

THE UNITED STATES DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

In the Matter of:)
)
THE AGENCY'S POLICY ON)
RAW BEEF PRODUCTS)
CONTAMINATED WITH)
ESCHERICHIA COLI 0157:H7)

Monday,
March 8, 1999

Washington Room
Hotel Washington
515 15th Street, N.W.
Washington, D.C. 20004

The public hearing in the above-entitled matter
was convened, pursuant to Notice, at 9:10 a.m.

BEFORE: TOM BILLY
Administrator

APPEARANCES:

On Behalf of the Agency:

TOM BILLY, Administrator, FSIS
CATHERINE WOTEKI, USDA/FSIS
CAREN WILCOX, USDA/FSIS
KAYE WACHSMUTH, FSIS
MARK POWELL, FSIS
MARK MINA, FSIS
MARGARET GLAVIN, FSIS
PHIL DERFLER, FSIS
DANIEL ENGELJOHN, FSIS
PATRICIA STOLFA, FSIS
JUDY NEIBRIEF, FSIS

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APPEARANCES: (Continued)

Other Participants:

ROSEMARY MUCKLOW, NMA
PHIL OLSSON, Olsson, Frank & Weeda
TOM BEILA, American Food Service
THOMAS POWELL, AMSA
JIM KEETON, AMSA
DELL ALLEN, Excel
ANN HOLLINGSWORTH, Keystone Foods
JILL HOLLINGSWORTH, Food Marketing Institute
WARREN MIRTSCHING, Con Agra
JOE HARRIS, Southwest Meat Association
DENNIS JOHNSON, Olsson, Frank & Weeda
CAROL TUCKER-FOREMAN, Safe Food Coalition
TONY DUGUAY, Jac Pac
DON COUNTRYMAN, Moyer Packing Company
NANCY DONLEY, STOP
DEAN DANIALSON, IBP
BERNIE SHIRE, AAMP
LYNN DELMORE, Golden State Foods
RODNEY HOUISKEN, Houisken Meats
HEATHER KLINKHAMER, STOP
MARK DUPP, Hogan & Hartsen
KIM RICE, AMI
STAN EMERLING, NAMP
MARTY HOLMES, NAMP
ALLISON BEERS, Food Chemistry News
RICHARD WOOD, FACT
JOE MOSS, JTM Provisions
JAMES MARSDEN, Kansas State University
RANDALL PHEBUS, Kansas State University
JIM HODGES, American Meat Institute
PETE MROZINSKI, Qualicon
JILL WHITE, IGEN

P R O C E E D I N G S

(9:10 a.m.)

1
2
3 MR. BILLY: My name is Tom Billy. I am the
4 administrator of the Food Safety and Inspection Service. It
5 is my pleasure to welcome all of you to this public meeting.
6 The purpose of this meeting is to discuss our policy on raw
7 beef products contaminated with E. coli 0157:H7. I have the
8 pleasure of introducing Dr. Cathy Woteki. Cathy is the
9 Under-Secretary for Food Safety at the U.S. Department of
10 Agriculture, and she will provide you some opening remarks.
11 Cathy.

12 DR. WOTEKI: Thank you very much, Mr. Billy. I
13 would like to extend my welcome to all of you who have come
14 this morning to this meeting. I add my welcome to
15 Mr. Billy's. And my comments actually this morning are
16 really very brief. This meeting is very important to the
17 agency, and it is also very important to the industry, and
18 it is also very important to consumers.

19 What we are considering today is the agency's
20 policy on raw brief products contaminated with E. coli
21 0157:H7. And the purpose of the meeting is to solicit
22 comment on a proposal that the agency has made public. This
23 meeting, like I think probably hundreds that have preceded
24 it over the last few years, are part of the way that the
25 agency goes about doing its business: seeking public

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1 comment on issues of policy and on regulatory policies.

2 So this is a very important part of the agency's
3 process, and I look forward to hearing the variety of
4 comments that will be forthcoming during this meeting this
5 morning. I offer you my apologies, though. I am not going
6 to be able to stay through the entire day. But I do very
7 much like to participate in these meetings to hear the
8 spectrum of comments that are under consideration.

9 So please do participate through the discussions
10 today. And at this point, I would like to turn the meeting
11 back over to Mr. Billy, who is going to talk more
12 specifically about what the agency's interests are in this
13 meeting today.

14 MR. BILLY: Okay. Thank you very much, Cathy.
15 Most of the meeting will be devoted to comments from all of
16 you in terms of our policy and the issues surrounding
17 implementing that policy. Before we get started on the
18 actual presentations, I would like to make a few remarks.

19 As you know, on January 19, 1999, we issued a
20 Federal Register notice clarifying our policy on raw beef
21 products contaminated with E. coli 0157:H7. In that notice,
22 FSIS determined that intact cuts of muscle should be
23 distinguished from non-intact products, as well as from
24 intact cuts of muscle that are to be further processed into
25 non-intact products prior to consumption.

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1 In addition, in another Federal Register notice
2 also issued on January 19, we made available our final
3 guidance document to assist processors of ground beef in
4 developing procedures to minimize the risk of E. coli
5 0157:H7 and other pathogens. In response to these notices,
6 industry raised a number of significant concerns about the
7 policy clarification. And in response to those concerns,
8 the agency took two actions. First, we prepared a draft set
9 of questions and answers that are based on the questions and
10 concerns that we have heard from industry. And if you don't
11 have a copy, there are copies available out on the table.

12 We have made those questions and answers available
13 today, and we welcome your comments on them. After we have
14 had an opportunity to consider that input, we will issue a
15 final set of questions and answers.

16 The second action we took was to hold this public
17 meeting. Today we are here to listen to you. We want to
18 focus on any practical concerns that remain so we can
19 implement the clarified policy in a way that makes sense and
20 protects the public health. We do not know all there is to
21 know about the extent of human health hazard associated with
22 non-intact products contaminated with E. coli 0157:H7.
23 Epidemiological data is lacking, although we do know from
24 preliminary analysis of 1998 Foodnet data that E. coli
25 0157:H7 cases have not decreased when compared to 1997 data,

1 nor do we have good data on the incidence of E. coli 0157:H7
2 in manufacturing trimmings.

3 Data are lacking, and we are responding to the
4 lack of data by taking an approach that is protective of
5 public health. E. coli 0157:H7 is an extremely serious
6 pathogen that requires aggressive oversight. Thus, our
7 decisions on how we implement the policy will benefit from
8 data. Our goal is to base our decisions on the best data
9 available. We need data on the risks associated with these
10 non-intact products, and on the incidence of E. coli 0157:H7
11 in manufacturing trimmings.

12 I am optimistic that today, as a result of this
13 meeting, we will receive data on these matters. We have
14 also received -- we have already received data from the
15 American Meat Institute, and I am confident that more will
16 be forthcoming.

17 In this context, I would like to point out that
18 FSIS is conducting a farm to table risk assessment for E.
19 coli 0157:H7 in beef products, and we expect to complete it
20 later this year. We hope to receive information at this
21 meeting and subsequently that can be used in that risk
22 assessment. Thus I encourage you to share data with us.
23 How we implement our policy will also depend on the steps
24 industry takes on its own to institute validated testing
25 programs for E. coli 0157:H7 for these products, as well as

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1 other steps to protect against the risks presented by this
2 pathogen.

3 Testing programs are a good compliment to process
4 control programs, and we encourage the industry to undertake
5 testing programs, as we know some have, and others intend to
6 do. I am hopeful that we will hear about some of these
7 programs today.

8 My final message is that producers, slaughterers,
9 processors, and the retail and restaurant industries need to
10 work together to protect consumers from the risks of E. coli
11 O157:H7 in beef products. It is through this cooperative
12 approach that the public will be best served. I encourage
13 all segments of the industry to work together and with us in
14 developing a workable solution.

15 As I said earlier, we are here today to listen to
16 you, and we will now proceed with the presentations that
17 many of you have indicated you wish to make. First let's
18 look at the agenda. As you can see, we are going to be
19 focused primarily on presentations. I'll try to have a
20 break about 10:00, 10:30, wherever there is a logical break
21 in the presentations, break again at noon time, and then
22 continue about 1:00 or a little after 1:00, and continue
23 until we have heard from all of you.

24 For those of you that are speaking, or if you are
25 going to raise questions or make comments, I request that

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1 you state your name and your affiliation each time that you
2 do so.

3 It is now my pleasure to introduce Jim Keeton.

4 Jim is with American Meat Science Association, and Jim will
5 be making the first presentation this morning. Jim.

6 MR. KEETON: Thank you, Mr. Billy. It is my
7 privilege and pleasure to be here, ladies and gentlemen. I
8 am representing the American Meat Science Association, and
9 what I have come to present this morning is a report from a
10 group of about 35 scientists that met in January to -- and
11 actually, these are microbiologists and statisticians and
12 meat scientists -- to look at the issues involved in
13 testing, to looking at the role of microbiological testing
14 in beef food safety systems. And this is consensus
15 statements that were derived from that. The final report
16 will not be out, and it will be coming out later this
17 spring.

18 But I would like for us to look at some of the
19 conclusions drawn from this. And, Thomas, if you would put
20 up basically the first consensus point. Can everyone see
21 those slides? It is pretty light. Hopefully, I will try to
22 read them for you. The main purpose of microbiological
23 testing of foods is to validate and verify process control
24 measures in the context of a properly implemented HACCP
25 system. We currently have a HACCP system which is a process

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1 control system. We believe that testing does have a part in
2 that, but it has certain components that need to be
3 recognized as a part of a whole.

4 Secondly, effective microbiological testing
5 programs are based on sound food safety objectives, with
6 definable microbiological performance criteria. And so
7 these objectives, certainly we recognize that there have to
8 be objectives, there have to be certain criteria adhered to.
9 And this was part of the consensus of this group of
10 scientists.

11 The third consensus point was that pathogen
12 testing at any stage in food processing will not assure food
13 safety. That it is not to say that testing is not needed,
14 but to absolutely guarantee that a microbiological test will
15 assure that the consumer will not encounter a pathogen is a
16 little bit too much. And basically, testing is appropriate
17 in certain definable conditions.

18 Fourthly, food borne pathogens will not be
19 detected consistently when they are non-randomly distributed
20 and/or occur at a low instance level. And this is the
21 difficulty that we have with some pathogens, not all
22 pathogens, but specifically E. coli 0157:H7 and some others,
23 is that they are not randomly distributed. They occur with
24 varying degrees of frequency, and that is the real
25 difficulty that we have in working with a pathogen like

1 this.

2 Also, the fifth, pathogens or other microorganisms
3 which typically occur in food at a low instance cannot be
4 used to assess process control. If you are trying to
5 control a process by pathogen that occurs in a non-random
6 distribution and with a relatively low degree of frequency,
7 it is very difficult to do because you basically have to
8 destroy the sample, all of the samples, in order to be able
9 to detect if the pathogen in fact does exist in the food
10 sample.

11 Next, the seventh declaration of a food borne
12 pathogen as an adulterant in raw products, that is, for
13 example, E. coli 0157:H7 in certain raw beef products,
14 discourages testing for that pathogen. It also leads to a
15 false sense of security among consumers, and discourages
16 evaluation of potential control measures and encourages the
17 inappropriate use of microbiological testing.

18 Basically, this is trying to test for absolute
19 assurance that doesn't work for this type of pathogen. It
20 is not to say that testing doesn't have its place. It is to
21 say that on certain instances, testing has a caveat
22 associated to it.

23 The eighth consensus point, and final consensus
24 point, was that microbiological testing of foods in
25 production is important. We think that is important. But

1 such testing is only part of the overall strategy for
2 controlling food safety. Again, testing in combination with
3 an effective HACCP program is basically what we view the
4 role of testing. Certainly the education concerning proper
5 handling and cooking is essential to the consumer, and that
6 should be part of an overall strategy to this, in addition
7 to using testing effectively in a program.

8 Thank you for the opportunity for these comments,
9 and I appreciate this opportunity.

10 MR. BILLY: Are there questions for Jim or
11 comments? Marty.

12 MR. HOLMES: Marty Holmes, with North American
13 Meat Processors. I just want -- Dr. Keeton, I just wanted
14 to double check. Your consensus point No. 4, I understand
15 it, I just want to make sure that it is understood when you
16 say that the pathogen is non-randomly distributed, what you
17 are saying is that it is not uniformly random.

18 MR. KEETON: Well, statistically, whenever you
19 have any type of sampling plan, the first assumption is that
20 you have a binomial distribution and that any sample that
21 you take has an equal opportunity of containing the
22 organism. We know that because of the low frequency and the
23 low numbers of this organism, it doesn't adhere very well to
24 a lot of statistical sampling plans. It is not to say that
25 you shouldn't be checking for it. But it is to say that we

1 know that even if you test a lot, there could very well be
2 organisms in this lot that bypass that detection because you
3 can't sample the entire lot.

4 So that is the problem that you deal with from a
5 statistical viewpoint. And so it would be nice if we had
6 some other organism that occurred with a greater frequency
7 that occurred at the same time that you had E. coli. Then
8 you could test for that organism and detect E. coli,
9 potentially. But unfortunately, we don't do that. We don't
10 have an organism like that. And it is not to say that you
11 shouldn't test the organism, but just be aware of the
12 limitations that you have in testing, particularly from a
13 statistical viewpoint.

14 MR. BILLY: Caroline.

15 MS. SMITH-DEWAAL: Thank you. Caroline Smith-
16 Dewaal, director of food safety with the Center for Science
17 in the Public Interest. You made one point that just always
18 confuses me, and I would really like you to explain it
19 fully. Why is it that a government requirement that says
20 there is zero tolerance for a particular pathogen, why does
21 the industry take that to mean they shouldn't test?

22 I mean, from a consumer vantage point, it would seem
23 that they should test more. They should try to find
24 products with that pathogen and keep them out of the market.
25 Why is it that you are saying that the industry would rather

1 not find it, they would rather hide their head in the sand
2 and put product out there knowing it may be tainted, than to
3 find it?

4 MR. KEETON: Well, I don't know if the industry is
5 saying that or not. But what the real dilemma that you face
6 with is because of the low occurrence of the organism, and
7 it just doesn't occur very frequently, the real risk is that
8 even though you have sampled the lot, there could be a few
9 organisms, let's say, in a 2,000 pound batch. And if there
10 are ten organisms in that 2,000 pound batch, then it would
11 be equivalent to taking a can of BBs and dumping them in the
12 Great Salt Lake, and then trying to reach down into the
13 Great Salt Lake and trying to pull that BB out. That is
14 kind of the analogy that you are trying to find.

15 So what I am saying is the industry may be
16 testing, and they may find it on occasion. And that is good
17 because they have found that one on occasion. But the
18 problem is if you are really trying to use this as a process
19 control measure, then you run into problems in that it
20 occurs so infrequently that it is not a good process control
21 measure. So I am saying -- what you are saying is you can't
22 use it for process control. I'm not saying don't test. But
23 you can't use it as a process control.

24 MS. SMITH-DEWAAL: Thank you. I just wanted to do
25 a follow-up on that. But wouldn't that indicate that they

1 should be testing earlier and earlier in the chain, that
2 perhaps finding it more randomly at the ground beef stage
3 may be true, but that as they go earlier and earlier, maybe
4 testing combines or testing carcasses or even testing live
5 animals that they would have greater certainty of
6 identifying contaminated carcasses and products.

7 MR. KEETON: You have made a very good point. And
8 what I would -- the thing that we don't know is we don't
9 know exactly, you know, how often it occurs on carcasses.
10 We don't know exactly where to test. We don't know -- there
11 is a lot of information that we don't know. And if we knew
12 that, then we could devise plans that would at least help be
13 able to test with a better degree of accuracy than we have
14 right now. But right now, it just occurs so infrequently
15 and at such low levels, we don't know where the best place
16 to test is.

17 So to be honest, we don't have enough information
18 to be able to come up with a plan to do that yet. Right
19 now, it would please us immensely if we had that information
20 because I am a consumer, too. My family is a consumer. And
21 I want them to have the best, safest food supply that they
22 possibly can. And I think that all of us, at least from a
23 scientific perspective, there is no other reason to deal
24 otherwise.

25 MS. KLINKHAMER: Heather Klinkhamer, with Safe
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1 Tables Our Priority. You mentioned that there is a lot of
2 data missing, and I am wondering what your group is doing to
3 collect that data.

4 MR. KEETON: Individual scientists compete
5 basically for competitive research grants. In other words,
6 they will write a proposal to different funding agencies.
7 It could be the USDA, it could be commodity trade groups.
8 It could be a variety of different organizations who support
9 looking for this organism. And so from a scientific
10 perspective, we submit proposals to those organizations to
11 try to study this particular organism.

12 Several initiatives have been started. I know
13 food safety is a very high priority for USDA funding
14 agencies, and there are several commodity groups. I know
15 the National Cattlemen's Beef Association is supporting
16 research in this area. So there are a lot of people
17 beginning to look now trying to find more about the
18 epidemiology of the organism, where does it occur in the
19 environment, how does it get into the food environment, how
20 can we intervene in that particular process. So it is being
21 worked on, but we just don't have enough information yet.
22 So several groups or working in that area.

23 MS. DONLEY: Nancy Donley, Safe Tables Our
24 Priority. I would just like to start out with a general
25 comment, and I would really like to thank you, Tom, and the

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1 agency for really taking what we perceive to be a very, very
2 positive, proactive step in this war, if you will, on
3 0157:H7. Obviously, with the sampling program that is being
4 conducted, the random sampling program by FSIS, we see that
5 there still is a problem out there, and that it is just not
6 good enough to -- what the agency is recognizing is that it
7 is just not good enough to do the 5,000 samples and catch
8 what we can, but let's do something further upstream to do
9 something about it. And I really appreciate all your hard
10 work and efforts in that.

11 I do have a question, however, and that is that to
12 Mr. Keeton, that you made a comment that we just don't know
13 right now where is the best place to look for this, the best
14 place to test. And I would just like to suggest that
15 perhaps there isn't just a single point, that perhaps this
16 is something that needs to be the multi-hurdle effect, if
17 you will, and be looking at it at various points along the
18 system in the live animal, at the carcass level, in the trim
19 level, and in the final product in and of itself. And have
20 you done any looking -- done any research into this type of
21 a process?

22 MR. KEETON: Well, let me answer in kind of a
23 roundabout way, but I'll get to where perhaps to answer
24 directly. Right now we just don't know enough about the
25 epidemiology of the organism to know, for instance, if it

1 occurs, for instance, from feeds. Let's say it occurs in
2 the feed and the animal eats the feed, and it then becomes
3 -- passing the organism along. We don't know enough about
4 that yet. We don't know if it might be coming through
5 water. It could be coming through water or something like
6 that.

7 The fact that you may have carriers and the animal
8 will sometimes stop carrying the organism, it kind of makes
9 it elusive. It is like shooting at a moving target, and it
10 is very hard to hit. I think the approach of multiple
11 hurdle approach is a good idea, though, because if you put
12 different hurdles in the way of an organism, or intervention
13 steps is basically what they are, then more likely are you
14 to intervene and not get that organism in the food supply.

15 So I have -- I think that is a good idea. We use
16 intervention steps many times in our food processes right
17 now. And I think that that may be a possibility. But until
18 we know more about the organism itself and its frequency of
19 occurrence, and where is the best place to look for it, and
20 where are the best points to intervene, we are still going
21 to be finding it a pretty tough battle until we can find
22 more information about that. Is there another question?

23 MR. BILLY: I have one final question, Jim. Your
24 group that got together, did they, notwithstanding the
25 limitations in our knowledge, as you just discussed -- did

1 your group have any discussions about how you would go about
2 setting up such an approach, given this current state of
3 knowledge?

4 MR. KEETON: Yes. One thing I didn't mention is
5 that we will have a final report coming out from this. A
6 draft has been written. It has been sent out to the
7 participants for comments. And there was a lot of
8 disagreement, if I could put it that way, of even among
9 scientists about what is the best way to approach this
10 problem at this time. However, we do think that we may be
11 coming out with two or three recommendations or possible
12 sampling schemes that were discussed.

13 And I am not privy to the authors writing the
14 report. But I am hoping that perhaps if they don't put it
15 in the final report, that they will put it in the working
16 group reports and perhaps suggest some possible schemes,
17 that we know that they are not the best, but there are some
18 possibilities. And I truthfully don't know if they will be
19 coming out in the main report, or if they will be in the
20 working group reports. But as soon as that information is
21 available, we will make it available publicly to anyone that
22 wants to use it.

23 MR. BILLY: I appreciate that. Since we are in a
24 comment period, I don't know if our comment period coincides
25 with your schedule for your report. But we would certainly

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1 welcome that kind of information in whatever form you could
2 get it to us. Thanks.

3 MR. KEETON: Thank you, Mr. Billy.

4 MR. BILLY: Okay. The next commenter is Dean
5 Danialson. Dean is with IBP, Incorporated. And we welcome
6 you and look forward to your comments.

7 MR. DANIALSON: Thank you, Tom. Let me guess,
8 that means I don't have to go through my own introduction
9 here. I appreciate that.

10 I am leading off a series of presentations from an
11 industry based coalition group that is composed of many
12 industry segments and associations from retail food service,
13 processors, packing/slaughter industry and livestock
14 producers. This coalition is moving forth with a common
15 goal to provide the consumer with a safe, wholesome beef
16 product.

17 In response to the agency's recent actions, many
18 segments of the industry have joined together in this broad
19 based coalition to attempt to provide the agency with
20 regulatory and voluntary alternatives that remove
21 disincentives that we currently perceive to be imposed by
22 regulatory policy or thought and allows the industry to move
23 forward in finding better solutions for food safety
24 enhancements and public health benefit.

25 The industry coalition has developed a program

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1 which includes a series of recommendations to the agency
2 intended to remove these so called disincentives to testing
3 and promote enhancement to our food safety efforts. As we
4 go through this series of presentations, there are several
5 interrelated issues involved that will be addressed. One is
6 in the area of trimmings and lot definition and
7 interpretations associated with that for 0157:H7.

8 Another is discussion on directive 10010.1 and
9 potential modifications that we perceive as being needed and
10 recommend further discussions on the non-intact versus
11 intact meat issue. We will discuss a carcass testing
12 program which serves to establish a voluntary performance
13 standard or food safety objective for 0157:H7 on the beef
14 carcass. And we will discuss an industry sponsored pilot
15 study for validation of the carcass food safety objective
16 program.

17 Furthermore, the industry has developed -- the
18 industry coalition has developed several consensus points
19 that I offer on the overhead that serve to define our
20 collective efforts and thoughts on this issue. One, the
21 beef industry will become more aggressive to reduce 0157:H7
22 in the beef supply, with the ultimate goal of elimination.

23 Two, all segments of the industry must be involved
24 and will be involved. We agree that the logical control
25 monitoring point is the carcass, or as early in the

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1 production process as possible. We agree that any carcass
2 and/or product, which includes ground beef or trimmings,
3 that are identified as positive 0157:H7 is removed from the
4 supply. We further agree that presumptive positives must be
5 taken to confirmation or treated as positives if they are
6 not.

7 And lastly, the fifth point is we strongly
8 encourage FSIS to create a regulatory environment that
9 encourages rather than discourages industry testing and
10 innovation.

11 Leading into our presentations, we encourage the
12 agency to work closely with industry to eliminate some of
13 our currently perceived disincentives or help us understand
14 them better relative to testing and to move forward together
15 and support some of our recommendations and efforts of this
16 coalition. And with that, I'm not in the technical
17 presenting aspects of this, but I will lead into Dr. Dell
18 Allen's presentation, which will be our first one, and he
19 will follow me.

