

APPEARANCES: (Cont'd)

USDA Staff Members:

Bob Elder (USDA-FSIS)
Mike Plajeck (USDA)

Attendees:

Ellis Branton, Tyson Foods
Nancy Donley, STOP - Safe Tables Our Priority
Mark Dopp, Hogan and Hartson
Bob Hibbert
Jim Hodges, American Meat Institute
Dennis Johnson, Olsson Frank and Weeda
Heather Klinkhamer, STOP
Dr. Barry Marshall, New Zealand Embassy
Kenneth May
Joe Pocius, Montclair Foods
Steve Pretanik
Stuart Proctor, National Turkey Federation
Deven Scott, NMPA
Bernard Shire, American Association of Meat
Processors
Caroline Smith DeWaal, CSPI
Mack Warren, House Agriculture Committee

P R O C E E D I N G S

(8:37 a.m.)

1
2
3 MR. BILLY: I think if everyone will take their
4 seats we will get started. I would like to welcome everyone
5 to this public meeting.

6 The purpose of the meeting is to discuss issues
7 associated with the publication of salmonella testing data
8 that we will be collecting as part of monitoring process
9 control under HACCCP.

10 This provision of the HACCCP and pathogen
11 reduction regulation was finalized last summer. We're going
12 to in the course of this meeting at the outset at least talk
13 briefly about the provision itself.

14 I think most of you are familiar with it. So we
15 don't want to waste a lot of time on that, but just to
16 review it quickly so everyone has the same understanding.

17 We will then talk about the testing methodology
18 and the protocol which we will be following so again
19 everyone has their minds refreshed on how that will work.

20 Then we want to review as sort of a starting point
21 our legal obligations under the Freedom of Information Act
22 and how that works so again everyone has that clear.

23 Then finally get into our current thinking in
24 terms of the issues associated with the subject matter.
25 Last summer we indicated our intent to publish this data in

1 some form. We indicated in particular our consideration of
2 publishing the data when it's ready to be published on the
3 Internet.

4 As a result of that indication we have received
5 both at meetings and in the form of letters to us the
6 expression of several concerns related to this idea that we
7 had indicated we were looking at seriously earlier.

8 Just to give you a sense of the kind of issues
9 that were raised, one relates to the fact that this data in
10 fact is designed to be a reflection of process control.

11 It is not designed to be a set of test results
12 that would determine the status, for example, on some
13 particular lot of product that was produced.

14 Given that, the relationship between test results
15 of this nature that are in an ongoing way verifying the
16 effectiveness of process control would likely have no bearing
17 or no relationship to the particular product that happens to
18 be in the marketplace at any given point in time.

19 So on that basis the concern was how would the
20 result, whatever they are, be interpreted by the public in
21 terms of the relationship of those results to the test data
22 which again are verifying process control.

23 The second issue and I think also an important
24 issue that needs to be talked about is the fact that if you
25 do share this type of process control verification data and

1 share it through a system like the Internet, then it is
2 available worldwide and the point has been made that there
3 are countries that do not monitor their products, probably
4 don't have any idea whether they have process control or
5 salmonella on their product or not or even if they do for
6 purposes of protecting their domestic industry or other
7 reasons they could use this data in a manner for which it is
8 not intended to be used in terms of discriminating against
9 U.S. product.

10 That's a concern that's been raised. I think it
11 deserves further discussion and we intend to do that this
12 morning.

13 Finally, just a couple of housekeeping things. As
14 we get into the meeting, we want to make sure that all of
15 your comments are recorded.

16 For that purpose it's important that when you are
17 recognized you state your name and affiliation and speak
18 very directly into a microphone so that we can get it on the
19 recording, because we want a good record of all of the
20 discussions that will take place.

21 If you need to use a rest room, the men's room are
22 to the right. My right. Your left if you're sitting
23 opposite me. Out through those doors to the corridor and
24 then to the left.

25 The ladies' room is in the opposite direction.

1 Same thing. We will take a couple breaks as appropriate
2 over the course of this meeting this morning.

3 With that I would like to turn it over to Margaret
4 Glavin, who is the deputy administrator for policy, program
5 development and evaluation. She's going to review briefly
6 the current requirements in the regulations.

7 MS. GLAVIN: Craig Reed and I are going to do both
8 the current requirements and how we plan to implement those
9 requirements.

10 I know you all are very familiar with them so I'm
11 going to do this quickly just to have a common starting
12 point for us all.

13 First of all, as Tom has already indicated the reg
14 sets out a pathogen reduction performance standard for
15 salmonella to enable the Agency to verify the aggregate
16 effectiveness of establishment's passive controls in
17 reducing harmful bacteria.

18 As you know, the standard is on the current
19 prevalence of salmonella by product class as determined by
20 our baseline studies.

21 Each establishment must meet the standard
22 consistently over a period of time through appropriate, well
23 executed process control and that's obviously a very
24 important piece of this.

25 As Tom mentioned, this is about process control.

1 It's not about product acceptance. We have a two-phase
2 testing strategy. First of all, pre-implementation which
3 will be an establishment-by-establishment survey to provide
4 us a reliable picture of each establishment's performance
5 relative to the standard.

6 This phase will inform the establishment and the
7 Agency of the establishment's performance with regard to the
8 standard prior to actual enforcement of the standards.

9 The results will be made available to the
10 establishment and should assist the establishment in the
11 design and validation of its HACCCP plan.

12 A concern we have about the pre-implementation
13 data is that because the testing will take place pre-HACCCP
14 and while the establishment is most likely designing and
15 validating its HACCCP system, the test results may not, in
16 fact probably will not be representative of the performance
17 level that the plant will achieve under HACCCP. So that's
18 one particular problem with the pre-implementation data.

19 The pre-implementation data results will assist us
20 in addition to getting an establishment-by-establishment
21 sense of where the establishments are in meeting the
22 performance standard.

23 It will also assist us in more effectively
24 targeting our compliance testing. The results of course
25 will be available to the public.

1 Secondly we have the compliance phase which is an
2 ongoing testing program to determine compliance with the
3 salmonella performance standard.

4 As you know, that phase goes into effect on the
5 same date as the HACCCP requirements go into effect. So it
6 is like HACCCP phased in according to the size of the plant.
7 In addition to the ongoing testing program, we will have a
8 targeted testing program where warranted.

9 Craig?

10 MR. REED: Most of you know that salmonella wasn't
11 the only pathogen that was considered when we started this,
12 but salmonella is usable enough for all of us in this
13 process control scheme to get an idea of what's going on in
14 the plant.

15 So as part of implementation all of us are going
16 to be looking at the utility of the samples to determine
17 what's going on in the plant with the process.

18 Now some of us can remember the first salmonella
19 test of USDA on cooked beef and it was on a product
20 acceptance basis. So we have that history of salmonella
21 results being either positive or negative being involved in
22 release or recall of product.

23 That was in a cooked, ready-to-eat product. This
24 raw product we're looking at of course as a process control
25 measure. To me and to you in production areas I think

1 what's going to be very useful is for us to find if there
2 are patterns and where we can find likely reasons for
3 salmonella positive results to be there.

4 I think those are going to be useful for us to
5 iron out glitches that we see in the process. That's what
6 these samples are for.

7 The enforcement is part of this, but the reason
8 that the salmonella samples as part of process control is so
9 important, for example, if we see that over the course of a
10 set of samples or a number of data points that there are
11 increases all during the week building towards the end of
12 the week or a certain day of the week or if plants can
13 identify a certain reason why a certain grower for example
14 or producer bringing in animals routinely that seemed to
15 test out salmonella positive, then these are things that you
16 can adjust your process for along the way.

17 I'm not saying we can sterilize the product along
18 the way, but I think there may be extra things to do along
19 the way given we have this information.

20 To me that's what it's about in implementation is
21 using the information to find out what's happening in the
22 process.

