

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

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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,

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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 0157: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

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?

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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

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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 O157: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

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

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

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