES DENTON, Sub-Committee Chairman
University of Arkansas

MR. CHARLES WILLIAMS
Office of Policy, Program, and Employee Development

MR. KEVIN ELFERING
Director, Dairy Food and Meat Inspection Program
Minnesota Department of Agriculture;
Instructor, University of Minnesota
Center for Animal Health and Food Safety

MS. SANDRA ESKIN
American Association of Retired Persons, Maryland

MS. DEANNA BALDWIN
Maryland Department of Agriculture

MR. CHARLES LINK
Cargill Meat Solutions, Cargill Value-Added Meats

MR. LLOYD R. HONTZ

REPORTER: MS. JANICE ADDINGTON

CONTRACTOR (NOT PRESENT): R & S TYPING SERVICE
(903) 663-9567

I N D E X

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P R O C E E D I N G S

2:45 p.m.

DR. DENTON: In conducting our evaluation of the assessment, I think what we'll do is first look at the overall plan. There will be, obviously, some cross-cutting kinds of issues with regard to the seven areas that have been identified with the teams. Your question that you asked earlier, Sandra, we might just add for clarification on the record here, now that we're being taped.

MS. ESKIN: Oh, about the -- the initial question about --

DR. DENTON: Uh-huh.

MS. ESKIN: Yeah, about how large this team is, you said it's 20 to 30 --

UNIDENTIFIED MALE: It's close to 30 people.

MS. ESKIN: -- 30 people within various disciplines, within FSIS. It is all FSIS employees, and they meet, obviously, within their teams frequently, and to date, about once a month.

DR. DENTON: Just in a way to get this kicked off here, I'll make one very brief comment, I don't want to dominate this discussion at all, but I was very pleased to see the approach that's been taken, particularly with the alternatives that are laid out within this.

It's a situation, I think, that the Agency has done a good job of identifying what they want and they have not tried to be prescriptive in the way that they have set this up and how to get the information that they want, and with

that, I'll -- floor open with anyone that has additional comments, you may approach. Sandra.

MS. ESKIN: Yeah. Sandra Eskin. Just a couple thoughts. Some of these will be specific and brought up again.

Again, it's an interesting approach, in sort of having this clearly-defined 18-month period in which you sort of get a dry run or a -- whatever you want to call it, to see if the rule as it's set up works.

I am concerned that some of that determination won't be able to be made within the 18-month period. For example, one of the key pieces here that I know consumer groups have brought up again and again is the lack of any sort of mandatory systematic testing, whether that's by the company itself or by FSIS. My understanding is some is being done but there's no sort of system.

And I understand one of the goals of this assessment, through the Sampling Verification Team, is to get to a point where they can establish a risk-based sampling program, but again, as we learned earlier today, FSIS has been hampered in moving forward. So, again, I'm a little concerned that for all of these variables, all of these factors, we won't have a really good sense after a year and a half.

So I just wanted to leave that open as a thought, that it may be necessary for some pieces of this to extend beyond 18 months. I know it's always out there, whenever

FSIS has a -- FSIS finalizes a rule, it can always change it, but that's --

MS. ESKIN: That's a burdensome process sometimes. And again, if there's an expectation, as there is now, there will be an official evaluation after 18 months, that makes it more certain, but we may need to go beyond that.

DR. DENTON: If I could, for one item, to help address that or maybe even alleviate that concern a little bit, earlier today it was referred to that the National Alliance for Food Safety and Security is undertaking a survey, if you will, or a benchmark study with regard to listeria, particularly at retail.

MS. ESKIN: Great.

DR. DENTON: This is a project that is very near completion as far as the design of the project, it's been engaged in discussion with folks at FSIS since early February. Our task force that is putting this together anticipates being able to start with the project in the latter part of August. We've met multiple times on conference calls, a couple of face-to-face kinds of meetings. We anticipate from the time that that starts until that project is finished will be a year.

MS. ESKIN: Uh-huh.

DR. DENTON: Which will help some in fitting within that 18-month window, because I know that there is this need for data at the various stages and it's going to encompass (inaudible) work, it's taking place at the processing plant

as well as what's occurring in retail --

MS. ESKIN: Retail.

DR. DENTON: -- in order to get at that. That's what's been kind of holding us down, we want to make certain that we are getting absolutely the most information out of the design of the project that we possibly can.

MS. ESKIN: And again, you're working with FSIS, so they're working with you on the methodology?

DR. DENTON: You bet. They requested that the Alliance do this --

MS. ESKIN: Right.

DR. DENTON: -- utilizing part of our annual budget to do it.

MS. ESKIN: Okay.

DR. DENTON: We realize that it's a very significant issue --

MS. ESKIN: Sure.

DR. DENTON: -- with regard to public health, and we're willing to commit about half of our annual budget to this particular project.

MR. LINK: But you indicated that we start August of this year?

DR. DENTON: Uh-huh.

MR. LINK: And run it for 12 months, so that doesn't really fit into this 18-month window.

DR. DENTON: Not quite.

MR. LINK: It kicks it all the way (inaudible)

December of next year. You have time to really assess what you've found and comment.

DR. DENTON: To get the full picture, yeah.

MS. ESKIN: And the Alliance is pretty --

DR. DENTON: But we are expected to provide progress reports as we go along in this, so that's going to help some.

MS. ESKIN: And the Alliance has -- if I remember, has a pretty broad membership, meaning it's academic and (inaudible) --

DR. DENTON: We have 19 institutions, plus our ARS counterparts.

MS. ESKIN: Uh-huh.

DR. DENTON: Which means that we have some awfully talented people that have been pulled together to get this done.

MS. ESKIN: Uh-huh.

MR. ELFERING: I think one thing -- this is Kevin Elfering. One thing I think I'd like to add, I really want to compliment FSIS for this approach. The only thing is that I was a little concerned when it's only FSIS reviewing -- doing the actual assessment.

We have an opportunity here of having many different disciplines, from regulatory agencies, consumer groups, industry, and academia. Maybe it would even be nice if we would even be able to be somewhat involved in these assessments; if nothing else, be able to review some of the

recommendations before they're published.

DR. DENTON: I think that's something that certainly should be brought before the Agency.

MS. ESKIN: So we could get a first look before it goes out to --

MS. BALDWIN: This is a little bit than what Kevin's saying, but with the same thing, that a lot of the things that are covered in the risk assessment and the things that are covered by these teams may not necessarily be FSIS's responsibility --

MS. ESKIN: Right.

MS. BALDWIN: So that's a concern with the teams only having FSIS on them, some would be FDA, some would be the states, through the Model Food Code, and I don't know -- you know, they mentioned earlier today that the FSIS couldn't include other agencies on their teams, but if there was a way to get those other people to have input into what was going to be done.

MS. ESKIN: Yeah, that's a good point, especially because -- again, this is so (inaudible) --

MS. BALDWIN: Well, there's things like the unpasteurized milk, that definitely -- that falls under FDA and states.

MS. ESKIN: Well, the whole retail piece of it is the food (inaudible) --

MS. BALDWIN: Retail is another.

UNIDENTIFIED MALE: (Inaudible.)

MS. BALDWIN: Yeah. In the risk assessment there's a lot about cheese, you know, that's not FSIS's, I don't believe, so --

DR. DENTON: Well, this entire risk assessment came from FDA.

MS. ESKIN: FDA and FSIS.

MS. BALDWIN: Uh-huh.

DR. DENTON: So the communication (inaudible).

MS. BALDWIN: But the coordination on what to do about it --

MS. ESKIN: Uh-huh.

MS. BALDWIN: -- is what I'm not seeing there in these teams.

MR. WILLIAMS: Just for a point of clarification, this is Williams, the FSIS focuses on what happens to the (inaudible) products at retail and we have, as was pointed out a couple of times in the earlier proceeding -- that we have this uncertainty about what happens to product that is packaged at the plant but that is sliced and otherwise handled at retail, what the effects are there, and so it's true that we worked and used the material that was developed with FDA, on the FDA FSIS (inaudible), and it was specifically the material that related to meat and poultry products and deli meats and hot dog products.

MS. ESKIN: Right, but ultimately, again, I think the point is, is that whatever recommendation comes out of this assessment, at the end of the day, it's the -- it will

be reflected in the Model Food Code --

MR. WILLIAMS: Sure.

MS. ESKIN: -- and then subsequently adopted or not by the states.

MR. WILLIAMS: Sure.

MR. LINK: (Inaudible.)

MR. WILLIAMS: This is Charles. I just want to make a general comment too before we get into all the specifics about this -- the issue paper, but I just want to echo the comments I've already heard as far as commending the Agency more on this approach, and I agree 18 months is probably not enough time to truly assess what's going on and what benefits and pitfalls we've come across, but it's more than we've ever had before.

MS. ESKIN: Oh, sure.

MR. WILLIAMS: So, you know, of utmost importance, it's very good, and, you know, there's been a lot of rules that have come out, that -- you know, overnight, it seems like, a rule comes out and we never go back and revisit.

So I think it's a great approach to -- something this important, to come out with a rule, to put a time limit on it and come back, we're going to come back and take a look --

MS. ESKIN: Right.

MR. WILLIAMS: -- rewrite, revisit, do whatever it is we have to do to make it right. So it's a great approach. Granted, there's problems, there's shortcomings, because it

is kind of -- it feels like, maybe being done in a vacuum because it's just the FSIS and not including some of the other agencies that would be helpful, but still, all in all, it's a good way to, I think, conduct business.

MR. LINK: I completely agree with what you're saying about the approach. I think this one is probably different and more complex than most of the things that the Agency has undertaken, because of the incorporation of that retail segment (inaudible), but I think that if that becomes apparent, that would be one of the things that we might recommend, that -- even an extension --

DR. DENTON: Yeah, during the comment period, if we're not where we need to be yet, may be an opportunity.

MR. LINK: I think one of the things too is, with -- for example, with the retail portion, I think FSIS is more involved with that now --

MR. ELFERING: Yeah.

MR. LINK: -- now than they ever have been also, and maybe it's an opportunity to have some of these reviewed by people (inaudible). They do have committees that are set up just for retail issues, and maybe you could even be submitted for -- to that committee also.

MS. BALDWIN: This is kind of jumping around, but I have a question, back on the testing end of it. In the Federal Register Notice it's saying, to alternative 3, that it's -- the highest level of testing is required. What level of testing has FSIS been requiring for that? I would assume

since it's an Interim Rule that there has been testing required for use in that alternative?

MR. WILLIAMS: The testing required for alternative 3 is mainly concerned with (inaudible) establishment (inaudible), using alternative 2, choice 2, and alternative 3 (inaudible), alternative 2 and alternative 3, they all have to have a food contact surface testing plan, and they all have to have a plan for holding tests, at least they have to state the conditions under which they hold the test, for alternative 3, if they (inaudible), then they are required to hold a test after getting two listeria positives (inaudible) food contact surface testing.

So I think that's what we mean when we say more intensive (inaudible) required. We also are contrasting in the Interim Final Rule the testing intensity in the Final Rule with what we proposed, which was that all establishments have to (inaudible) food contact surface testing, and with a greater amount of testing being performed by larger establishments, under the assumption that the amount of product that they produce can be greater, there could be a larger exposure of the public.

So I think that's what we meant when we made those -- there's an implicit comparison.