20 MR. BILLY: Hold on just second. Just so everyone
21 is aware of what you are interested in doing, there are a
22 series of industry presenters that will lay out
23 systematically an overall strategy for addressing E. coli
24 0157:H7 consistent with these points that you just outlined.
25 Is that correct?

1 MR. DANIALSON: I believe that the objective of
2 this coalition is to present that information, not only
3 here, but we'll further enhance it in the comments that come
4 in on the 22nd.

5 MR. BILLY: Okay. And given your strategy, would
6 it be preferable to hold questions till the series of
7 presentations are finished? Do you think that is a better
8 strategy?

9 MR. DANIALSON: That seems to be what everyone
10 thinks would be the best approach.

11 MR. BILLY: Okay. All right. The next presenter
12 is Dell Allen. Is that correct?

13 MR. ALLEN: Correct, right. Thank you. And thank
14 Caroline for setting me up for my part of the presentation.
15 I think it is difficult sometimes for people who are outside
16 the industry to understand the very question she asked, you
17 know, wouldn't it be advisable to test and not -- find this
18 product and get it out of the industry or out of the system.
19 She doesn't understand the disincentives that we talk about.
20 And so part of our purpose here this morning is to kind of
21 show you some of why that becomes a disincentive to test.

22 Before I do that, I would basically say that --
23 two things. Number one, I think we are now at a point as an
24 industry where we should have been probably back about five
25 years ago. But unfortunately, we weren't at that point this

1 time, or at that time. And I think we have finally reached
2 there. I have always heard of the carrot and stick approach
3 to getting and achieving results, and I think the January 19
4 notice was definitely a stick, you know, that prompted the
5 response that you are seeing here today from the industry.
6 And hopefully now, with that in mind, hopefully we'll get a
7 carrot later on.

8 (Laughter)

9 MR. ALLEN: Just to put things in a little bit of
10 perspective of why the industry basically almost went
11 bananas, I guess, after that January 19 notice, I thought it
12 would be useful at least to take a look at one day's
13 production and what happens to that one day production in a
14 plant, in this case, of 4,000 head per day production
15 facility. This plant happens to be our Schuyler, Nebraska
16 plant. Their basic running capacity is 4,000 head per day,
17 both on the slaughter and the fab side -- and to see what
18 happens to that product.

19 And to do that, we basically went back on
20 February 15, six days after the fact, and did a mock, not a
21 real, but a mock trace, mock recall I guess I would say. We
22 don't like the word "recall", so we say it is a "product
23 retrieval", is what we conducted, basically, on the 15th.
24 And that is where this information basically comes from here
25 in the first part of the presentation.

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1 On that day, our total production was 2,652,672
2 pounds of product. The various components of the carcass
3 there, it shows the primals that would break out of it, and
4 basically how much of each primal was produced, how many
5 boxes in each primal, the combos of each primal. Basically,
6 a total of 30,564 boxes, 161 combos, and 92 carcasses were
7 left or were produced in that facility and/or left that
8 facility on that given day.

9 Everybody wants to know, well, why the carcasses?
10 The carcasses go out of our facility basically because of
11 several criteria. Number one, they can be the wrong weight
12 for our carcass weight specifications in the fabrication.
13 Some cases they are a dark cutter, which is a stress pruned
14 animal that shows up in carcass form as a dark cutting meat,
15 and our customers don't like that, so they go out to
16 specialized customers. You could have hard boned cattle or
17 older cattle than what our specifications allow us to
18 fabricate. So therein lies why the 92 carcasses left our
19 facility and went somewhere else to be processed.

20 Of the products that are left, they went to 87
21 different distributors, 40 processors, three freezers, and
22 nine international customers on that day. That is basically
23 the customer mix of that day's production.

24 MR. BILLY: Dell, excuse me.

25 MR. ALLEN: Yes.

1 MR. BILLY: What that means is on the 15th, when
2 you did the mock recall, that is the picture you are looking
3 at in terms of where the product had been delivered.

4 MR. ALLEN: Those were what we identify as our
5 primary customers, Tom. That's where all that product was
6 shipped on that given day, to that mixture of customer. Put
7 this together, and what we did here was said all right,
8 that's great.

9 Actually, we have got a big flow chart that we put
10 this all together on. But it is too complicated to go
11 through in a short presentation. So the young man that put
12 this together went to one of those distributors that we
13 talked about, or 87 distributors. And this was one in the
14 Chicago area who happened to have a pretty good handle on
15 where product went out of his facility. And we say where,
16 when you ship this product, where does it go from your
17 facility? And this is kind of the breakdown here: He sub-
18 distributes to 140 other different distributors in this nine
19 county, or eight -- yeah, nine county area. They service
20 26,700 hotel and restaurant institutions and 886 retail
21 stores. The one distributor out of the 87 that we sent to,
22 his broke out that way. And so basically, if we get into a
23 recall situation, you know, these are the kinds of
24 complexities that we are looking at on it.

25 The shipment of that product on that day went to

1 32 different states. They are the states here that are
2 colored in yellow. So it was pretty widely distributed
3 around the country. The Northwest is kind of vacant on
4 that. Two reasons: just probably accident, number one, but
5 number two, this plant primarily does not service those
6 areas. We service those out of another plant.

7 The international countries involved here were
8 Canada, Mexico, Korea, and Taiwan, were the countries
9 involved. There were nine different customers in those
10 countries. And again, they are the countries shaded here in
11 yellow.

12 From just the ground beef standpoint, this is just
13 the breakdown here quickly on ground beef. And we have been
14 living under the umbrella, if you will, of potential recall
15 on ground beef all along, and so it was nothing new to us.
16 But basically, we produce different varieties of ground
17 beef. Ground sirloin, ground round, ground chuck are
18 specific to the primal that they are produced from. On the
19 ground sirloin case, they went to one distributor on the
20 East Coast, a small order, obviously. Ground round went to
21 four different distributors, 309 boxes of it.

22 We had one box still in inventory. That is a
23 mistake. We don't intend to keep it around, but it was
24 there. Under the ground beef side, basically that is a
25 mixture of ground beef dependent upon lean percentages. And

1 we produce a 93, a 90, an 86, an 81, a 75, and a 73 on lean
2 content. And so that all is a mixture of those different
3 lean contents that represent ground beef. There were 1,531
4 boxes that went to 19 distributors nationwide. There were
5 153 boxes that went to three processors, who would in turn
6 then service food service establishments out of that in
7 Arizona, Florida, and Pennsylvania. There were six boxes
8 again that we had still had in inventory. Ground chuck-
9 wise, of course, went to 19 distributors nationwide on it.

10 So it is a fairly diverse spreading of product
11 across the country. From the trim standpoint -- and I think
12 it is important to notice here, up to the January 19 thing,
13 ground beef was the thing that we were under the gun on all
14 the time, and the trim and the primals were not. And I
15 failed to point it out on the primals, but on those primals
16 the top butt is one that is widely needle tenderized. I
17 would guesstimate that probably 70 percent of the top butt
18 production that we produce gets needle tenderized at some
19 point in the production chain.

20 The round, a lot of that round is also either
21 needle injected and marinated and/or cubed at retail. So
22 that becomes one that is a muscle structure that has surface
23 penetration. Chucks are another one that get cubed a lot of
24 the time. So all of a sudden, on January 19, we were taken
25 from looking at ground beef as a possible problem to trim as

1 a possible problem, as well as all of these other sub-
2 primals as possible problems. And therein it really boiled
3 down to the reaction that came from the industry.

4 In our trim there, we shipped out 91 combos to six
5 processors on a nationwide basis. This would be people who
6 in turn take that trim, and a large quantity of it is what
7 we call 50/50 trim, 50 percent fat, 50 percent lean, that
8 goes to people who then in turn mix other lean trimmings
9 with it, and it goes out as ground beef products from those
10 processor facilities.

11 We also had in this case some frozen trim that
12 went in the freezer, and that is a very common thing.
13 People will take frozen trim or trim a lot of times and put
14 it in boxes and freeze it, stick it in the freezer, keep it
15 for three to six months for a variety of reasons. In some
16 cases, it is traders who are speculating on the market. In
17 other cases it is people who use frozen trim on a routine
18 basis, and they just want to have a surge supply available.

19 And so all of a sudden we were also looking at
20 potential, let's say, of having the box of trim that had
21 been in the freezer for three to six months coming out,
22 somebody doing a test on it, and getting a positive
23 potentially, and then we -- most of this product had already
24 been -- obviously would already have been dispersed and gone
25 out of the marketplace by that time, and yet we were back

1 under the "recall" type of mentality. And so again, it was
2 a big concern to us on it.

3 So out of all this -- and you will hear a lot more
4 about this in the future presentations. Again, just to
5 illustrate what our thinking is -- and it has been a long
6 time coming, I will admit, as an industry. Our thinking is
7 since we need to conquer or at least address this situation,
8 the logical point at this point in time is the choke point
9 of the funnel of the production chain, and that is in the
10 carcass form.

11 And basically, if you look at this, there are
12 1,115,650 operations in all 50 states. I mean, there are
13 cattle operations in every state in the union. That is the
14 total number of cattle operations in the nation according to
15 USDA figures in 1998. If you look right under there -- and
16 this is the cow test segment of that industry, there are
17 679,000 of those operations that have fewer than 50 head of
18 animals. There is 101,000 that have between 50 and 100
19 head, 70,000 of them that have been 100 and 500 head,
20 basically, and 5,550 that have over 500 head.

21 So as you can see, that industry is a ubiquitous
22 industry, it's a very -- you get down to the cow test level,
23 it is really a small producer driven industry, and it is
24 widely, widely scattered. So to try to conquer or identify
25 at that end, I think, is really as task that probably we

1 shouldn't tackle at this point in time at least. We need to
2 look toward the middle there and start identifying the
3 incident of it.

4 There are 822 federally inspected slaughter
5 plants, according to USDA numbers. Then as you go out the
6 other way -- and these are numbers that surprise me. I
7 would have bet there were more retail stores than that, but
8 there are 127,000 retail stores, and there 815,000
9 restaurants, and that includes fast food establishments here
10 in the U.S. The thing that really hit me when I got done,
11 you have got essentially the same number on the top of the
12 funnel as you do out on the bottom of the funnel.

13 So with that, we have decided or tried to come up
14 with, and have, industry agreement on some of the things
15 that we can do. And that is if we can go to and move to
16 carcass testing, assuming we get this carrot that we are
17 talking about, and 80 percent of the FSIS slaughter was
18 tested, the industry would be doing on their own about
19 94,000 tests per year of E. coli 0157:H7. With that in
20 mind, let's look at this next one if we could.

21 What we are actually going to propose, since we
22 are void of information and data, knowing where it is coming
23 from, how effective we are in the plant of getting rid of
24 it, et cetera, et cetera, et cetera, we are going to propose
25 a pilot type program here for a test period where we will

1 actually survey the incident level of 0157:H7 coming into
2 our facilities. We will actually then look at the incident
3 -- how good we are at keeping it off of the carcass during
4 the dressing process, okay? And that is before the steam
5 cabinet there, or before the intervention system.

6 Then we'll look at it again after those
7 intervention systems to see how effective the intervention
8 systems are once we get it off. Basically, it is a
9 validation of intervention systems which have already been
10 validated in a research setting. But we are going to look
11 at it from the standpoint of what is it in the commercial
12 setting, and how effective is it.

13 With that, I will turn the next commenter over to
14 Warren Mirtsching with Con Agra. Warren will show you some
15 data, I think, that was collected actually by Colorado State
16 University in their facilities, which begins to show you the
17 effectiveness already of these microbial intervention
18 systems in our plants. Warren.

19 MR. MIRTSCHING: Thank you, Dell. I would like to
20 thank the group for having the opportunity to present today.
21 I would like to thank Nancy from STCP for opening up the
22 multiple hurdle opportunity for us. But what we are going
23 to walk through today is indeed first some education
24 practice to identify what is the multiple hurdle impact.

25 Multiple hurdles as defined up here is the use of

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1 repeated aggressive attacks on microorganisms at critical
2 process points. You get an added benefit by staggering
3 these intervention steps throughout your process. The
4 multiple hurdle intervention systems are designed to really
5 accomplish two distinct differentials. One is to prevent
6 bacteria attachment to the carcass surfaces or products, and
7 the second is to prevent the embedding of the bacteria.

8 We do these through three or four different
9 significant steps. The first is a physical removal of the
10 process. You can do that by either trimming, by vacuuming,
11 steam vacuuming process, by washing, or by blowing. The
12 second is a method of reduction of bacteria through the use
13 of organic acids. The third is an increase in temperature,
14 whether that be the use of a steam cabinet or hot water
15 process. Either way, they are both effective and proven
16 through scientific study. And last is a decrease in the
17 temperature that you use through either the use of cold
18 water and/or cold air temperatures.

19 For those of you that have not been in a
20 processing facility, we have brought some pictures along to
21 show some examples of what it is. This is a steam vacuuming
22 process whereby the employee on the right has a tool in his
23 hand which applies the steam to the surface of the carcass
24 and then that is then vacuumed off so you are in turn
25 removing again any bacteria. It is focused around the area

1 where the knife initially marks the pattern or it breaks
2 through the hair, through the hide, and to the surface of
3 the carcass. That is the focus point.

4 Through scientific study, we have been effective
5 in looking at a one to one-half log reduction with the use
6 of the steam vac coming into play.

7 MR. BILLY: Is that a reduction of E. coli
8 0157:H7?

9 MR. MIRTSCHING: It is a TPC log reduction, total
10 plate count. The second step that we are using, and it is
11 at our facilities, is a pre-evis carcass wash. The idea
12 behind the process is to remove via washing any minute
13 particles which cannot be identified with sight. So you are
14 taking off any hair, any dust that you might not be able to
15 see in your normal practice. This is done immediately after
16 the hide has been removed in the process. So your chances
17 of again recontamination are minimized.

18 Within seconds of the pre-evisceration wash, there
19 comes an organic acid application. In this case the use of
20 acetic acid or lactic acid are common choices. And again,
21 the effectiveness is a one to one and a half log total plate
22 count reduction.

23 To minimize selecting either steam or hot water as
24 the choice of pasteurization, it is a thermal pasteurization
25 process by which is undergone. This is done after the

1 carcasses have been eviscerated, split, and gone through the
2 final rail of the zero tolerance location for visible
3 identification of contamination. It both focuses not only
4 on the exterior of the carcass, but as well the interior of
5 the carcass. At this location, we are seeing anywhere from
6 a one and a half to two log TPC reduction.

7 The last step -- and this is right before you are
8 going into your hot boxes or chill coolers. But this is
9 where the last organic acid is being applied today. And
10 again, at this level, we are seeing a one to a one and a
11 half log reduction. And then the animal proceeds, and the
12 carcass proceeds, on into the chill coolers, where you will
13 have anywhere from an 18 to a 36, sometimes even a 48, hour
14 chill practice that takes place.

15 But that gives you an example of the multiple
16 hurdle concepts of physical activities. Along with these,
17 there are two real key things that take place in just about
18 any slaughterhouse that is out there today, and that is the
19 SOPs and the GMPs. Multiple hurdles interventions tax onto
20 those sound practices the good methodology of removing the
21 hide, preventing contamination by the hourly employee. And
22 the management of your HACCP system therefore complies
23 directly with, and it gives you a multiple hurdle concept.

24 So these four steps by themselves are not the
25 issue. It is a more critical step than that even with the

1 GMPs, the SOPs, add in four intervention steps, add in the
2 chill process. And therefore, you end up with results.

3 To this extent, in working with Colorado State
4 University and the National Cattlemen's Beef Association, we
5 lined up to do a validation of the multiple hurdle process.
6 The study included multiple facilities. It encompassed the
7 entire geographic location of the United States. It
8 encompassed total facility process. We started with the
9 live animal, and we went through to a chilled carcass. Our
10 time frame on this study was done between September and
11 December of 1998, and the data has not yet been totally sent
12 out to the trades. But it has been presented in numerous
13 occasions.

14 To give you a concept of where we actually broke
15 down all of the different testing data throughout these
16 multiple facilities and multiple geographic locations, we
17 actually started at the sticking and stunning area. So this
18 is where the animal still has hide on. De-hairing was
19 immediately after the hide has been removed, prior to any
20 interventions, such as the steam vacuuming. Then the steam
21 vacuum, then the pre-evis, then the actual evisceration and
22 splitting of the carcass, then the ZT, which we call the
23 final rail inspection for zero tolerance, federal
24 pasteurization, organic acid-rinse, and then chill.

25 So there are nine locations where we actually

1 tested. We tested for issues whereby we knew we could find
2 what the results would be again to validate the intervention
3 systems that were there. Here are the results. At site
4 one, which is immediately at stick and stun -- so with the
5 hair on the animal -- you have the manure content, et
6 cetera. You'll see that the total plate count, TPC, the
7 average across the facilities that we had was a seven and a
8 half log starting point.

9 Site two was immediately after the hide was
10 removed, but no intervention systems placed. Site eight is
11 after the last intervention process, which would have been
12 the organic acid prior to chilling. Site nine is chilling.
13 So we have chilled the carcass. And it could be anywhere
14 from 18 -- a low of 18 hours at that point to a high of 48
15 hours on the chill process. But you can see the reduction
16 process on the total plate count. We also measured the
17 total coliform count, and we also measured generic E. coli.

18 The conclusions of the intervention microbial
19 effectiveness -- again, that is what we were proving in this
20 process, is to prove that on a total plate count, we are
21 looking at a six log reduction from a seven and a half to a
22 one and a half, and that is what the previous chart showed.
23 The total coliform count, you saw a six log reduction,
24 generic E. coli, a six log reduction. So hide on to a
25 chilled carcass, control points in place, validated by third

1 parties.

2 The question is going to come up, so we decided to
3 answer it anyway, and that was why was E. coli 0157:H7 not
4 tested in this process. And again, I brought up in earlier
5 conversations this morning, 0157:H7 occurrence is random,
6 and it is not a good use of validating an intervention
7 system because of that randomness. We wanted to test for
8 organisms that we knew we would find, and those three that
9 we identified, total plate count, TCC, and ECC are things we
10 know we have the ability to test. The relationship of their
11 biological structures to 0157:H7 intervention systems is
12 validated.

13 The key point here is this is a third party test.
14 Ohio State University came into the facility, rated the
15 testing. They marked things through the process and came up
16 with these results. With that, we believe that the multiple
17 hurdle steps, the intervention practices that can and should
18 be in place in facilities, does indeed work. It eliminates
19 the risk of microbial contamination, and we have good
20 indication methods whereby we know that kill steps work.

21 It is not a silver bullet, it is not the final
22 step. But it is indeed the right move toward the right
23 direction. And adding it back to Dell's point earlier, the
24 carcass is the funnel point where it all comes together.

25 With that, I will leave this turned over to Ann

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1 Hollingsworth from Keystone.

2 DR. HOLLINGSWORTH: The things that I want to talk
3 about are the issues that we believe need to be addressed
4 with the directive 10010.1, what are our recommendations as
5 an industry across all segments of the industry as to how we
6 would like to see the policy change so that it would
7 encourage processors to test for and hopefully find E. coli
8 0157:H7 when it exists on a carcass or in meat products.
9 And we decided that the best way to do this was to start by
10 making sure everybody is on the same page with what the
11 directive currently states, and these are just kind of the
12 highlights of that.

13 The current directive provides three ways for
14 establishments to be eligible for reduced sampling by the
15 USDA. The first is that they can conduct routine daily
16 testing of their raw ground beef products or boneless beef.
17 The second is that they can require suppliers of boneless
18 beef to certify that each lot received has been tested and
19 found negative. And the third way is that they can use
20 validated pathogen reduction interventions on beef carcasses
21 and routinely verify the intervention effectiveness on a
22 periodic basis.

23 And the next point that we believe is important
24 that everybody understands is that the current directive to
25 qualify yourself for this reduced sampling program requires

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1 a six month record of all negative results.

2 The changes that we would like to recommend be
3 considered to the directive are first that you would
4 maintain the first two options as they currently read. The
5 second is that the third option should read something to the
6 effect of "use of pathogen reduction intervention steps on
7 beef carcasses, which are validated through carcass swabbing
8 for E. coli 0157:H7."

9 Additional changes that we would like to talk
10 about is that we would like to alter the six month
11 requirement for eligibility, that the eligibility for
12 reduced sampling would flow through the marketing channels
13 so that a slaughter operation that has qualified for reduced
14 sampling could pass that eligibility for reduced sampling on
15 through to the processor and then to the ultimate consumer,
16 whether that would be a retailer or a food service type
17 establishment.

18 This would depend precisely on the fact that the
19 people who were buying from the slaughterer at whatever
20 level would have to buy only from slaughterers who had this
21 reduced sampling. If they bought from people that did not
22 have reduced sampling eligibility, then they would not be
23 able to maintain the reduced sampling eligibility.

24 And lastly, there needs to be an appropriate
25 identification mechanism to identify to those people that

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1 would be involved in the testing from the USDA perspective
2 that this product had all been through one of these systems
3 or a group of these systems.

4 Now let's talk a little bit about the carcass
5 swabbing specifics. We believe that is the major issue that
6 we are trying to get forward in these changes that we are
7 asking for. First, we believe that it should be a pilot
8 test so that we can prove that we can find the EC-H7 where
9 it exists at a level equal to what we are finding now or
10 greater. And we are asking for 180-day period in which to
11 prove that, much as Dell Allen described in his talk at the
12 very end of his discussions.

13 The carcass swabbing program would have to be a
14 written program individualized by plants that would specify
15 at what frequency they would test carcasses, what those
16 carcasses represented, and what kind of corrective action
17 would be put in place in the event that positives were
18 found. Any positives would have to be removed from the
19 system. And as we stated earlier, presumptive positives
20 that are not taken to full conclusion must be treated as
21 positives.

22 The swabbing sites that we are initially
23 recommending would be those similar to what we do for
24 generic E. coli, probably on the other side of the carcass
25 from the same generic E. coli carcass that is currently

1 being tested. And we believe that a minimum sampling level
2 should be one carcass in 300.

3 What are the advantages of this system that we are
4 proposing? First, we believe that it allows for increased
5 traceability into the live animal as to what the cause -- so
6 that we can find out what the cause of E. coli 0157:H7 is,
7 where does it come from, what is the incidence. It allows
8 us some interaction with the farm so that if there are farms
9 that are having more problems than others, we can hopefully
10 begin to try to figure out what are the causes of that. And
11 lastly, we believe it is a more effective testing procedure
12 than trying to go across the bottom of the funnel, as Dell
13 explained in his talk.

14 With that, I would like to turn it over to Tim
15 Beila from American Food Service. And he is going to talk
16 about the additional changes and thoughts that we would like
17 to propose.

18 MR. BEILA: Good morning. Thank you, Ann. Thank
19 you, Mr. Chairman, for the opportunity to make comments here
20 this morning. I am Timothy Beila, vice president of the
21 food safety and quality assurance for Texas American Food
22 Service Corporation in Fort Worth, Texas. I want to address
23 a topic this morning regarding the definition of point
24 source or lot as it relates to the 0157:H7 rule
25 clarification.

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1 Let me state first that I do not believe that
2 there is any argument at any level within the industry that
3 0157:H7 is a pathogen that does not deserve considerable
4 attention. The low dose infection rate associated with this
5 organism and the concept of zero tolerance, however,
6 presents some very new and unique challenges for those of us
7 involved in the production and distribution of raw food
8 commodities.

9 Individuals that have responsibilities for food
10 safety within the industry are constantly researching,
11 developing, and utilizing new and innovative methods for
12 reducing the risks associated with this virulent bacterial
13 organism. Microbiological testing of raw materials and
14 finished products, the multiple interventions that have been
15 mentioned several times this morning, can be applied at a
16 microbial level as well, can be used to assess and reduce
17 risks associated. However, they do not and cannot guarantee
18 the complete elimination of 0157:H7 from beef products.