23 If we can square away even a few glitches, let's
24 say every Friday we've got a problem of salmonella and we
25 start seeing that people are in a hurry on Fridays and they

1 want to get out of there on Fridays and people are taking a
2 few extra short cuts on Fridays, then that's useful for us
3 to know.

4 It means we can be a little more vigilant, all of
5 us, on that day. Or if there's a certain livestock producer
6 that seems to be having a problem with salmonella as a live
7 animal problem that comes in that's useful for us to know.

8 I'm looking at the utility of the samples for us
9 to end up with a product that's overall safer. You know
10 you've heard from three of us that it's about process
11 control not product acceptance.

12 The baggage we have is that with the cooked roast
13 beef it was product acceptance, but that was a ready to eat
14 product. So we've got to make the distinction.

15 MR. BILLY: Okay. The next brief presentation
16 will be on the testing methodology and I would like to call
17 on Ann Marie McNamara to briefly review that.

18 MS. McNAMARA: Sure. Good morning. What I would
19 like to share with you today are the methods that FSIS is
20 using to sample carcasses and to isolate and identify
21 salmonella in support of this regulation.

22 Everything I'm going to be discussing is detailed
23 in the appendix E of the pathogen reduction HACCCP rule and
24 I would refer you to that for more details. Today I'm just
25 going to give you a brief overview.

1 Right now we're sampling poultry carcasses using
2 the whole bird rinse and this is the same technique that was
3 used in the baseline studies.

4 For cattle and swine, we are using a three-side
5 sponging technique for salmonella and this differs, as you
6 know, from the excised tissue method that we used in the
7 baseline studies.

8 However, before we began this program we had ARS
9 look at the sponging technique to see how well it recovered
10 salmonella and they determined that for pork and beef
11 carcasses that this method could detect as little as one
12 salmonella bacteria present on the tissue.

13 So we are highly confident that this sponging
14 technique will detect salmonella when it's there.

15 The samples are sent then to our labs,
16 refrigerated in overnight delivery and the labs are working
17 seven days so that they're continuously processing these
18 specimens.

19 Once the sample arrives in the lab, we put them
20 into appropriate pre-enrichment broths and we screen it
21 using a traditional ELISA screening test to rule out the
22 negative samples.

23 Any samples that are positive by the ELISA
24 screening test will then traditionally confirm as salmonella
25 isolates by five chemical tests and serology.

1 We then report out the result as either being
2 positive or negative for salmonella. We are not quantifying
3 these isolates. We are just determining positive or
4 negative and looking at the frequency recovered.

5 We have spent a lot of time automating this
6 system. Most laboratories are not processing the number of
7 specimens we're processing per day and so they use manual
8 techniques.

9 What we have done is gone to an automated ELISA
10 system using equipment and two of our laboratories are now
11 fully up and functional. They're able to process between
12 200 and 250 samples per day.

13 Our third laboratory is coming on line next week.
14 So our capacity will be increased even further, but we're
15 not going to stop there.

16 In order to do more samples we're also looking at
17 roboticizing the methodology and by this we're working with
18 a company to get robotic arms to do all the transfers
19 between steps so that we can hopefully when we're finished
20 we'll have a fully automated system so that once the sample
21 comes in, you take the sample, start putting it on machines,
22 the robotic arms do all the transfers for you, the automated
23 ELISA runs the plate and so we will be fully automated from
24 start through the ELISA screening. Then a microbiologist
25 will take over to do the confirmation.

1 So by following this vision of the future we hope
2 to be able to do even more samples. Thank you, Mr. Billy.

3 MR. BILLY: Okay. Thanks.

4 What I would like to do is stop there now and open
5 it up for questions. If there are any general questions
6 about the requirements, the application of the requirement
7 in terms of process control or the methodology. Does anyone
8 have any questions?

9 MR. MAY: I have a question.

10 MR. BILLY: Please state your name and
11 affiliation.

12 MR. MAY: Ken with National Meat Association. I
13 have a question concerning the sampling. When a plant
14 implements a HACCCP program, will they then be collecting
15 their own salmonella samples or will FSIS continue to
16 collect samples?

17 MR. BILLY: The approach is that this requirement
18 is a regulatory requirement in terms of verification of the
19 HACCCP control measures.

20 So we will continue to collect the samples and
21 analyze them as we do for a number of other similar sampling
22 programs where it's a regulatory requirement.

23 Plants are free, in fact are encouraged, to
24 collect samples and analyze them for salmonella as well and
25 we think that's a good idea, but we would intend to collect,

1 if you will, an official set of samples to test and then
2 based on results verify that the plant is in fact complying
3 with the standard for that product class that's contained in
4 the rule.

5 If it's not then the rule lays out a procedure to
6 be followed in terms of working with the plant to identify
7 appropriate changes or corrections or perhaps tighter
8 control limits at the critical control points.

9 Some steps like that that would have an impact in
10 terms of the plant conforming to the applicable requirement
11 in the rule for that type of product that they're producing.

12 So that's a little longer answer, but it gives you
13 an overall sense of how we're looking at that.

14 MR. MAY: Would there be any consideration down
15 the road for if a plant was to make the sampling part of
16 their HACCCP plan? Would there be any consideration
17 possibly that the plant would do the sampling at that point?

18 MR. BILLY: Again, we welcome or encourage plants
19 to consider carrying out sampling and if that's the case and
20 they're producing data and sharing that data with us, then
21 we would take that under consideration.

22 MR. MAY: Okay. Thank you.

23 MR. REED: Can I add something? Ken, I think
24 there's a lot of good reasons for plants to do some
25 salmonella sampling on their own.

1 Not the least of which is to get an even better
2 handle on the process. If we're taking X number of samples
3 per day a plant wishes to take some number in addition to
4 that, I think it just gives people even more information on
5 what's going on with their process, because it changes from
6 one hour to the next in many cases.

7 It may change from one minute to the next in other
8 cases. I think the more data points and the more
9 information you have, whether it's salmonella or whether
10 it's E. coli or whether it's any indicator of your process
11 the better it's going to be.

12 MR. BILLY: Okay. Thank you.

13 Also, I would like to remind you that under the
14 HACCCP principles one of the requirements in the rule is
15 that plants periodically verify the effectiveness of their
16 HACCCP plan.

17 One way to do that, given the overall requirements
18 in the rules is to do a set of salmonella samples. Test for
19 salmonella.

20 I would expect to see as part of a plant's HACCCP
21 program that kind of a provision or perhaps using some other
22 organism, but some periodic verification strategy that would
23 include that type of testing and it would depend on the
24 circumstances of the plan and it could change over time. It
25 would just depend on what their overall scheme or strategy

1 is.

2 MR. MAY: Thanks again.

3 MR. BILLY: Caroline? State your name and your
4 affiliation.

5 MS. DeWAAL: Caroline Smith DeWaal, Center for
6 Science in the Public Interest. You said you were doing 250
7 samples a day.

8 That's your current capacity. How many plants
9 does that represent? How many plants are you doing sampling
10 in for any given day given that capacity?

11 MS. McNAMARA: I'm probably not the one to ask
12 that, but I know that it represents the majority of the
13 large companies. We started with the large companies that
14 were part of the baseline and we've gradually increased the
15 number, but I just process the samples. I don't give out
16 the sampling.

17 MR. REED: It's about 250 per each lab.

18 MS. McNAMARA: Right.

19 MR. BILLY: Each of the three labs.

20 MR. REED: Each of the three labs.

21 MS. DeWAAL: So how many --

22 MR. REED: It's around 700 samples a day.

23 MS. DeWAAL: You're doing 700 samples out of how
24 many plants?

25 MR. REED: We've got --

1 MS. McNAMARA: I don't think that --

2 MR. REED: -- 480 some plants that we are looking
3 at in this first round. It's roughly 500 plants.

4 MR. BILLY: What that means is the approximate
5 number of plants that will be required to implement HACCCP
6 on January 26, 1998, I think that's the right date, is
7 approximately 500.