MS. BALDWIN: Sorry if I step out, but back to this testing, my understanding is, again, the current status, the Interim Final Rule, again, doesn't set any sort of -- doesn't endorse necessarily those proposed levels that were at least

suggested in the Proposed Rule, there's no minimum mandatory --

MR. WILLIAMS: No.

MS. BALDWIN: Right.

MR. WILLIAMS: Except for the -- what the establishments in alternative 3 --

MS. BALDWIN: 3, right, the presumption is that they're going to --

MR. WILLIAMS: (Inaudible.)

MS. BALDWIN: Right.

DR. DENTON: Any additional comments on the overall --?

(No response.)

DR. DENTON: Okay, why don't we take the individual teams that the Agency (inaudible) together and make comment with regard to whether or not we think that they are approaching their particular part of the puzzle in an accurate and thorough way. We'll start with the Economic Impact Team.

MR. ELFERING: This is Kevin Elfering. I think one of the things that we really always struggle with a little bit is, we assess these issues (inaudible) the industry as one --

MS. BALDWIN: (Inaudible.)

MR. ELFERING: Yeah, one size fits all, we look at the very small establishments the same as the very large establishments, and they are very different (inaudible),

processing plants that are probably only producing one or two crops, where in a very small establishment producing multiple (inaudible), so really the burden of doing some of these HACCP plans and assessing for listeria is more burdensome on the very small plants.

I would be real interested to see the economic impact on the sampling based on volume of the plants, how it affects the very small plants compared to the very large plants, and if you're looking at environmental sampling and you're looking at -- very large plants is three samples per surface, or per (inaudible) per month --

MS. ESKIN: They're not requiring that, though, right? Environmental sampling is not required by the Rule.

MR. ELFERING: In 3, in option 3.

MS. ESKIN: For environmental --

MR. ELFERING: Contact surfaces.

MS. ESKIN: I thought that was different, I thought environment was different than food contact.

MR. ELFERING: Well, yeah, you're right.

MS. ESKIN: There's --

MR. ELFERING: Environment would be other than food contact.

MS. ESKIN: Yeah. Food contact only because --

MR. ELFERING: I always consider anything that's not product is --

MS. ESKIN: -- is the environment. They --

MR. WILLIAMS: I do that too.

MS. ESKIN: But you do distinguish between contact and non-contact surfaces --

MR. WILLIAMS: Oh, yeah.

MR. ELFERING: So, yeah, let's -- we need to clarify that, food contact surfaces. Where these very small plants are looking at one sample per month per contact surface. What's the economic impact -- we're looking at these for a very small plant, having a contract with a private laboratory, but the economic impact is certainly going to be -- per pound of product produced, is going to be much greater for the very small plants.

MR. WILLIAMS: Well, one comment on that, and we addressed this in the Rule; that is, we reconsidered volume-based approach and in fact the proposal was based on the assumption of a larger establishment, a larger volume, but we found in comments that that wasn't always the case, so you have some very small plants producing ultimately a large volume of product.

MS. ESKIN: So then that would argue for production, not for size, I mean not using size of plant or anything?

MR. WILLIAMS: Well, we'd have to look at the small plants for legal reasons (inaudible) --

MS. ESKIN: No, no, I'm just saying --

MR. WILLIAMS: (Inaudible.)

MS. ESKIN: Right.

DR. DENTON: I think what we're talking about here

is the fact that there are -- that one size fits all. You may have one small plant that produces one product --

MS. ESKIN: Uh-huh.

DR. DENTON: -- and that's all they produce, and so that's a fairly substantial volume.

MS. ESKIN: Sure.

DR. DENTON: Where the plant you're talking about has got a multitude of products, none of which are very large volume --

MS. ESKIN: Right.

DR. DENTON: -- and that creates the burden.

MS. ESKIN: Right. But it's -- yeah, it's dicey --

DR. DENTON: With regard to the higher percentage of the output from this one --

MS. BALDWIN: Right.

DR. DENTON: -- than what that one may be.

MS. ESKIN: From a safety point of view, right. I mean, I understand the problem here, because if you have a small plant, and therefore the costs of doing whatever would be required are going to be greater for them, and yet if they produce -- so that would argue towards some sort of an exemption or at least some sort of reduced burden. On the other hand, if they're producing a lot of product, then they potentially could be putting out much more contaminated --

DR. DENTON: (Inaudible) before, that (inaudible) percentage --

MS. ESKIN: It does.

DR. DENTON: -- of their output.

MR. ELFERING: And, you know, even some of these very small plants, you may have a retailer across the street that's producing the same types of products, same volumes of products, that are not subjected to any requirements [phonetic] whatsoever.

MS. ESKIN: Right. Again, one of the variables, obviously, here, through all of this, we're talking yet again about verification, getting some sampling data, so obviously this is FSIS, FSIS employees have the authority to go into a plant and say, "Can we see your sampling data," I mean that's what they're going to be doing in order to figure this particular piece out. I mean, one of the things they're looking at is, is the data that the companies are producing, right, or is it just their own data?

MR. WILLIAMS: We -- before the verification sampling, that's episitis [phonetic] only.

MS. ESKIN: So for this -- so for this -- right. This -- we're talking only about whatever the inspectors --

MR. WILLIAMS: The data used in this --

MS. ESKIN: -- economic impact?

MR. WILLIAMS: -- economic impact, was -- it's only from episitis, and that isn't to say that other data sources shouldn't be considered.

MS. ESKIN: But they could, if they wanted to, ask the plants they're looking at for that data.

MR. WILLIAMS: Well -- I believe so.

MS. ESKIN: It seems that if -- at this point we're operating under a system that has no minimum sampling requirement either for the plants or for the FSIS, the more data they can take a look at, the better.

MR. WILLIAMS: Sure.

MS. ESKIN: That's just a presumption.

UNIDENTIFIED MALE: Sure.

MR. WILLIAMS: Yeah.

DR. DENTON: See anything else in that one, Charles?

MR. LINK: No. I just -- I have a problem with, you know, looking -- and I don't want to put anybody, again, on the disadvantage, but I have a little bit of a problem, looking at this model plan [phonetic], some very small plants saying well, they can't afford it, therefore let's don't make them do the testing, let's don't make them find a place to store their product, let's don't make them do these things, because we've got some small guys, to your point, that can kick out a lot of product. My (inaudible) thing to do might be an alternative 3, which --

MS. ESKIN: Which would require them to be --

MR. LINK: -- puts you on edge a little bit maybe. So I think it's important, though, to look and see what kind of impact has this rule had on it, have we put people out of business, have we put them into a situation where the retailer across the street is taking all the business because they don't have to do these things, but I don't want to get

into a situation where we're looking at it and saying well, because they're small they don't have to do these things --

MS. ESKIN: Yeah, I agree.

MR. LINK: -- because this is not -- I'm not sure it's (inaudible).

MR. ELFERING: I don't think so either. I think, though, that we have to look at -- the small businesses are very diversified.

MS. ESKIN: Right.

MR. ELFERING: You might have plants that are slaughtering, so they have to do generic E. coli testing, they're making sausage, so they're having to do listeria testing, it just compounds in a lot of cases, where you're looking at facilities that are, for the most part, very small operations, and just one more test is just another nail.

MR. LINK: Yeah, oh, yeah, understand.

MR. ELFERING: But no, there's no reason they should be -- they have to produce product and monitor that product as well as the larger operations.

MS. ESKIN: One way to just address this, and maybe this is what this Team's going to look at, is that there's more than one variable that needs to be considered when you're looking at, you know, who should -- what type of requirements vis-a-vis whatever, testing or otherwise, it's not just -- it's not just plant size, it's also production, it's also the nature of the product that they produce, because obviously some are identified as higher-risk. So

you've got to look at lots of different factors when you try to figure out how to regulate it.

DR. DENTON: That may be how to get at this, with that very first item on there, where they're talking (inaudible) sales and then (inaudible) the data, to get some sort of feel for what that volume issue is related to the impact of the Rule, but it doesn't hurt for us to (inaudible) being spelled out in that regard.

MS. ESKIN: Right. We can get [phonetic] plant profile, sales, employment, that gets to some of it, but you also want the kind of products they produce, I mean there may be other factors you can add to that last.

MR. ELFERING: Frequency of producing that product.

MS. ESKIN: Yeah.

MR. ELFERING: You might have a small, very small, plant that produces hot dogs one day out of two weeks [phonetic].

MS. ESKIN: Right. There may be other variables to look at.

DR. DENTON: Deanna?

MS. BALDWIN: No, I didn't have anything else (inaudible).

MR. LINK: Is this the team -- and maybe (inaudible). Is this the team that's going to look at (inaudible) the data that's being collected, using the different alternatives (inaudible) --

MS. ESKIN: Sampling.

MR. LINK: -- sampling verification --

MS. ESKIN: Yeah.

MR. LINK: You know, looking at alternative 1, 2, and 3 (inaudible), what has been found, is alternative 3 really more high-risk than -- you would think it would be, simply because you're doing formulation of post-lethality treatment, but --

MS. ESKIN: I think that's (inaudible).

MR. LINK: -- you know, it (inaudible) program issue, you know, and maybe it's not as bad as we think and it wouldn't force people to --

MR. WILLIAMS: Yeah, I --

MR. LINK: -- spend money in formulation and things to update.

MS. ESKIN: I think it's (inaudible).

MR. LINK: So I'm on the wrong team.

MS. ESKIN: You're on the wrong team.

MR. WILLIAMS: Well --

MS. ESKIN: We'll get to it.

DR. DENTON: Okay. Let's move then to the (inaudible) consumer education group.

MS. ESKIN: I just want to reiterate a point I raised in the general session, and I feel very strongly about this, I think it's too narrow a focus for FSIS to just look at what it calls incentive labeling. I know that's what it focused on in the Interim Final Rule, but I think it should do focus groups, surveys, whatever, not only on incentive

labeling, I have mixed feelings about incentive labeling, but also on appropriate safe-handling statements, about -- this is again related to foods at high risk for listeria contamination -- as well as possible warning statements for vulnerable populations.

I just think it's -- we've been looking at only one piece of the larger universe here, and I think that -- as indicated here, they're talking about doing a focus group on particular publications. Education is important, but I think statements on labels can be very effective under the right circumstances, which is why consumer testing is absolutely essential.

DR. DENTON: (Inaudible) in the safe-handling realm --

MS. ESKIN: Well, it --

DR. DENTON: -- than it is in the incentive [phonetic] (inaudible) --

MS. ESKIN: Basically, yeah, focus groups. In other words, right now they've only proposed to companies: you may want to put incentive labeling, "This product has been treated for" -- you know, "to prevent contamination," that's what they're focusing on, and I think yes, you obviously need to get those type of statements tested to see what -- how real consumers react to it, but I also think it's an opportune time to consider other possibilities.

Safe-handling labels, again, they have them for raw meat and poultry generally, as well as warning labels for

vulnerable populations. You have that on unpasteurized juice products. They sort of mention it in the -- I think just in the Proposed Rule that maybe down the road they would have these, but I think that these are very important things that they need to consider as long as they're looking at labeling.

MR. LINK: The first thing on the list is to continue monitoring the incentive labeling and --

MS. ESKIN: There's none.