19 Over the last several years, there have been many
20 different types of raw material, beef raw material, sampling
21 schemes developed and applied to reduce the risk associated
22 with this pathogen in raw ground beef. Although there are
23 some differences between the various schemes, there are also
24 a lot of similarities. Most are well written, defined, and
25 attempt to break down a typical truckload of raw materials

1 into defined lots.

2 Samples are collected from all of the defined lots
3 and tested for E. coli 0157:H7. Positive lots have both
4 been rejected and condemned, or in some cases returned to
5 the slaughter fabricator. Other lots within the load which
6 have tested negative have then been used in normal
7 production and processing of ground beef products. It is
8 regarding this particular practice of defining the
9 contamination to only the positive lot or point source where
10 the most concern has been raised regarding the recent Q and
11 As supplied by the USDA.

12 In those Q and As, the position that is taken in
13 answer No. 1 appears to recognize the individual sampling
14 schemes which clearly define the portion of the load or lot
15 that is affected by a particular positive sample. However,
16 subsequent responses in questions six and eight tend to
17 confuse the USDA's position and would suggest that supplying
18 establishments, number one, either conduct rigorous sampling
19 and testing of the source materials, i.e., other beef
20 manufactured on the same day and on the same line if still
21 available. And as Dell pointed out, most of that is
22 distributed fresh and very quickly. Very little of it ends
23 up and is available to go back to.

24 Review documentation to ensure that procedures are
25 in place for identifying the distribution channels -- I

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1 think you can see by Dell's -- again going back to his data
2 -- that most individuals do maintain very good information
3 about the distribution channels for beef and inform other
4 receivers -- and this is a very important one -- inform
5 other receivers of the same source raw materials about the
6 positive finding.

7 This position would clearly create a significant
8 disruption to the meat and food industry. And it has been
9 stated that it would in effect result in the cessation of
10 raw material testing as we know it today. I am sure this is
11 something that concerns everyone in this room, and would
12 result in an increase of potentially contaminated products
13 entering the marketplace.

14 In these same Q and As, the USDA recognizes that.
15 And I want to quote here: "Microbiological testing can
16 provide only a limited measure of assurance that product is
17 not contaminated with E. coli 0157 because the pathogen is
18 distributed sporadically in beef at extremely low levels."
19 This is a true and enlightened statement of fact.
20 Contamination of beef carcasses occurs during the actual
21 slaughter and dressing. And the distribution of the
22 pathogen is extremely variable since the contamination of a
23 carcass is a random event.

24 It has been further stated by researchers that the
25 presence of pathogenic bacteria on raw meats and poultry is

1 primarily a result of their incidence in the live animal
2 rather than as a result of inferior hygiene, and that the
3 occurrence of these pathogens in raw meat cannot be entirely
4 prevented by the application of strict sanitary hygiene
5 practices.

6 Further, it must be noted that the National
7 Research Council has stated that currently available
8 production and processing procedures cannot entirely
9 eliminate these microorganisms from raw meat, hence the fact
10 that we really need to clearly define point source and
11 continue with the raw material testing programs as they
12 exist today.

13 Information from three individual companies which
14 process USDA inspected boneless beef raw materials and
15 distribute raw ground beef products has been presented both
16 to the industry associations and the USDA, which supports
17 the concept of point source or lot definition. Documented
18 incidences of positive results in raw material lots and the
19 subsequent use of other lots from the same load which tested
20 negative for the organism, when applied in an intensive
21 finished product sampling and testing product for 0157, have
22 resulted in no positive results associated with the use of
23 these negative lots.

24 I appreciate -- and I know I'll get comments on
25 that point -- I appreciate the fact that a negative result

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1 in any microbiological sampling scheme is not evidence of
2 absence, but rather absence of evidence. But however, it is
3 clear that although not statistically valid, existing raw
4 material programs and testing schemes have been successful
5 at detecting and eliminating some suspect raw materials, and
6 have reduced the opportunity and risks of food borne
7 outbreaks and illnesses associated with 0157:H7.

8 In these documented incidences which I refer to,
9 the processors all have very strict and intensive documented
10 protocols for sampling and testing finished products. Most
11 of these programs require sampling every 15 minutes
12 throughout the production day, and are considered to be the
13 most intensive finished product sampling and testing
14 programs for 0157:H7 in this country. All of these programs
15 have been successful at detecting and eliminating a
16 substantial amount of product from the marketplace that was
17 contaminated.

18 It is extremely important for individuals and
19 companies like ourselves that process USDA inspected
20 boneless beef that the USDA clarify its position regarding
21 point source or lot as it applies to existing raw material
22 sampling and testing programs. No one in this industry
23 feels that the cessation of these kinds of programs will
24 benefit either the industry or consumers.

25 Further, the industry is currently discussing

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1 enhancing raw material sampling schemes to focus on
2 carcasses. And you have heard that stated by several
3 individuals this morning. The ability to enhance our
4 detection and elimination of positive carcasses may prove to
5 further enhance the ability of the industry to reduce risks
6 associated with this organism.

7 This fact was stated in January of this year at a
8 meeting of the American Meat Science Association, where Dr.
9 George Milliken of the Department of Statistics at Kansas
10 State stated that microbiological sampling programs used in
11 the meat industry have a very small chance of detecting
12 contamination when in fact contamination is present.
13 However, Dr. Milliken went on to further state that a system
14 must be devised to prevent the contamination from entering
15 the system.

16 It seems that this can be accomplished by testing
17 carcasses and rejecting those that are contaminated. In
18 order to continue to move forward with these types of
19 research programs and projects, the industry must have a
20 clear and concise definition of the USDA's position
21 regarding point source contamination and the recognition of
22 defined microbiological lotting, sampling, and testing
23 programs.

24 Thank you very much for your attention.

25 MS. MUCKLOW: I'm the last speaker. And I've got

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1 good news, and really good news. The good news is that I am
2 losing my voice, so I won't talk a lot today.

3 (Laughter)

4 MS. MUCKLOW: And the other good news is I'm the
5 last one. Today beef packers, processors, distributors have
6 presented important recommendations to orient sampling and
7 testing towards the prevention of illness and recalls and
8 away from after-the-fact sampling and testing of inspected
9 and passed product. This type of testing has proved to be
10 oriented more to punishment and prosecution than to the
11 prevention of illness and recalls.

12 In the past five years, beef packers have invested
13 hundreds of millions of dollars in sophisticated hot water
14 steam and organic acid intervention systems and in HACCP-
15 based process controls, all designed to make beef safer for
16 consumers. The recommendations proposed by a united
17 industry today are designed to provide ongoing verification
18 that those interventions and controls are effective on a day
19 by day, plant by plant basis.

20 In January, when the agency proposed to expand its
21 definition of adulteration, there were serious concerns
22 within the industry that this legal step would expand the
23 agency's capacity for punishment and prosecution, while at
24 the same time impairing the ability of companies and
25 inspectors to prevent the shipment of USDA inspected and

1 passed product which could later be the subject of recall
2 and prosecution.

3 The key to using sampling and testing to prevent
4 illness and recalls is to provide test methods which are
5 sufficiently rapid and to sample lots which are sufficiently
6 well defined, that the sample product can be held back from
7 shipment until test results become available. The sampling
8 procedures that have been proposed today meet these goals.

9 This orientation to prevention and away from
10 punishment is in the interests of providing safe meat to
11 consumers. It is in the interests of the commercial
12 activity of the industry, and it is in the interests of
13 government regulators to meet their responsibility. Thank
14 you.

15 MR. BILLY: Thank you, Rosemary. I think what we
16 will do now is take about a 20 minute break, and then we'll
17 get back together.

18 (Recess)

19 MR. BILLY: I would like people to take their
20 seats, please.

21 (Pause)

22 MR. BILLY: I think what would make sense right
23 now would be to provide some time for questions to the group
24 of industry presenters that have laid out a proposal here
25 for an approach for dealing with E. coli 0157:H7 that

1 focuses on carcasses. It includes an idea that there be a
2 pilot study that would essentially validate the approach,
3 collect data that would inform us all about the impact of
4 this kind of a strategy. So with that, I would like to open
5 it up for questions of what was presented, on what was
6 presented. Who would like to be first? Caroline.

7 MS. SMITH-DEWAAL: Thank you, Tom. It is Caroline
8 Smith-Dewaal with the Center for Science in the Public
9 Interest. I think my question is for Warren Mirtsching.
10 Did I say that correctly? Okay. You outlined a number of
11 hurdles that your plants are implementing. Is that
12 accurate?

13 MR. MIRTSCHING: Yeah. We did the testing on
14 inside Con Agra facilities. That is correct.

15 MS. SMITH-DEWAAL: How widespread are the use of
16 these multiple hurdles, including the wash post-evisceration
17 -- or no, post-hiding washing equipment and things like
18 this? How widely are those things used?

19 MR. MIRTSCHING: I could not address for each
20 individual company where they stand. I would believe that
21 probably steam vacuuming is being most utilized across the
22 industry today. Of course, every facility has their GMPs
23 and their SOPs which they follow, which again are the first
24 phase of anything. Past that, I would have to let each
25 individual company respond on their own.

1 MS. SMITH-DEWAAL: You said that your total plate
2 count started at about seven and a half logs?

3 MR. MIRTSCHING: That is correct.

4 MS. SMITH-DEWAAL: And that it reduced it by six
5 logs?

6 MR. MIRTSCHING: That is correct, down to 1.5.

7 MS. SMITH-DEWAAL: So there is some bacterial
8 contamination remaining on the carcasses. These aren't --

9 MR. MIRTSCHING: Yes. It is naturally airborne
10 contaminations that come into play.

11 MS. SMITH-DEWAAL: Okay. I am particularly
12 interested in some of your comments on why you didn't test
13 for E. coli 0157:H7. And while I understand the issue of
14 randomness, part of the difficulty we have with some of
15 these hurdles is in fact E. coli 0157:H7 survives acid
16 rinses. In fact, it can survive in apple cider, for
17 example, for weeks or longer. So we have -- many of your
18 hurdles, while appropriate for some pathogens, may not in
19 fact address the problem with E. coli 0157:H7.

20 So it would give us somewhat more comfort if you
21 had tested because then perhaps we could see more data on
22 that. But the reality is, well, some pathogens may have
23 been reduced that may not -- that 0157:H7 isn't going to be
24 reduced by every one of those hurdles.

25 MR. MIRTSCHING: Then again, the multiple hurdle

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1 concept is what we are addressing, and that was the validity
2 of what we had tested. The thermal wash or the thermal
3 process we know for a fact has and does kill 0157:H7. You
4 can go back to the scientific studies to validate
5 temperature as one of the very critical issues. And steam
6 application at the steam vacuuming points, you know, is
7 again another thermal process step, be it very minute in its
8 total carcass application. But it still does get the
9 critical point and opening a pattern where you are first
10 bringing in an external pathogen potentially to the carcass
11 surface.

12 MS. SMITH-DEWAAL: Okay.

13 MR. MIRTSCHING: So a combination of those is
14 where we were looking at to say what really worked
15 throughout the process.

16 MR. BILLY: I assume that the data that you
17 presented which was developed by your company was designed
18 to show and argue for the concept of multiple hurdles, that
19 that was -- and while it didn't include 0157:H7, you showed
20 the impact of a combination of hurdles at different points
21 in the process, and it is that very concept that is embedded
22 in the proposal that the industry has put forward as a
23 multiple hurdle type approach, whatever the appropriate
24 interventions are.

25 MR. MIRTSCHING: Right. That is very true. And

1 again, let me make sure that we add in that the intervention
2 systems there are additions to good GMPs and good SOP
3 executions because that is the foundation by which you then
4 add to with the multiple hurdles intervention process.
5 Again, the tests done, CSU gathered all the data. NCBA was
6 there to support that, you know. They were just in our
7 facilities.

8 MR. BILLY: And I further assume that one of the
9 reasons for the proposal to include a recommended pilot
10 study would be to collect specific data on 0157:H7.

11 MR. MIRTSCHING: That is correct.

12 MS. WILCOX: Could I follow up on Caroline's
13 question? Caren Wilcox. How many plants do you know of
14 right now that are using all four hurdles?

15 MR. MIRTSCHING: I know of six of the eight Con
16 Agra facilities today. We lack one and two facilities, and
17 they will be installed, one in April, and the other one will
18 be completed in September. We have still more renovation
19 that we have to do. But we will be complete with all of
20 those steps by September of '99.

21 MS. WILCOX: Now I know you can't speak for the
22 other companies, but can we get some idea from the coalition
23 members about the percentage of plants that is probably
24 using four hurdles right now?

25 DR. HOLLINGSWORTH: I am probably the best person

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1 to answer that, in that I buy from all of those guys, I or
2 folks within our system buy from all those folks. And,
3 Lynn, I would like your help, too, if you can help me if I
4 misstate. It is our experience that most of the plants in
5 this country do use multiple steps, multiple hurdles. The
6 exact description of what those multiple hurdles are and
7 whether it is the four that Warren elucidated or others --
8 it would be hard put to tell you what percentage do the same
9 four as Warren talked about.

10 But all of the ones that we go into do use some
11 combination of multiple hurdles. Some of them -- as Warren
12 said, most people use some type of steam vacuuming or steam
13 pasteurization. All of them use a hot water wash or an acid
14 wash after the carcass has been split and eviscerated. A
15 growing number, if not all of them, do pre-evis washes at
16 this point in time. And I don't know how many that would do
17 both a pre-evis, hot water wash and a pre-evis acid wash.
18 That is more of an anomaly, I think, today than a standard
19 procedure.

20 Does that answer your question?

21 MS. WILCOX: Gets at it.

22 MR. BILLY: How about some of the smaller plants,
23 smaller slaughter plants?

24 DR. HOLLINGSWORTH: We buy from smaller slaughter
25 plants, too, and we don't find a difference in the

1 performance. And we measure their performance not only
2 through audits to verify that their systems are in place,
3 that they have the critical control points under control.
4 We also measure their microbiological performance for H7 as
5 well as for generic E. coli and salmonella. And we don't
6 see a vast difference between the smaller guys and the
7 bigger guys.

8 MR. MIRTSCHING: I believe it does come back to
9 the concept -- again, it is Warren Mirtsching from Agra.
10 But it comes back to again the base that you support with,
11 and that is the GMPs and the SOPs. You have to have a solid
12 base there and the multiple hurdles come in on top of that
13 process.

14 MR. HARRIS: I'm Joe Harris from Southwest Meat
15 Association. And we do represent a lot of those smaller
16 processors. And the vast majority of them would have at
17 least one intervention in place. I think it would be more
18 unusual for them to have multiple interventions in their
19 slaughter process, but I think that Ann spoke very well to
20 the fact that in combination of the things that they are
21 doing with the intervention that they have in place, I think
22 they do a very nice job. But one would be very common
23 amongst the smaller processors. More than one, I think,
24 would be somewhat more uncommon.

25 MR. BILLY: Others on this same point? Go ahead,

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1 Bernie.

2 MR. SHIRE: Bernie Shire, American Association of
3 Meat Processors. To second what Joe said and to explain a
4 little further, we have a large number of small slaughterers
5 still active. Many of them will use one of these hurdles
6 that was outlined during the presentation today. Some will
7 use two. For the most part, they rely very strongly on the
8 preliminary steps, the SOPs and the GMPs. But in using one
9 or two of these hurdles, as has been referred to, there have
10 not been problems in terms of this pathogen.

11 MS. SMITH-DEWAAL: Just to follow up on --

12 MR. BILLY: Hold on just a second. I think there
13 is one more expression about it.

14 MS. DELMORE: I'm sorry. Lynn Delmore, Golden
15 State Foods. I just wanted to comment to the fact that
16 there was previous research done at Colorado State
17 University that was documenting the efficacy of not only one
18 intervention, two interventions, but up to four
19 interventions, and showed that all of them can be effective,
20 and there is some additive or synergistic effect. But it is
21 not necessary that you always have four in place, that there
22 are other combinations that may be just as effective.

23 MR. BILLY: Thanks. Caroline.

24 MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center
25 for Science in the Public Interest. Just to get back to one

1 of the major points that I am trying to make, and that is
2 that not all hurdles are the same, particularly when it
3 comes to 0157:H7. Ms. Hollingsworth, do you rely -- does
4 McDonald's or Burger King or any of the other fast food
5 outlets that you know rely on companies which are simply
6 using organic acids as their hurdle? And I ask you that
7 because organic acids per se may not be adequate to address
8 the challenge of 0157:H7.

9 DR. HOLLINGSWORTH: Do we rely on -- we rely on a
10 number of issues when we determine that we are going to buy
11 from a specific supplier. And that is based on a yearly
12 audit that we do with every individual plant that we buy
13 from, which totals 60, Lynn? It is about 60 suppliers.

14 We go in and do a yearly audit on each of them.
15 We verify that their HACCP plans are in place. But even if
16 they don't have HACCP plans, that we also have a number of
17 control points that we verify that are in place and are
18 being -- are in control, things like their SOPs are in line,
19 they are cleaning their knives and their aprons and their
20 hands between every carcass so there is no carcass to
21 carcass contamination, that their air systems are in line so
22 that they are not contaminating when they remove the hide
23 from one carcass to the next, that their evisceration
24 procedures and handling of the byproducts do not
25 inadvertently release aerosols that would contaminate

1 carcasses.

2 All of these are the kinds of things we look at in
3 every audit. There are a lot of intervention steps that can
4 be utilized that we certainly verify the efficacy of, but we
5 don't depend just on that per se. We also are looking at
6 the microbial records that they have and that we have.

7 MS. SMITH-DEWAAL: So these are microbial test
8 records?

9 DR. HOLLINGSWORTH: Yes.

10 MS. SMITH-DEWAAL: Is that accurate?

11 DR. HOLLINGSWORTH: Yes.

12 MS. SMITH-DEWAAL: So you rely on them to have the
13 systems in place, but you also look at their own microbial
14 test records. And then how frequently -- you're the
15 grinder. Is that --

16 DR. HOLLINGSWORTH: That's correct. We're the
17 grinder.

18 MS. SMITH-DEWAAL: So you take their products and
19 you grind it to make hamburgers for fast food restaurants.
20 And how frequently do you test in your grinding facility?

21 DR. HOLLINGSWORTH: Well, that is a matter of
22 company policy that I am not at liberty to describe because
23 it would refer to a lot of them. But we do do it to verify
24 that they have done -- I mean, we verify their records with
25 some of our testing on a very limited basis at least once a

1 week from every supplier that we buy from.

2 MS. SMITH-DEWAAL: We have heard earlier today
3 that some people test as frequently in grinding operations
4 once every 15 minutes. Do you have some people who you
5 supply to that require that level of testing?

6 DR. HOLLINGSWORTH: That I supply to? Do you mean
7 do I have customers who require me to test every 15 minutes?
8 I think I will have to answer that with that is a matter of
9 the individual company specifications, and if that
10 individual company does not choose to give that information
11 out, I would prefer not to, as to how often they test.

12 MR. BILLY: Other questions? Yes, Heather.

13 MS. KLINKHAMER: Heather Klinkhamer with Safe
14 Tables Our Priority. I have actually several questions. I
15 wanted to start with Dean Danialson. When you made your
16 presentation, you said that you were speaking on behalf of
17 an industry coalition. Could you tell us who are the
18 members making up this coalition?

19 MR. DANIALSON: Excuse me. Dean Danialson. I'll
20 just kind of wheel through a list of the ones that I can
21 recall that have been involved, and I am going to miss a
22 few. But, Kim -- maybe I'll defer that to the AMI because
23 they have been somewhat spearheading the effort, and she can
24 probably reel off the names and associations more completely
25 than me.

1 MS. RICE: The majority of the work was done by a
2 task --

3 MR. BILLY: Kim, state your name.

4 MS. RICE: Oh, sorry. Kim Rice, AMI. The
5 majority of the work was done by a task force of AMI
6 membership that was not only slaughterers but also grinders,
7 large and small. We brought in or asked for participation
8 from also non-members who had interests in the slaughter and
9 the grinding, and also some of the customers of these
10 members, as well as the retail outlets and other trade
11 associations. So, I mean, it is pretty broad based.

12 MS. KLINKHAMER: Would you be willing to give us a
13 list for the record?

14 MS. RICE: I'll talk to them about it.

15 MR. BILLY: Other questions?

16 MS. DONLEY: Nancy Donley, Safe Tables Our
17 Priority. One question that I have, I guess, of the
18 coalition here is how do you marry, if you will, the idea of
19 testing carcasses as opposed to point four, which I'm sure
20 you all remember, of the eight points that the American Meat
21 Science Association, Mr. Keeton, presented, which states
22 that food borne pathogens will not be detected consistently
23 when they are non-randomly distributed and/or occur at a low
24 incidence. And we know that for a fact with 0157:H7 and its
25 incidence on carcasses.

1 It seems to me that if we are really interested in
2 finding it, if it is there, we are more likely to find it,
3 if it is there, when it is in a situation where the pathogen
4 would be more evenly distributed. And that, I would
5 suggest, would be in something more as in trimmings.

6 MR. BEILA: Tim Beila, American Food Service
7 Corporation. I want to address that question as best I can
8 because I believe that you may have a little bit of a
9 misconception there. Depending upon how much upgrading is
10 taking place when a carcass is being broken and how much
11 meat is being taken off that goes out as primals and sub-
12 primals will vary from plant to plant and from the type of
13 animal that is actually being slaughtered, fat cattle and
14 cows.

15 If you look at combo then sampling and testing,
16 less than 7 percent of the surface material on a carcass
17 actually ends up in a combo bin, and it doesn't seem like
18 the appropriate place to go looking for it. Its numbers
19 have been extrapolated between one and 7 million and one in
20 20 million opportunity to detect, depending upon the type of
21 methodology for collecting the sample in combo bins. And
22 that was based on trimming, coring, purge sampling. And
23 there has been a lot of research done that says that purge
24 is not a good method for collecting a sample.

25 So going to the carcass and exposing or sampling a

1 very large portion of the surface relative to the carcass
2 and testing for 0157 may hold promise for a statistically
3 valid method of detecting and reducing the risks associated
4 with the organism versus combo bin sampling and testing.
5 What we are asking for is the opportunity to be able to
6 continue with the raw material sampling and testing programs
7 that exist today in combo bins until the research and
8 analysis of that research can be carried out on carcass
9 sampling and testing.

10 But again, the surface of the carcass is where the
11 contamination is occurring. Going to the surface of the
12 carcass may in fact give you a better statistical
13 representation or ability to detect the organism.

14 MS. DONLEY: Nancy Donley, STOP. So are you
15 positioning this then as a kind of a let's hold back thing,
16 wait and see, because what we would like to do is conduct
17 this study, and if this study shows that carcass testing is
18 the way to go, and that we can get a good idea of just what
19 kind of loads carcasses are carrying, what frequency they
20 occur, that this then after -- that this study would be
21 conducted prior to any change in directive 10010.1. What is
22 the time frame or time -- the progression, I guess?

23 MR. ALLEN: I'd like to address that, Nancy. Dell
24 Allen. I think it is imperative that the directive be
25 changed, and maybe it happens after the carcass testing, I

1 don't know, or after this pilot test. I don't like -- I get
2 nervous when people talk about a research project. We work
3 in a commercial facility, and commercial facilities are not
4 designed for research projects.

5 I think we can get some numbers of what is going
6 on. I am not going to -- I don't think I want to
7 characterize it as a research project. Research projects to
8 me are much more intensive in their nature, and should
9 probably more properly be carried out in a research facility
10 than in our commercial labs.

11 But getting back to the directive, to me, if we
12 have got -- I talked about the carrot and the stick. The
13 industry, I think, needs the carrot to be able to move
14 forward in this whole thing before they are going to be real
15 willing and -- it is very critical that we have that carrot
16 to take that next step.