8 So we are now and have been collecting samples in
9 the pre-implementation phase from those plants, but we've
10 started now to collect samples from additional plants as our
11 capacity has been increasing up to the maximum we designed
12 it for from the set of plants that will be in the second
13 phase and have a deadline of the year later.

14 So we're moving into that and as we complete the
15 sample set from the first set of plants then we'll pick up
16 with the other ones up to our capacity. So that's what's
17 happening now.

18 As Ann Marie said, our original thinking was we
19 could accomplish this involving just two labs. We have
20 since equipped a third lab so that we have the capacity we
21 need and that's just coming on line now.

22 MS. DeWAAL: This is Caroline Smith DeWaal, CSPI.
23 Phase two plants are ones that go on line when?

24 MR. BILLY: It would be January 25, 1999.

25 MS. DeWAAL: You're already beginning to sample in

1 those plants?

2 MR. BILLY: Yes. We're also doing some baseline
3 work in terms of new data for a baseline for certain product
4 classes. So that is simultaneously going on in our labs as
5 well.

6 MS. McNAMARA: I think maybe I should point out
7 that what I was speaking to is that that was our capacity.
8 It doesn't necessarily mean that we're running that many
9 number of samples.

10 They could be samples for other purposes, as
11 Mr. Billy said, baseline studies that we intend on coming on
12 line. We intend to repeat the baselines for swine and
13 cattle using a sponge technique.

14 So what I want you to understand, Caroline, is you
15 just can't divide those numbers and figure out how many you
16 think are coming in per plant. It's lab capacity, not that
17 that capacity may be being fully utilized and they vary from
18 anywhere between 200 to 250 samples a day.

19 MS. DeWAAL: Are you reporting those results of
20 the samples you're currently doing back to the plants that
21 you're sampling?

22 MS. McNAMARA: No, not yet. We are still in the
23 pre-implementation phase. We have not decided on what date
24 actually that the samples will be considered official.
25 Again, our third laboratory is only coming on line this

1 week. This coming week.

2 MR. BILLY: Barry?

3 DR. MARSHALL: Thank you, Mr. Billy. Barry
4 Marshall, New Zealand. A question for Ann Marie. Bearing
5 in mind that the method that you're actually using now for
6 validation purposes is qualitative rather than quantitative
7 test, what is actually the sensitivity of the ELISA test
8 that you are actually using?

9 MS. McNAMARA: The sensitivity of the ELISA test
10 is greater than or equal to 97 percent. By our cultural
11 method in previous studies we have determined that we can
12 detect as little as .03 salmonella cells or less than one.
13 So we feel that there's great confidence in what we're
14 doing.

15 We also repeat every ELISA test in two wells. So,
16 we're doing duplicate samples on every test that goes
17 through. So I think that gives us even increased confidence
18 that if there is salmonella in that broth we will detect it.

19 We use the pre-enrichment broths. We can take one
20 salmonella cell and grow it up to ten to the fifth to ten to
21 the seventh cells and that's actually what the ELISA is
22 testing. So we're pretty confident that this is working
23 well.

24 MR. BILLY: Any more questions?

25 MS. DeWAAL: Caroline Smith DeWaal again. How are

1 you transporting the samples to the labs?

2 MS. McNAMARA: The labs are being transported
3 refrigerated with overnight Federal Express delivery and the
4 Federal Express delivery for this program has been extended
5 so that we now have Federal Express delivery through
6 Saturdays.

7 Previously we only had it Monday through Friday.
8 We've increased that to Saturdays and the labs work seven
9 days a week to process the samples continuously.

10 MS. DeWAAL: Do you need refrigerated transport,
11 seeing that you are just getting a positive or a negative?
12 Does it matter that you have it refrigerated? Won't it just
13 increase the enrichment if it's not refrigerated? In other
14 words, more salmonella will grow on the sample if it's
15 not --

16 MS. McNAMARA: No. What you're doing is you don't
17 want die off. You wouldn't want to transport it at room
18 temperature, because you would get die off.

19 It's best to send it refrigerated or frozen and
20 there's no point in sending it frozen, because then you go
21 through a freeze/thaw cycle and you may lose some. So we've
22 determined that the best way to do it is sending it
23 refrigerated.

24 MR. BILLY: Yes, sir.

25 MR. WARREN: Mack Warren.

1 MR. BILLY: Mack, could we get a microphone to
2 you?

3 MR. WARREN: I thought I was loud enough. All
4 right.

5 MR. BILLY: Thanks.

6 MR. WARREN: Mack Warren, the House Agriculture
7 Committee. I want to see if I could get you to confirm how
8 many samples you're going to take. Is this random or is it
9 every day for so many days by product line? How are you
10 doing the sampling?

11 MR. BILLY: Okay. The basic design strategy was
12 during the pre-implementation phase of the salmonella
13 sampling is to target one sample a day over about a year
14 period or 250 day period.

15 We have indicated in the preamble to the final
16 rule that we're flexible on that in terms of particularly
17 for the smaller, much smaller plants where they don't even
18 perhaps operate 250 days in a year.

19 That we would have an alternative modified
20 approach to that and we're looking at how to do that now.
21 So the whole idea as Maggie pointed out in that part of the
22 sampling, this is prior to HACCCP being a requirement and
23 the requirement therefore to meet the performance standard
24 for salmonella kicks in, pre-implementation sampling is to
25 give us and the plant we think valuable data that they can

1 use to finalize their HACCCP plan, supplement whatever
2 analysis they're doing and give us an early signal for as we
3 swing into the compliance phase of how plants relatively are
4 doing at that point.

5 That will guide us in terms of designing our
6 compliance sampling. We recognize it's not a perfect
7 situation and that if I'm a plant and I'm designing my
8 HACCCP program, I may want to do a little experimenting.

9 I may want to try a piece of equipment. I may
10 want to try some different control units for certain parts
11 of the process and then do some analysis.

12 If we're in there and we happen to be sampling,
13 those results may or may not reflect what will be the case
14 under HACCCP.

15 That's why we thought it was important, one of the
16 reason we thought it was important to talk about that data
17 in the context of making it available publicly. So I think
18 that's an important area that we need to discuss more fully
19 a little later.

20 MR. WARREN: You're doing that for each line item
21 or each product?

22 MR. BILLY: Each product class that this
23 requirement applies to. Yes, sir. So it would be --

24 MR. WARREN: In those 500 plants?

25 MR. BILLY: In those 500 to begin with and then

1 phase two is about roughly 3,000 plants. Phase three, the
2 final is roughly another 3,000 plants.

3 So really 500 plants compared to 3,000 plants give
4 you a sense of why we need to gear up and get the system
5 working effectively as we swing into that next phase.

6 I would like to move on now and have a brief
7 overview of our obligations with regard to the Freedom of
8 Information Act. Ralph Stafko is going to give us a brief
9 review of those requirements and how they play into this
10 particular area.

11 MR. STAFKO: Thank you, Tom.

12 As many of you know, I was the Agency's Freedom of
13 Information Act coordinator for a number of years and have
14 become pretty familiar with the law in that area.

15 Prior to 1966 the government did not have an
16 obligation to disclose the information such as it does now.
17 The burden of proof was at that time on people who wish to
18 obtain information from the government to show why they
19 needed it.

20 With the Freedom of Information Act the burden of
21 proof has shifted to the government. We must establish why
22 we are not providing information that people want and that
23 burden of proof is a fairly strict one.

24 There are basically three classes of records under
25 the FOIA. There are records that we have to publish.

1 Things like rules of practice, rules of general
2 applicability, things that we generally go through the
3 Federal Register and codify in the code of federal
4 regulations.

5 Second class are reading room materials. These
6 are things that we use in the ordinary course of our
7 business. Things like manuals, policy statements,
8 recurring reports of various kinds that we know are general
9 public interest.