MR. LINK: -- to point there is none --

MS. ESKIN: Right.

MR. LINK: -- and I think what you would find -- you know, Lloyd's sitting out here, FDA, (inaudible) keep quiet that --

(Laughter.)

MR. LINK: He could probably comment on, you know, industry focus groups that have looked at that very thing, to say, "What do you think about this, as a consumer," and what they found out is they don't like it, it sounds a little scary, so we're not going to do it, and --

MS. ESKIN: Right.

MR. LINK: Now, whether the companies have gone out and looked at alternatives such as -- what about safe handling, can we add some language, or do the warnings --

MS. ESKIN: Right.

MR. LINK: -- I know, and, you know, Lloyd might know, but I can't recognize Lloyd over there. He might know more about it (inaudible), just because he's been industry-

trained (inaudible).

MS. ESKIN: Uh-huh.

MR. LINK: Now, focus groups are done all the time in the industry (inaudible) USDA (inaudible), because I don't know that there's any effort to continue --

UNIDENTIFIED MALE: (Inaudible.)

MS. ESKIN: Oh, yeah.

MR. LINK: Yeah.

MS. ESKIN: And they spent a lot of time developing that label.

MR. LINK: So I don't know that you're going to see anything happen in incentive labeling.

MR. ELFERING: This is Kevin Elfering. I don't have any answers, but I don't totally agree with putting some of the things on -- you know, on an unpasteurized product there should be a warning.

MS. ESKIN: Right.

MR. ELFERING: On a product that is fully cooked and processed, under a HACCP plan, why would you put a warning on that? Who would have thought that we would have had a huge salmonella outbreak in ice cream or a huge salmonella outbreak in a dry toasted cereal. So to put warning labels on those products, because those too have also been shown to have contamination. One of the largest foodborne illness outbreaks we've ever had was in pasteurized milk.

MS. ESKIN: Right.

MR. ELFERING: So we don't process a product (inaudible) warning (inaudible).

MS. ESKIN: I'm not saying to put it on every single product. The point is there may be some products where it is appropriate based on the risks -- the high-risk products that have been identified in the risk assessment. I think it's -- this is a situation where what your goal here is: to keep people from getting sick and ultimately maybe dying, and particularly in a scenario where you've got vulnerable groups, as you do with E. coli, you know, older people, children, and people with compromised immune systems. The message for the whole population is different than the message to those people, and the way to get it to them perhaps most effectively is by putting it on the product.

All I'm saying is I think the only way to assess any of this is to test it on real people.

MS. BALDWIN: It may not --

MR. ELFERING: Go ahead.

MS. BALDWIN: Well, I was just -- it may not be the same kind of safe-handling statement that we're used to seeing, because when you read the risk assessment, it's saying just the temperature and the storage time can have a significant impact, so it may be just to advise consumers to keep it below 41 degrees --

MS. ESKIN: Yeah.

MS. BALDWIN: -- and not to keep it more than so many days. And then we also have the other committee, the

Microbiological Committee is looking at effective use-by dates, so maybe -- you know, that information should be used to develop the labeling requirements, possibly.

MR. ELFERING: Perhaps one different than (inaudible).

MS. ESKIN: Right. And there's --

MR. ELFERING: (Inaudible.)

MS. ESKIN: Right. There's even an egg -- you know, the egg-handling statement that you put on it, to prevent illness from bacteria, keep eggs refrigerated, okay, cook yolks until firm, that took a lot of work, to figure out that one, I'm saying -- not facetiously, but they -- how are you going to say it, "They shouldn't be runny," and then "Cook foods containing eggs thoroughly."

It is not a warning, and I understand any food producer's trepidation about putting a label on a product they're selling that essentially says "Don't buy this product" at some subconscious level. However, there are so many labels that can say "This is how you can eat this safely generally" or if you are someone who is particularly vulnerable.

MR. ELFERING: One thing that was kind of interesting, after we had the E. coli outbreak (inaudible), is the company -- the retailer that was involved, right after that they started putting labels -- separate labels on the packages of ground beef, but they were bright pink, and then they would change color (inaudible), so people were actually

seeing that label, even after -- after they (inaudible) hot-pink label, all of a sudden it was fluorescent orange and people noticed it again, it was advising them of (inaudible), and maybe that's even something that -- an incentive or just more inventive ways --

MS. ESKIN: Right.

MR. ELFERING: -- of trying to put some educational information (inaudible) --

MS. ESKIN: Yeah. They --

MR. ELFERING: -- maintaining it at 40 degrees (inaudible).

MS. ESKIN: Right. They should look at -- you know, if they're thinking about ways of presenting this information, there's plenty of people out there who specialize in exactly what Kevin's talking about. For example, sometimes like with cigarettes you have a rotating warning for that very reason, that people get so numb to it they don't really look at it, or they use symbols in addition to language, and there's a whole science out there about how to tell -- you know, how to present information that may be a warning or instruction. So --

MR. ELFERING: (Inaudible) put all that (inaudible).

DR. DENTON: (Inaudible) inclined to talk about safe handling warnings.

MS. ESKIN: Okay.

MR. ELFERING: Yeah, safe handling.

MR. LINK: (Inaudible) advisory labeling as opposed to a warning.

MS. ESKIN: It's a euphemism.

MR. WILLIAMS: Yeah, you do a lot of that.

MS. ESKIN: Yes.

(Laughter.)

MR. ELFERING: That and acronyms, right?

(Laughter.)

MR. ELFERING: I get a kick out of the new one (inaudible), somebody said E-I-E-I-O --

MS. BALDWIN: Right, exactly.

(Laughter.)

DR. DENTON: Okay. Have we covered the issue of labeling (inaudible)?

(No response.)

DR. DENTON: That being the case, let's move forward with Training Team (inaudible).

MR. ELFERING: (Inaudible) one of the difficulties in training personnel is to try to assess how well you've trained them, especially -- how many employees are -- how many inspection personnel are there in --

MR. WILLIAMS: We have over 6,000 inspectors working at 7,000 plants.

MR. ELFERING: So how do you -- how do you assess and how do you -- you can develop a curriculum, probably, but how do you assess whether or not that training has been sufficient? They just --

MS. ESKIN: Yeah.

MR. ELFERING: I think that's --

DR. DENTON: You're asking if FSIS does it?

MR. ELFERING: I mean how anybody does it, how anybody can really truly assess -- I just don't know how -- a good way of going about it.

MR. WILLIAMS: Well, we do training assessments (inaudible) part of the work (inaudible), the evaluation staff.

MS. ESKIN: So how do they do that, do they like test the inspectors to see if they learned their lessons --

MR. WILLIAMS: Well, a lot of it is -- it's the same -- well, I don't want to get into (inaudible) because frankly (inaudible). We do do course evaluations on recipients --

MS. ESKIN: Right.

MR. WILLIAMS: -- recipients of the course, with feedback on them, but then you do surveys of people who received the training, to get an idea and report back to management on how effective the training was.

MS. ESKIN: Uh-huh.

MR. WILLIAMS: Then of course we have the (inaudible) -- the experience of the employees in the field, doing their jobs, and get a good sense through supervisory oversight.

MS. ESKIN: Uh-huh.

DR. DENTON: I don't know if this helps or

(inaudible), we have -- or at least I have a way of -- two different ways (inaudible). We have ten courses that we teach via the Web --

MS. ESKIN: Uh-huh.

DR. DENTON: -- each of which has examinations at several points along the way, some only at mid course and some at the end of the course. Also do some -- train the trainers the kinds of things -- which we have two-day workshops, but there is a certifying exam --

MS. ESKIN: Uh-huh.

DR. DENTON: -- that they're required to take to become certified as a trainer. So there's got to be some sort of accountability --

MS. ESKIN: Sure.

DR. DENTON: -- or quality assurance in there somewhere, to ensure that they will do -- are taking the training or participating in the training, are actually demonstrating a mastery of the material. Now, what has to do with this here (inaudible).

MS. ESKIN: Do you know if the Lm training is being done both through workshop-type -- in class as well as CD-ROM? I know there was an earlier discussion in the main session and some news reports that the training on the E. Coli Directive wasn't being followed through. Is it similar?

MR. WILLIAMS: Well, the approaches are similar but not the same in the E. coli training and listeria. The

listeria training was packaged as part of the food safety regulatory enforcement training and it's a separate module dealing entirely with listeria as part of that training. So (inaudible) the processing phase, process products phase, FSRE called (inaudible) --

MS. ESKIN: It was in-class.

MR. WILLIAMS: -- (inaudible).

MS. ESKIN: Uh-huh.

MR. WILLIAMS: The E. coli is a separate (audible).

MS. BALDWIN: (Inaudible) be incorporated (inaudible).

UNIDENTIFIED MALE: Good point, it's --

MS. ESKIN: E. coli is now or --

UNIDENTIFIED MALE: It's being incorporated into (inaudible) new version of that (inaudible), that's the latest --

MS. BALDWIN: In addition to (inaudible) CD-ROM?

UNIDENTIFIED MALE: In addition, right. We all got CD-ROMs, we have to make time for that (inaudible).

MS. BALDWIN: They're happy to have them.

UNIDENTIFIED MALE: (Inaudible.)

MR. LINK: The EIAO and the CSO receive additional training over and above the CSI?

UNIDENTIFIED MALE: Yes. That's --

MR. LINK: Is that right?

SECRETARY: That's right.

UNIDENTIFIED MALE: (Inaudible) evaluate the

effectiveness of (inaudible).

MS. ESKIN: Is this assessment of the effectiveness of the training part of what's done for every type of training or is this because it's Lm that we've got this comprehensive picture, it's being done either more thoroughly or in a more compressed period of time? Do you know?

MR. WILLIAMS: For the purposes of this rule, it was thought that we needed to have evaluation of the training because it's integral to the effectiveness of (inaudible).

MS. ESKIN: Uh-huh.

MR. WILLIAMS: So I can answer to that extent, (inaudible) in the Agency.

UNIDENTIFIED MALE: (Inaudible)?

SECRETARY: No, I don't have anything else but training.

MR. LINK: I think -- the reason I was asking that very complicated acronym question, I think there's a perception that, you know, the CSOs and the EIAOs have a pretty good handle on or understanding of listeria, the listeria programs, and what have you, and maybe the CSIs don't, but probably because they haven't received quite the extensive training, and when you're looking at evaluating this whole training program, it might do to just visit what the differences are in those training methods and see. You know, whether it's truly different or not, I don't know, but there's a perception, anyway, that it is.

MS. ESKIN: (Inaudible.)

MR. LINK: Pardon?

MS. ESKIN: Which one --

MR. LINK: The CSI.

MS. ESKIN: That's what I thought.

MR. LINK: The consumer safety inspectors.

MS. ESKIN: Is the one that actually does the --

MR. LINK: Formerly known as the GS-7.

MS. ESKIN: Still a GS-7.

MR. LINK: Still a GS-7.

MR. WILLIAMS: (Inaudible.)

MS. ESKIN: Acronyms.

DR. DENTON: Okay, moving on to Team B, Sampling Verification.

MS. ESKIN: I would just want to emphasize how important this part of the assessment is. I don't know if anyone else concurs, it's a pretty generic statement, but -- the goal in this whole program is to produce product that is, hopefully, pathogen-free, and the only way you can tell that is by checking the product.