17 MS. DONLEY: What is the carrot for the public?

18 MR. ALLEN: I think the carrot for the public is
19 an immediate increase in the number of tests that are going
20 to be conducted for 0157:H7.

21 MS. DONLEY: But I guess what I am not comfortable
22 with is knowing that conducting the -- I think your number
23 was 94,000 tests will be conducted -- that we don't have any
24 sort of data that supports that that will indeed be
25 effective in culling out 0157 at a significant rate from

1 getting into the system. We have no data showing the
2 prevalence of carcass contamination with 0157 to begin with.
3 I think that is the problem. And so if we knew that -- I
4 don't know if 1 in 300 is a good number, if it is a bad
5 number, if it is an indifferent number. I don't know if we
6 need to be testing 1 in 50, 1 in 500. We don't know.

7 MR. ALLEN: Nor do we. And I think that is why we
8 need to take this step. I mean, that is really where the
9 industry is. I think one of the things that needs to be put
10 in context that we failed to do in our presentation, because
11 most people don't understand the complexity of testing for
12 this organism -- and I'm talking about just the time, the
13 manpower required to do it.

14 First of all, at least in our slaughter
15 facilities, at least to this point -- and I'm probably
16 getting ready to change it. But we have had a rule that we
17 will not do pathogen testing in any plant that we work --
18 you know, any in-plant laboratory. I think the reason is
19 obvious, you know. You don't want to fool around with
20 pathogens in a production facility where you might even have
21 the remote chance of getting them out of control.

22 So when we test for a product -- for this
23 organism, we send that test out. It goes out by air
24 express, Federal Express, one of the courier systems, to an
25 outside laboratory, a third party laboratory. But when you

1 operate in Friona, Texas, folks, and other places like that,
2 air service is not the greatest, you know. And so when we
3 are operating two shifts, the samples that we collect after
4 about anywhere from noon to 3 o'clock in the afternoon sit
5 until the next day before they get air freighted. And then
6 if you really want to get it complex, do it on a Friday
7 night, when they don't ship on Saturday. Then you have a
8 got a Friday evening kill that you tie up then until Monday
9 before you can actually get the sample out, okay?

10 One day of getting the sample to the lab, at best,
11 under the best conditions. After they have gotten the
12 sample, it takes them one day basically to prep it and get
13 back your first results, which are either a negative, which
14 is what you want, or a presumptive positive. If it is a
15 presumptive positive, then typically it is at least two
16 additional days before you get the final results back. And
17 so you are sitting there -- and again, if you think of the
18 Friday evening kill where we didn't get the sample out until
19 the following Monday. If it is a worst case scenario, we get
20 results back; it is almost the next Friday. We have held
21 that product for one week.

22 We literally don't have the capacity to hold
23 product and test it. If we had moved to an in-plant lab --
24 I have already addressed this with my laboratory people, for
25 a plant laboratory. And it won't be in-plant, it will be

1 off-site, but near the plant, where we are doing the testing
2 on our own. First of all, it is going to take qualified
3 people. You don't do this with Joe Blow off the street,
4 pardoning my expression. But it has to be somebody that is
5 fairly, highly trained.

6 Secondly then, under the best scenario, to go
7 through the pre-enrichment phase of that test, my lab people
8 tell me it takes one person to do 12 of those pre-
9 enrichments, 12 tests, 8 hours to get it done, the pre-
10 enrichment part. So if you are talking about a lot of
11 tests, there is just no way we have the physical capability
12 of doing it at this time.

13 Now I would say that there are a lot of dollars
14 being addressed -- and I defer this to Randy and Jim Marsden
15 over here and some of the people that know. There are a lot
16 of people working intently on getting a very rapid testing
17 method for this organism. I'm convinced it will happen. If
18 and when it happens, I think we will be very willing to step
19 to the plate and do more testing. But the limitations are
20 what we are talking about right now that keep us from that.
21 And it just will physically cannot handle much more.

22 MR. BILLY: Do you want to continue, Nancy?
23 Heather?

24 MS. KLINKHAMER: Heather Klinkhamer with STOP. I
25 wanted to follow up. I had a question for Warren at Con

1 Agra. In your slides, you mentioned some multiple plants
2 have been tested. Is that the six out of the eight Con Agra
3 plants?

4 MR. MIRTSCHING: We tested all eight facilities.

5 MS. KLINKHAMER: Okay. And the testing went from
6 September to December of 1998?

7 MR. MIRTSCHING: That is correct.

8 MS. KLINKHAMER: Okay. And will there be a peer
9 reviewed study published based on this information?

10 MR. MIRTSCHING: That will come through the CSU
11 and NCBA.

12 MS. KLINKHAMER: Do you know if they have
13 submitted their data to a publication?

14 MR. MIRTSCHING: No, I do not.

15 MR. BILLY: Caroline.

16 MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center
17 for Science in the Public Interest. Tom Beila just said
18 that the way we are going to get greater statistical
19 certainty here is by carcass sampling using a large
20 proportion of the carcass. How big is the sampling -- how
21 much of the carcass are you proposing to sample in what you
22 proposed today?

23 DR. HOLLINGSWORTH: What we are proposing, at
24 least until we can do additional tests that might show us
25 additional ways that we can find it, is essentially the same

1 way that we currently are testing for generic E. coli on the
2 carcass, which includes at the knife point. And Dell is
3 going to put it up there. On his presentation, his last
4 slide showed those points, if he can find the switch. There
5 we go.

6 The places where we have traditionally been most
7 successful in finding it, which is along the midline, where
8 the carcass is opened -- where the hide is opened, excuse
9 me, and on the back of the round of the animal, which is
10 between the two hind legs, and then down on the bottom,
11 where the throat is, if you will, those are the places that
12 we would say that initially should be tested. We have plans
13 as well, if this pilot program is approved, to do additional
14 testing to determine if there are better places to find it.

15 MS. SMITH-DEWAAL: Okay. So what you are
16 proposing initially is that you would sample it the same
17 sampling frequency as we now have the generic E. coli
18 sampling occurring and the same sites?

19 DR. HOLLINGSWORTH: The same sites. However,
20 right now, the one site -- the generic E. coli is done on
21 one side of the carcass. And we're saying that you will
22 take the other side to do the E. coli 0157:H7 test. If a
23 plant chooses to go with a wholly different carcass, they
24 may also do that. But what we are proposing is since you
25 are already isolating the generic E. coli carcass, that the

1 other half that is not being tested today would be tested
2 for E. coli 0157:H7.

3 MS. SMITH-DEWAAL: And exactly what questions will
4 the pilot test resolve for us? I mean, because I can see --
5 I have a lot of questions about -- as Nancy said, the 1 in
6 300, whether that is enough, whether we are testing enough
7 of the carcass, is that what Tom meant by a huge proportion
8 of the carcass. I could see it being bigger than what you
9 are proposing. How many of these questions that are being
10 raised at this meeting is the pilot test going to resolve?

11 DR. HOLLINGSWORTH: It is our plan to try to
12 address all of those questions. Some of those questions we
13 have for ourselves, and some of them we don't. The first
14 question that we want to ask and get an answer to is what is
15 the prevalence of the organism coming into the back door.
16 So we are going to do some live animal tests so that we know
17 across a number of different slaughter plants, not just done
18 at one slaughter plant, what is the prevalence coming in.
19 Then we are going to test at the various hurdles, much like
20 what the study that Warren presented to you was done, what
21 is the reduction after those various points in the process.

22 Have we been successful when we removed the hide
23 at not carrying the organism from the hide onto the carcass?
24 Have we been successful after a pre-evisceration wash in
25 reducing it further et cetera et cetera. That is one

1 test, one pilot test that we would like to do to verify
2 that, number one, if it is there we can find it, or that the
3 intervention systems are eliminating it.

4 MS. SMITH-DEWAAL: And you are saying you would
5 test for 0157:H7?

6 DR. HOLLINGSWORTH: Yes. That is correct. The
7 second test would be done in a research environment where we
8 would look at other potential methods for swabbing to verify
9 that we can get the organism off the carcass by -- that our
10 swabbing methods are effective. If the organism is there,
11 are our swabbing methods effective?

12 MS. SMITH-DEWAAL: And so out of the pilot test,
13 you may come back to the department with additional
14 recommendations for how sampling should occur, the frequency
15 of sampling, the sites for sampling, what tests should be
16 utilized. Is that accurate, that you would come back to the
17 department with information on how to best do the -- how to
18 best they require you to do the test?

19 MR. ALLEN: I think the key point here, Caroline,
20 that hasn't been made maybe -- and it is a good point you
21 are making. Our intent, if we go this pilot test period,
22 all of that data will go to the department. They will have
23 all of that data.

24 DR. HOLLINGSWORTH: So to answer your question is
25 yes, it is our intent that if there is something that we

1 find out in this that is different than what we think we
2 know today, we would come back with that information.

3 MS. SMITH-DEWAAL: But Dell just made a very
4 important point.

5 DR. HOLLINGSWORTH: Yes.

6 MS. SMITH-DEWAAL: So all the data, good or bad --

7 DR. HOLLINGSWORTH: Yes.

8 MS. SMITH-DEWAAL: -- that suggests a change,
9 doesn't suggest a change. Everything will go back to the
10 department with respect to the pilot.

11 DR. HOLLINGSWORTH: Yes, absolutely. And the key
12 point here is that this group is interested in reducing
13 and/or eliminating this organism to provide a safer food
14 supply to the public.

15 MS. SMITH-DEWAAL: And then my final question. In
16 terms of what you are proposing the department do in terms
17 of modifying their regulation, do you see this as a
18 preliminary step prior to the data coming back from the
19 pilot test?

20 DR. HOLLINGSWORTH: We believe there are a couple
21 of ways that they can approach this. They can hold in
22 abeyance the clarification as they publicized on January 19
23 for an additional 180 days for us to do the test. They can
24 make the changes that we recommend with the clarification
25 that they may change them again after this 180 day test

1 period. Either/or is fine with us.

2 MS. SMITH-DEWAAL: And the two biggest changes
3 are, just to really nail this down, are to -- that companies
4 that do intervention, that companies that will be exempt
5 from -- what? -- retail testing, from testing in the plants
6 -- I mean, what is the -- just clarify for everybody the
7 current practice and what will be -- who is going to be
8 exempt.

9 DR. HOLLINGSWORTH: Okay. First off, we are not
10 suggesting that anybody is exempt. Secondly, what we are
11 asking for or proposing is that these intervention steps and
12 carcass swabbing methodology for reduced sampling is carried
13 through to all levels in the food chain, that it allows you
14 to be eligible for reduced testing if you follow these
15 procedures. If there is a reason to believe that there has
16 been an epidemiological problem, someone has contacted EC-H7
17 and there is a problem, all bets are off. We are not saying
18 that that is going to change.

19 In the event that someone gets sick and any of our
20 products are implicated, then we understand that we still
21 have to protect the public, and that we are willing to
22 accept that. What we are asking for is that as long as we
23 are trying to make this happen, we are trying to reduce the
24 organism, we are trying to eliminate the organism, to allow
25 us the opportunity to get this information without putting

1 us in a penalty box. And the reason that the directive
2 hasn't been utilized any more strongly than it has to date
3 is the six month penalty, essentially, that you have to have
4 six months of negative data.

5 And we are saying that if we find positive, that
6 stuff is removed from the chain, from the supply chain. Any
7 positive is removed from the supply chain. And therefore,
8 the requirement for six months of negative data should go
9 away. That is in my mind the biggest change we are asking
10 for.

11 MS. SMITH-DEWAAL: So you are saying that once a
12 plant implements carcass sampling together with these
13 intervention techniques, at that point, they should
14 immediately be exempt from random E. coli 0157:H7 testing by
15 the U.S. government.

16 DR. HOLLINGSWORTH: We are saying that they should
17 be eligible for reduced testing. We are not saying that
18 they are exempt. The agency has never given anybody an
19 exemption from testing for E. coli 0157:H7.

20 MS. SMITH-DEWAAL: Maybe my questions actually
21 goes to Mr. Billy. There is a lot of confusion about what
22 the exemption is, where it is applied. I mean, my
23 understanding is that once a company implements this
24 directive, that they won't be tested, either in the plant,
25 or I believe at retail for 0157:H7, as part of your 5,000

1 sample random sampling surveillance program. But if there
2 is clarification there, please.

3 MS. STOLFA: Hi. This is Pat Stolfa, FSIS. The
4 directive, as it is now in place, applies to ground product
5 testing, some of which occurs in retail locations, and some
6 of which occurs in official establishment locations. It
7 does not apply to carcass testing at the present time. And
8 I think that -- and my understanding is the same, that it
9 does not qualify one for an absolute exemption. It does
10 qualify -- if one of the three criteria are met, what the
11 establishment has is the possibility of reduced testing
12 because the inspector, via the directive, is given
13 instructions that he may choose not to take a sample when he
14 receives the form that generally instructs him to take a
15 sample.

16 And what was your other question?

17 MS. SMITH-DEWAAL: Well, I'm wondering, the
18 application of that ground beef testing requirement then to
19 a plant that does, as they proposed -- that has multiple
20 interventions and does carcass swabbing, what would be the
21 impact on whether they would get tested?

22 MS. STOLFA: Well, it depends on whether or not
23 the grinder, which is subjected, you know, potentially
24 subjected to the testing, has documented a system that meets
25 one of the three criteria.

1 MR. BILLY: Remember that the -- as I recall the
2 presentation, it talked about records that would associate
3 the raw material with one or more of the plants that are
4 part of this kind of approach and, you know, that if they
5 used other material from plants that weren't part of this,
6 then that would be a different situation. So I think we
7 need to see the whole proposal. But it sounds like it is
8 designed to provide a continuity from the slaughter plants
9 on through to the marketplace, is what I heard. I don't
10 know if you want to amplify on that some more to help people
11 understand.

12 MS. SMITH-DEWAAL: I just want to be clear. So
13 this directive just has the promise that they may get
14 reduced testing, if they do more sampling. And all you want
15 is a promise that maybe they will reduce their testing. You
16 are not going to be exempt from testing. Is that accurate?

17 DR. HOLLINGSWORTH: Well, I think certainly if we
18 were going to be guaranteed we weren't going to be asked for
19 testing, we would say yes.

20 (Laughter)

21 DR. HOLLINGSWORTH: But that's all we are asking
22 for. All we are asking for is essentially the status quo,
23 but we would like to pass it on through the market chain.

24 MR. ALLEN: Just a clarification, Caroline. Dell
25 Allen. We now are eligible for reduced testing. Our

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1 inspectors still get requests to pull samples. When they
2 get those, they come to us, or we go to them, usually. We
3 don't wait on them to come to us. And basically, we have to
4 share with them our records on the testing that we do, plus
5 -- they still have, even after that, they still have the
6 option -- in fact, we have had them take it anyway, whether
7 they shared the records or not.

8 So it is not -- I sincerely wish it were an
9 exemption. But I have never gotten that word out of the
10 department.

11 MR. WOOD: Richard Wood, Food Animal Concerns
12 Trust. By the way, the greater hope that the comments that
13 you made this morning on paper will be made available to us
14 -- I stopped taking notes about five minutes in, and it
15 sounds like an important proposal for us all to look at and
16 think about.

17 In the proposal, with an increased carcass
18 testing, I was hearing, I think, that the supplier end of
19 things was minimized. And at the other hand, I thought I
20 was hearing that if the prevalence of E. coli or E. coli
21 0157:H7 or other pathogens were found, that may raise some
22 red flags. In your proposal, is there any part of that
23 proposal that deals with steps that you might take with your
24 suppliers, particularly producers, to the slaughterhouses,
25 and what might those steps be?

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1 MR. ALLEN: Excuse me. All right. We have
2 definitely discussed what we would consider doing. Yes, our
3 decision is it is not totally appropriate for us to make
4 that decision. Then again, I think part of it again depends
5 on what is found out in this pilot test, you know, as to how
6 that works out. We definitely have some of our own ideas on
7 what should happen.

8 Basically, our concept is that we ought to address
9 the E. coli 0157:H7 as best as we can on a process control
10 model, which is where HACCP is, more so than just a flat,
11 totally negative all the time type of approach. Because
12 again, the negative all the time, believe it or not, is a
13 deterrent to anybody wanting to even get in the box in the
14 first place and start looking for it. It is a visible
15 deterrent. I know that may be difficult for some people to
16 comprehend, but it is there.

17 MR. BILLY: That was Dell Allen from Excel.

18 MR. DANIALSON: Along those lines -- Dean
19 Danialson, IBP. If the positive event occurs in a carcass
20 testing program, there are several events that any
21 responsible organization would take in the spirit and
22 application of HACCP, and that involves going back and of
23 course taking care of the product that is affected, and this
24 would be the carcass. You would go back and review your
25 process, investigate your process, measure/check the CCPs

1 that are in your process and the control points in your
2 process.

3 You go through that activity all the way through.
4 It becomes an investigative process. At the carcass level,
5 we have then the opportunity to look further back into the
6 supply chain in the surveillance mode to see and understand
7 better location effects, seasonal effects, and those types
8 of activities. It gives us the opportunity to get a much
9 broader amount of information when and if any event occurs.

10 Now obviously the thermal processes and all of the
11 multiple hurdles, no one in this room would say they are
12 100 percent. But obviously, the science, the support, and
13 the development that has gone in the last few years puts
14 those systems in a much -- gives us a much greater
15 confidence that we're addressing and enhancing food safety.
16 And we wouldn't be going forward with this type of approach
17 if we didn't think that there was significant effect that
18 these systems are going to offer us in terms of reducing the
19 incidence of the 0157:H7.

20 But when the positive occurs, in the HACCP
21 concept, you go back and review all of your systems and
22 processes. You couple it with other known information like
23 the associated coli species information, is there a gross
24 contamination situation, is it a spot random incident. This
25 is information that we will learn as we go along, but we

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1 want the opportunity to learn it as we go along.

2 MR. BILLY: Nancy.

3 MS. DONLEY: Nancy Donley, Safe Tables Our
4 Priority. I would just like to say that the idea of a
5 scientifically proven, statistically proven carcass sampling
6 regime would be very welcome. I think it would lead to
7 something that I think it could be very beneficial by
8 weeding out at that earliest point carcasses that are
9 contaminated with 0157. It makes great sense, as long as we
10 know that -- I just don't think we're there yet, and that
11 unless there has been a lot more that has gone on in this
12 coalition meeting that I don't know about, the design of the
13 program itself.

14 But we support the idea of carcass testing.
15 Perhaps it has to be included as a part of where you have
16 multiple hurdle interventions. Maybe we need a multiple
17 testing -- I know that is going to go over real well in this
18 room -- a multiple testing regime as well -- I'm just going
19 to throw that out -- until we know that, hey, we can
20 effectively address it at the carcass level. If we can, I
21 think that is great.

22 I think what would be very helpful to me is, Ann,
23 you had a slide, and there were a couple of slides that you
24 showed us. I just am a very slow writer. If you could put
25 it back up on your overhead. And it was the one where you

1 said you wanted to alter the third option to -- and you
2 had --

3 (Pause)

4 MS. DONLEY: And what did you mean by alter the
5 six month requirement?

6 DR. HOLLINGSWORTH: Alter the six month
7 requirement for eligibility. Is that your question?

8 MS. DONLEY: Mm-hmm. Eliminate it.

9 DR. HOLLINGSWORTH: Our preferred word would be
10 eliminate, simply because we believe that the six months
11 negatives discourages you from trying to find the positives
12 and remove them.

13 MR. BILLY: Carol.

14 MS. DONLEY: Thank you very much.

15 MS. TUCKER-FOREMAN: Carol Tucker-Foreman with the
16 Safe Food Coalition. Would you, Ann and Dell and others if
17 you want to address it, give us some specifics of why this
18 discourages people from doing the testing. Talk to us about
19 the specifics of that problem.

20 DR. HOLLINGSWORTH: A six months negative result
21 means that if you are successful in finding it, even though
22 you eliminate it from the system, you still have another six
23 months before you can go into the reduced sampling program.
24 It is very difficult, particularly if you are doing it at
25 the carcass level, to guarantee -- if you are doing it at

1 any kind of reasonable level of testing. If you are testing
2 one carcass a week, and you do that for six months, and you
3 have all negatives, then chances are you would be able to
4 meet it. But is that reasonable? I don't think so.

5 So our thought process is let's increase the
6 sampling, which is what we are proposing to do, to a minimum
7 of 1 in 300 carcasses slaughtered, and eliminate the six
8 month requirement so that if we find it, all we are doing is
9 removing it. We are removing it from the system. We are
10 doing the investigation to find out why it was a positive,
11 going back to the farm to determine what the origin was, and
12 then we will continue forward.

13 And if we have another event during a specified
14 time period, then we will put in a very rigorous corrective
15 action plan.

16 MS. MUCKLOW: Can I interrupt just a minute, Dean,
17 before you go? Is it permissible to ask you all why it is
18 you incorporated the six months?

19 MR. DANIALSON: Mm-hmm.

20 MS. MUCKLOW: That being the answer, then I would
21 ask the question.

22 MR. DANIALSON: Thank you. Dean Danialson. In
23 terms of specifics, I want to expound on that just a little
24 bit. As we understand 10010, it was basically, from my
25 understanding, developed to offer industry an incentive to

1 pursue these enhancements. And 90 percent of it is right
2 there. I mean, it truly can offer the incentive. However,
3 you know, the six month aspect -- the whole formation of the
4 infrastructure in the industry associated with developing
5 into 10010 will result in downstream customers, grinders,
6 perhaps maybe retailers, developing their associated
7 programs and business relationships tied into this -- I'll
8 use the word -- I won't use the word -- tied into meeting
9 that 10010, any one of the three.

10 So in a business that has established these
11 customer relationships, all of a sudden now gets a random
12 positive event in a testing program. The entire business
13 relationship of that facility is disrupted for six months.
14 If you have established that infrastructure with the
15 downstream customers that are relying on that compliance,
16 all of a sudden you don't have anything -- anywhere to go
17 with the cart for six months based on most likely a random,
18 sporadic event that does not necessarily, at least to our
19 understanding now, signify a process failure.

20 That is kind of the key to me on how that penalty
21 of six months is a detriment to participating in the
22 program.

23 MS. STOLFA: Pat Stolfa, FSIS. I think I can
24 recollect how the six months feature was developed in the
25 directive. Initially, it was designed principally to deal

1 with the fact that if an inspector were to offer a company
2 the opportunity for reduced sampling, we didn't want
3 inspection program personnel to do that on the basis of a
4 company that said, well, I started my program yesterday, and
5 I don't have any positives. So we said you need to have
6 some history in order to demonstrate that the company has
7 been doing this for awhile.

8 I think -- now again, my recollection is not
9 perfect here. But relatively early in the process, as we
10 were putting this in place, we were confronted with an
11 international situation and an effort to try to make this
12 work between companies that had close relationships either
13 within their own corporate structure or -- I think it was
14 mostly within their own corporate structure across the
15 Canadian border.

16 And we wanted -- things got slightly more
17 complicated then because our import program, when -- because
18 remember now we're not testing carcasses. We're testing
19 ground product. And I think the six months got more
20 institutionalized in our effort to make it somewhat similar
21 to other things that we did relative to a finding of non-
22 compliance in imported products throughout the rest of our
23 import testing program. And that is the best of my
24 recollection.

25 And again, it was a ground product testing program

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1 that we were designing, not a carcass testing program.