10 Those things are on public display and available
11 for copying in our reading room. That's co-located with our
12 docket clerk.

13 A third category is all other records. The law
14 requires we make no distinction between requesters. Anyone
15 who wants to have a record that is in our custody, whether
16 it's in hard copy or electronic form, has a right to that
17 record unless it is within the scope of one of nine
18 exemptions.

19 None of those exemptions apply to salmonella test
20 results. After my brief statements now if anyone wants me
21 to go into particulars on a particular exemption, why I'll
22 be happy to do that.

23 In 1996, last year, there was an amendment to the
24 FOIA and in pertinent part it redefines those classes of
25 materials that go into reading room disclosure as being

1 essentially anything that we know or can anticipate will be
2 subject to multiple requests.

3 Reading room materials as of November, 1996 have
4 to be made available in electronic form. As of November of
5 this year we have to have what we call an electronic reading
6 room.

7 Congress expressly voiced its preference for
8 making those reading room materials available on the
9 Internet as both most efficient and effective way on both
10 the public and the government availability side of the
11 issue.

12 That is the essence of what the FOIA says with
13 regard to this issue. Are there any questions?

14 MR. BILLY: Yes, sir. Get to a microphone and
15 identify yourself, please.

16 MR. PLAJECK: Yes. I'm Mike Plajeck. I'm with
17 the USDA fruit and vegetable division, processed products
18 branch. Would the results that you are getting from these
19 tests be considered reading room material or under the all
20 other documents?

21 MR. STAFKO: They would be considered reading room
22 material, because I think it is reasonable to expect we will
23 be getting more than one single request for this data.

24 By the way, also I have outside for anyone who
25 wants to have a general overview of the FOIA and what it

1 requires and how it works.

2 This is a citizen's guide to using the FOIA and
3 Privacy Act prepared by House of Representatives a few years
4 ago. It doesn't include the electronic provisions enacted
5 last year, but otherwise it's a very good overview so I
6 commend it to you and there are copies available outside.

7 MR. MAY: Ken with National Meat Association.
8 Ralph, what kind of format is there? Do you have any idea
9 what kind of format it's going to be placed in?

10 Is it going to be like a whole list of plants or
11 is there like a separate sheet like the laboratory forms
12 itself? Are they going to be copied and available on the
13 Internet?

14 MR. STAFKO: Well, that's still being worked on.

15 MR. BILLY: If you're willing to hold that
16 question, that's really what we want to get into in the next
17 section.

18 MR. MAY: Okay. Sure.

19 MR. BILLY: We'll come back to your question.

20 MR. POCIUS: Joe Pocius of Montclair Foods. Real
21 quickly could you run over that second class of documents
22 again?

23 MR. STAFKO: The reading materials.

24 MR. POCIUS: Yes.

25 MR. STAFKO: Okay. Reading materials under the

1 electronics amendments of last year, let's see I had the
2 actual language here someplace, are basically those which
3 have become or are likely to become the subject of
4 subsequent requests for substantially the same records.

5 That's what's going into your reading room or now
6 electronic reading room records. Now, even if it wasn't in
7 that class the law also provides that we have to make it
8 available and it has to be available in electronic form, if
9 it is reasonably available and of course that is the essence
10 of the data that we got that we're maintaining
11 electronically.

12 MR. POCIUS: The third class if you would do that?

13 MR. STAFKO: We still have to make it available
14 even if it wasn't a reading room item. It would just be
15 more tedious.

16 MR. POCIUS: Sure. The third class of documents,
17 would you go through that one again, please?

18 MR. STAFKO: That's everything else we got.

19 MR. POCIUS: Just everything else.

20 MR. STAFKO: Everything else.

21 MR. POCIUS: That's the way they say it in the
22 statute?

23 MR. STAFKO: Essentially.

24 MR. POCIUS: This is the kitchen sink.

25 MR. STAFKO: You got it.

1 MR. POCIUS: Okay.

2 MR. BILLY: Deven?

3 MR. SCOTT: Yes. Deven Scott with NMPA.

4 Ralph, you connected a date I believe with the
5 reading room material when that has to be done --

6 MR. STAFKO: Yes.

7 MR. SCOTT: -- electronically.

8 MR. STAFKO: November of last year if it is within
9 that class of information that is supposed to be in the
10 reading room we have to prepare it or have it available in
11 electronic format as well as any other format.

12 MR. SCOTT: Okay. Thank you.

13 MR. STAFKO: As of November of this year it has to
14 be made a part of our electronic reading room, which is
15 however we are making it available to the general public.

16 MR. SCOTT: November of this year.

17 MR. STAFKO: Yes.

18 MR. BILLY: Nancy?

19 MS. DONLEY: Nancy Donley from STOP. Is that
20 retroactive this November, 1996 so is that documents that
21 predate that date or just from here on in? From that date
22 on?

23 MR. STAFKO: It's not retroactive, no. There's
24 case law about the availability of stuff in electronic
25 format and there's a general proposition even prior to this

1 if we have it in electronic format and somebody wants it in
2 that format they can get it under the law.

3 MR. BILLY: Now, my understanding is that as these
4 samples are analyzed and the results are produced in our
5 system, our intent will be to have these results in an
6 electronic format.

7 So that's how the lab's going to manage the data
8 and they have it available to any other lab or to us here in
9 Washington. So we will be in electronic format in terms of
10 the raw results. The data results.

11 So again, this is a prelude to the next section,
12 but given that then to the extent there needs to be some
13 explanation of data or data set one needs to think about
14 that in the context of these types of samples and the
15 results that we will be generating both for pre-decisional
16 or pre-sampling prior to HACCCP and then the sampling that
17 we will be doing under the compliance phase as well.

18 MR. SCOTT: Yes. Deven Scott again.

19 Ralph, the fact that it has to be made available
20 electronically do you interpret that to mean that you have
21 to publish it say on the Internet then? Do you interpret it
22 that way?

23 MR. STAFKO: The use of the Internet or the
24 Worldwide Web is not statutorily mandated, but it is
25 referred to as the most logical way to go about doing it.

1 The most efficient way for both the government to make it
2 done and for the people who want to get the information to
3 get it.

4 MR. BILLY: Okay.

5 MR. POCIUS: Ralph, Joe Pocius again. A little
6 educational informing, if you wouldn't mind. I think the
7 statute as it is written right now, requests from foreign
8 nationals, how are they handled?

9 MR. STAFKO: As a practical matter, we make no
10 distinction. The law basically says we cannot make
11 distinctions on whoever requests it.

12 MR. POCIUS: Russian government. Chinese
13 government.

14 MR. STAFKO: It's public.

15 MR. POCIUS: Anybody.

16 MR. STAFKO: It's public. It's public. Certainly
17 if it's national security information it's not disclosable
18 to anybody.

19 MR. POCIUS: Is that one of the exemptions we're
20 not told about?

21 MR. STAFKO: Well, we don't ordinarily use that
22 particular exemption.

23 MR. POCIUS: Let's talk about that, Ralph.

24 MS. DeWAAL: Will it --

25 MR. BILLY: Who are you?

1 MS. DeWAAL: Caroline Smith DeWaal with CSPI. How
2 are foreign governments going to comply with the salmonella
3 requirements? The salmonella testing requirements and how
4 will that be made available?

5 MR. BILLY: I don't know if the gentleman sitting
6 to your right could provide an answer or an example. We
7 would expect to find the same or equivalent testing
8 protocols, analytical procedures being used and data results
9 in each of the countries that are allowed to ship to the
10 United States.

11 We would have access to that data in the normal
12 ways that we now have access to data that's available under
13 the terms of our arrangements with those countries.

14 MS. DeWAAL: Who will do the actual sampling?

15 MR. BILLY: It will be the same as the arrangement
16 in the U.S. So it will be sampling done by the inspection
17 program. Officials of the inspection program and then the
18 analysis by labs. Either government labs or labs certified
19 by the government. However their particular program works.