MS. BALDWIN: With the testing that's being done for this, with the sampling verification, would that also be used to evaluate the effectiveness of the three alternatives or is it not being done for those purposes as well?

MR. WILLIAMS: Well, I assume that it could. I'm not -- probably not going to be involved -- well, if something needs to be changed I'll be involved (inaudible), that evaluation, but we will be certainly using the findings

to determine the effectiveness of (inaudible) and any progress being made (inaudible), data from performance of establishments using each of the different alternatives --

MS. ESKIN: Right.

MR. WILLIAMS: -- will be (inaudible) essential pieces (inaudible).

MS. ESKIN: They're collecting that data?

MR. WILLIAMS: The Agency will be collecting the data.

MS. ESKIN: They're the ones that -- again, I'm just trying to make it clear.

MR. WILLIAMS: They're still --

MS. ESKIN: The Agency is still testing.

MR. WILLIAMS: The Agency -- verification is done by the Agency --

MS. ESKIN: Right.

MR. WILLIAMS: -- (inaudible) establishments (inaudible) --

MS. ESKIN: Whatever they're --

MR. WILLIAMS: Yes.

MS. ESKIN: -- (inaudible) release (inaudible).

MR. ELFERING: Is anybody doing anything with assessing the industry's training, what they have -- what they're doing as far as (inaudible) -- FSIS personnel, is there a way that they can assess the industry's mastery of obtaining samples, especially food contact surface samples?

MR. WILLIAMS: (Inaudible.) They will be assessing

whether establishments are following the correct plan in doing sampling, such as food contact surface sampling, whether they've identified the --

MS. ESKIN: CCPs [phonetic].

MR. WILLIAMS: -- the areas that would be sampled and what the areas represent, and the frequency (inaudible) and that procedural stuff. As far as the specific methodology that we'll be following, that will be something else.

MR. ELFERING: I was just thinking, getting back to -- with the industry's mastery, it almost looks like these EIAOs are going to be doing all the food contact surfaces for FSIS. Is that correct?

MR. WILLIAMS: (Inaudible.)

MR. ELFERING: But who is going to be -- who is going to be reviewing the plant's technique is probably the IIC.

MR. WILLIAMS: The IIC has (inaudible) supervisory authority and would be expected to (inaudible).

MR. ELFERING: But if they're not being trained in the mastery of obtaining food contact surfaces, how are they going to observe the plant and be able to determine if the plant is doing things properly, if they've not been trained?

MR. WILLIAMS: Is that a rhetorical question or -- I don't have the answers on (inaudible).

MR. ELFERING: I think that's what we need to know, is if -- whether or not the IICs are going to be trained

also.

(Pause.)

DR. DENTON: Deanna? Same thing?

MS. BALDWIN: I just had the question about how they were going to use it and that was it.

DR. DENTON: Charles.

MR. LINK: I was just looking at -- you know, I'm curious as to -- in the sampling verification, back in the misplaced question earlier on, that when they're evaluating all the sampling and the data, are they going to be looking at what they've found for those folks in alternative 3 versus 2 versus 1 and comparing -- and maybe revisiting the entire --

MS. ESKIN: -- approach.

MR. LINK: -- approach --

MS. BALDWIN: Yeah, that's what I was --

MR. LINK: -- the risk-based approach, and is alternative 3 getting it done?

MS. ESKIN: Maybe the point is: focus on assessment of the three alternatives, you're saying, right, see if they can determine which, if any, is most effective (inaudible) alternative 1 --

MR. LINK: Yeah, I think early on there was an assumption that, you know, if you do sanitation, that's good, if you do sanitation plus 1 --

MS. ESKIN: -- that's better.

MR. LINK: -- that's better, if you do sanitation

plus 3 that's even better, it probably is, but we ought to have data to demonstrate that.

MR. WILLIAMS: So you're suggesting, really, that (inaudible) risk assessment, because that's where all this comes from.

MS. ESKIN: Well, the risk assessment didn't dictate how to -- maybe it did -- how to approach each of these three different types of -- I mean, the risk assessment identified at-high-risk products, right?

MR. WILLIAMS: Well, it identified --

MS. ESKIN: Among other things.

MR. WILLIAMS: -- the risk ranking --

MS. ESKIN: Right.

MR. WILLIAMS: -- of that, the risk assessment that FSIS did identified those (inaudible) --

MS. ESKIN: Uh-huh.

MR. WILLIAMS: -- efforts or combination of approaches that (inaudible) --

MS. ESKIN: Right, and it --

MR. WILLIAMS: -- and --

MS. ESKIN: And it may be, again, that's a presumption based on some good data, but we're -- this assessment in a sense is questioning all of the assumptions, right, so you -- sure, it may wind up that the assessment, at least based on the data that's been acquired by this -- these teams, may be at odds with what is proposed. That's part of the reality of what you might see. Otherwise why do it?

MR. LINK: Why do all that --

MS. ESKIN: Yeah.

MR. LINK: -- you may find that deli products that are alternative 1 are no longer high risk. Maybe it'll be replaced by cheese.

MS. ESKIN: Officially. So that cheese semi- --

MR. ELFERING: Semi-soft, yeah.

MS. ESKIN: -- from unpasteurized --

MR. LINK: I believe (inaudible) have the number-one position here.

(Laughter.)

MS. BALDWIN: Well, that leads to another question, though, with how the FSIS testing is being done now, because in the Rule it's saying for alternative 3 to do more testing. Is FSIS also doing more testing if the plant is using alternative 3?

MS. ESKIN: That is only their testing (inaudible).

MR. WILLIAMS: Yeah, it's -- we deliver that (inaudible) product, and if they're only using alternative 3, then they are likely to be visited more often.

MS. ESKIN: And they should be testing, but that's not, again, what the Rule says. It says that's what FSIS --

MS. BALDWIN: But what my question is, though, is if FSIS -- which is what he just said, that they're going to be visited more often, so -- in theory, so therefore they're going to have more testing, so it's not going, then, to be a good comparison of the three alternatives.

MR. WILLIAMS: Well, I think (inaudible) tested more often, that's what I mean by -- for the purposes of collecting samples.

MS. BALDWIN: Right.

MS. ESKIN: Right.

MS. BALDWIN: But if you're going to --

MS. ESKIN: You're not taking a hundred --

MS. BALDWIN: -- assess the three alternatives --

MS. ESKIN: Right.

MS. BALDWIN: -- you're not getting the same amount of samples --

MS. ESKIN: A hundred samples from each.

MS. BALDWIN: -- from each of the three alternatives, which could make it turn out -- it may not, but it could make it turn out -- you'd have more shots at getting a bad test if your testing more often [phonetic].

MR. ELFERING: No, not necessarily. With listeria, it is really difficult to try to isolate, sometimes. With other pathogens, maybe, we're going to have a little more consistency. And you might have a period of no listeria in your plant for a period of months, and, just bringing in some raw ingredients, you may bring listeria in on a pallet of -- on a wood pallet, with raw ingredients. So I don't know if more -- you know, if you look at, you know, confidence factors, yeah, the more tests you take -- but you get to the point where you've got to take so many tests, just to get a 95-percent confidence factor, that you'd be testing almost

all of your product, practically, and that's just to find it at 1 percent.

So it's not always true. You would think that, generally, but that --

MS. BALDWIN: Yeah, just -- if you're looking at comparing three methods and if you're testing, you know, this one because you're making the assumption that this is the least effective method -- and I guess some of that would depend on what was used to develop that as being the least-effective method in the risk assessment. I mean, common sense would tell you if you do two things you have -- to prevent it, you would have less chance, but sometimes common sense doesn't work out.

(Laughter.)

MR. WILLIAMS: There's always (inaudible).

MS. BALDWIN: Yeah.

MR. ELFERING: Foodborne illness outbreaks, in my experience, have always had some very strange breakdown, there is never the obvious -- it's never the obvious thing, it's always just some very odd breakdown that occurs, that most times you would never even think of.

What we're suggesting into our small plants is, is if they're doing -- if they're doing option 3, that they do some baseline data first, do an environmental sampling, and if then there is isolated any species of listeria in the environment, that they would be doing additional testing of food contact surfaces. So even if they are finding listeria

innocua --

MS. ESKIN: This is your inspectors.

MR. ELFERING: Right. -- if they're finding any listeria species, that that would trigger doing additional sampling of food contact surfaces.

MS. ESKIN: That's not this approach.

MR. ELFERING: No, it isn't. But we're -- and ours is unique, and the next state is probably going to be doing something different.

MS. ESKIN: Now, are you guys sort of assessing how your program is doing, in terms of many of all of these type of factors?

MR. ELFERING: Well, I don't think we have anybody that is doing anything other than option 3.

MS. ESKIN: Uh-huh.

MR. ELFERING: So -- we're not finding any problems at all right now, but, you know, this is pretty -- pretty early in the game.

(Pause.)

DR. DENTON: Okay. Let's take a look at the next team, which is the Small Plant Guidance Team.

(Pause.)

MR. ELFERING: I'm going to start again, if that's all right. I think, again, one of the difficulties with some of these very small plants is we have -- we always have -- we have training sessions or workshops throughout the country, but for somebody -- and even with the new E. Coli Directive,

for us, I don't even know which was the closest workshop, but it would have been in another state, and if they could -- if they could maybe take some of this, this guidance, and maybe even bring it to the universities, to be able to disseminate that information -- one of the things that we do is, is we have what we call Just in Time training, where whenever a new directive comes out, we have remote satellite sites where we put on a workshop at the University in Minnesota and it goes out to about 20 sites --

MS. ESKIN: So you're using the University as sort of a conduit.

MR. ELFERING: Uh-huh, right. To be able to do some of that, but maybe have some --

MS. ESKIN: (Inaudible.)

MR. ELFERING: And we've even done that where we've had somebody from the Minneapolis District Office involved in that, where they're there to answer questions.

MS. ESKIN: It's probably more accurate to say guidance through the university, isn't that the point, is that you're using the universities as a way to get to all these small plants.

MR. WILLIAMS: We have contacts in every state for delivering training and guidance material, and a lot of these people are affiliated with -- are members of the extension programs in their states, with the universities and so forth. So you're suggesting that we keep on doing this, just make sure the compliance guidance for various regulations gets

disseminated out through those programs?

MR. ELFERING: That, and in this particular case what we do is videotape it, videotape this Just in Time training, and if plant operators are not able to go to one of the remote sites, we give them a copy of the videotape. So any of this training, to be able to just break it out even further by using some of the technology that's available.

MS. ESKIN: Maybe you just want to add here what we mentioned earlier, the fact that there are small plants out there that actually do produce a lot of product, so, again, you might want to -- those might be treated differently than other small establishments.

MR. LINK: Well, here "small" is defined by number of employees.

MS. ESKIN: I know.

MR. WILLIAMS: Right.

MR. ELFERING: Right. I think dollar volume too.

MS. ESKIN: Is it both?

MR. ELFERING: I think it's dollar volume -- or pounds of product. Pounds of product, I think. Numbers of employees. I think very small is like less than 10 employees and less than -- volume of two and a half --

MS. ESKIN: Are you saying it does or does not take into effect the volume?

MS. BALDWIN: It's in the Federal Register notice here somewhere.