2 MR. BILLY: Are you finished, Carol?

3 MS. MUCKLOW: I am, thank you. That helps me a
4 lot.

5 DR. WACHSMUTH: I wanted to pick up on something
6 that Nancy said. It is something I was thinking as you were
7 going through the presentations. It would be optimal
8 scientifically if the testing on the carcass, if indeed you
9 could follow this all the way to the end user or the retail,
10 to during the pilot associate that with testing of ground
11 beef, to see -- you know, to determine precisely how one
12 relates to the other since we don't have those data. But
13 instead, it sounds like, from what Dean said, that may not
14 be a part of the plan. I wonder if anyone has comments on
15 that.

16 Would it be possible to do this in association
17 with testing ground product as well? Because I like the
18 idea of the aggressive sampling, and going back as close to
19 the farm as possible is absolutely what we would want to do.
20 But it would give us the assurance that something isn't
21 appearing downstream.

22 MS. MUCKLOW: I think the problem is that carcass
23 gets co-mingled with a lot of other carcasses, and then I
24 don't think that is a possibility, unless I am
25 misunderstanding your question.

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1 DR. WACHSMUTH: I don't know that it would have to
2 be the exact same carcass. But if the flow were to be
3 followed downstream and then testing of ground product
4 associated in some way with this pilot, I think that would
5 be optimal.

6 MS. MUCKLOW: I'm sure if there was a way to do
7 it, the people who have thought the details of the program
8 would try to work that out. But I think the commingling of
9 product may deny that happening. But I'm sure they would be
10 happy to think about that. And again, this is a very strong
11 concept here today. As Dell said, it has taken us five
12 years. We are probably five years too late with it today.
13 But you guys weren't ready for it five years ago either.
14 So, you know, we are all busy trying to put something
15 together that would really be useful and beneficial, and
16 beneficial to everybody.

17 DR. WACHSMUTH: Again, it is fine. And I am
18 pleased. I think the closer you get to the source the
19 better. The only thing that I was suggesting is that if
20 there were a way to associate that, maybe even with current
21 testing -- I know some of the people that you supply are
22 probably testing. I would hate to see that discouraged
23 until the pilot has a chance to evaluate the whole system.

24 MS. MUCKLOW: Tell you are pleased again. We like
25 to --

1 (Laughter)

2 MR. BILLY: Ann.

3 DR. HOLLINGSWORTH: Ann Hollingsworth, Keystone
4 Foods. One point we didn't make probably crystal clear is
5 that during this 180 day pilot test, when the carcass
6 testing will be verified, it is our intent as grinders to
7 continue the testing programs we have of the trims. So I
8 think, Kaye, the answer to your question is yes. But one
9 thing you need to remember is that if we find a positive on
10 a carcass, that carcass is removed from the system.

11 So it will not be a direct test combination. But,
12 yes, it is our intent to until we are positive as grinders
13 that the carcass testing will indeed pick up an out of
14 control system, we will continue to test our trim. And it
15 is our intent that we will do that for the 180 day test
16 period, so there will be some correlation.

17 MS. TUCKER-FOREMAN: It's Carol Tucker-Foreman
18 again. I want to make sure I haven't missed something here.
19 Even though a positive carcass would be removed, we could
20 attach ground beef sampling to your pilot. You could attach
21 it to your pilot project if for no other reason to see that
22 your proposal that carcasses that come through this system
23 get some positive labeling as it has passed a higher
24 standard. So it would seem that Kaye's suggestion that you
25 test the ground beef to show that in fact the carcass

1 testing does have that impact would be a useful part of the
2 pilot.

3 DR. HOLLINGSWORTH: Yes. It is our intent that
4 that will be done. Those organizations that are doing
5 testing now will not stop the testing that they are
6 currently doing. That is part of the agreement across the
7 coalition.

8 MS. TUCKER-FOREMAN: I wonder if maybe you need to
9 do more of it so it is an integral part of the pilot so that
10 you show that the theory actually does work out at the end
11 of the line.

12 DR. HOLLINGSWORTH: Okay. I think we can arrange
13 that.

14 MS. TUCKER-FOREMAN: I think that would probably
15 be reassuring.

16 DR. HOLLINGSWORTH: I don't think that is a real
17 difficult thing for us to add. The intensified testing that
18 you are talking about in the product you are talking about,
19 I don't think it is a difficult concept to incorporate into
20 the test, the pilot test.

21 MS. TUCKER-FOREMAN: It is or is not?

22 DR. HOLLINGSWORTH: Is not a difficult --

23 MS. TUCKER-FOREMAN: That's what I thought.

24 DR. HOLLINGSWORTH: -- thing to incorporate.

25 MR. BILLY: Heather.

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1 MS. KLINKHAMER: Heather Klinkhamer, Safe Tables
2 Our Priority. I want to assume, but I want to make sure by
3 asking, will you be preparing an outline or a detailed
4 written document about what you are proposing? Will that be
5 going to the docket at USDA by March 22?

6 DR. HOLLINGSWORTH: Absolutely.

7 MS. KLINKHAMER: Would you be willing to share
8 your paper with the public sooner than that so that we can
9 incorporate comments on that into our comments by the --

10 MR. DERFLER: We're working on it. But, yeah, I
11 mean, this is going to be an open bid at some point.

12 MS. RICE: Kim Rice, AMI. I want to make sure I
13 have got what you are asking for. Are you asking for our
14 written comments, or are you asking for the protocol for the
15 pilot? Because those are two different things.

16 MS. KLINKHAMER: What I am asking for is more
17 details about this pilot before the comment period and the
18 protocol.

19 MR. ALLEN: Dell Allen. I would address the
20 protocol part. To get that by the 20th I think is going to
21 be difficult. When our protocols are finally outlined, they
22 will be available to the agency, which makes them available
23 to the public. We're still wrestling with details,
24 particularly like on the live animal and how we are going to
25 sample, what we are going to sample. All of those types of

1 things have not been worked out yet.

2 MR. BILLY: If there was a sense coming out of
3 this meeting that the addition of a week or two of comment
4 time to facilitate providing the public in advance of the
5 protocol and other related information so that they could
6 incorporate their comments into -- include in their comments
7 their reaction to the protocol, I think it sounds from the
8 sense of the discussion here that that would be a good
9 thing.

10 MS. TUCKER-FOREMAN: Yeah. It's Carol again. It
11 seems to me that would avoid us having to write a set of
12 comments on the proposal that might then be altered
13 substantially by the details of your protocol. So maybe we
14 could all get together and get some scheduling here that
15 would make it possible for us not to have to be passing each
16 other and stretch this process out forever. None of us
17 wants to write comments on something that is going to be
18 rendered irrelevant in the next step.

19 MS. MUCKLOW: The flexibility on extending the
20 comment time is deeply appreciated.

21 (Laughter)

22 MR. BILLY: Do you have it in your pocket yet?
23 Caroline.

24 MS. SMITH-DEWAAL: Thank you. Caroline Smith-
25 Dewaal with the Center for Science in the Public Interest.

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1 I have two questions regarding your proposal for altering
2 the third option. One is that you move the phrase
3 validation down -- or validated pathogen reduction steps now
4 into being validated through carcass swabbing for 0157:H7.
5 Don't you mean verified using carcass swabbing for 0157:H7?
6 Shouldn't they already be validated and just the use of them
7 is being verified? So that would be my first question. You
8 don't have to answer it right now, but I'll be interested to
9 see if that would change.

10 The second thing is you have removed the language
11 and prevent the use of boneless beef or carcasses from
12 outside sources. And I wanted to know whether that was
13 intentional or not.

14 MR. DANIALSON: As I interpret it, it is not --
15 that will remain. It was unintentionally not included in
16 there because it is just a status quo activity.

17 DR. HOLLINGSWORTH: It is not something we are
18 changing.

19 MS. SMITH-DEWAAL: Okay. Do you have any comment
20 on the validated versus verified issue?

21 MR. DANIALSON: Semantics.

22 MS. SMITH-DEWAAL: It is not really.

23 MR. DANIALSON: Well, the validation is a -- the
24 pilot in essence is a validation. Ongoing testing becomes a
25 verification.

1 MS. SMITH-DEWAAL: I would recommend you may --
2 having been a lawyer who sat through many meetings on this
3 topic, that you want validated intervention, meaning those
4 interventions proven to control 0157:H7, of which organic
5 acids probably isn't one, and that the carcass swabbing is
6 to verify that those interventions are in fact working.
7 Perhaps I should make my proposal to the department,
8 however.

9 DR. HOLLINGSWORTH: Caroline, this is Ann
10 Hollingsworth from Keystone. I think it was just a -- as I
11 go back and look at the two different languages, the intent
12 was not to change the language that much, and I think we
13 just got the V words mixed up, if you will.

14 MS. SMITH-DEWAAL: Perfect.

15 MR. BILLY: Can I -- and part of it ties into this
16 a little bit, and I'll start with Dell maybe. Dell, you
17 used the word carrot. And it would be useful, I think, for
18 everyone if we sort of reviewed what it is that you view as
19 the carrot. And I'll broaden that out to all of the
20 coalition in terms of what constitutes the carrot here in
21 terms of the proposal and your overall reaction to the
22 policy change and clarification.

23 MR. ALLEN: Dell Allen. I'm glad you opened it up
24 to everybody else because I may not cover the whole thing
25 where I can see it. As I see it in the industry, the

1 alteration, if you will, of some of the mechanism on the 300
2 negative tests as it particularly relates to carcasses, I
3 think that needs to be couched in some kind of process
4 control model. That, as I have perceived it, and I think as
5 most people have perceived it, notwithstanding what she
6 said, we interpret that as being any test, whether it be --
7 of course, in fact I have talked to some of the people in
8 the agency, and I get both reads on it, where one time it is
9 ground beef, the other time it is any test, and so that is
10 unclear. That is one of the big ones.

11 The other one is the definition of lot size and
12 how we handle lots as it relates to trim positives so that
13 that does not discourage the testing as far as trim is
14 concerned. Those are the two of the biggest ones, I think,
15 and then the other is the extension, if you will, of the
16 reduced sampling incidents. If I'm on the program to the
17 customers that I supply to and/or that purchase product from
18 people who are on that type of a program, to me those are
19 the big three carrots, or parts of that carrot, the top,
20 middle, and bottom thirds of the carrot.

21 If I missed any, please --

22 MR. BILLY: That last item would include the
23 retail -- passed through to retail on the ground beef or --

24 MR. ALLEN: Or sub-primals or in non-intacts or
25 whatever that we deal with.

1 MR. BILLY: Rosemary.

2 MS. MUCKLOW: I would just like to add something
3 for Caroline, and we can certainly find this if you don't
4 have it, Caroline. I have heard you say several times this
5 morning you are concerned about the use of acid rinses.
6 There is some good research that has been done, and it is
7 published research, that demonstrates that the use of lactic
8 acid rinses following a thermal process magnifies and
9 improves the results of both immeasurably. So we are still
10 learning a lot about this microorganism. If you need that
11 information, we'll dig out the research paper and send it to
12 you. But I would hate anybody to go away thinking we are
13 using the wrong stuff.

14 MR. BILLY: Carol.

15 MS. TUCKER-FOREMAN: This may not be especially
16 appropriate right now, but I don't want to forget it and not
17 get it said. This is Carol Tucker-Foreman with Safe Food
18 Coalition again. The presentations from the industry
19 continue to be couched in terms that suggest that
20 microbiological testing of product and particularly of
21 finished product is not and will never be scientifically
22 valid.

23 I think it is fair to say that those of us on the
24 consumer side do not accept that. To the extent that you
25 can couch your proposals in terminology that do not tend to

1 foreclose or argue that this is the beginning of an era,
2 then I think it may be easier because we don't have to work
3 through all of that morass and argue with you about it. I
4 would be very reluctant to be in favor of anything that got
5 stated as foreclosing for all time the validity of ground
6 beef testing at retail or any retail testing for other
7 microbiological contamination.

8 I think we are right -- you know, the department
9 -- we are, Dell, five years behind on all sides because the
10 department for so many years insisted it had no authority to
11 even regulate in that period pathogens in raw product. We
12 have gotten past that now. The tests are being developed.
13 I am confident that there will be tests that will come along
14 that don't require pre-enrichment that can be a lot faster
15 and more accurate than they are now. And I don't want to
16 have a precedent that says we foreclose the use of those
17 tests because they are not available now.

18 I thought it was ironic that last night on
19 television, just before this meeting, there was a guy from
20 somewhere out in Colorado saying he had a swab test for
21 ground beef that would show it right that instant, and that
22 some day they could sell it to people like me to use at
23 home. Well, you know, I don't think it was a nighttime soap
24 opera I was watching. I think it was a news report. I know
25 it is not there.

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1 But really, I would urge the government not to get
2 into a situation that anybody could interpret as taking us
3 back to an era that assumes that we can't do this. And I
4 sure don't want anybody to discourage the development of
5 better technology because I think we are really just opening
6 the door to some very exciting technology in this area.

7 MR. ALLEN: Let me clarify -- excuse me, Dell
8 Allen -- clarify for you. We are not asking for that. We
9 are not discouraging it. There will be tests developed that
10 are better, faster than what we do now. And at such time,
11 I'm sure we will use them more. That is just the way, to
12 me, as I have told our people, that is the boat in the
13 future. You have just got to get ready for it.

14 MS. TUCKER-FOREMAN: And that is the incentive
15 that I want us to create at the same time that we deal with
16 immediate problems. I don't want to foreclose that
17 incentive.

18 MR. ALLEN: Just a side comment. I hear from
19 those guys probably about once a month, so --

20 (Laughter)

21 MR. BILLY: Dan.

22 DR. ENGELJOHN: This is Dan Engeljohn with FSIS.
23 I have a question, I think mainly for Ann. With regard to
24 corrective action on the carcass in the protocol that you
25 are coming up with, what is it that you intend to do about

1 the carcass before and after the one that is tested? Are
2 you looking to see if there is a potential for cross-
3 contamination on those carcasses? And then are you
4 intending to do any corrective action with them?

5 DR. HOLLINGSWORTH: If the plant -- this is Ann
6 Hollingsworth responding to Dan's question. If the plant
7 does not have adequate spacing so that there is a potential
8 for cross-contamination, then yes, the two carcasses on
9 either side would need to be addressed. We believe this has
10 to be a plant by plant issue that needs to be looked at in
11 the corrective action program that is put together for every
12 individual plant as they go forward in this potential change
13 to the directive.

14 MR. BILLY: All right. Two more questions, and
15 then we'll break for lunch.

16 MS. SMITH-DEWAAL: Caroline Smith-Dewaal, CSPI.
17 Can I just follow up on that? I would hope if you have got
18 a positive that it would mean your interventions weren't
19 working, and that we would see much more in the form of
20 corrective action than just taking care of carcasses on
21 either side of the positive. I mean, it is a much more
22 significant finding. Cross-contamination might be an issue,
23 but --

24 DR. HOLLINGSWORTH: I was trying to respond to
25 Dan's specific question of the carcasses on either side.

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1 Clearly, the rest of the corrective action program would be
2 that you would go back and verify that your interventions
3 steps were working or not working and why, and then make the
4 appropriate corrective action depending on the answer to
5 that.

6 MS. SMITH-DEWAAL: I mean, I would see it
7 potentially would impact the 299 carcasses prior to the last
8 test.

9 MR. BILLY: Heather.

10 MS. KLINKHAMER: I have a couple of questions.
11 One is a follow-up on something that Dean said. He
12 characterized random E. coli 0157:H7 positives as not
13 necessarily being a process failure. And I wanted to know
14 if that is how FSIS views an 0157:H7 positive, that it is
15 not a HACCP process failure.

16 MS. STOLFA: Pat Stolfa. I'm not sure I
17 understand the question, Heather. Could you just say it one
18 more time?

19 MS. KLINKHAMER: Earlier Dean had said -- and
20 correct me if I'm wrong -- that an 0157:H7 positive should
21 not be considered a process failure. And I wanted to know
22 if that was a view shared by FSIS.

23 MS. STOLFA: I think that Dean was speaking to the
24 issue of the low level and the non-uniform distribution of
25 0157:H7 positives, or 0157:H7 on carcasses and within

1 carcasses that are part of the same herd, et cetera. And I
2 think that therefore -- and, Dean, you know, you can tell me
3 where I have gone wrong here. Therefore, it was not
4 usefully an indicator of whether or not the process was
5 maintained in control as we normally look at things that
6 indicate whether or not the process remains in control. And
7 as far as I understand the scientific data, that that is a
8 fair way to characterize how we must take an 0157:H7
9 positive finding.

10 It is not like generic E. coli findings, which by
11 looking at over some period of time you can get some
12 indication of whether or not your process is in control.

13 And I believe we generally agree with that. That doesn't
14 say we don't think this is a serious problem that needs to
15 be addressed somehow. But it is not a good indicator of the
16 status of the control or non-control status of a process.

17 MS. KLINKHAMER: Thank you.

18 MR. DANIALSON: Just to follow up on that real
19 briefly. Dean Danialson. And along the same lines, there
20 is a coupling effect of an event on a carcass with a generic
21 E. coli that is a good -- generic E. coli that is an
22 indicator of gross contamination if it occurs for a process
23 failure versus the sporadic random, and then in addition the
24 investigative activities and the verifications of CCPs
25 functioning and hygienic practices. It is a whole mixture

1 of events and activities that would couple with a positive
2 finding if it occurred.

3 MR. BILLY: Rosemary, you have the final word
4 before lunch.

5 MS. MUCKLOW: Could I just get Warren Mirtsching
6 to clarify for us so that we go all away -- because a lot of
7 us are not number people, and he keeps talking about six log
8 reductions. In a percentage basis, Warren, what is a six
9 log reduction?

10 MR. MIRTSCHING: A six log reduction represents
11 99.999 percent competence factor in risk minimization. Six
12 logs equals that. So it is a fairly high competence factor
13 that I think you could take to Las Vegas with you.

14 MS. MUCKLOW: Thank you.

15 MR. BILLY: We have nine more presenters, so I
16 would like you back here promptly at 1:30.

17 (Whereupon, at 12:25 p.m., a luncheon recess was
18 taken.)

1 remains intact and that a positive sample represents only
2 the lot tested and not the entire production day. Further
3 isolation and disposition requirements of positive lots
4 should not change.

5 It should be recognized that great strides in the
6 control of 0157 have already been made and extensive
7 research is underway which will undoubtedly provide
8 additional direction. The three initiatives just discussed
9 have great merit and will provide further enhancement of the
10 ability to control 0157. Jack-in-the-Box and Dave Theeno
11 implore the agency to be supportive of these efforts and to
12 table further regulatory controls until we can all gather
13 the data from these three programs.

14 As the company that has the most experience in
15 data regarding 0157 testing and control, Jack-in-the-Box
16 believes that a much improved control system is closer today
17 than it has ever been. This problem can and will be solved
18 by all of us, including the regulatory and consumer advocacy
19 communities working together to achieve one common goal, the
20 elimination of the threat of 0157 from our food supply.

21 Thank you very much.

22 MR. BILLY: Thank you. The next person on my list
23 is Marty Holmes.

24 MR. HOLMES: Marty Holmes, North American Meat
25 Processors. I would like to change gears here a little bit

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1 and talk about the part of the clarification policy that
2 addressed mechanically tenderized product. To this point,
3 we have mainly focused on trimmings and carcass testing.

4 The North American Meat Processors Association
5 represents over 350 companies that process beef and other
6 types of meat and poultry products. Many of our members and
7 beef processors from other organizations, including the
8 great majority of all retail stores, rely on mechanically
9 tenderizing products to satisfy their customers. The
10 process is used not only on high quality choice and prime
11 grade sub-primal cuts, but it is used to a large degree on
12 select and lower grade products to assure their palatability
13 and tenderness.

14 The process acts like an insurance policy for
15 tenderness and enhances consumer satisfaction, both at the
16 food service and retail levels. We feel for a number of
17 reasons that it is unreasonable to put this entire industry
18 that uses mechanically tenderized product in jeopardy
19 without some undeniable proof that the use of mechanically
20 tenderized products represents a risk to human health.

21 Given the fact that the National Advisory
22 Committee for the Microbiological Criteria for Foods
23 recommended a full risk assessment of these type of products
24 be done prior to any regulatory action being considered, and
25 the fact that no cases of O157:H7 food borne illness

1 associated with mechanically tenderized products has ever
2 been documented by CDC or anyone else that we are aware of,
3 and that each carcass is treated with pathogen intervention
4 methods, and further must pass a zero tolerance check before
5 entering commerce, and that the cuts are trimmed further
6 before being tenderized or cut into steaks so that the
7 external surface from the original carcass, even if it had
8 been contaminated in any way, never actually reaches the
9 mechanical tenderizer.

10 In the only data and research conducted to date,
11 which will be presented next, that even suggests a possible
12 contamination with inoculation levels far beyond any levels
13 currently found to be documented in industry, exist --
14 excuse me. Let me rephrase that. The only data and
15 research conducted to date suggests that the possible
16 contamination levels on the inoculated product is far beyond
17 what can be found in industry currently.

18 Consequently, we fail to understand why FSIS is
19 not including a risk assessment of its process critical to
20 the well-being and possibly ultimate survival of an industry
21 in their current 0157:H7 risk assessment study. We feel
22 that USDA must do a full risk assessment regarding non-
23 intact mechanically tenderized products before any
24 regulatory changes are considered since these products play
25 such a vital role in the nation's food supply.

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1 MR. BILLY: Thank you. And I think the next
2 presenters, Jim Marsden and Randy Phebus, are also dealing
3 with the same issue. So why don't we move ahead with their
4 presentation, then we can get comment and questions.

5 DR. MARSDEN: Thank you, Tom. I'm here today with
6 Dr. Randy Phebus from Kansas State University to discuss the
7 results of a recent study that we conducted to address this
8 issue of non-intact steaks. The copy of the slides actually
9 is available out there, if you haven't already picked one
10 up. The title of the study is "E. coli 0157:H7 Risk
11 Assessment for Production and Cooking of Blade Tenderized
12 Beef Steaks."

13 In this study, we intentionally inoculated beef
14 cuts with high levels of E. coli 0157:H7 in order to
15 quantify the effects of mechanical tenderization on the
16 trans-location of bacteria from the surface of those beef
17 cuts into interior muscle. E. coli 0157:H7 was used in
18 order to obtain data specific to the pathogen of concern.
19 The levels of contamination used in this study do not
20 reflect levels that are likely to be present. In actual
21 practice, the source point of contamination for E. coli
22 0157:H7 is at the carcass level, and contamination is
23 prevented or reduced through the application of HACCP,
24 including validated anti-microbial technologies and
25 enforcement of USDA's zero tolerance policy for physical

1 defects.

2 The potential for contamination is further reduced
3 by the removal of the carcass surface by trimming before
4 mechanical tenderization occurs. Even by applying worse
5 than worst case inoculation levels, our study demonstrated
6 that there is no difference in risk between intact and non-
7 intact steaks over the range of cooking procedures from rare
8 to well-done. Both intact and non-intact steaks are safe
9 for consumers. Any recommendation to address cooking
10 temperature would apply equally to intact and non-intact
11 steaks.

12 And with that, I will introduce Dr. Phebus, who
13 will talk about the procedures for the study.

14 DR. PHEBUS: All right. This is literally data
15 fresh off the grill, as you might say. And I appreciate the
16 opportunity to present it because I think it is very
17 important as we go forward with future risk assessments with
18 this type of product. I think the data will be very
19 beneficial for you. There has been a lot of people involved
20 with this and a lot of industry support in getting the work
21 done, so I think we have all pulled together to bring this
22 to you.

23 We are currently going to present data on blade
24 tenderization process. We have studies that are underway
25 with the restructured type products, and we are also looking

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1 at beef and pork issues here. In case you don't know what a
2 blade tenderization unit looks like, that is the blade
3 tenderization unit. And that is the tenderizing head that
4 is associated with it. And actually, there are two heads,
5 and I'll further describe that with some cartoons here.