20 As we begin now shortly in our continuous round of
21 visiting countries to verify that the foreign inspection
22 systems are working in a manner equivalent to ours, we will
23 be looking in particular at the new requirements that are
24 now in place.

25 Keep in mind that the same deadlines apply to

1 foreign plants in terms of HACCCP. So if a foreign country
2 has large plants versus small versus very small those same
3 requirements apply.

4 So they will be work out a strategy for carrying
5 out this kind of approach consistent with the country's
6 actual plant size and so forth.

7 MS. DeWAAL: Will we have to go to a different
8 place in the electronic reading room to get results of
9 foreign countries or will that also be published in this
10 wonderful electronic reading room?

11 MR. BILLY: We don't as a matter of routine and
12 this is subject, I don't know if anyone from import is here
13 from the staff, we can check, but I don't think we routinely
14 receive that kind of data.

15 MR. REED: No, we don't.

16 MR. BILLY: The way the program works we expect
17 that foreign government program to have that data and to use
18 that data in the manner that we intend to use it in the U.S.
19 So we have access to the data and we'll look at it.

20 Some of the countries that are currently
21 authorized to ship to the U.S. have similar Freedom of
22 Information laws, but I'm not familiar with them.

23 Someone would have to look in particular to see
24 the extent to which that data is available. In the manner
25 that the data is available under our law.

1 Nancy?

2 MS. DONLEY: Nancy Donley from STOP. You
3 mentioned that the standards will be the same for another
4 foreign country's inspection process and under equivalency
5 does that mean that the Agency is reviewing other than
6 government inspected product as equivalent to our own?

7 MR. BILLY: I'm not sure I --

8 MS. DONLEY: You said that whatever the particular
9 country's inspection system is. Does that mean governmental
10 oversight? It certainly would be deemed equivalent, but if
11 countries have plant employee inspection, is that considered
12 equivalent?

13 MR. BILLY: We currently don't have any agreements
14 with countries where they have that kind of inspection
15 approach. We are aware that there are a handful of
16 countries that are looking at some changes in their
17 inspection program.

18 We will look at that very closely to make a
19 decision in terms of whether in the end if they make changes
20 along that line the inspection program would satisfy our
21 requirements. That's a very current area of activity that
22 we're looking at now.

23 Questions? Yes, Dennis.

24 MR. JOHNSON: Dennis Johnson, Olsson, Frank and
25 Weeda. Ralph, I have two questions for you. One, what do

1 you anticipate besides these testing results you're going to
2 throw into that reading room, because that could get real
3 crowded.

4 MR. STAFKO: That's why it's in electronic format.

5 MR. JOHNSON: For example, PDR's.

6 Establishment --

7 MR. STAFKO: Those are generally available now.

8 MR. JOHNSON: So you would have PDR's in this
9 electronic reading room? The area summaries of the PDR's.
10 I mean God knows --

11 MR. STAFKO: We have information that we receive
12 from field operations folks now that is available up there,
13 yes, because we get recurring requests for it. As a matter
14 of convenience to ourselves we just place it up there.

15 Now, if it's a particular establishment, a
16 particular item of information that is not something
17 generally people want to know. It's not a summary kind of a
18 report. That would not be the kind of thing we'd keep up
19 there, but it is nonetheless available.

20 MR. JOHNSON: I'm just trying to figure out what's
21 going to be plopped into that reading room and what we still
22 have to go through the old fashioned way yet.

23 MR. STAFKO: I can read you what they said again.
24 It's basically if it's likely to have more than one request.
25 Subsequent requests for that same item of information.

1 MR. JOHNSON: Okay. The second point is
2 traditionally you have allowed a review of at least
3 documentation, not that you will have a major wide call or
4 that the information is not accurate.

5 If I remember the FOIA, there is a pre-release
6 review that could cause damage. How is that going to
7 interface with this reading room material?

8 MR. STAFKO: It's not. What you're referring to
9 are items of information that are non disclosable under
10 exemption four, which applies to trade secrets or financial
11 or commercial information obtained from a person, disclosure
12 of which might lead to some competitive disadvantage.

13 This is not financial or commercial information.
14 It is not obtained from the industry. It is information.
15 It is data that we are gathering incident to enforcement of
16 our law.

17 MR. JOHNSON: Okay. Thank you.

18 MR. BILLY: Okay. Other questions? Barry?

19 DR. MARSHALL: Thank you, Mr. Chairman. I would
20 just like to make a comment on behalf of foreign countries.
21 I'm not sure whether there's others here today, to both
22 Caroline and Nancy.

23 Barry Marshall, New Zealand. From a New Zealand
24 point of view our country relies on its agricultural
25 exports, particularly meat, for survival and therefore it's

1 certainly in New Zealand's interest to make sure that food
2 safety is paramount and also the longevity of the product so
3 that everyone has a good experience eating New Zealand meat
4 amongst other things.

5 In this respect, we are acutely aware of the
6 program that's being put in place by FSIS over the past
7 couple of years and New Zealand, as I mentioned, are fully
8 supportive of this drive to make food safer and certainly
9 we'll be moving and doing everything in our power to ensure
10 that at least we are equal to if not exceed more stringent
11 than perhaps what's being suggested and perhaps later on if
12 someone is interested I could tell you a little bit more
13 about the New Zealand program.

14 Certainly we will be at least meeting. In fact we
15 have been monitoring for quite some considerable time now
16 what the expectations of the FSIS is from a market
17 biological point of view and we do have quite an in depth
18 alert system with industries so that every company knows on
19 a weekly basis how their results compare with the national
20 average and amongst other things.

21 So the New Zealand industry anyhow is totally
22 behind this thrust of ensuring that consumers are not put at
23 risk. Thank you.

24 MR. BILLY: Okay. Now I would like to move on to
25 the next section, which is to sort of characterize our

1 current thinking in this are and flag in particular several
2 issue or areas that we would encourage dialogue on.

3 So I would like to turn to Maggie again to set the
4 stage.

5 MS. GLAVIN: Okay. I guess as is clear from
6 Ralph's presentation the one given that really isn't up for
7 discussion is that the data that will be collected under the
8 salmonella testing program is available to the public.

9 That just is a given in this discussion. Beyond
10 that, I can talk about our current thinking, but in the
11 context of this meeting is to help us solidify that thinking
12 and determine how best to make this data available.

13 We have stated before that our intention to make
14 the data available using the Internet. So that's kind of a
15 working assumption at this point. Obviously the results
16 will go back to the individual establishments. That's a
17 working assumption.

18 We have talked about making data available in full
19 data sets only. That is, when a complete sampling frame has
20 been completed for an establishment and product class within
21 that establishment it would be available, not individual
22 test results as they are completed.

23 We've also talked about and Tom alluded to this,
24 the need to give a context to the data. There is both a
25 need for an open availability of this data and a need for

1 comprehension of what this data means.

2 That's what I'm talking about when I say there
3 needs to be a context for this data and that somehow needs
4 to be communicated along with the data.

5 So we have kind of working assumptions. We have
6 the one given, which is the Freedom of Information Act. We
7 have some working assumptions on how best to meet these
8 needs of availability and comprehension, but we're looking
9 for input from you all on what are your concerns, what are
10 your preferences, what are your suggestions on how to meet
11 those somewhat competing notes.

12 MR. BILLY: Okay. Caroline?

13 MS. DeWAAL: Caroline Smith DeWaal. Maggie, can
14 you elaborate a little more on what this context is? What
15 are we talking about?

16 MS. GLAVIN: Well, I think the context is what
17 does this data mean and I'll go back to my introductory
18 statement that this is not product release data.

19 This is not about this particular product is or is
20 not acceptable. It's about process control. Does a
21 particular establishment have control of their process in a
22 way that enables them to produce a suitable, acceptable,
23 safe product.