MR. ELFERING: Less than $2 and a half million in

sales, fewer than 10 employees and less than 2 and a half million in sales. So if you had --

MS. ESKIN: (Inaudible) a very expensive product (inaudible).

MR. ELFERING: If you had five employees but you had $3 million worth of product, you were not a very small plant (inaudible).

MS. ESKIN: Okay.

(Pause.)

DR. DENTON: Okay. Anything else on that?

MS. BALDWIN: It has "Identify specific problems with the small plants." I would assume it's just not stated that there would be some process or some attempt to figure out ways to address those specific problems? I mean as I just --

MR. WILLIAMS: Well, problems that are unique to small plants, I think it's -- I mean, there could be a variety of things, some are minority-owned, some that lack technology (inaudible), draft noted that it wasn't possible for a lot of these very small outfits to get the compliance guidance which we have posted on our website. So we're talking about a very (inaudible) situation --

MS. BALDWIN: By identifying the intention would be to come up with a way to resolve those problems?

MR. WILLIAMS: Yes. You know (inaudible) that come from (inaudible).

MR. LINK: (Inaudible) the videotape might be an

opportunity.

MS. ESKIN: I guess they don't have --

MR. ELFERING: They should all have VCRs (laughing).

MS. ESKIN: (Inaudible) internet don't give a CD-ROM, because that's (inaudible).

MR. ELFERING: No (laughing).

MS. ESKIN: They all have VCRs? I don't know, those are being --

MR. WILLIAMS: If they don't have VCRs (inaudible).

MS. ESKIN: How about mailing them some paper?

MR. WILLIAMS: Well (inaudible).

MS. ESKIN: Low-tech.

(Pause.)

DR. DENTON: Okay. Hearing no additional comments, we will now move to the Retail Team, Team F.

MS. ESKIN: Back to the point about just having this be FSIS employees, we understand why they chose that, this seems like the one area where there should be at least FDA involvement because of their role in developing the food code. Just a suggestion.

MR. ELFERING: And I think FSIS has some expertise in a lot of areas but retail is not one of them.

MS. BALDWIN: Yeah.

MR. ELFERING: They're really never worked at all in retail. As a matter of fact, if you have an establishment -- an official establishment that also has a retail

exemption, the IIC doesn't even look at the retail product.

MS. ESKIN: Really.

MR. ELFERING: So there's -- they do need some guidance.

MS. ESKIN: Yeah. I think there's no "e" on "suit." "Long suite."

MR. ELFERING: Strong [phonetic].

MS. BALDWIN: (Laughs) Oh, as in long in the tooth.

MR. ELFERING: Long in the tooth, yeah.

MS. BALDWIN: Forte.

(Laughter.)

MS. ESKIN: Now you need an accent on your "e," if we're going to make it --

MR. WILLIAMS: It's French but it's --

MS. ESKIN: It's Anglicized now?

MR. WILLIAMS: It's an adjective.

MR. ELFERING: Uh-oh, this could be a whole new --

MS. ESKIN: I thought it was a noun.

MR. WILLIAMS: (Inaudible.)

MS. ESKIN: "Strong forte," someone's "forte," that's a noun.

UNIDENTIFIED MALE: (Inaudible.)

MS. ESKIN: I'm bringing my dictionary tomorrow.

MS. BALDWIN: And he's doing such a good job of getting all this down, he's going to get mad at us.

MS. ESKIN: We're picking on him.

(Laughter.)

MS. ESKIN: Forte is a noun.

MR. WILLIAMS: Well, it is in English.

MS. ESKIN: I know. Okay.

MS. BALDWIN: How is this team, the Retail Team, going about evaluating the current control programs that retail establishments use, are they actually going out to retail establishments or -- do you know that, or --

MR. WILLIAMS: We do go out to retail establishments, compliance officers make visits to check on things like labeling and to maybe do some surveillance sampling, monitor examining [phonetic] I should say, products that are in the retail chain, but obviously we don't do continuous inspection or anything of that sort.

MS. BALDWIN: Right. I knew they did that, but are they providing that information to this retail team, as to how they're going about evaluating the current control programs in retail, or are they getting information from like local health departments or --

MR. WILLIAMS: They're getting it from a variety of sources, state and local, and --

MR. ELFERING: That's right, I think one of the earlier discussions was maybe getting AFDO involved with some of that.

SECRETARY: Yeah, good idea.

MR. ELFERING: And what we may do there is visits some stores, we're looking at whether or not the product is

labeled properly, they don't do anything with operations in a deli or anything like that.

MS. BALDWIN: That's what I was wondering, if they had selected ones doing that, to feed back to the team, or where they were getting their information from.

DR. DENTON: Is there any work at all with Jill's group (inaudible), the relationship between FSIS and Food Marketing Institute?

MR. WILLIAMS: I'm not sure about that (inaudible).

(Pause.)

DR. DENTON: Anything else?

MR. WILLIAMS: No, I don't have anything to add on that beyond what Phil provided earlier.

DR. DENTON: You see anything else there, Charles?

MR. LINK: No, sir. The (inaudible) comment was to bring in some other parties (inaudible).

DR. DENTON: Public Health Team, Team D.

MR. ELFERING: In Minnesota we call that Team D, Team Diarrhea.

MS. ESKIN: I was about to say, does the D stand for something? Obviously it does.

(Laughter.)

MR. ELFERING: That's who investigates all of our foodborne illness, they do the --

MS. ESKIN: They do the dirty work, so to speak.

MR. ELFERING: They hold the bags, Team Diarrhea.

DR. DENTON: Well, I'll make one general statement. I'm kind of glad to see the idea of this rule being held to a public health --

MS. ESKIN: -- standard.

DR. DENTON: -- issue with regard to whether or not it's effective.

MS. ESKIN: Uh-huh.

MR. ELFERING: I think one of the things that they can certainly do is what they're doing right now with salmonella, is taking their data, FSIS's data -- and we're never going to get the plant data on something like this, but using anything -- any positive samples, having those moleculars subtyped with the illness cases that are occurring with molecular subtyping on illness cases, and try to correlate any comparisons.

(Pause.)

MR. ELFERING: (Inaudible) most effective in molecular subtyping for listeria, is it doing -- using ribonucleic [phonetic] acids or is it with (inaudible) gel (inaudible)?

DR. DENTON: I think it's (inaudible) gel, but --

MR. ELFERING: Okay.

DR. DENTON: That's a --

UNIDENTIFIED MALE: (Inaudible.)

MR. ELFERING: Because I know ribo- --

DR. DENTON: There's a [phonetic] scientific view of that.

(Pause.)

MR. ELFERING: I can't think of anything else, it looks like they've covered that, actually, quite well.

MS. ESKIN: Yes.

UNIDENTIFIED MALE: I think this one is.

MS. ESKIN: Yes.

MR. ELFERING: Yes. Charles, is that the one you worked on?

MR. WILLIAMS: No. Members of the Human Health Sciences Division, including Dr. Goldman, spoke this morning on that.

DR. DENTON: One additional thing here, looking at what we're -- the next steps are going to be, once the assessment teams complete their reports, FSIS plans to take action with regard to conducting an internal Agency review of the report of the results of the assessment and make that report available for public comment and then analyze the comments in conjunction with (inaudible) Interim Final Rule. So I think that that's appropriate, I don't know that we need -- we may or may not need to make a recommendation if there is --

MR. LINK: It was mentioned earlier to be shared with the Committee.

DR. DENTON: Yeah, that and --

MS. ESKIN: Earlier, I think.

UNIDENTIFIED MALE: Uh-huh.

MS. ESKIN: And the obvious last point, which I

guess is obvious, I can't imagine they're going to go through this whole assessment and not think there needs to be some tweaking of the rules --

DR. DENTON: That's where I was getting to.

MS. ESKIN: Okay. Sorry. Sorry to jump the gun.

DR. DENTON: No, no, no, you're doing good.

MS. ESKIN: Right, but, yeah, that appropriate revisions to the Rule will be made.

DR. DENTON: Adjustments and improvements as identified or something.

MS. ESKIN: Yeah, (inaudible), there's that presumption. I'm surprised they didn't say that.

DR. DENTON: I agree.

(Pause.)

DR. DENTON: Okay, I think we probably answered the three questions, I don't know that --

MS. BALDWIN: I think we did too.

DR. DENTON: -- that we need to pull them out and ask them any differently, I think it probably makes better sense to leave them with those particular issues that we've identified them with.

MS. ESKIN: We'll just give this to the whole group tomorrow, just the way it is.

UNIDENTIFIED MALE: (Inaudible.)

MS. ESKIN: I actually, unfortunately, have to excuse myself, I have a personal obligation and I'm sorry I can't continue this afternoon, but I'll be there tomorrow.

For what it's worth, on this little piece of paper I wrote down some suggested language if in fact we're going to kind of flesh these out a little bit. The issue that I brought up and made some comments on the labeling. So I can give it to you, if you want, and you can share it with everybody. Obviously I assume everybody's going to tweak it, revise it, whatever. (Inaudible), I'm sorry --

DR. DENTON: You're doing good. It's just a little smaller than what I'm used to.

MS. ESKIN: Sorry.

DR. DENTON: (Inaudible.)

MS. ESKIN: I assume there's no way that I could see what everybody agreed to before tomorrow morning? I have an e-mail address, that's the only thing I was going to throw out there, it's in the book. I don't have that capability from here.

MR. WILLIAMS: Well, yeah, I'm sure that -- well, I could personally e-mail it.

MS. ESKIN: That would be much appreciated. Again, obviously I'll --

MR. WILLIAMS: (Inaudible.)

MS. ESKIN: Yeah, it's in the book, it's on there too. I'm sorry, I --

MR. HONTZ: Mr. Chairman, was there an opportunity for some input (inaudible)?

DR. DENTON: There is. I've been waiting for that to happen.

(Laughter.)

MR. HONTZ: Well, I did my best to (inaudible).

MS. ESKIN: I'll just wait another few minutes.

MR. HONTZ: (Inaudible.) So I did want to make that point. Again, there were some consumers who thought that, looking at the suggested language, they would actually avoid this food and pick another one which didn't have such a scary statement on it, so that's something to think about. And there's also going to be another industry survey, the results of which will also be shared with the Agency.

One point I wanted to mention is that perhaps you wouldn't want to totally overlook the other options for consumer education. In a recent committee meeting that we had, one gentleman who had two daughters who were both pregnant and it was indicated in both cases -- they were in different locations around the country, but both of their physicians had given them very specific instructions about things to avoid in regard to listeria. I think that's a tremendously effective means for getting information out, and to encourage the Agency to continue working with physicians' groups and others would be very valuable, in my opinion.

There was discussion about the Agency verification testing, and it would seem to me that that type of work, along with CSI review to see that companies are doing what their plans say in regard to listeria control, and EIAO visits where they would look very much at that, at what the company is doing and the validity of their plans, would be a

very good indicator, I should think, of the industry's mastery of the regulations.

One other thing I was going to mention is there has also been an industry survey -- and I didn't know if you had anything on it, Charles, or not, but -- industry survey about the impact of the regulations on the industry. The survey indicated that companies were doing a lot of things, some of which was before the Rule was published and some which has occurred since then, in regard to going to alternative 1 and alternative 2 type situations. So that information is also going to be shared with you as well. A few observations.