6 First of all, the system works by taking the sub-
7 primal underneath the heads with a moving stainless steel
8 belt. And that belt moves one and a quarter inch forward
9 and a half inch laterally each cycle. And the result of
10 that is 32 penetrations per square inch. And that is pretty
11 much the standard, I think, in the industry.

12 Our objectives of these studies, first of all,
13 were to quantify and microscopically visualize the magnitude
14 and depth of sub-surface penetration of surface inoculated
15 0157 due to the blade tenderization process of beef top
16 sirloin sub-primals. Then secondly, we wanted to determine
17 and compare the effectiveness of all of the cooking
18 temperatures, rare to well done, on reducing populations
19 that might be carried into the center of the steaks.

20 Starting with the study one, depth of penetration
21 -- I am going to do these pretty quickly -- we uniformly
22 misted the inoculum on the surface of these sub-primals, and
23 we did this at a high inoculum level which was grossly high,
24 ten to the sixth per square centimeter, and then a lower
25 level, ten to the three per square centimeter, and allowed

1 them to attach for 30 minutes.

2 We then passed the sub-primals through the blade
3 tenderization unit. After that, we excised three two inch
4 diameter cores with a sterilized coring device from the
5 bottom up so that we weren't carrying contamination in
6 artificially with our coring method. And basically, each
7 core represented 100 penetrations of the needle.

8 And this would be a representative core. And the
9 arrows you can see represent the way that the blades
10 penetrate, the direction. We took this core and aseptically
11 evaluated the first centimeter, the second centimeter, and
12 then the fourth and the sixth centimeters, and took those
13 sections and cultured them and enumerated the organisms that
14 were carried in. What we found -- and this, I might say,
15 has been six replications done in triplicate. E. coli
16 0157:H7 from the surface was carried into the center, and it
17 was at about a 3 to 4 percent rate, and that was uniform
18 across high and low inoculum conditions.

19 And when we looked at the numbers, these were the
20 numbers we found. I put up the lower inoculum level, which
21 is still worse case in true life, but it is still more
22 representative. If we have 3,000 on the surface, we would
23 carry in about 100 to the geometric center, which would be
24 about this point. Then the subsequent steaks that we cut
25 off of that sub-primal would have the inoculum at the

1 center.

2 Okay. So 3 to 4 percent is what we have in the
3 center. We then went to the cooking studies to see what
4 level of control was needed to take care of that 3 to
5 4 percent. And we looked at again inoculating the surfaces
6 with a five strain mix of E. coli at ten to the six per
7 square centimeter. And then we again tenderized the units.
8 We also looked at non-treated, non-tenderized controls,
9 which are intact steaks.

10 All the sub-primals were uniformly hand sliced,
11 and we looked at three different weights, which in effect
12 was three different thicknesses, those being a half inch,
13 three-quarter inch, and 1.25 inch. And from our surveys,
14 that pretty much represents the industry. The steaks, which
15 were tenderized and non-tenderized, were randomly assigned
16 to one of five target internal cooking temperatures being
17 120 to 170. Actually, we considered 130 rare, 170 well
18 done, and we put in the 120 just to complete our graphs and
19 things. We also evaluated a non-cooked inoculated control
20 to establish our initial levels.

21 We cooked these steaks in an oven, and that oven
22 was at 300 degrees Fahrenheit, and monitored the internal
23 temperature by inserting a thermocouple attached to our data
24 log-in system. This thermocouple was in the geometric
25 center of the steak to monitor. And we monitored the

1 temperature every ten seconds. Immediately after cooking
2 reached the internal target temperature, we brought the
3 steaks off the grill into a plastic bag and immediately went
4 into an ice bath to stop the temperature rise, and we
5 continued to monitor temperature until we cooled to 100
6 degrees Fahrenheit.

7 Then we went and analyzed these steaks to see how
8 much was left of the E. coli populations. And I'll turn it
9 over to Dr. Marsden at this point to discuss the data that
10 we actually found.

11 DR. MARSDEN: This slide shows the log reductions
12 in E. coli 0157:H7 across the various temperature ranges.
13 130 here, as Dr. Phebus said, represents a rare cooked
14 steak. And you can see that we are looking at for the non-
15 intact steaks a log reduction of just over five logs. The
16 number on top is standard deviation, which was .8. For the
17 intact steak, it was right at five logs. And this 130
18 temperature is pretty much, I think, the lower limit in
19 terms of the thermal process required to control these
20 levels of E. coli 0157:H7, assuming that you are looking at
21 a five log reduction.

22 And even then, with those high standard
23 deviations, you are pretty much right at that limit. As we
24 move forward in temperature, 140, 150, 160, 170, we got a
25 six log reduction across the top. And even more

1 importantly, you can see that the variation is much less at
2 140 degrees and higher. So the data at 130 I'll explain in
3 a little bit more detail in a moment. But that is pretty
4 much the lower limit. Next.

5 Okay. Now this slide shows the target versus
6 final endpoint temperatures. And we had done some
7 preliminary work that suggested that the temperature
8 continues to climb quite a bit if you don't put it in ice
9 and slow that process down. And even with putting it in ice
10 and slowing down the temperature rise, there still is a
11 significant temperature increase. At 120, the actual
12 temperature crept up to 126 to 135, at 130, 137 to 142, and
13 so on. In practice, this would actually add to the
14 lethality of the process, of course, and even more so than
15 we are seeing here because in practice obviously you are not
16 going to put the steak in an ice bath. The temperature is
17 going to continue to climb after it is cooked. So we feel
18 that that would provide some additional lethality. Next.

19 Okay. Now at 130 degrees -- I put this up so that
20 you can see the difference in the three different
21 thicknesses. We had the 5 ounce, the 8 ounce, the 12 ounce
22 weight steaks. In the tenderized steaks, the log reduction
23 at 5 ounce was 5.5 plus or minus .9, the .9 being the
24 standard deviation; 8 ounce, 5.3 plus or minus 1.1; and for
25 12 ounce, 6.2 log reduction plus or minus .4. So relative

1 to the 12 ounce or thicker product, cooking it to the rare
2 temperature was quite sufficient to absolutely assure
3 effective control.

4 For the thinner products, the 5 ounce and 8 ounce,
5 if you factored in that standard deviation, you may not
6 always be achieving a five log reduction. This same trend
7 held true also for the non-tenderized steaks. So really the
8 issue at 130 is not to do with intact versus non-intact. It
9 is just that you are riding the lower control in that
10 relative to controlling E. coli 0157:H7. Next.

11 Okay. So this -- you can go on. That basically
12 just explains what I have just said. Okay. So in
13 considering the 130 degree question, which again is the most
14 rare temperature that was evaluated, it is important as the
15 agency moves forward with a risk assessment to consider what
16 constitutes a likely worse scenario contamination level,
17 then determine the margin of safety desired. If we use ten
18 to the three, for example, as the worst possible surface
19 contamination level, which I understand has been done in
20 other risk assessment studies, then you would actually need
21 a one log reduction to control the microbial population.
22 And then if you added a two log margin of safety, that would
23 put you at a 3D thermal process.

24 We are obviously well above that with the 130
25 degree cooked. But in terms of risk assessment, those

1 things really need to be defined. Another thing is that the
2 oven broiling method is what we are referring to when we
3 talk about this lethality. This is a method that provides
4 some consistency, and it may be useful to go back in the
5 future and look at other cooking methods as well to see
6 whether the same results are obtained.

7 Okay. If a five log reduction is what is
8 required, then the 130 or rare temperature is not going to
9 always provide a five log reduction because of that
10 variation, especially in the cuts that are thinner. In the
11 12 ounce or thicker cuts, that really -- it was actually
12 sufficient.

13 In summary, statistical evaluations of data were
14 based on target internal temperatures. At the lowest target
15 internal temperature of 120 and 130 degrees, the internal
16 temperature after removal from the oven rose considerably,
17 10 to 11 degrees Fahrenheit. Of course, as we mentioned,
18 this additional temperature rise actually results in a
19 greater log reduction, a greater lethality in the thermal
20 process, and would actually work to make the products even
21 safer. Next.

22 The 120 degrees temperature, which we did
23 basically just to establish the point where we are unable to
24 control, we saw a 3.2 log reduction in E. coli 0157:H7
25 populations with a large standard deviation 1.6 logs. For

1 the non-tenderized steaks, we had a 5.2 log reduction, with
2 a standard deviation of two logs. So clearly, 120 is too
3 low of a temperature to affect control. And even though we
4 did get the five log reduction at 130 degrees, the standard
5 deviations were considerable, up to 1.8 logs.

6 To assure the greatest margin of safety based on
7 the work that has been done to date, if steaks were cooked
8 to an internal temperature of 140 degrees, you would have
9 absolute assurance in all cases of control. At 130 degrees,
10 you would have control for the thicker steaks. It is still
11 an open question really about whether or not you could get
12 five logs, depending on how much increased lethality was
13 associated with the additional rise in temperature post-
14 cooking.

15 Some points I wanted to make just in general.
16 Meat safety, of course, is a function of the integrated
17 pathogen control measures throughout processing. And we
18 have talked about that all day. Validated anti-microbial
19 interventions during processing greatly decrease the
20 likelihood of even low levels of pathogens being present on
21 sub-primals destined for blade tenderization, decreasing the
22 level of process lethality required during cooking of
23 tenderized cuts.

24 So we really don't know just exactly what level of
25 control is necessary. I don't believe that it is five logs.

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1 In all probability, a risk assessment would show a lower
2 requirement. But the data I have just showed you shows you
3 what is required to get the five logs. Importantly, I think
4 all the data shows that there is no difference in risk
5 between intact and non-intact steaks at cooking temperatures
6 ranging from rare to well-done, and also that both intact
7 and non-intact steaks are safe for consumers. And I think
8 this goes a long way to explaining why we haven't seen
9 epidemiology associated with this whole category of
10 products.

11 The detailed results of this study will be
12 submitted to FSIS during the comment period. And also we'll
13 be writing a scientific paper for submission to a peer
14 reviewed journal. Thank you.

15 MR. BILLY: Thank you very much. I would like to
16 open it up for comment now on the last couple of
17 presentations, sets of comments. Any questions or comments?

18 MR. DUGUAY: Mr. Billy, I have got a couple of
19 comments from -- I am Tony Duguay, Jac Pac Foods. My
20 company is the manufacturing segment of this industry, where
21 many, many products come in from our various supplies for
22 grinding, for steaking, for cooking.

23 In everything I have heard this morning, in all of
24 the information we have had over the past couple of months
25 on this issue, Jac Pac is looking -- and anyone in this

1 position is looking at how much testing can we do. And we
2 are testing, and we are verifying. But we are up to 750
3 tests a week right now and heading for more. We are a HACCP
4 plant. We have our programs in place, our SOPs, our GMPs.
5 And everything to me is pointing back to lot identification,
6 isolating this pathogen as much as we can at the earliest
7 stage in the process of this industry.

8 So my comment is I like what I am hearing. I
9 certainly hope everyone else in this segment and the
10 consumer groups here like what we are hearing and USDA likes
11 what we are hearing. To isolate and get back to the
12 carcass, and to get back to where we need to be with the
13 proper kind of testing, and really look at a prevention
14 HACCP program the way it was designed, is where we need to
15 be and where we need to go.

16 On the non-intact issue, all I can say is we are a
17 company that suddenly we are faced with many, many sub-
18 primal cuts that come into our organization. They are
19 already trimmed. But we are going to have to face something
20 new again, once again, with the issues that are coming
21 along. Again, it all points back to control and to
22 prevention, and that is really where we need to be. HACCP
23 is truly a prevention program when it is in its proper
24 perspective. Thank you.

25 MR. BILLY: Thanks, Tony. Other questions or

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1 comments about the information presented by the folks from
2 Kansas State University?

3 MR. MOSS: My name is Joe Moss. I am with JTM
4 Provisions in Cincinnati, Ohio. I just want to add to what
5 was just stated. Indeed, over the last several years, us
6 grinders, everybody seems to keep pointing the finger to us
7 to take care of this E. coli problem. To date, you know, I
8 have worked on it a great deal. And I stand a lot of risk
9 each day as to whether someone might get sick on something
10 that I produce. That certainly would ruin my whole life's
11 work.

12 I have studied hard to see how it is that I can
13 make 0157 not be in my product, and I haven't come up with a
14 solution. Indeed, if 0157 comes into my plant, there is
15 really no way for me to get rid of it, since I make raw
16 hamburgers. I certainly also would like to reiterate then
17 as well that I particularly like what I am hearing today,
18 that I have been really frustrated over the last several
19 years of having the fingers pointing at me every day to say
20 that I am the problem, as though there is something much
21 that I can do about it.

22 The questions and answers that were submitted by
23 FSIS prior to this meeting today actually continue to point
24 at that, quite frankly. There were, you know, what if a
25 receiving establishment finds 0157 in their product or in

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1 the meat that they receive, what should they do. And the
2 answer was, well, reassess your HACCP plan, take corrective
3 actions. Well, you know, again, I read something like that,
4 and I go why do I reassess my HACCP plan, I didn't do
5 anything. What corrective actions do I have available to
6 me? I am not sure I have any.

7 So indeed, you know, the issue is a bit more of a
8 carcass. If we are going to try to get rid of 0157 out of
9 the food supply, continuing to try to point at the grinders
10 seems illogical, that indeed if we are trying to get rid of
11 0157 out of the food supply, that that would have to be
12 something that would happen at the carcass level. Thanks.

13 MR. BILLY: Thanks. Any other -- okay. Tony, did
14 you have any other points you wanted to make?

15 MR. DUGUAY: Excuse me?

16 MR. BILLY: Do you have any other points you would
17 like to make?

18 MR. DUGUAY: Not really. Just that the non-intact
19 issue, I think, again from what I am hearing on the research
20 that has been done so far, I think that I would like to see
21 us go back and reevaluate, and the agency consider the
22 carcass testing program and the interventions and risk
23 assessment that needs to be performed on both non-intact and
24 the carcass sampling method that we are proposing this
25 morning.

1 MR. BILLY: We will carefully consider all data,
2 as I said in my opening remarks, all data and information
3 that is made available. So you can be assured of that.

4 The next person on my list is -- oh, yeah, go
5 ahead, Marty.

6 MR. HOLMES: Does that mean that you would re-look
7 at your risk assessment that is being done now with Mark to
8 consider intact steaks? I had understood at this point that
9 it did not include intact steaks at all in the risk
10 assessment -- non-intact steaks, excuse me.

11 MR. BILLY: Yeah. Our original plan for risk
12 assessment was focused on ground beef. But we have
13 reconsidered that, and we are looking at doing some
14 additional work after we complete the initial planned risk
15 assessment on ground beef to look at other beef products. I
16 don't know if you want to add to that at all.

17 MR. HOLMES: Would that mean you would be willing
18 to consider holding this policy clarification in abeyance on
19 non-intact steaks until that risk assessment is done?

20 MR. BILLY: We are going to look at all of the
21 data and information. We are not going to reach any
22 conclusions at this public meeting. But we encourage that
23 kind of data and information to inform us about decisions
24 like that. Caroline.

25 MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center

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1 for Science in the Public Interest. I just wanted to add
2 some data to what you are considering in terms of the other
3 cuts of meat issue. In our review of 225 food borne illness
4 outbreaks, we identified two outbreaks of E. coli 0157:H7
5 linked to roast beef. One was in 1990, July 1990. The
6 second was in August 1995. And we can't tell you whether
7 those products were needle tenderized or not.

8 In addition, we believe CDC would have better
9 information related to outbreaks linked to meats -- of
10 0157:H7 linked to meats other than ground beef. But there
11 are some outbreaks which occur. And clearly, the issue is
12 whether the needle tenderizing or some other step may have
13 contributed to that.

14 MR. BILLY: Marty.

15 MR. HOLMES: Marty Holmes from North American Meat
16 Processors. I would like to follow up that we did approach
17 CDC to ask them if they had any data, and they said they do
18 not, on mechanically tenderized products associated with
19 illnesses from 0157:H7. We tried to find that data.

20 MR. BILLY: All right. The next presenter is
21 Richard Wood. Is he here?

22 (Pause)

23 MR. BILLY: As I say, going, going, gone. All
24 right. Heather.

25 MS. KLINKHAMER: Heather Klinkhamer with Safe

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1 the company's hamburger patty suppliers. Jack-in-the-Box
2 considers it a critical element in its overall food safety
3 system. It must be clearly stated at the outset that no
4 technique and/or amount of 0157:H7 testing can ensure that
5 uncooked ground beef is absolutely free of the organism.
6 However, the Jack-in-the-Box 0157 testing program has
7 successively enabled the company to select vendors that are
8 doing a superior job of controlling microbial contamination
9 in the slaughter and fabrication process.

10 The Jack-in-the-Box 0157 testing program was
11 recently reviewed by outside experts and found to be
12 statistically effective at detecting 0157:H7 contamination
13 levels in ground beef. Jack-in-the-Box has also been in
14 communication with other companies involved with sampling
15 programs and believes that these other programs are
16 effective for their intended uses.

17 The 0157 problem cannot and will not be solved by
18 individual efforts. Jack-in-the-Box would not have been
19 able to achieve its current levels of control had the
20 company not had working partnerships with its suppliers.
21 The only way that the entire food system or any members of
22 it will make improvements is by working together. To that
23 end, several initiatives are underway or soon shall be that
24 will have a significant positive impact on the control of
25 0157, in the opinion of Jack-in-the-Box.

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1 First, a working consortium within the beef
2 industry is proposing initiation of carcass 0157 testing as
3 a verification procedure for in-plant interventions. Since
4 the introduction of the organism to the edible food supply
5 occurs in the transformation from live animals to food, this
6 is the proper place to focus efforts. There will
7 undoubtedly be debate over sampling techniques and
8 frequency. However, those issues can be addressed as we go.
9 This initiative deserves the agency's support.

10 Secondly, the beef industry consortium supports
11 doing a pilot study in conjunction with a consortium of
12 quick service restaurant operators which will assess the
13 efficacy of the in-plant intervention and investigate
14 enhanced sample acquisition and analytical technologies.
15 These two initiatives will require six to nine months to
16 complete and perform the proper assessment of the results.

17 USDA FSIS has a risk assessment underway which
18 will further help define how we may all collectively better
19 focus our efforts to control the threat posed by 0157.
20 During the period of time required to evaluate this
21 proposal, Jack-in-the-Box will continue its current testing
22 program. It is Jack-in-the-Box's understanding that its
23 counterparts in the food service industry will also continue
24 their current testing programs. During this time, it is
25 imperative that the existing discretionary lotting system

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1 Tables Our Priority. I want to begin by thanking FSIS for
2 responding to STOP's May 1998 ground beef guidelines
3 comments by addressing the contaminated intact products
4 intended to be processed in a manner that would introduce
5 surface contamination to the interior of the product. This
6 was the right thing to do to protect public health, and we
7 strongly urge FSIS to implement the new policy as soon as
8 possible. Consumers are counting on you to enforce food
9 safety laws and to enact policies that promote public health
10 like this one.

11 Instead of giving you a presentation, I actually
12 have a list of questions to ask you. Some of these are for
13 clarification on the directive and also about portions of
14 the Q and A, if that is okay.

15 MR. BILLY: Mm-hmm.

16 MS. KLINKHAMER: I'll also just add that some of
17 these questions arose from responses that I had gotten to a
18 FOIA request regarding the E. coli O157:H7 sampling program.
19 The first question that I have is the definition of raw
20 ground beef products in the directive 10010.1 version from
21 February of '98. It describes products that may be
22 distributed to consumers as such. And I wondered what you
23 meant by that.

24 DR. ENGELJOHN: This is Dan Engeljohn with FSIS.
25 The products affected by that directive for raw ground beef

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1 products were those that most likely would be purchased by a
2 consumer, sold to a consumer as such. So manufacturing
3 trimmings or boneless beef products that in and of
4 themselves would not normally be sold in that form but would
5 be formulated into ground beef to make a certain lean meat
6 requirement, a certain fat content requirement, would in
7 fact then not be sampled themselves, but the finished
8 product would be. So it would be what normally would be
9 available to the consumer.

10 I think we identified a number of products, such
11 as products derived from advanced meat recovery, which
12 normally in and of itself is not sold as ground beef.

13 MS. KLINKHAMER: Okay. Just a comment for you.
14 And after I am finished analyzing the responses that I have
15 gotten, I'll send a document to you. But I have noticed
16 just by leafing through the returned documents that quite a
17 few inspectors are not including samples in the sampling
18 program because they say it is intended for retail, which
19 seems -- it seems that they are implementing what is
20 opposite of the intent here, so just for your information.

21 With regard to the section 4(b), No. 2, could you
22 explain the excepted criteria to be exempt, so to speak? In
23 No. 2, it says each lot is specific enough -- sorry. What
24 amount of product is to be tested under No. 1, and how
25 frequently should it be tested to meet the requirements in

1 No. 1, B1?

2 DR. ENGELJOHN: I'm sorry, Heather, I can't
3 remember what that section is.

4 MS. KLINKHAMER: Oh, I assumed you had a copy in
5 front of you.

6 DR. ENGELJOHN: With section 1 --

7 MS. KLINKHAMER: It is under section 4(b)(1).

8 DR. ENGELJOHN: And that is the situation where
9 samples are collected at inspected establishments, where
10 they conduct routine daily testing.

11 MS. KLINKHAMER: Right.

12 DR. ENGELJOHN: We don't have defined what would
13 be the minimum requirements for a sampling program.

14 (Pause)

15 MS. KLINKHAMER: Could you -- okay. Moving to
16 No. 3 in the same section, could you tell me which
17 interventions have been accepted under No. 3?

18 (Pause)

19 MS. GLAVIN: None of us is able to do it out of
20 our memories, but we do have in the regs a list of
21 interventions in the HACCP pathogen reduction reg, accepted
22 interventions. And to the best of my memory, it includes
23 steam vac and steam pasteurization, and I believe some other
24 things, but I wouldn't go with my memory on that.

25 MS. KLINKHAMER: So it is interventions that are

1 mentioned in the Federal Register notice on the pathogen
2 reduction HACCP regulation. And to your knowledge, no new
3 interventions have been adopted since?

4 MR. BILLY: I think they are not in that part of
5 the regs. They are in a different part that lists approved
6 or accepted process interventions. Can you come up? Speak
7 in the microphone.

8 MS. NEIBRIEF: Judy Neibrief, FSIS. I agree. I
9 am just not sure that they are in any regulation as opposed
10 to preamble discussions of the work done so far and what
11 people have been using in order to satisfy regulatory
12 requirements. But without the reg book, I would hate to
13 swear.

14 MS. KLINKHAMER: I have another question related
15 to No. 3. I was wondering how prevention of the use of
16 boneless beef or carcasses from outside sources is enforced.
17 For instance, in mixing ground beef, I understand that
18 sometimes a product like AMR is added as a constituent of
19 the ground beef. Are those constituents part of this
20 exemption, or would those be tested separately?

21 MS. GLAVIN: I think No. 3 has to do with someone
22 at a grinder or at retail relying on testing of trimmings.
23 And so if you are going to rely on that exemption, you can't
24 have trimmings from another source, or anything from another
25 source since you are relying on the testing of those

1 trimmings.

2 MS. KLINKHAMER: Okay, thank you. And I have a
3 very basic question. If you could explain to me the process
4 of condemning the product. Is it held in storage, is it
5 guarded, you know, is it under FSIS control, is it
6 discolored so that it won't be used?

7 DR. MINA: I'll address the handling of condemned
8 product in general. Normally, that product is disposed of
9 under the direct supervision of the inspector. And it is
10 normally decharacterized or denatured to make sure that it
11 cannot be used for human food. And it is either disposed by
12 or is removed through a rendering company or is rendered on
13 the premises.