24 But it's not about if there is a positive that
25 that particular product is or is not able to be sold in the

1 marketplace.

2 MS. DeWAAL: I'm following along that. I agree
3 with that context. What about making available as part of
4 that context the information clearly stated of whether in
5 fact the company meets the program criteria?

6 So in other words, in this reading room that we're
7 electronically hooked up to, instead of giving me a document
8 that on the one hand talks about a full data set of how a
9 company did on salmonella test results and in another
10 document tells me what the national averages are, can you
11 give us a data set that really puts it in context and says,
12 this is how this company performed on this product line.

13 Here's the complete data set and here is your
14 national average or here is your target that we're trying to
15 get the company to. So that it all appears in the same
16 document and I believe that would put it in context as well.

17 MR. BILLY: Let me give you two hypothetical
18 examples so that we can further explore the question that
19 you've just asked.

20 Let's assume that you're in the compliance phase
21 and company X is producing a carcass where the requirement
22 is that no more than ten out of 50 of the samples in the
23 sample set, the sample set is 50, more than ten out of 50
24 can be positive.

25 As the results are coming out and we're providing

1 the results to this company X and they end up with ten or 11
2 positives in the first 20 samples that are produced, but the
3 company having that information or even before they crossed
4 the threshold of ten, they're approaching that, that company
5 says well gee, we've got some concerns about our process.
6 So we're going to make an adjustment now.

7 We're going to change what we're doing and as a
8 result in that hypothetical example they may or may not go
9 over the ten. Let's assume they did, but at the end of our
10 sample set what's true in the plant now at that point is not
11 reflected by the results of that sample.

12 How do we explain that? What is the right context
13 for that possible situation?

14 Then there's company Y where in again the same 50
15 sample set rather than ten or 11 they have 49 positives and
16 you know there's no apparent effort to improve the process
17 or they are not able to identify an approach in the
18 immediate term that will address that effectively or however
19 you want to characterize it.

20 That's a different context then, if you see what I
21 mean and under the required provisions and regulation then
22 we take certain steps and the company takes certain steps
23 and there's a procedure that's followed.

24 In fact, if the company takes an action, then we,
25 at our discretion, can go back in and take a second set of

1 samples.

2 So what's the context then if there's action by
3 the company clearly they were having a problem, they've
4 taken some kind of action in that situation as well and now
5 we've decided we're going to take a second set of samples.

6 How do you provide a context for those two kinds
7 of situations? That's what we're interested in figuring
8 out. What's the fairest, most effective way for all
9 interested parties to deal with that?

10 MS. DONLEY: Let me add one other question, which
11 your question made me cognizant of and that is, in this
12 discussion should there be a distinction between the context
13 and how we report pre-implementation versus the post
14 implementation compliance base sampling? They are very
15 different kinds of things and should there be a distinction.

16 MR. BILLY: Okay. Steven?

17 MR. PRETANIK: Steve Pretanik, National Boiler
18 Council. You have indicated that at least initially you're
19 thinking of releasing data as a whole set rather than
20 individual.

21 In getting back to the regulation and compliance,
22 my question is if a facility is complying with whatever
23 level is established for their product, why is it necessary
24 then to publish a data set for them, since they're in
25 compliance?

1 Why couldn't you say they passed or just say
2 they're in compliance? Why is it necessary to have numbers
3 out there if they're in compliance with the regulation?

4 I bring that up. That might be one way to address
5 part of what you raised with context. Those that perhaps
6 fail maybe it would be appropriate to have the whole data
7 set.

8 That's hard for me to fathom if somebody is
9 operating properly, they're in compliance, then why are they
10 handing out numbers which could have a significant impact on
11 their other trade businesses?

12 MS. GLAVIN: The numbers would of course be
13 available. You're talking about whether they're proactively
14 published?

15 MR. PRETANIK: Published in electronic reading
16 rooms.

17 MR. BILLY: Keep in mind these aren't numbers.
18 These are pluses and minuses.

19 MR. PRETANIK: I understand that. We're not
20 talking about product acceptance. Sometimes they're good
21 and if we're talking about trade with other countries they
22 can certainly be used for whatever purpose they want to use
23 them for.

24 MR. BILLY: Okay.

25 MR. SHIRE: Bernie Shire, American Association of

1 Meat Processors. The question I pose I guess is for the
2 Agency is who does the Agency visualize, besides the plants
3 that are being tested, who do you see as the audience for
4 this information that's going to be released?

5 MR. BILLY: I think it's the general public. You
6 know it's part of a regulatory program to accomplish what
7 the HACCCP rule is about. So it's a mechanism to verify
8 process control.

9 That's what this is about and it's a measure of
10 the effectiveness of the HACCCP program in the context of
11 the rule and what we're trying to accomplish.

12 So it's just information that's being generated to
13 demonstrate that that's what's happening. That there is
14 compliance.

15 MR. SHIRE: But if it's kind of being thrown out
16 there and I understand what you're saying, that this
17 information is to verify process control rather than product
18 testing itself, but if it's just kind of being thrown out
19 there I guess that's the question I would have.

20 Who besides the plants themselves, who does the
21 Agency visualize as people that are going to be receiving
22 this and making use of it and for what means?

23 MR. BILLY: It's public data subject to FOIA. So
24 we don't have any grand scheme about it ought to in
25 particular go to this group or this type of person.

1 It's just information I think to show the American
2 public that the product is being produced consistent with
3 the regulatory requirements. I mean that's I think the
4 value that it has.

5 Bob?

6 MR. HIBBERT: Good morning. This is Bob Hibbert.
7 Forgive me if this gets us back into what is or isn't exempt
8 under the Act, but isn't this in effect, given my
9 understanding of the Agency's salmonella program, isn't this
10 pre-enforcement activity?

11 I mean as I understand the salmonella program, a
12 single sample is not bad. A single sample does not indicate
13 an adulterated product. A certain set of samples leads to a
14 conclusion as to lack of process control.

15 I think overall that's debatable in the sense that
16 you're putting yourself in a situation where you might be
17 suspending operations where you don't have any evidence of
18 product being adulterated or being prepared under unsanitary
19 conditions and I also think it's debatable because
20 ultimately the logical is circular.

21 Ultimately you are concluding that the process is
22 out of control and giving certain salmonella results and
23 those salmonella results are the only evidence of that.

24 But that's not the issue. Your position is that
25 that is an enforcement conclusion. Now you did plenty of

1 sampling now within your compliance program that is
2 pre-enforcement in nature and compliance is very hard to an
3 enforcement exemption in terms of saying we cannot give you
4 that information.

5 It would seem to me given my understanding of the
6 salmonella program, as you envision it, that this is very
7 much in the same category.

8 That you are looking into how a plant is doing.
9 It might lead to a conclusion about enforcement action. If
10 you take that enforcement action that might then be a public
11 event, but until you get there, it's not.

12 MR. STAFKO: Bob, early on the Agency tried to do
13 that very kind of thing with regard to a lot of the
14 routinely gathered inspection information that potentially
15 could lead to some kind of a compliance or enforcement
16 action against a plant.

17 Wellford V. Harding, 1971. Goldschmidt v. USDA,
18 1983. Were both testing that exemption seven ability to not
19 disclose information gathered in preparation for some kind
20 of enforcement action.

21 The courts basically said if you're providing that
22 information to the plants then obviously disclosure is not
23 going to inhibit your execution of any prosecution and
24 that's what that exemption is for.

25 It's to prevent the frustration of the exercise of

1 conduct of an investigation that might lead to a prosecution
2 or enforcement of the law. These are not the kind of data
3 disclosure which is going to preclude us from enforcing the
4 law.

5 MR. BILLY: I have a question, Bob, just to
6 clarify what you were asking about. Are you asking about
7 the situation where a plant fails to meet the standard in a
8 given sample set? That limited circumstance or was your
9 question in general about all of the salmonella sampling
10 that we would do?