MS. ESKIN: Thank you.

DR. DENTON: Thank you, Lloyd.

MS. ESKIN: I just want to respond to the first point you made, Lloyd. I've had experience looking at labeling of both foods and drugs, and your point is well-taken and I think it supports the proposition that you always have to test label statements on real people because it is remarkable if -- it's remarkable how often people can work hard at crafting a statement that they think -- a group of people, not just one side, collaborate on a statement, think it means A, and then you actually test it on consumers and they think it means Z, it's just remarkable, you know.

MR. ELFERING: Especially when those bureaucrats start crafting them.

MS. ESKIN: Absolutely. And we presume -- or us consumer advocates can presume we know, you know, what people

will understand. I've done so many surveys where it's come out differently.

Excuse me, I'll see you tomorrow.

(Ms. Eskin exits meeting.)

MR. LINK: Just to follow up, what Lloyd just mentioned there, there was -- I think the pre-implementa-tion survey, a lot of things went on with the industry with regard to listeria control, but most (inaudible) the Rule, saw movement from Category 3 to 2 or from 2 to 1, so a lot of effort to try to move up the chain, which I think is positive.

DR. DENTON: We may want to incorporate this language that Sandra recommended to us, and it has to do with the labeling, consumer education, and I'll try to read this.

"The Sub-Committee recommends that the Labeling/ Consumer Education Team conduct focus groups and other consumer testing to assess various types of incentive labeling and other informational labeling regarding safe handling and particular risk to vulnerable populations for products susceptible to listeria monocytogenes contamina-tion." That's long. It captures about four different things that we talked about.

MR. LINK: I'd have to see --

DR. DENTON: If we want to see that on print --

MR. LINK: Well, I'm not sure why she still has the incentive labeling things in there, because I don't think

it's going to happen, but informational labeling, if it's used (inaudible) advisory or --

DR. DENTON: Advisory, or safe handling, or --

MR. LINK: -- whatever term, "safe handling" might be an appropriate way to state that. Once we see it, once it's there, we can tweak it.

DR. DENTON: As I was thinking about this during that discussion, you know, safe-handling labels can come for a variety of different products, one of which would be raw meat and poultry, which is the way the thing was designed. It may be that we're looking at another version of a safe-handling label, that doesn't get into the issue of alarming people, as you mentioned earlier, by putting in too much technical language.

MS. BALDWIN: Well, I mean, if you word it -- because it was saying in the risk assessment that the storage and refrigeration were so effective that if you worded that "to maintain food safety" and you're not saying that it's not safe, you're telling them that "It's safe, now this is what you've got to do to keep it that way," that's a much more positive statement.

DR. DENTON: But I do think that Sandra's right about the focus group approach in designing that content.

MS. BALDWIN: Uh-huh.

DR. DENTON: Because of just exactly what you're saying.

MS. BALDWIN: Uh-huh.

DR. DENTON: You've got to be soft but still convey the message.

MS. BALDWIN: Uh-huh.

MR. ELFERING: I think really stressing the importance of maintaining proper temperature is a big issue but how do you frame that.

MS. BALDWIN: Yeah.

MR. ELFERING: You've got to have the industry not being (inaudible) because it's saying too much, putting too much fear into the consumer.

MR. LINK: Well, I certainly can't speak for the industry, but I think if you had a safe-handling label that said, you know, "hold this product at X temperature," nobody's going to complain about that.

MS. BALDWIN: Yeah. And then the use-by dates, if they're based on -- but I mean that might be something the focus group -- because I know a lot of consumers -- I mean, I get confused, "best if used by," "use by," "expiration date," "sell by," so, you know, maybe do some --

MR. LINK: And the Micro Committee is doing some work on that currently.

MS. BALDWIN: Yeah, use their information to come up with the best -- might want to word some of that into what Sandra had, as far as -- if nobody's doing incentive labeling, it kind of seems like it's a dead issue. There's not much incentive to do it, if nobody has decided to do it in that amount of time.

MR. LINK: Well, it's -- you know, like I say, it's perceived as "this one's good, this one's not so good, so I better buy the" -- "I'll stay away from the one that says 'post-lethality treatment,'" we were kind of (inaudible) that earlier, when you say -- something says "treated" -- you know, "post-lethality treatment applied" or whatever, it sounds kind of -- what does that mean (inaudible)?

MR. ELFERING: Lethality to the consumer means --

DR. DENTON: Just what it says, if you take off the i-t-y.

MR. ELFERING: That's right.

MR. LINK: That's right. "That's bad stuff."

MR. ELFERING: That's exactly right.

MR. LINK: So those kind of things scare consumers, and, you know, when you look at the -- as Lloyd mentioned, the survey, industry survey, in the focus groups that they conducted, they -- that's what they found, you know, so that's why they're not out there.

DR. DENTON: Folks, how about we take a five-minute break and then get a print-out of this thing and see if we can --

MS. BALDWIN: A plan.

DR. DENTON: -- get this thing put to rest.

(Off the record and reconvened.)

UNIDENTIFIED MALE: I've got a question, that second statement in there, I'm not sure what we're after there. I mean, to start with, I don't think -- I don't think

FSIS is going to get industry data to evaluate --

UNIDENTIFIED MALE: I don't either.

UNIDENTIFIED MALE: -- not sure how we got that in there, but the statement itself just doesn't seem to make much sense to me.

MS. BALDWIN: Which one?

UNIDENTIFIED MALE: The second -- I guess you'd call it the second paragraph, under A. I'm just asking the question --

UNIDENTIFIED MALE: Yeah, I think we can just pull it out of there.

UNIDENTIFIED MALE: On A, though, at the end of the first paragraph, in addition to going out of business, put -- maybe we want to insert "or relinquish their grant of inspection," because some of them may not go out of business but some of them may relinquish their grant of inspection only on retail.

UNIDENTIFIED MALE: Only on retail.

UNIDENTIFIED MALE: It's an official establishment -- let's say you have a small meat processor that's under continuous inspection, they may relinquish their grant of inspection and just choose to just sell product at retail. So they're not really going out of business, but they're not producing inspected product anymore because of the -- because of the rule.

MS. BALDWIN: So the parties want to take out (inaudible) evaluate (inaudible) data and industry data, that

it would be useful to take that statement out?

UNIDENTIFIED MALE: Yes. Yeah, I just think you could pull it out of there.

(Pause.)

UNIDENTIFIED MALE: Are we going to leave in the "needs sampling data to assess"?

UNIDENTIFIED MALE: No.

UNIDENTIFIED MALE: Just take that whole piece out.

UNIDENTIFIED MALE: I think that whole thing needs to come out --

UNIDENTIFIED MALE: Yes.

UNIDENTIFIED MALE: Just scratch it.

UNIDENTIFIED MALE: -- that whole sentence, or second, pardon me, paragraph.

(Pause.)

UNIDENTIFIED MALE: I assume we're supposed to take all these statements and kind of pull them together. Make some sense?

UNIDENTIFIED MALE: Right.

UNIDENTIFIED MALE: That's right.

UNIDENTIFIED MALE: Maybe the very first part ought to be -- this last paragraph on here, I'm just talking out loud here, but -- on this one page, "Focus groups to assess consumer response to labeling and reporting and industry surveys show consumers refused" yada yada --

UNIDENTIFIED MALE: You're talking about move that up front?

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED MALE: The very first --

UNIDENTIFIED MALE: I'm just trying to get -- trying to get some kind of flow here, and then maybe --

MR. ELFERING: Well, you might just start out with -- the first paragraph would be "This" -- "The Sub-Committee recommends that this team focus" -- "that this team conduct focus groups," put that paragraph first.

(Pause.)

MR. LINK: Yeah, "The Sub-Committee" --

MR. ELFERING: And then maybe "the focus groups need to assess customers' response," by having it all in the same paragraph.

MR. LINK: Yeah. And then say -- and if you want to say -- yeah, that makes sense to me.

MS. BALDWIN: Maybe for the first one, though, leave out -- put "The Sub-Committee recommends that this team conduct focus groups and other consumer testing to assess various types of labeling" and just leave it at that, and then go into the -- because I think we should say in here that the -- you know, maybe they should move away from this incentive labeling because it doesn't seem to be getting anywhere, and then have a sentence about what things they ought to be assessing in these focus groups, like modified safe handling, consumer recommendations, the guidance on sell-by/use-by labeling, we could have just one sentence and kind of incorporate all those things in it.

MR. LINK: Incorporate that, yeah.

MR. ELFERING: How about this: "The Sub-Committee recommends that this team conduct focus groups and other consumer testing to assess various types of incentive labeling and other informational labeling regarding safe handling and particular risk to vulnerable populations for products susceptible to listeria contamination. The focus groups need to assess consumers' response to labeling, as an industry survey showed that consumers are confused regarding various labeling statements." We can scratch off -- "This is indicative of why the industry is not presently using incentive labeling."

MS. BALDWIN: Uh-huh.

UNIDENTIFIED MALE: Did we want to leave the term "incentive labeling" in there or strike that?

MR. LINK: I'm okay with just saying "various types of informational labeling regarding" --

MS. BALDWIN: Yeah.

MR. LINK: -- "safe handling and particular risk" --

MR. ELFERING: Informational --

MR. LINK: -- and maybe even put in the sell-by/use-by piece in there.

MS. BALDWIN: Uh-huh.

UNIDENTIFIED MALE: Particular risk --

MR. ELFERING: In regarding safe handling.

UNIDENTIFIED MALE: Did you get all that?

SECRETARY: Well, he's saying a couple different things. So if we take out incentive labeling, then we take out the statement of --

MS. BALDWIN: Since this is also the Consumer Education Team, should we just make a statement, I mean I think it's implied, but that we're using the labeling as a method of consumer education, basically, as opposed to a warning.

DR. DENTON: Right.

MS. BALDWIN: We might want to incorporate a sentence saying that.

UNIDENTIFIED MALE: I think that would be good. (Pause.)

UNIDENTIFIED MALE: (Inaudible.) Do you want to try and read back all of that?

SECRETARY: Okay. "The Sub-Committee recommends that this team conduct focus groups and other consumer testing to assess various types of labeling and other" -- do we -- we (inaudible) "incentive" back in?

UNIDENTIFIED MALE: No.

SECRETARY: No, no label, I mean no incentive.

-- "various types of labeling and other informational" -- no.

UNIDENTIFIED MALE: (Inaudible.)

SECRETARY: Yeah, various types of --

UNIDENTIFIED MALE: Uh-huh, including safe handling, particular risk to vulnerable population,

sell-by/use-by information --

SECRETARY: Okay, "including safe handling and labeling statements addressing particular risk" --

UNIDENTIFIED MALE: -- "to susceptible populations" --

SECRETARY: -- "to vulnerable populations for products susceptible to Lm contamination. The focus groups need to assess consumers' response as industry surveys showed that consumers are confused regarding various labeling statements. The focus groups should assess modified safe-handling statements and consumer information. The team should be guided by NACMPI recommendations on sell-by/use-by labeling."

UNIDENTIFIED MALE: I think that last sentence there, when you finished with "products susceptible to Lm contamination" --

SECRETARY: Yeah.