14 MR. BILLY: How is it isolated in the plant, say,
15 in a --

16 DR. MINA: Yeah. Well, these products are
17 retained, meaning they apply a tag, the inspector will apply
18 a tag, or put it under seal in a retaining cage until that
19 carcass is disposed of. And I said, it is under the direct
20 supervision of an inspector. We do have very tight controls
21 on condemned product to make sure that they are disposed of
22 properly.

23 MS. KLINKHAMER: I wanted to also ask you, when I
24 read the directive it seemed to me that the inspectors are
25 taking the samples within the processing plants, but

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1 compliance officers were taking the samples at retail. Is
2 that correct?

3 MS. GLAVIN: Yes.

4 MS. KLINKHAMER: Okay. And just to confirm, this
5 directive does cover the -- it covers retail product and
6 product that is intended for retail, right? Okay. Now I
7 have the Q and A questions. Can I continue, or do you want
8 me to --

9 MR. BILLY: Have at it.

10 MS. KLINKHAMER: Okay. Under question No. 1, the
11 very bottom of the answer, it says, "Only the product units
12 that are represented by the positive sample will be
13 considered contaminated." Could you please define what the
14 product unit is?

15 DR. ENGELJOHN: This is Dan Engeljohn with FSIS.
16 The qualification for question No. 1 starts out with this
17 being product at a receiving establishment. So at that
18 receiving establishment, there would have been some
19 declaration as to what the lot for that particular sample
20 represented. So if there were four combo bins that
21 represented a sample of product that was positive, then it
22 would be those four combo bins affected.

23 So again, the question sets this up as being
24 product that is being delivered at another location other
25 than where it was slaughtered and broken down into the

1 various combo bins. So there are defined segments of
2 product at the receiving establishment.

3 MS. KLINKHAMER: Okay. Now under section -- I'm
4 sorry, question No. 3, at the end it says, "In addition, the
5 remaining eight combos would be sampled and tested in order
6 to determine if the 0157:H7 is present." Who would do the
7 testing in this instance? Would it be FSIS or the plant?

8 DR. ENGELJOHN: Again, in this -- this is Dan
9 Engeljohn again. In this situation, question No. 3 was set
10 up as a receiving establishment would be doing the sampling.
11 This is not of ground beef but of manufacturing trimmings or
12 something other than ground beef. So it would be the
13 establishment.

14 MS. KLINKHAMER: Okay. I think I know the answer
15 to this, but I just wanted to make sure by asking you. Is
16 the industry or are the labs testing for 0157 required to
17 notify FSIS of positive samples?

18 DR. ENGELJOHN: I think we answered that in one of
19 the questions. It must be question -- No. 14 was about
20 notification of a positive sample. And if it is the
21 industry sampling or a laboratory sampling, there is no
22 regulatory requirement to notify FSIS.

23 MS. KLINKHAMER: Okay. And No. 5, FSIS does not
24 intend to attempt to trace back the product or to take any
25 regulatory action of supplying establishment that shipped

1 0157:H7 contaminated product unless there is reason to
2 believe that the supplying establishment knew that the
3 product was contaminated and did not have in place and
4 followed the controls necessary to prevent adulterated
5 product from being distributed to consumers. How would you
6 establish intent?

7 DR. ENGELJOHN: The issue here -- again this is
8 Dan Engeljohn -- is that we are aware of situations where a
9 supplying establishment has worked out an agreement with a
10 receiving establishment in that a sample is pulled at the
11 supplying establishment and sent off to a laboratory to be
12 analyzed. Those results may not be known until that product
13 arrives at the receiving establishment.

14 In that case, the status of that product is
15 unknown until it arrives at the receiving establishment, so
16 the question that was posed in the original set of questions
17 that we issued shortly after the January 19 issuance of this
18 policy was that in that particular situation, is the
19 supplier shipping product that in fact turned out to be
20 positive. And the answer was that they didn't know that it
21 was positive until it arrived at the receiving
22 establishment.

23 So that would be a situation where the status of
24 it is not known until the lab results come back in. It
25 would be a different situation if in fact that product was

1 knowingly identified as positive. There may be records in
2 the plant that it was positive, and they shipped it to be
3 ground as opposed to being handled as intact product. And I
4 think that is a situation we would have to deal with on a
5 case by case basis.

6 MS. KLINKHAMER: Okay. For question No. 7, I have
7 a few questions here. How could a receiver take corrective
8 action once they have received contaminated product?

9 DR. ENGELJOHN: Again, we didn't present that
10 information in that we don't know all of the situations that
11 could or should occur at a receiving establishment. But it
12 may be that establishment doesn't have in place a purchase
13 specification, for instance, where they are specifying
14 pathogen testing on that particular product. One corrective
15 action may be that that would be something that they would
16 design into their system. But I can't answer your question
17 specifically.

18 MS. KLINKHAMER: Okay. Does FSIS have protocols
19 for the proper disposal of product?

20 DR. ENGELJOHN: Yes, we do. I think we answered
21 part of that in a situation where a product is identified as
22 being positive for 1057 and asked what would be appropriate
23 actions that that particular establishment would take.

24 MS. KLINKHAMER: Caroline, sorry to interrupt your
25 reading, but I recall, and I just want to verify, that you

1 once mentioned that you heard of product being disposed in a
2 landfill.

3 MS. SMITH-DEWAAL: We had discussions about what
4 would be appropriate disposal for E. coli 0157:H7 tainted
5 meat, I believe at one of the public meetings that Dell
6 Allen was at. And I think that I mentioned that that would
7 be inappropriate to dispose of it there. And actually, I
8 think some companies have mentioned to me that that is one
9 of their options when they face that situation.

10 MS. KLINKHAMER: Is that an option?

11 MR. ALLEN: Could you repeat -- I didn't hear what
12 would be appropriate or inappropriate.

13 MS. KLINKHAMER: The initial question was whether
14 FSIS had protocols for the proper disposal of E. coli
15 contaminated product. And I had heard a comment at another
16 meeting from Caroline about disposal of E. coli contaminated
17 product in landfill and a concern about that disposal
18 method. And I was wondering if that was a disposal method
19 that FSIS approved of or had a policy on.

20 MS. GLAVIN: We do not have a policy on disposing
21 of product in landfills. When the product is condemned, it
22 has to be diverted from human food channels.

23 MS. KLINKHAMER: Okay.

24 MS. MUCKLOW: May I also clarify that when product
25 goes to a landfill, it would be denatured. You can't go and

1 dig it up again and eat it.

2 MS. SMITH-DEWAAL: But that's not the point. Just
3 for clarification, that is not the problem, Rosemary. There
4 are many outbreaks linked to 0157:H7 from tainted water.
5 And the question is how 0157:H7 might get into the
6 environment. So putting tainted raw meat into a land fill
7 where it could grow and then cause further problems
8 downstream would be an issue.

9 MS. KLINKHAMER: And just for the record, STOP
10 does have members who contracted E. coli 0157:H7 from well
11 water, so that is a concern. With regard to question No. 8,
12 you say, "Appropriate action would include the following:
13 number one, performing appropriate corrective action." And
14 I just would appreciate if you could give me some examples
15 of that type of action.

16 DR. ENGELJOHN: I'm sorry, Heather. I didn't
17 catch the question.

18 MS. KLINKHAMER: Oh, that's okay. For question
19 No. 8, the answer is, "Appropriate action would include the
20 following: number one, performing appropriate corrective
21 action before reassessing a HACCP plan." And I am asking if
22 you could give me some examples of corrective action in this
23 instance.

24 DR. ENGELJOHN: Again, this is Dan Engeljohn. In
25 response, we didn't identify specific things that could be

1 done. But this was a situation where the plant may not have
2 a sample -- may have a sampling program, but it may be a
3 rather loose program where they don't test routinely but
4 maybe on occasion. And it could just be that this product
5 was not tested, and that would be one thing that they could
6 look at, again reassessing maybe the purchase specifications
7 that they would have in place from the supplier of this
8 product.

9 MS. KLINKHAMER: Okay. Thank you. For question
10 No. 9, "At this time FSIS does not have specific regulations
11 regarding the control and handling of product that has
12 tested positive for 0157. It does have general procedures
13 for handling the movement of product between official
14 establishments." Could you please describe those
15 procedures?

16 MS. KLINKHAMER: The answer to No. 9 is also sort
17 of contained within one of the scenarios presented in the
18 answer to No. 13. Part of that corrective action or that
19 control that may be in place would be that if in fact a
20 manufacturer of raw ground beef does not have in place -- or
21 does not have access to cooking facilities and would want to
22 make this product ready to eat, they may in fact work out a
23 method of transferring this product between two official
24 establishments so that the second establishment would in
25 fact fully cook that product so that everything could be

1 distributed into commerce.

2 And so one control procedure may be that it could
3 be identified for further processing, and that they have in
4 place procedures to ensure that that other federal
5 establishment would in fact be able to process all that
6 product and account for it.

7 MS. KLINKHAMER: Earlier you had mentioned that E.
8 coli 0157:H7 contaminated product, if it was to be
9 condemned, would be under an inspector's supervision. In
10 the case where it is going to be sent to another
11 establishment for further processing, is it under an
12 inspector's supervision during the transfer period?

13 DR. ENGELJOHN: In that particular situation that
14 you just presented, the product is not deemed adulterated
15 because it is going to be further processed to be made ready
16 to eat. And so it is in fact not adulterated product. It
17 is contaminated, but it is under control to be processed.

18 MS. KLINKHAMER: And is there any special marking
19 or labeling on that product so if it got lost you could
20 identify it as something that has been identified as
21 contaminated with 0157?

22 DR. ENGELJOHN: Again, this is Dan Engeljohn. The
23 procedures that we would have in place would be the control
24 between those establishments, what they would work out. We
25 don't have regulations that would require special labeling

1 on that.

2 MS. KLINKHAMER: Okay. Thank you. I have a
3 question with regard to No. 7. I was wondering if you have
4 any data regarding whether this type of product could absorb
5 E. coli 0157:H7 or other E. coli along with the marinade.

6 (Pause)

7 DR. ENGELJOHN: I'm sorry, Heather. I am having
8 difficulty hearing your question. What is the question?

9 MS. KLINKHAMER: Question No. 12 is regarding a
10 beef cut that has been marinated. And the answer was that
11 as long as the surface of the beef was not scored, the
12 product would be considered intact. And what I wondering is
13 whether there is any science or data regarding whether E.
14 coli organisms are absorbed by a beef product like this that
15 has not been scored, if the organism can work its way into
16 the product when it is in a marinade.

17 DR. ENGELJOHN: In response to your question is we
18 would generally believe that an intact cut would have the
19 surface in place such that there would not be the
20 opportunity for the organism to transfer from the exterior
21 to the interior, that that surface that is not cut would in
22 fact prevent that from happening, or it would only be at the
23 exterior surface. So product that simply was marinated, in
24 which it is just coated with it or is sitting in a solution
25 of that, would not present an opportunity for the organism

1 to transfer into the interior of that normally sterile
2 product.

3 MS. KLINKHAMER: Okay. With regard to question 13
4 -- this is with what procedures should an establishment
5 implement if it wants to further process beef that is
6 contaminated with E. coli 0157:H7, in scenario B. These are
7 briskets with corning solution, and then there is a purchase
8 specification that has been negotiated with the specific
9 retail outlets specifying that the corned briskets in the
10 retail ready package will be either sold in the packaging or
11 returned to the official establishment at the end of their
12 use by date.

13 The retail outlet, is this a restaurant or a
14 grocery store? Is that what you intended by retail outlet?

15 DR. ENGELJOHN: It certainly could be an option,
16 having either a restaurant or a super market.

17 MS. KLINKHAMER: I just -- sorry to be repetitive,
18 but I just want to make sure I understand. And so in this
19 instance, the agreement between the retail outlet and the
20 establishment providing these products, that agreement would
21 be the oversight over the handling of these products. The
22 FSIS would not be involved in oversight. Is that correct?

23 DR. ENGELJOHN: That's true. We would not
24 necessarily be involved in that oversight.

25 MS. KLINKHAMER: Okay. I'm done. Thank you very

1 much.

2 MR. BILLY: Oh, you are very welcome. The next
3 speaker is Nancy Donley.

4 MS. DONLEY: Thank you. Nancy Donley from STOP.
5 I think I can safely say that we all agree in this room that
6 E. coli 0157:H7 is something that must be addressed at all
7 stages along the food chain, starting at and including the
8 farm. So in that spirit, I urge the National Cattlemen's
9 Beef Association to resurrect their on-farm research
10 projects that they shelved earlier.

11 I also want to say that we believe that carcasses
12 are a logical place to be testing for 0157:H7, but that they
13 are not the only place that it should be looked for and
14 looked at. So we think that that is again a good starting
15 point, or a continuation, I should say, because I hope the
16 first part is going to be done on the farm, and that we put
17 in place a carcass testing program.

18 Major quick service establishments are requiring
19 multi-tests, even though they retain control of their
20 product through the final end product that winds up in the
21 consumers' hands and in their mouths. And if they see it as
22 something necessary to go back to their suppliers and say,
23 look, we want to have testing done at multiple points and at
24 multiple -- and under strict guidance and rules, I say that
25 I think that we should all be able to expect that same level

1 of protection in the food that we buy in our grocery stores
2 as well.

3 It is a sad day if we ever get to the point where
4 we can say, you know, you are safe to eat a hamburger at a
5 fast food establishment, but I wouldn't trust it out of your
6 own refrigerator or cooking it in your own home. I hate to
7 see that day. And I think I'm really urging that FSIS take
8 the course that we will have an equal level of protection
9 for all consumers, that I can see where a problem with some
10 of the things we heard about today will -- where we could
11 conceivably have less safe product.

12 I think we do have less safe product in some
13 instances in supermarkets today, and that we don't let the
14 -- I can rattle off a list of names of victims in our
15 organization, including my own son, who became victims, fell
16 victim to contaminated meat through grocery store outlets as
17 well, where those supplier contracts may not be demanding
18 such a high testing regime for product.

19 We are also asking consumers in a sense to test
20 product as well. And in that sense, I mean that we are now
21 -- our mantra at STOP, and I know FSIS has all their printed
22 documents say use a meat thermometer, make sure it reaches
23 an internal temperature of 160 degrees. So we are asking
24 consumers as well to conduct tests, if you will, to test
25 their food to make sure it is safe before they eat it.

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1 So in that, just to kind of recap, is that the
2 implementation of any one of these strategies that I have
3 mentioned on the farm, on the carcass, in trimmings, in
4 final product, in cooked product -- not any one of those
5 alone is good enough. We need to be doing it all if we are
6 really committed to making meat safer. And so in that
7 spirit again, I would like to urge FSIS to continue its
8 course of action that it is taking on this. And again, I
9 would like to thank you, Mr. Donley, and your agency for
10 really being very proactive.

11 MR. BILLY: Bernie Shire.

12 MR. SHIRE: Good afternoon. Bernie Shire from
13 American Association of Meat Processors. My presentation is
14 going to be more in the form of some questions, like a few
15 other people here, and not necessarily to be answered this
16 afternoon, but some things to think about.

17 The American Association of Meat Processors
18 represents a large part of the small meat industry. We have
19 1,800 members; 1,500 of them are meat plant operators. They
20 are involved in all phases of the meat business. Some of
21 them make one product, some make dozens of products. Some
22 slaughter one species of animal, other several species.
23 Others do nothing but grind beef. Others still make the
24 bulk of their living from ready to eat products. Still
25 others do a little bit of everything. They have their feet

1 virtually in all the camps.

2 They all have one thing in common, though, whether
3 they are slaughtering or processing or dealing in non-intact
4 products. The quality they all share is that whatever they
5 do, they do it on a small scale. I mention that because I
6 have listened to the proposal that the big packers have
7 posed, and some of those proposals sound very promising.
8 But the discussion also raises a lot of questions, questions
9 that I hope will be answered over the next few weeks.

10 How will this proposal affect small slaughterers
11 as well as the big packers? What responsibility will the
12 ranchers and the farmers have in this matter? It has been
13 proposed as a voluntary program. What happens to
14 slaughterers and others that don't get involved, for
15 whatever reason? Will their product be considered not as
16 good? Is there a danger of a two tier system being set up
17 at some point down the road, a two tier system for
18 inspection?

19 I was in a small slaughter facility recently where
20 they killed one animal at a time, ten a day, only two days a
21 week. They do a very fine, clean job. And part of that, I
22 guess, is because they don't have to deal with the numbers
23 and other problems that arise in large slaughter plants.
24 They may only have one intervention set up. It seems to
25 take care of everything. If the proposal as outlined goes

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1 through, will these small folks need to go to three or four
2 interventions as well to keep up? What if they don't? Will
3 they be discriminated against? And then what next? What
4 will the next step be down the regulatory road?

5 Months ago -- I can't see the last part. I guess
6 the last thing I would say is that we hope the agency will
7 extend the comment period for a few more weeks. Our meat
8 inspection committee would like the opportunity to examine
9 more closely what is being discussed, as well as any other
10 changes that may be made, to determine how it will affect
11 all of our members and others in the small meat industry.

12 Thank you.

13 MR. BILLY: The last person that is on the list is
14 Caroline Smith-Dewaal.

15 MS. SMITH-DEWAAL: Thank you, Tom. It is Caroline
16 Smith-Dewaal, with the Center for Science in the Public
17 Interest. I do want to thank you for holding this meeting
18 and airing many views. This is a bit of a different kind of
19 a meeting because we are used to coming in and having, like,
20 a whole morning of the agency presenting its policy, and
21 then the rest of us responding. And today I felt like we
22 came in and the industry presented its alternative or idea
23 for dealing with it, and then there were a lot of questions
24 left over for some people on how the actual policy would
25 work.

1 I do want to say on behalf of CSPI's one million
2 members that we support the clarification of E. coli 0157:H7
3 policy. And I think that what -- it is exciting, the kind
4 of innovation and the ideas which are now being tossed
5 around about how to really get a better handle on
6 controlling E. coli 0157:H7 in the pipeline before it gets
7 to the retail, before it gets to the further processor. So
8 I am very excited to hear about the carcass sampling ideas
9 that have been put forward by the largest slaughter
10 operations and the pilot testing which they are agreeing to
11 do. These are all very, very positive things.

12 I think the problem comes with the carrots. And
13 if it weren't so serious, I would kind of think about my
14 kids, who are always saying, well, if I clean my room, what
15 will I get, you know. It is like, well, you'll get a clean
16 room. Well, that is not necessarily -- they want to know if
17 they'll get their allowance or they'll get something else if
18 they do the right thing.

19 The reality is that what E. coli 0157:H7 is
20 forcing -- there is a lot of uncertainty. And the question
21 is should the uncertainty be on the fast food restaurants,
22 should the uncertainty be on the meat packers, should it be
23 on the cattlemen, should it be on the consumer. Where
24 should that uncertainty lie? And you, Tom, are the pivotal
25 point to make that decision. And so everyone is saying,

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1 well, don't leave us holding the bag, leave someone else,
2 put the uncertainty somewhere else.

3 When I look at Dell's map -- and I thought the
4 presentations today were just excellent from the industry.
5 But when I look at Dell's map of where his product went, I
6 think also back to many maps I have seen at presentations by
7 CDC on where the outbreak was. And as we see these products
8 being transported incredibly quickly all over the country,
9 that is what the outbreaks look like. And in addition, it
10 is what the recalls, the nightmare of a recall, looks like.
11 And so I just want to say to the industry, the carrot is
12 that the recall nightmare should be lower.

13 If you do the carcass sampling proposal that you
14 have put together, you should see fewer recalls, fewer
15 positive O157:H7's in the marketplace. It should be --
16 you'll get a cleaner room. I know that doesn't -- it never
17 works with the people I am dealing with. But what you are
18 proposing is a good idea, regardless of what the agency
19 gives you as a carrot, if anything.

20 I think there is some confusion that I have heard
21 today about the role of the government, and this issue of,
22 you know, less -- we want more prevention from the
23 government and less punishment. Well, the reality is the
24 prevention is within the hands of the industry. It is not
25 the government's job to prevent the problem. And so I don't

1 see your programs as punitive. I see your programs as
2 designed to try to get the industry to address a problem.

3 I also strongly believe as a result of the
4 discussions today the industry testing isn't a substitute
5 for government testing. And so don't fall in that trap,
6 saying, well, they are testing, so we don't need to, and
7 making that trade. I don't think that is a fair trade.
8 Consumers want multiple hurdles. We want both the industry
9 testing and the government testing. That is a multiple
10 hurdle approach.

11 But all of that said, I do support incentive based
12 regulation. And what the industry has come forward with
13 today is a system saying, you know, gosh, if you could make
14 these clarifications and these changes, we'll do more
15 testing, and we want more testing. I would like to suggest
16 some improvements to what we have discussed today in terms
17 of the carcass sampling proposal. I like the clarification
18 where it says -- can I borrow the regulation? And I'll be
19 brief, I hope. Thank you.

20 I liked the clarification where it changes the
21 language of 4(b)(3) to instead of saying routinely verify
22 the intervention's effectiveness periodically through
23 testing, but where it says through carcass sampling. It
24 should be verification through carcass sampling. I think
25 that gives greater clarification to this policy.

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1 I made my point on the validation versus
2 verification issue. I think that is already in the record.
3 And I also -- I would like to make one addition to what has
4 been proposed today, and that is I think in the issue of
5 certainty, in the issue of not leaving consumers holding the
6 bag with this change, on the issue of a fair policy for
7 consumers, the department should consider the issue of lot
8 size.

9 If you are going to give an exemption to testing
10 not only to the specific slaughterer or processor, all the
11 way down to retail -- if you are going to give that kind of
12 -- if you are going to have that kind of carrot for the
13 industry, I think you really need to look at lot size. What
14 the industry is saying is we're going to sample 1 out of
15 every 300 carcasses. And I think in that case, the lot size
16 should be from the point of the last negative result to the
17 point of the next negative result because that positive
18 result, that single carcass that is positive for 0157:H7
19 shows that the interventions, the multiple hurdles in use in
20 that plant, were not working.

21 And so if you had a lot size that encompassed from
22 the last negative to the next negative, you would encompass
23 the period during which the interventions, the process, was
24 out of control. And we don't know how many of those
25 carcasses went by that were positive for 0157:H7. But I

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1 believe a policy like that, even if the sampling frequency
2 was a minimum frequency of 1 in every 300, it would
3 encourage more sampling. It would encourage the industry
4 because then you could reduce the lot size. And it would
5 encourage faster testing technologies. They would want to
6 get tests that were less than 24 hours as soon as they
7 became available.

8 I think that that kind of a change would provide
9 much greater certainty for consumers, that this policy
10 actually will serve consumers' interests as well as
11 industry's. Thank you.

12 MR. BILLY: Thank you. Well, I would like to --
13 I'm going to open it up for comments generally, both to the
14 most recent comments as well as any other comments that
15 anyone might like to raise at this time. We'll start with
16 Dell.

17 MR. ALLEN: I'd like to address Caroline's last
18 point. I assure you, as I have said before, if it were
19 physically possible, technologically possible, I would not
20 argue with some of the things you are saying. So I just
21 today -- and this is sharing data, okay -- had a return on
22 it. We are testing carcasses. And when we test a carcass,
23 we isolate the carcass, and that begins by isolating it all
24 the way through the chain so that we don't have cross-
25 contamination possible.

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1 But anyway, carcass slaughtered last Monday, okay,
2 one week ago today, March 1 -- the tests went in as I have
3 indicated before, via air express. Sometime last week, and
4 it was either Wednesday or Thursday, we got the word back
5 that it was a presumptive positive. So the next step is
6 taken. You go through the confirmed negative step. I got
7 those results today, just about an hour ago. If I have that
8 situation in a lot of 300 carcasses, this deal is dead on
9 arrival because my people -- and I am talking -- we cannot
10 afford to have the space. There is no way on God's green
11 earth that we can hold that many carcasses for that length
12 of time.