11 MR. SHIRE: I think it's both. I think the
12 implication of my question is that the data might not be
13 public until you get into a failure.

14 A specific plant failure that would be based upon
15 those data. That prior to that time it is investigatory and
16 pre-enforcement in nature.

17 MR. BILLY: No. These are routine data gathering
18 exercises. These are not taken with a view to compiling a
19 case against the individual plant such that disclosure of it
20 would allow that plant in some way to avoid exercise of the
21 law.

22 MR. SHIRE: But isn't that the only purpose of the
23 sampling to ultimately support conclusions that the plant's
24 process is out of control and therefore the plant is subject
25 to an enforcement action?

1 MR. STAFKO: No. It's to provide a standard by
2 which plants can measure their ability to reduce pathogens
3 in their product.

4 MR. BILLY: I think the preamble to the rule has a
5 fairly clear expression of this in terms of the intent is to
6 verify compliance, verify process control. It's looked on
7 as a positive measure of the effectiveness of the HACCCP
8 plants and that's its intent.

9 Nancy?

10 MS. DONLEY: Nancy Donley from STOP. I would like
11 to revisit company Y. Company Y in a large operation
12 certainly has a chance with another set of sample data to
13 get out of its predicament and can effectively correct the
14 situation and obviously be in compliance and very well
15 control.

16 My concern is the very small companies where the
17 rule calls for one set of 12 samples and in that case if
18 three of them come back with a positive that allowed the
19 three and these are the months of June through August --

20 MR. BILLY: I think you're confusing the E. coli
21 testing with the salmonella testing. What you're talking
22 about would only apply to the E. coli testing.

23 The salmonella testing is testing that we do and
24 there's various size sample sets that are defined in the
25 rule depending on the product class.

1 MS. DONLEY: Okay. That's continuous with the
2 very, very small --

3 MR. BILLY: Well, it would be continuous in the
4 sense of consistent with days of operation. If they
5 operated two days a week, we --

6 MS. DONLEY: Right.

7 MR. BILLY: -- would take that into account and so
8 forth.

9 MS. DONLEY: Right. Sorry.

10 MR. BILLY: That's okay.

11 Ken?

12 MR. MAY: Ken May of the International Boiler
13 Council. We are one of the groups that have written you a
14 letter, Mr. Billy and we are very concerned about the
15 possibility of international trading problems if this data
16 is put on the Internet.

17 In the poultry industry we ship about one fifth of
18 our product to foreign customers. We compete for that
19 business with other countries around the world who export
20 hopefully to the same countries that we do.

21 Those countries, exporting countries, do not have
22 this same regulatory requirement. They would not publish
23 any of their data if they even have any data on salmonella.

24 We feel that by the time these data are collected
25 and they're posted they are not necessarily reflective of

1 what's going on in the plant at any given point in time,
2 because they're historical of the time they're reported and
3 they could be used by competitors of ours and other
4 exporting countries to make our product look bad and to lose
5 a lot of business.

6 We think that it's extremely important. We
7 realize this information has to be made available. We
8 understand that's important in this country, but we see
9 nothing to be gained by a competitor in a foreign country
10 being able to pull up our salmonella data on the Internet
11 and use it against us in some way when they might have much
12 worse results than we have.

13 It would be taking customers away from us.
14 Likewise, some of our international trading customers have
15 their own salmonella protocols which we have to test for and
16 meet in order to ship to their countries.

17 The protocols are not the same as USDA is using
18 under this regulation and the results therefore would be
19 different.

20 So we might be in the position of a foreign
21 customer looking at our government's data and saying, what
22 are you doing. You're reporting to us one thing. Your
23 government says something else about your industry. What is
24 the true case.

25 We see it as a possibility of really having a

1 tremendous negative influence on our trading and I'm sure
2 the meat people feel the same way, because they have the
3 same circumstance, maybe not quite as much as we have.

4 It could influence our international trade in a
5 very, very large way. We're not talking about product
6 because we have found some salmonella in this raw product.
7 We're not talking about product that the department has
8 deemed to be illegal, which cannot be sold. That's not what
9 we're saying at all.

10 But we can understand how somebody who doesn't
11 understand our regulatory set up and how it works might come
12 to that conclusion that this was a dangerous and unusually
13 dangerous product, because it might have such access to this
14 information and not understand what it means.

15 So we feel that the Department should give very
16 serious consideration to not posting this on the Internet
17 and that you do work out a scheme of some kind to explain it
18 fully in your reading room or wherever you put it so that
19 people clearly understand that this data doesn't mean the
20 product is illegal.

21 One company might be different than another,
22 because they have a little different data on their last set
23 of information.

24 We think it clearly needs to be stated so that
25 people understand what it is and what its purpose is. We

1 think that people could draw the wrong information from it.

2 MR. BILLY: Let me ask you a couple of questions
3 to get a better sense from you of how this could work in
4 that international trade setting.

5 Going back to my company X that was a sample set
6 of 50 and the ten is the standard and you have this company
7 X reflect a set of samples and they analyze them and the
8 results are that there were eight positives out of the 50.
9 So they're below the limit.

10 The company Y, we collect a sample set and they
11 have four positives out of 50. Again, within the
12 performance standard as we've established it.

13 Is it your view given how the international
14 marketplace works that those results, the fact that there
15 are even positives could be used in the manner that you're
16 talking about even though they're within the limits that
17 we've established?

18 MR. MAY: I definitely think that they could and I
19 think that people might erroneously believe that the company
20 that had four is better than the one that had eight, which
21 really is not true at all.

22 All of the product is legal and you know it could
23 lead to some I think grave international misunderstandings
24 to the detriment of our country and our trade.

25 MR. BILLY: Joe?

1 MR. POCIUS: Joe Pocius with Montclair Foods.
2 Picking up on Ken's notion there. I have to agree with him.
3 Unfortunately with all the good intentions and explanations
4 of how this data is to represent process control within a
5 facility and all of that, I don't think that that's the way
6 it will actually be used, particularly on the international
7 market.

8 I'm not in a position to argue the legality of
9 this thing. Ralph and the other lawyers can get together
10 and have fun doing that some time.

11 But the mechanics of this thing, of posting these
12 numbers on the Internet carte blanche, bothers me and a lot
13 of other people in this room I think.

14 One suggestion that you might want to consider
15 that keeps the current mechanism while using the electronics
16 available is to use E-mail. Requests come in through
17 E-mail. The results or the answer go out through E-mail.

18 Anybody who has access to the Internet right now
19 their server provides an E-mail service to them. That would
20 control this somewhat without just laying it out there where
21 anyone who is surfing can just pass by.

22 You know I've got an extra five minutes on my
23 lunch. I'll just go up and see what company X and Y are
24 doing these days.

25 If you really want that information, you really

1 have a reason for getting it, you'll have a reason for
2 requesting it. It won't be on paper. It will streamline
3 your system internally and it will maintain the controls
4 that currently exist.

5 MR. BILLY: Do you think that with your suggestion
6 that through the E-mail then the context that Maggie
7 referred to that would enhance that or is that part of your
8 thinking or what?

9 MR. POCIUS: Anything that you can or would put
10 onto the Internet or normally would respond through hardy
11 copy can be put into and answered through E-mail requests.

12 MR. BILLY: Okay. Nancy?

13 MS. KLINKHAMER: Heather Klinkhamer, Safe Tables
14 Our Priority. Earlier when Ann McNamara had mentioned that
15 you're receiving data now but it's not considered official
16 yet, what do you estimate will be the lag time between
17 receiving results on salmonella testing and making them
18 official and placing them in the electronic reading room or
19 available through FOIA?

20 If you proceed with an electronic reading room
21 with this information available on it, how often do you
22 anticipate updating that site?

23 MS. McNAMARA: I can't give you an exact date of
24 when all these different steps will be in place. As you can
25 see, there's a lot of involved in this and some of this new

1 electronic data requirements are quite new.