UNIDENTIFIED MALE: -- "and" --

SECRETARY: -- "and safe" --

UNIDENTIFIED MALE: -- "and NACMPI recommenda-tions on sell-by/use-by labeling."

SECRETARY: Okay.

(Pause.)

UNIDENTIFIED MALE: In other words, what we're recommending is, is that if they put -- if there is a sell-by date on that package, it cannot be sold beyond that date.

UNIDENTIFIED MALE: Well, I don't know what the

recommendations from NACMPI are going to be --

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: -- you know, and "they should be guided by their recommendations," I don't know what they're going to (inaudible) --

UNIDENTIFIED MALE: (Inaudible.)

UNIDENTIFIED MALE: And if they come out with (inaudible), you'll see use-bys on everything (inaudible).

MS. BALDWIN: In here, I forget which tab that is --

UNIDENTIFIED MALE: Or should consider (inaudible).

UNIDENTIFIED MALE: So we need to (inaudible).

UNIDENTIFIED MALE: Well, you can make that happen.

UNIDENTIFIED MALE: Watch this happen.

MS. BALDWIN: You're going to write it all down?

UNIDENTIFIED MALE: He's going to put it on the screen so we can see what you're doing. Oh, you're writing, you're not typing.

MS. BALDWIN: (Inaudible.)

UNIDENTIFIED MALE: Why don't you just re-type it and then maybe read it back and let's --

SECRETARY: (Inaudible) just that paragraph.

UNIDENTIFIED MALE: Yeah.

SECRETARY: (Inaudible.)

(Pause.)

MS. BALDWIN: In the report they're calling it "refrigerated shelf life based on safety," but somewhere

today -- that's all they have in that report. Somewhere today, and I can't find it in my notes, somebody that was up there talking, they were specifically addressing sell-by/use-by and the basis for those.

UNIDENTIFIED MALE: (Inaudible) sampling of purge [phonetic] on some of these extended-shelf-life products, once they have reached their recommended use-by date, some of (inaudible), just out of that purge.

UNIDENTIFIED MALE: Out of the purge.

UNIDENTIFIED MALE: Yeah.

UNIDENTIFIED MALE: I'm sure it wasn't ours.

(Laughter.)

UNIDENTIFIED MALE: I thought that's what I heard.

(Laughter.)

MS. BALDWIN: (Inaudible.)

UNIDENTIFIED MALE: (Inaudible) thought they didn't (inaudible).

UNIDENTIFIED MALE: (Inaudible.)

UNIDENTIFIED MALE: Yeah, they (inaudible).

(Laughter.)

(Pause.)

MS. BALDWIN: (Inaudible.)

UNIDENTIFIED MALE: No, you can read it, why don't you just read it.

SECRETARY: All right. "The Sub-Committee recommendations that this team conduct focus groups and other consumer testing to assess various types of informational

labeling, including safe-handling statements and statements addressing particular risk to vulnerable populations for products susceptible to Lm contamination and sell-by/use-by labeling. The team should consider" (inaudible) "recommendation on sell-by/use-by labeling. The focus group" (inaudible) "to assess consumers' response to labeling as industry surveys showed that consumers are confused regarding various labeling statements."

MS. BALDWIN: (Inaudible.)

UNIDENTIFIED MALE: Yeah, I -- sorry.

UNIDENTIFIED MALE: I don't think that mattered, for the --

SECRETARY: (Inaudible.)

UNIDENTIFIED MALE: I'm sorry. It doesn't. This is all going in a document. I failed to pick up the mic.

UNIDENTIFIED MALE: It sounded pretty good to me.

MS. BALDWIN: Uh-huh.

UNIDENTIFIED MALE: Did to me.

UNIDENTIFIED MALE: Did to me.

UNIDENTIFIED MALE: And then I guess that takes care of that page, that little piece, additionally, there are other means that should be considered for consumer education, for example --

UNIDENTIFIED MALE: I think that one's a good one.

MS. BALDWIN: Should we just make a statement that it appears they have covered many effective ways, other ways, of educating consumers, since that committee -- I mean that

team is covering both things, and we have the one comment about working with health professionals to disseminate information, is very effective. Well, that's something that they're doing, so should we just say that their consumer education efforts or activities appear to cover everybody? (Laughs.)

SECRETARY: So instead of saying (inaudible), saying, "In addition, FSIS is exploring other means"?

MS. BALDWIN: Well, the team report is saying that they're exploring these methods and we're supposed to be saying whether we think they're missing anything, and what I was getting at was like a statement to say that we've reviewed that there are other consumer-education activities and feel that they are covering many important ones, something along those lines.

SECRETARY: Oh, more like (inaudible) --

MR. LINK: But to consider other opportunities, such as the medical profession --

MS. BALDWIN: Well, they've actually got here that they're doing the medical profession.

MR. LINK: It's in there already.

MS. BALDWIN: But I was -- since he said that was so effective to reinforce, that what they're doing is effective.

UNIDENTIFIED MALE: Right. And that's a good positive statement to end on.

SECRETARY: (Inaudible) has reviewed the

(inaudible) labeling?

UNIDENTIFIED MALE: Emphasizes --

MS. BALDWIN: Consumer education --

UNIDENTIFIED MALE: Is pursuing that.

MS. BALDWIN: Uh-huh.

UNIDENTIFIED MALE: The Sub-Committee agrees, and approves.

UNIDENTIFIED MALE: Uh-huh.

SECRETARY: Okay, so has reviewed and has approved -- has reviewed and approved of FSIS' other means -- of means other than labeling (inaudible) consumers.

UNIDENTIFIED MALE: Uh-huh.

MS. BALDWIN: Yeah.

SECRETARY: And the Sub-Committee believes (inaudible) -- and then, for example, we could say, "The Sub-Committee believes that FSIS is" (inaudible) "professionals is very effective"?

UNIDENTIFIED MALE: (Inaudible) effective, but it's a good idea.

SECRETARY: (Inaudible.)

MS. BALDWIN: I think the one statement's probably enough.

SECRETARY: Okay.

MS. BALDWIN: You know, just --

UNIDENTIFIED MALE: (Inaudible) effective (inaudible).

MS. BALDWIN: Yeah.

UNIDENTIFIED MALE: (Inaudible.)

MS. BALDWIN: It looks like FSIS has covered every way that I can think of to get the information out there, so -- basically what we're saying.

MR. LINK: And it is very effective, because most people trust health professionals.

UNIDENTIFIED MALE: Yeah.

MS. BALDWIN: Uh-huh.

UNIDENTIFIED MALE: Are you going to read it back?

SECRETARY: So I'll read that statement, the "for example" statement?

UNIDENTIFIED MALE: Uh-huh, I think so.

(Pause.)

DR. DENTON: Okay. Does that take care of 10B?

UNIDENTIFIED MALE: Yeah, I'm good with that.

DR. DENTON: How about C?

UNIDENTIFIED MALE: That statement about the belief that EIAOs and CSOs get it and CSIs don't kind of stem from that industry survey Lloyd was referring to.

UNIDENTIFIED MALE: So should we use perception --

MR. LINK: Well, I was going to suggest, or ask, I guess, should we say "an industry survey indicated there is a perception that EIAOs and CSOs understand while CSIs do not fully grasp" or whatever, "as a result, FSIS should evaluate the differences in the training methods for the two different groups and ensure that the training includes accountability and some level of quality assurance" (inaudible)?

DR. DENTON: Have you got all that written down?

UNIDENTIFIED MALE: What?

DR. DENTON: Have you got all that written down?

UNIDENTIFIED MALE: Yeah, sorta, kinda. It's in various stages of disarray, but I do have it written down.

UNIDENTIFIED MALE: You'll never get it (inaudible) --

UNIDENTIFIED MALE: I think that --

MR. LINK: I'll come over and help you with (inaudible), is that okay?

DR. DENTON: Yeah. I think that gets out the issue that we're trying to convey.

MR. LINK: There's a perception out there that these guys -- one group gets it and one group doesn't, FSIS should look at the differences in the training methodologies (inaudible), ensure there's accountability and some level of quality assurance, to assure that those who participate do gain some mastery in the subject.

UNIDENTIFIED MALE: Uh-huh.

MR. LINK: Okay. Well, I can help you with that one in a minute, if you want.

UNIDENTIFIED MALE: Uh-huh.

MS. BALDWIN: Maybe we might want -- because they have as one of the things the training team is doing is "evaluate current verification and accountability measures that pertain to the training of inspection personnel," we might want to point out that we think that that's an

important component of the training, is the accountability, and to make sure that that accountability is there for different types of employees, and then say what you're saying?

MR. LINK: You'll have to help me with that (inaudible)?

UNIDENTIFIED MALE: That's (inaudible).

(Pause.)

MR. LINK: Okay, sampling verification.

(Pause.)

MR. LINK: In the first paragraph, can we say that -- instead of saying, "Will the ISEs receive adequate training," make a statement, rather, that "The ISEs should receive adequate training to verify the" -- or "to assess the industry's mastery of sample collection of Lm testing"? Will that take care of those last two paragraphs too, if we could do something like that?

DR. DENTON: I'm sorry, say that again.

MR. LINK: I'm looking at that first paragraph, where we say -- instead of saying, "Will the ISEs receive adequate training" --

DR. DENTON: Uh-huh.

MR. LINK: -- we should probably make a statement, that "They should" --

UNIDENTIFIED MALE: Convert it from a question to a statement, yeah.

MR. LINK: -- "They should receive adequate

training to ensure their ability to assess whether the plants' testing program is sufficient" and that -- "a mastery of sample collection program for Lm testing" and take those last two paragraphs out.

UNIDENTIFIED MALE: You're talking about the question and then the industry survey paragraph?

MR. LINK: Uh-huh.

DR. DENTON: Probably so, because we can't recommend anything on either of those, can we, to emphasize?

MR. LINK: I don't know. All we're saying is that in their sampling verification that they should -- they should make sure we're doing what we say we're doing and understand that -- when they look at it, what they're looking at.

DR. DENTON: Right.

MR. LINK: And really all it is is -- you know, as you said, "Have you got a program, are you following it, are you doing it, do you understand what you're doing?" Is that what we were trying to get to there?

DR. DENTON: I think that's where we were going, asking some of these questions among ourselves. What does Kevin think?

MR. ELFERING: I'm not sure. What have we got so far?

MR. LINK: On this one?

MR. ELFERING: Uh-huh.

MR. LINK: "FSIS' Lm verification testing is a

critical aspect of the implementation of the Rule. FSIS verification activities will include determining whether establishments are following the correct sampling and testing procedures in compliance with the rules. ISEs should receive adequate training to assess whether a plant's testing program is sufficient and whether industry has mastered sample collection" -- "or industry has mastered sample collection for Lm testing."

MS. BALDWIN: Well, maybe that -- instead of joining it with the ISEs, just make that -- there should be a separate statement that FSIS should assess whether -- not just the ISEs but (inaudible) --

MR. LINK: Yeah, okay, that works.

MR. ELFERING: Inspection personnel? More than just ISEs, probably, if you have --

SECRETARY: Yeah. Just overall FSIS.

MR. ELFERING: More -- even like "The Agency must ensure that inspection personnel receive adequate training."

UNIDENTIFIED MALE: (Inaudible.)

UNIDENTIFIED MALE: (Inaudible.)

SECRETARY: Well, isn't that going to cover the training too [phonetic]?