13 So until and unless we have some of these testing
14 methods that are more rapid and more readily done, what you
15 are suggesting just will kill this thing before we ever get
16 it off the ground.

17 MS. RICE: Kim Rice, AMI. I want to address
18 something Bernie said and something Caroline said. And it
19 goes to the issue of large versus small. I just wanted to
20 clarify that there were both large and small processors and
21 packers who participated in this coalition and came up with
22 these recommendations. So this is not large packers
23 bringing something to the table that the small could not.
24 And it has been a discussion all along: make sure we still
25 provide opportunities for the small people to participate in

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1 the directive 10010. And anybody else on the coalition who
2 wants to talk to that can.

3 MR. BILLY: Marty.

4 MR. HOLMES: I would confirm with Ken what I said
5 in those meetings, and more than once I heard the large
6 packers say wait a second, we have got to make sure this is
7 workable for the small packers as well. That is not my
8 point, though.

9 My question is actually for Caroline. I heard you
10 say that you were in support of the USDA's clarification
11 policy. I see their policy as two separate issues, one on
12 trimmings of ground beef and testing of carcasses, which has
13 been proposed here, the other being mechanically tenderized
14 products. And I just wanted to clarify whether you agree
15 with the thing in full or if you see clarifying with part of
16 the issue.

17 MS. SMITH-DEWAAL: Thank you for your question.

18 It is Caroline Smith-Dewaal. I'm going to have to look at
19 the Kansas State data. We haven't fully -- I mean, I think
20 the issue of needle tenderizing needs to be considered by
21 this industry in light of 0157:H7. I think some of the
22 data, though, that I saw for the first time today was
23 certainly interesting and may inform us as we move forward
24 in writing our comments.

25 MR. BILLY: Carol.

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1 MS. TUCKER-FOREMAN: Carol Tucker-Foreman again.
2 Could we have a little discussion involving the FSIS people
3 about the point that Dell just made in response to Caroline
4 about the carcass testing and the numbers and how we deal
5 with this problem of isolating every carcass that is tested?
6 I would like to get your response on that.

7 MS. GLAVIN: What is your question, Carol? How
8 should we handle those carcasses?

9 MS. TUCKER-FOREMAN: Dell says everybody, when
10 they test a carcass, they isolate it. Therefore, they are
11 reluctant to test more carcasses because it is holding more
12 meat. If they don't isolate it, you are obviously exposed
13 for all of that product in the plant.

14 MS. GLAVIN: I think what Dell was talking about
15 was not necessarily that if you test more you have to hold
16 more, but it was responding to Caroline saying that every
17 one you test stands for 300 in this proposal, which means
18 that all of your production, every single thing you produce,
19 is held until you have test results. And I think that is
20 what he was reacting to.

21 MS. TUCKER-FOREMAN: No. Caroline, is that what
22 you were suggesting?

23 MS. SMITH-DEWAAL: No. It is not that everything
24 was held. It is that you would release lots as you got two
25 negative tests. From negative test -- you are testing 1 in

1 every 300 cattle, carcasses. So your test would have -- you
2 would move through 300 at a time. Where you got a positive,
3 though, it would implicate meat on both sides. It would
4 actually be 599 carcasses.

5 But understand, these carcasses go into a cooler
6 for anywhere between 24 and 36 or even more hours. And
7 testing technology is available where if you have enrichment
8 you can get a presumptive positive or negative back within
9 about 24 hours. Now there is a problem Dell has with
10 mailing the carcass -- or mailing the samples from Texas
11 somewhere. So I understand that.

12 But what we are doing here -- Dell today is
13 dealing with a problem where he -- the policy now would
14 require him to recall 200 million pounds of meat or
15 2 million pounds of meat a day from that plant from clean-up
16 to clean-up. Or it is some huge amount of meat that is
17 implicated. Here we are saying it is a much smaller amount
18 of meat. We are talking about 599 carcasses versus 4,000
19 carcasses.

20 So it is essentially -- it certainly gives us much
21 greater certainty. And otherwise, what Ann Hollingsworth
22 has been suggesting is that you are just going to run this 1
23 every 300 until there is an outbreak. And as soon as there
24 is an outbreak and your product is implicated, then gosh,
25 you are going to take all kinds of control measures. But

1 what that does is that leaves consumers holding the bag.

2 MR. ALLEN: I would defer to some of the
3 microbiologists here in terms of the number of presumptive
4 positives that occur that end up being negative. My
5 experience is they are considerable. I cannot -- I'll
6 emphasize it again. If I go back to my people who run my
7 operations and tell them we have got to hold 300 -- now you
8 have got it to 600 -- carcasses from Monday last March 1 to
9 this day, they are going to look at me and say we're much
10 better off not even knowing, so let's don't even test. That
11 is going to be the reaction of about anybody that faces that
12 kind of a situation.

13 MS. SMITH-DEWAAL: But it also creates an
14 incentive, Dell, for you to test more frequently.

15 MR. ALLEN: Yeah. But I can't. I have already
16 told you that I can't, physically cannot do that.

17 MS. TUCKER-FOREMAN: It is Carol again. Is the
18 problem that it takes you too long to get the test results
19 back? Are you holding for so long because you have to get
20 those test results back?

21 MR. ALLEN: That is exactly right. Once we test,
22 we will not release whatever is tested until we get the test
23 results back.

24 MS. TUCKER-FOREMAN: Dell, this goes back to who
25 ends up having to -- I hate to use the term "hold the bag"

1 on this. We would like to keep the pressure on you to
2 create a technology that gets you those answers a lot faster
3 rather than create a system that is dependent on less
4 testing. You have much more influence in order to be able
5 to drive that technology. And if you remove that pressure
6 to drive the technology, you'll never be able to do more
7 testing.

8 MR. ALLEN: That pressure is there and will not go
9 away, I assure you.

10 MS. TUCKER-FOREMAN: I think your proposal, which
11 I find very interesting and, you know, I would like to find
12 a way to be more positive about it, is -- one of the things
13 that just keeps coming back to me is it removes the pressure
14 to drive the testing technology forward as quickly as I
15 think that it has to go forward.

16 DR. HOLLINGSWORTH: Ann Hollingsworth, Keystone
17 Foods. The pressure for increased testing, regardless of
18 what happens here, is not going to go away. There are a lot
19 of dollars to be made to the person or group of people who
20 develop the testing that can give us more rapid answers.
21 There are, as Dell alluded to earlier, those of us that are
22 in positions like his position, my position, and many of the
23 rest of the guys on this side of the table at least,
24 probably most of us around this room.

25 We get people that have a new test that is going

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1 to give us everything we want to know at least once a week
2 and many times multiple times in a week. It takes time to
3 develop those tests. It takes time to verify that what we
4 think we have got in the develop of tests will indeed do
5 what we hope it will do. It takes a lot of what we call
6 beta-site testing. And there are numerous machines and
7 systems out there that are in beta-site testing protocols
8 right now that are working towards making this kind of thing
9 a reality.

10 I don't believe that regardless of what the agency
11 does on E. coli 0157:H7 testing that that pressure is going
12 away, because there is a lot of money to be made and the
13 people that are working in that area or have the expertise
14 to work in that area are fighting feverishly to be the first
15 guys to cross the line.

16 DR. WACHSMUTH: I can clarify the technology
17 question.

18 MS. TUCKER-FOREMAN: I beg your pardon?

19 DR. WACHSMUTH: I wanted to clarify the technology
20 of the screens just to give you some context for what Dell
21 mentioned. With our screening test for 0157:H7, we get
22 between 20 and 25 false positives for every confirmed
23 positive. And we have looked at things like the Qualicon
24 and other instruments, and they have approximately the same
25 rate. What you don't want is something faster that is going

1 to give you false negatives so that you miss something. You
2 want to make sure you pick up everything. And the cost of
3 picking up everything is a large number of false positives.

4 MS. TUCKER-FOREMAN: It is Carol again. I think
5 that I at least end up being in the position of saying when
6 you get the technology to do more tests, then we can talk
7 about what you are proposing. And it is hard to talk about
8 it when it is just 1 in 300, and we clearly feel very
9 uncomfortable about it.

10 MR. DANIALSON: Carol and Caroline, just a couple
11 of responses, the holding the bag issue, who is holding the
12 bag. I don't think that we can -- I mean, I will emphasize
13 that, you know, I mean, putting the validated interventions
14 into this bag, the policy bag, is the key element here. If
15 we were just sitting over here and saying, let's just go to
16 this carcass testing program and we don't need these
17 interventions, you don't need the HACCP process, I think,
18 you know, you could legitimately question that we are losing
19 something here.

20 The interventions and the validated interventions
21 in the process is key of where we have evolved over the last
22 few years. You say we are reducing frequency. Well, the
23 pilot will tell us that. One in 300 sounds like a lot. If
24 I have one of my beef plants 1 in 300, that is about once an
25 hour, where today that plant is getting sampled four times a

1 year by USDA. One in 300 sounds a lot in -- or doesn't
2 sound like much. In reality, it is a lot of sampling, and
3 it is a lot of surveillance that is being conducted in these
4 plants in association with the interventions that are
5 coupled with them.

6 MR. HOUISKEN: Rod Houisken, Houisken Meats. I
7 believe everybody in this room is doing the very best that
8 they can do to help with this problem, from industry with a
9 lot of innovative ideas, the USDA, as well as the consumer
10 groups here. We have a very tough problem. But there is
11 one thing that we can do, each one of us, to help eliminate
12 the illnesses from E. coli 0157:H7. I would like to talk
13 about that in just a second.

14 As I travel around the country, when I go to a
15 restaurant or when I visit homes, I will ask for a hamburger
16 and ask if I can have it rare. And in about eight cases out
17 of ten, the waitress will say sure, we serve it your way.
18 And I say, aren't you worried about E. coli? And she says
19 no, my product has been tested.

20 Okay. What can we do to help solve this problem?
21 Many of you people here are in front of public television or
22 radio quite often. And I would like to put out a challenge
23 to the consumer groups, to the USDA, anybody that has a
24 voice, when you talk about this problem, there is one sure
25 and easy way to solve it. In addition to what we are all

1 doing in this room, the housewife needs to fully cook the
2 patty. And that message needs to get through. So I
3 challenge each one of you, when you have the opportunity,
4 speak about fully cooking your patties. Thank you.

5 MR. MROZINSKI: I would like to -- my name is Pete
6 Mrozinski, and I with Qualicon. And I just want to make a
7 couple of statements. There has been a lot of talk about
8 false positives and confirmed negatives. And I am not a
9 microbiologist, but I have been working in this area using
10 DNA methods for detecting E. coli. And I think the term
11 "confirm negative," first of all, is misleading. You cannot
12 confirm a negative, especially for this organism. The
13 standard methods for confirmation are not adequate to either
14 confirm a positive or a negative.

15 There are DNA methods available today that can
16 specifically find the organism at very low levels in ground
17 beef or in any beef. The term "false positive" is another
18 term that has been used a lot. And when you are talking
19 about a screening method in microbiology, a false positive
20 is defined traditionally as a positive that the screening
21 method finds that your standard method does not find. That
22 can't really hold in this case because the standard methods
23 are not good enough to find the organism.

24 So you need to think of a false positive as a
25 known interaction, a known failure of the test. And with

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1 many screening tests, there are known failures, there are
2 known cross-reactivities. And that is a real false
3 positive. With genetic tests that can be tuned to the
4 organism specifically, we know that we can get tests that do
5 not cross react with other organisms and therefore do not
6 produce false positives. But they also cannot be confirmed
7 culturally, but that is a failure of the culture method, a
8 failure of the confirmation, not a failure of the screening
9 test.

10 So there is a lot of talk about false positives
11 and confirmed negatives that I think get confused a lot,
12 especially when you are talking about this organism in
13 particular because it is very difficult with standard
14 methods to culturally isolate. Thank you.

15 MR. BILLY: Phil.

16 MR. OLSSON: Thank you. I would like to address
17 -- Phil Olsson of Olsson, Frank & Weeda. I would like to
18 address Carol Tucker-Foreman's comment regarding more rapid
19 test methods. And I think there are a number of people who
20 share the desire to see more rapid test methods. I was
21 speaking earlier with Nancy Donley, speaking about a desire
22 for real time test methods.

23 But I don't think it is entirely up to the Dell
24 Allens of the world to get there. And the reason I say that
25 is that if you would look on the ARS Web site right now, you

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1 would find that they identify a new test method for E. coli
2 0157:H7 with a six hour turnaround that is 10 to 100 times
3 more sensitive than what is available.

4 This was introduced to the industry at a meeting
5 two or three weeks ago in California with a caveat from an
6 FSIS official that it would need to be enriched. And so
7 don't look at six hours, look at 24 hours. So suddenly you
8 are getting back into the very problem that Dell Allen
9 describes, which is that if you have got a six hour machine,
10 you buy it, you make the test right at the packing plant.
11 If you have got a 24 hour process and enrichment, you send
12 it out, and you get a three or four day process, and that is
13 what backs him up, the point being that this is an area like
14 so much of what is going on here that we need cooperation.

15 And I think -- I mean, you are as cooperative as
16 anyone. I'm not, you know -- we are not on opposite sides
17 of this issue. But I think there is a lot of potential in
18 all of us working with the agency to get better test
19 methods. Industry only wants to use test methods that are
20 being used by the agency because you want to do the same
21 thing they are doing. Thank you.

22 MR. BILLY: Rosemary.

23 MS. MUCKLOW: Tom, Phil is absolutely right. And
24 new and better test methods are going to be welcomed. Even
25 as we sit here today, there are people researching, out

1 there doing some field tests on new interventions. This
2 industry is looking in a very fertile way to try to solve
3 this problem. They recognize it is a problem. The Beef
4 Industry Food Safety Council Consortium has been looking at
5 it and doing a lot of stuff to try to address the issue.

6 I did want to raise a point that I didn't mention
7 earlier on, and that is it is like a shoe shop. No one size
8 fits everybody. And Kim Rice has talked a little bit about
9 there being involvement of some of the smaller firms in this
10 effort to come to you today and to suggest truly that there
11 is going to be a great deal more testing and more
12 information to give us a better handle on looking for this
13 microorganism.

14 I would urge you that we also need to remember
15 some people that I once upon a time forgot, and they
16 reminded us when they came to the Michael Taylor six day
17 meetings, and that is some of the ethnic slaughterers, halal
18 and kosher. They don't like interventions at all. And so
19 we must be very mindful of the fact that there are people
20 who can get a carcass clean with methods other than the ones
21 that we are talking about today, and we need to be very
22 careful not to count them out as we sweep along with some
23 new ideas -- a lot of ways of getting to the end of the line
24 that are called "food safety outcomes," I think is what
25 Dr. McKenzie from New Zealand calls them. We need to be

1 able to determine what those food safety outcome
2 expectations are.

3 We are talking about a lot more testing. And I
4 could read you the statement again, but you don't want to
5 hear it for the second time. No, I didn't think so. I
6 haven't got the voice for it anyway. Thank you very much.

7 MR. BILLY: Yeah. We have talked about that and
8 are aware that there are special ways of slaughtering and
9 processing animals to meet certain religious requirements.
10 And we will take that into account as we move forward in
11 this. Over here.

12 MS. WHITE: My name is Jill White. I am from IGEN
13 International, the company to which Phil Olsson referred to
14 for the technology that FSIS just announced. And that six
15 hour test includes the enrichment time. It takes one hour
16 to run the test on our machine, 50 samples analyzed at one
17 time, and the enrichment time is five hours, actually, so it
18 is six hours total for the test.

19 MR. OLSSON: And let me point out that the slide
20 was correctly presented. It is correctly presented on the
21 ARS Web site. It is just that it was introduced at the
22 industry meeting as requiring additional enrichment, even
23 though it is already 10 to 100 times as sensitive. And I
24 think what we are hearing today is we need 10 to 100 times
25 as fast.

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1 MR. BILLY: Okay. Heather and then Jim.

2 MS. KLINKHAMER: I have a couple of questions
3 about the testing. I can't remember which one of the
4 industry representatives earlier in the meeting said that
5 the combo purge test was not a good one. And I was hoping
6 that whoever made that remark could explain why the purge
7 test has been dismissed. And also, I wanted to know if
8 anyone here has information about whether testing intact
9 beef products would yield more results than ground products
10 because it is my understanding that because ground products
11 come from a larger pool and are mixed around that you are
12 more likely to get a positive test in the ground product, if
13 there is E. coli there.

14 MR. BEILA: Tim Beila with American Food Service.
15 I made the comment about the purge sampling and testing.
16 There was research published -- I don't have it here with me
17 today -- that addresses or actually compared different types
18 of sampling and testing methods, specifically comparing
19 combo purged trimming and things like that. And there is no
20 good correlation that can be established between surface
21 sampling and testing and the purge that is collected from a
22 combo bin.

23 To go further with that, there are some types of
24 trimming that do not have a significant amount of purge
25 available to sample. And again, I don't have that in front

1 of me, but if you would see me afterwards I can get you a
2 copy.

3 MS. KLINKHAMER: Do you recall, was it a research
4 institution or ARS?

5 MR. BEILA: It was a university research project.

6 MS. KLINKHAMER: Okay.

7 MR. BILLY: Jim.

8 MR. HODGES: Thanks, Tom. Jim Hodges, American
9 Meat Institute. The point we have reached today has
10 virtually taken us years to get here. It is a point where I
11 think no one in the industry would have supported four years
12 ago, and it is not without burden, it is not without cost.
13 But it is something that we think is necessary to be done.
14 It is necessary because one, it will give us more
15 information than what we have today.

16 The American Meat Institute Foundation is
17 initiating a very aggressive research agenda. One of those
18 things that will be coupled, hopefully, if this moves
19 forward -- one of those areas that we hope to couple with
20 this carcass sampling program is to determine the incidence
21 level of 0157 coming in on animals, whether it be on the
22 hide, whether it be in the intestine. But we can't do that
23 unless we have some ability with the regulatory agencies to
24 cooperate to make this logistically possible.

25 If we don't -- if we are talking about holding 300

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1 carcasses, we are not talking about verification of an
2 intervention system. What we are talking about is an accept
3 or reject criteria on some defined lot. And there is not
4 any sampling program that can be designed that is
5 statistically valid that will accept or reject product.

6 So I am pleading with this group, both the
7 regulatory agencies and the consumer community, that we need
8 the ability to take a step forward. It is not where we were
9 hoping we were going to be. It is not the solution to the
10 problem in its entirety. But it is clearly and
11 unequivocally a step forward. And if we start to put it in
12 the context of being a disincentive, we are going to stay
13 right where we are. We have got to move forward, and we
14 need your help.

15 MR. BILLY: Caroline, and then I think we'll wrap
16 it up.

17 MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center
18 for Science in the Public Interest. I really don't see a
19 proposal on the lot size issue as making it an accept or
20 reject system at all. And I really -- I think the industry
21 has made tremendous progress here and carcass sampling is --
22 you know, you have convinced me this is the way to go. The
23 issue is, how do we protect consumers while we are gathering
24 the data that will give us sufficient certainty in the
25 carcass sampling system?

1 And I think you have gone a tremendous way. I
2 just don't think we are quite there yet with the certainty
3 of the sampling proposal. So I would like -- I just wanted
4 to be clear that what we are talking about very much is a
5 HACCP system that chose interventions -- a positive result
6 would show interventions are not working as well as they
7 should be. Thank you.

8 MR. BILLY: All right. I would like to wrap this
9 up, unless someone else has a burning comment, a burning
10 comment.

11 (Laughter)

12 MR. BILLY: I think that notwithstanding some of
13 the issues that have been raised, that we have reached a
14 very important crossroads. The feel of this meeting and the
15 ideas that have been put forth and the concerns and so forth
16 that have been raised have a remarkable different feel to
17 them than what at least I experienced a few years ago. I
18 think there is a chance represented in what has been put on
19 the table, as well as considering the issues raised. There
20 is a chance to turn in a new direction. And I am going to
21 do my best and have the agency do its best not to lose this
22 opportunity.

23 The dialogue is real important. And the dialogue
24 doesn't have to be limited to a public meeting called by
25 FSIS. People are around, and there are phone numbers

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1 available. And I think as we move forward continuing the
2 dialogue can do a lot to help all of us collectively figure
3 out the proper approach in this new direction.

4 The industry coalition has put a proposal, at
5 least in an outline form, on the table. You have heard some
6 support for it. You have heard some questions raised about
7 it. We are prepared to provide a framework in which you
8 have some time to consider all of this input and then to
9 provide us in writing a more specific proposal that all of
10 the participants and anyone else could then consider and
11 comment on this part of this process. I think that makes a
12 lot of sense to me and will net us a better record, a better
13 set of comments to consider how to continue this positive
14 direction.

15 I think that the comment period is very important,
16 and I know that all of you here, because you are here, care
17 about this. And I think you can provide a very valuable
18 service in terms of public health by being an active
19 participant in this process.

20 For some of us, it is hard to appreciate the kind
21 of numbers that Dell Allen put up at the beginning in terms
22 of one plant and the production from one day and what
23 happens to that production and the logistics and the
24 practicalities of dealing with some of these issues.

25 At the same time, it is important that we

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1 appreciate the concerns of the consumers in terms of having
2 an approach that nets for them the best possible protection
3 from a public health perspective. And therein, I think, is
4 where we need to continue this process and sort out an
5 approach that will net us the kind of movement in a new
6 direction that this discussion today represents.

7 So I guess if I wanted to leave you with anything,
8 it is to encourage you all to continue this dialogue, be a
9 full participant in this process. And I think if you are,
10 we will really achieve something here that we can all be
11 proud of. So again, thank you very much for your
12 participation today.

13 MS. MUCKLOW: Tom, before we go, do you understand
14 that now there will be a request to extend the comment
15 period? We'll get a document from -- a fuller document from
16 the industry and you'll publish that?

17 MR. BILLY: My intent is to take the request from
18 Bernie and other comments today as a request for a longer
19 comment period. I heard earlier from the industry a
20 willingness -- and they can confirm this -- to provide
21 something in writing that would help all participants
22 comment, if that is correct, a proposal that would put in
23 writing what we heard about today. I believe I heard that,
24 Kim.

25 MS. RICE: Say that again.

1 MR. BILLY: It is a proposal that lays out the
2 approach that was outlined here today for a pilot project
3 that would include the various features that were put on the
4 table and how this would all work. Is that correct?

5 MS. RICE: Yeah.

6 MR. BILLY: I see some heads shaking. I don't
7 hear a yes.

8 MS. RICE: Yes.

9 MR. BILLY: And when would be a reasonable time
10 for that, maybe by the original deadline?

11 MS. RICE: We'll get back to you in a couple of
12 days.

13 MR. BILLY: Okay.

14 MS. RICE: I'll get back to you by Wednesday.

15 MR. BILLY: Yeah. I think what we'll do is make
16 it available.

17 MS. GLAVIN: If we did it on the Web site through
18 the constituent update, that kind of thing? Okay.

19 MR. BILLY: We'll get it available.

20 MS. GLAVIN: Putting it in the Federal Register
21 will take us the rest of the year.

22 MS. MUCKLOW: I understand. No, no, no, no.
23 We'll be doing this.

24 MR. BILLY: Okay. And then we'll provide an
25 opportunity for comment. All right. Is that clear? Is

1 everyone clear on that? Any questions? Okay. Again, thank
2 you all very much.

3 (Whereupon, at 3:30 p.m., the public hearing was
4 adjourned.)

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Name of Hearing or Event

N/A
Docket No.

Washington, DC
Place of Hearing

March 8, 1999
Date of Hearing

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