MR. ELFERING: Well, yes, but -- no --

MR. LINK: We're just reiterating. A little more emphasis.

MR. ELFERING: I think it's (inaudible), it's kind of involved in a sense, because what we're trying to say, is,

is that -- is that when industry is doing this, and they're responsible for doing the sampling, who's responsible for ensuring that the industry knows what they're doing? I mean, you're not going to be able to do that unless you have your inspection personnel properly trained to be able to know the proper techniques. They don't have to necessarily be masters but they've got to at least have some basic knowledge.

MS. BALDWIN: Yeah. I was just thinking it might be broader than inspection program personnel, it could be like "the peer" -- right, Chuck? I mean, it could be the evaluation (inaudible) --

MR. WILLIAMS: Yeah, you're right, that's a good point.

MS. BALDWIN: -- (inaudible).

MR. WILLIAMS: That's a good point.

MS. BALDWIN: There's other personnel.

MR. WILLIAMS: Yeah.

MS. BALDWIN: So if you just said --

MR. WILLIAMS: Even district managers --

MS. BALDWIN: Yeah.

MR. WILLIAMS: -- should know, should be aware of the proper methods.

MS. BALDWIN: And the point is to -- that emphasize means to ensure that the -- what was that statement -- that FSIS needs to --

MR. ELFERING: The industry needs to assure that all --

MS. BALDWIN: -- ensure that the industry's -- that the industries master the sample (inaudible) -- you know -- right?

MR. WILLIAMS: Uh-huh.

MS. BALDWIN: -- needs to ensure that industry has adequately mastered sample collection for Lm testing, and that could be -- numerous (inaudible) could be (inaudible).

MR. WILLIAMS: Right.

UNIDENTIFIED MALE: (Inaudible.)

UNIDENTIFIED MALE: It does.

DR. DENTON: Except it is focusing on the testing that's part of that sampling verification.

MR. ELFERING: It's a verification -- yeah, the Sampling Verification Team, so --

DR. DENTON: Yeah.

MR. ELFERING: It does fit in with training also, but I guess this is more of a --

MR. WILLIAMS: Well, the other things they discuss certainly won't come into play or they won't be -- they won't be adequate (inaudible) the training is insufficient.

MR. ELFERING: Right.

DR. DENTON: Yeah, there is some overlap in that.

MR. WILLIAMS: Because I know the preoccupation of this team, it's like the scheme of the sampling plan, the automated system that's used to generate the sampling, and all that.

DR. DENTON: Okay.

MS. BALDWIN: Okay, "The Training Team indicates it is evaluating the effectiveness of Lm training and the verification and accountability measures pertaining to the training. Currently there is a perception that EIAOs and CSOs understand the Lm rule while CSIs may not. As part of their evaluation the team should review whether the same training is effective for EIAOs, CSOs, and CSIs," all these letters, "and whether the accountability measures are adequate to ensure all employees are trained."

UNIDENTIFIED MALE: It works for me.

UNIDENTIFIED MALE: (Inaudible) both disks (inaudible)?

UNIDENTIFIED FEMALE: Yeah.

UNIDENTIFIED MALE: And then give one to Dr. Denton and one to me.

UNIDENTIFIED FEMALE: Okay.

UNIDENTIFIED MALE: So the prospect of us both being hit by a bus is slim to (inaudible).

MR. WILLIAMS: I have to send a copy to Sandra.

DR. DENTON: Yes.

MR. WILLIAMS: So I (inaudible).

SECRETARY: Well, maybe there's (inaudible).

MS. BALDWIN: That's the Training Team, if she can read my writing.

(Pause.)

MR. ELFERING: Did we finish that first paragraph, under "sampling verification"?

DR. DENTON: That's the second paragraph under that one, right, or is that to replace the whole thing?

MR. ELFERING: That takes care of the Training Team.

DR. DENTON: So it replaces everything.

MS. BALDWIN: For the Training Team, I think that covers what we had there.

DR. DENTON: Okay.

MS. BALDWIN: Right?

UNIDENTIFIED MALE: Yes, ma'am.

DR. DENTON: Replaces both paragraphs.

MS. BALDWIN: Uh-huh.

MR. LINK: Are we still struggling with the first paragraph under D, because of the training commentary? Or did we finish that?

DR. DENTON: I think we finished that, didn't we?

MR. LINK: I don't know.

DR. DENTON: It's off-screen, can't tell.

MR. LINK: Well, if we're okay with that, do we need to -- on the second paragraph --

(Pause.)

MR. LINK: I just don't (inaudible) -- maybe deli meats'll be replaced with soft cheese.

(Laughter.)

UNIDENTIFIED MALE: Popularly-held position.

(Laughter.)

SECRETARY: How about if we just said "to verify

the assumptions made in the risk assessment" instead of saying that?

UNIDENTIFIED MALE: That's okay with me.

MR. LINK: We've had (inaudible) that first paragraph, on D.

SECRETARY: (Inaudible) is there something --

MR. LINK: Yeah, can you read it back, I don't know where we are.

SECRETARY: The first paragraph, "Emphasize Lm testing" -- "verification testing is a critical aspect of the implementation of the Rule. FSIS's verification activities will include determining whether establishments are following the correct sampling and testing procedures in compliance with the Rule. ISEs should receive adequate training to assess whether a plant's testing program is sufficient. FSIS" -- that's (inaudible), whether it's just FSIS. "FSIS needs to ensure that industry's mastery of sample collection for Lm testing is sufficient."

MR. LINK: See, I'm not even sure we need that, because that's what, basically, the second sentence says, is they're going to verify it, to include --

DR. DENTON: That's right.

MR. LINK: We'll determine whether we're doing it right and in compliance.

MR. ELFERING: That's right.

MR. LINK: So we need to delete that last statement.

MR. ELFERING: Yes, definitely.

MR. LINK: Did the lights change?

UNIDENTIFIED MALE: I think they did.

MR. LINK: I'm passing out.

(Laughter.)

DR. DENTON: You're passing out, I'm going with you, because I think the light changed.

MR. LINK: And what was it you're adding on the second paragraph?

MS. BALDWIN: Okay, instead -- it would say, "FSIS should focus on assessment of the three alternatives to determine which alternative is most effective," or how about if we just determine the effectiveness of the mitigations?

SECRETARY: Of the mitigations or of the alternatives?

UNIDENTIFIED MALE: Alternatives.

MS. BALDWIN: Yeah, okay, "effectiveness of the alternatives." And then the next sentence would be: "Through this process FSIS can determine whether the assumptions on product risk made in the quantitative assessment of the relative risk" blah blah blah blah blah, "and the FSIS mitigation strategies are accurate." Does that say the same thing? It's (inaudible) hearing it.

UNIDENTIFIED MALE: (Inaudible) the second part of the sentence or --

MS. BALDWIN: Yeah.

UNIDENTIFIED MALE: Well, mitigation (inaudible).

MS. BALDWIN: Uh-huh. But you -- would you -- you could be evaluating both of those, because what we were saying was whether the risk assessment was correct in its evaluation of risk mitigations and whether products FSIS has considered the riskiest with regard to Lm are actually the riskiest.

How about if we just -- because we've already said about -- to see if those three alternatives, so how about if we just say this, then: "Through this process FSIS can also determine whether the assumptions on product risk made in the quantitative assessment of the relative risk to public health" blah blah blah --

UNIDENTIFIED MALE: -- "are accurate."

MS. BALDWIN: -- "are accurate."

UNIDENTIFIED MALE: Take out all the "riskiest."

MS. BALDWIN: Uh-huh.

SECRETARY: (Inaudible.)

MS. BALDWIN: The first sentence -- okay.

SECRETARY: (Inaudible.)

MS. BALDWIN: (Inaudible) can do that.

UNIDENTIFIED MALE: Can we scratch that entire last -- the one sentence in the last paragraph?

UNIDENTIFIED MALE: Uh-huh.

MR. ELFERING: I just don't like "industry will share with FSIS the results of their surveys" (laughs).

MR. LINK: I can't speak for industry.

MR. ELFERING: (Laughs.)

MR. LINK: However, Cargill --

(Laughter.)

(Cross-talk.)

(Pause.)

DR. DENTON: Are we working on Small Plant Guidance Team yet?

MR. ELFERING: We certainly can, and here's what I brought up. We changed it a little bit. "FSIS should include universities in disseminating guidance information to small plants. Universities can help deliver FSIS messages to industry" -- no, actually, just -- wait a second. "The district offices" -- are you writing it, or are you -- should I write all this out?

SECRETARY: I'm trying (inaudible). "FSIS" --

MR. ELFERING: "FSIS should include the universities in disseminating guidance information to small plants."

SECRETARY: Got that.

MR. ELFERING: "Representatives of the district offices would be involved to help deliver messages to industry through Just in Time training. FSIS should use available technology to train industry and FSIS personnel by using remote broadcasts and making videotapes available for those not able to attend the remote session."

MR. LINK: I don't want to disturb you while you're on a roll there, but the next statement there, that we -- what's the point?

MR. ELFERING: I think we should just take it out of there.

MR. LINK: Take it out completely, right?

MR. ELFERING: Uh-huh.

MR. LINK: I agree with you. I'm not sure what our mission was there, but it doesn't seem to make any sense.

MR. WILLIAMS: Just (inaudible) -- yeah, treatment difference (inaudible) --

MR. ELFERING: Yeah, we --

UNIDENTIFIED MALE: (Inaudible.)

MR. ELFERING: The only thing is, is maybe FSIS should recognize the difficulty of very small plants -- or very small plants' difficulty in implementing food-safety programs without having guidance.

MR. LINK: That should probably be the very first statement, and then to address that difficulty they may want to go to to the universities and --

DR. DENTON: And leverage that resource and training.

MR. LINK: Take those last two paragraphs out.

MR. ELFERING: Uh-huh.

SECRETARY: So the first statement is -- how about I just type it (inaudible) faster, instead of trying (inaudible).

(Pause.)

SECRETARY: So is the first statement "FSIS should recognize very small plants' difficulty in meeting food-

safety requirements"?

UNIDENTIFIED MALE: Well, "implementing" or --

UNIDENTIFIED MALE: (Inaudible.)

UNIDENTIFIED MALE: I wouldn't say "in meeting food-safety requirements" but maybe "in" --

SECRETARY: New requirements, new regulatory --

MR. HONTZ: Special needs.

UNIDENTIFIED MALE: (Inaudible.)

MR. HONTZ: Should recognize the special needs of the small plants in --

MS. BALDWIN: That they face additional challenges in complying, how would that be?

SECRETARY: "FSIS should recognize that very small plants face special challenges" --

UNIDENTIFIED MALE: At 7 o'clock we might be --

UNIDENTIFIED MALE: At 7 o'clock (inaudible).

UNIDENTIFIED MALE: We might have been premature in that statement.

SECRETARY: (Inaudible.)

MR. ELFERING: Were you bringing beer in at 5? (Laughter.)

MR. ELFERING: You were supposed to bring in beer at 5, weren't you?

UNIDENTIFIED MALE: No, I thought it was 6, needed it at 6, trying to speed things up.

(Laughter.)

(Whereupon, at 5:20 p.m., the sub-committee meeting was

adjourned.)

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CERTIFICATE