2 But we are working on that and I expect that it
3 will be soon. I expect that we will be able to give the
4 large plants before they come on line completed samples of
5 data so that they will be able to look at what they're doing
6 and what their processes are showing now and get some
7 feedback.

8 So that is our goal is to give the data out there
9 to the plants in completed sample sets before they come
10 online and I believe that that will be achievable.

11 MR. BILLY: The other relevant time frame is as we
12 indicated in the final rule it is our intent to hold a
13 public meeting on the salmonella testing area.

14 It was 15 months after the final rule was
15 published, which would be some time I guess about October of
16 this year and that is our intent.

17 So as part of the preamble we said we would share
18 what data we had available at that time in anticipation of
19 that meeting.

20 MR. HODGES: Mr. Chairman, Jim Hodges, American
21 Meat Institute. We fully concur with the Boiler Council's
22 concern about the international trade implications of this.
23 Publishing this data in a readily accessible form for
24 foreign countries.

25 Our export programs have yielded very good results

1 for us in the last decade. We are not at the level of the
2 poultry industry in terms of exports, but we're at that
3 eight or nine percent level, which is a significant amount
4 of dollars for the industry.

5 It's our firm belief that foreign countries will
6 use that against us. They've used a lot of things against
7 us. E. coli sampling is one that has been very problematic
8 over the last few years to try to work through that with our
9 trading partners and ultimately in the end these samples
10 will be used in our opinion for a trade barrier and that's
11 going to hurt our producer community.

12 That's going to hurt the pork producers. That's
13 going to hurt the cattlemen. It's going to hurt the sheep
14 producers in the end.

15 Because that is our growth potential in foreign
16 markets and if we do anything to damage that I think that's
17 going to be very, very difficult for them to recover from.

18 MR. BILLY: Caroline?

19 MS. DeWAAL: Caroline Smith DeWaal, CSPI. I just
20 want to weigh in on this international trade issue. I
21 understand the Boiler Industry's concern and in fact I
22 remember after the rule came out that we had a meeting with
23 the Turkey Federation, because they were frankly embarrassed
24 by the numbers of the ground turkey figure of 49 percent,
25 which is in the rule.

1 I think one way that the government could clearly
2 help these industries that are struggling with these very
3 high contamination levels for salmonella is to ratchet those
4 numbers down as quickly as possible so it's less of an
5 embarrassment on an international trade front.

6 I think that that would be the best thing you
7 could do. I think the industry should also be embarrassed
8 because American consumers I think find those levels of
9 contamination unacceptable and embarrassing to the industry
10 as well.

11 So I think that the goal here should be to get
12 those numbers down and let's get them to acceptable levels.
13 I think the salmonella testing will help to do that and I
14 think we should just drive the system as quickly as possible
15 so that those numbers are things to be proud of and not
16 things to be embarrassed about.

17 MR. BILLY: Okay. Ken?

18 MR. MAY: Well Caroline, I'm sorry I didn't bring
19 my sheets of paper again today. You always seem to think
20 that chicken is so much worse than anything else and yet I
21 should have brought them.

22 Ann Marie asked me about it. We test a 750 pound
23 beef animal with a little thing like this, 300 square
24 centimeters and we test a three and a half pound chicken
25 with one like this, 2,000 square centimeters and about 45

1 percent of the birds that are found positive in chickens you
2 can't enumerate the numbers, because they're so small.

3 They're positive, but you can't enumerate them. I
4 will ask Ann Marie to verify that as a fact. We just have a
5 huge sample. We're not a whole lot dirtier, which you seem
6 to think.

7 But our foreign trading partners have no other
8 countries who export have absolutely no rule like this.
9 They may not even be taking salmonella samples, but they may
10 use this data to take our markets internationally.

11 You may not be concerned about that, but there are
12 a lot of poultry producers and meat producers in the United
13 States that are concerned about it and rightfully so.

14 Now we're not against Freedom of Information and
15 getting this data out, but we don't think there's any point
16 in putting them on the Internet so that somebody in another
17 country can use them against us as an exporter and we think
18 that we use them in this country they need to be used in a
19 thoughtful way where people clearly understand what they
20 mean.

21 You think perhaps we're going to be embarrassed
22 and we can just dot better. I can tell you we're doing
23 everything we know how to do and we're trying to find better
24 ways to do things. Sometimes our government slows us down
25 doing that.

1 I've written Mr. Billy a letter and asked him why
2 can't we go out in our plants and test antimicrobials once
3 they're approved by FDA. Now we've got to go to USDA and
4 fiddle around sometimes for a year to ever get permission to
5 even try them even though they're approved for the use.

6 So we're getting frustrated about the government
7 talking about the Freedom of Information and we want you to
8 integrate. We want you to get better and yet every time we
9 turn around somebody is hitting us on the head with
10 something.

11 So we have a concern about this. It's a big
12 international market. It's important to meat and poultry
13 and we think we need to be careful about how this is used.

14 MR. BILLY: Okay.

15 MR. PROCTOR: Stuart Proctor with the National
16 Turkey Federation. Caroline, are we happy with some of our
17 salmonella numbers? Not particularly. Are we embarrassed
18 by them?

19 I think that's an exaggeration and I'm not sure.
20 I think you're maybe taking that out of context. I'm not
21 sure who you met with. You certainly didn't meet with me.

22 The point though that is being missed is, is the
23 industry doing everything that it's technically capable of
24 doing today and the answer to that is yes.

25 We can only go so far technologically with control

1 and elimination of pathogens and I think that's the point
2 that you're missing and I think that's probably the point
3 that the general public is going to miss when this
4 information is published.

5 So you know that's where we're concerned about the
6 domestic misuse of the information, number one and ask we've
7 just talked about here about the international misuse.

8 Let me go a little bit farther to tell you how
9 this will actually work internationally. Foreign buyers
10 will go to this company and say we have your salmonella
11 numbers and we show four. They'll go to this company and
12 they'll say you show six.

13 So in your price, we want this adjusted in this
14 way. There will be an effort there to negotiate on price
15 used with those salmonella numbers.

16 Then in an international context they'll use
17 French turkey exporters against U.S. turkey exporters and
18 say your numbers are X. The French are X minus Y and
19 therefore we want an adjustment in your price or we're not
20 going to buy from you, et cetera.

21 So it's just another example of the misuse of the
22 numbers and that's what we're concerned with. Both
23 international and domestic misuse of these numbers in the
24 reporting.

25 MR. HIBBERT: I think it's fairly clear that

1 foreign countries will be reluctant to release the data that
2 they are collecting for use by other countries, particularly
3 the United States.

4 They may not even be testing in some cases, even
5 though there is equivalency requirement and that's something
6 that the Agency ought to look at.

7 It seems to us that if you want to try to put this
8 kind of information into context you've got to put it in the
9 context that the sole purpose of that is a measurement of
10 compliance.

11 I would not even subscribe to the fact that it is
12 an absolute definitive measure of process control. I think
13 it is related a lot to a variable of factors, whether it be
14 the birds or animals coming into the facility, seasonality,
15 time of year and so forth, but this is not the forum to try
16 to get into that kind of discussion.

17 There is a rule there. Let's call it compliance.
18 That compliance should be determined based upon the numbers
19 that you have and you are not out of any regulatory scheme
20 until you have an effect, had your three strikes, you're
21 out.

22 Now the question is, if that's the intent of the
23 regulatory purpose to determine compliance or determine not
24 compliance and the subsets of those data are going to be
25 used for domestic and foreign trade competition, which I

1 don't think was ever the intent of the rule, then it leaves
2 us very discouraged about whether or not we're intent on
3 measuring process control or whether we are intent on
4 relaying the data to what the media and the marketplace
5 determine where we should be going.

6 MR. BILLY: Bernie?

7 MR. SHIRE: Bernie Shire, American Meat
8 Processors. We certainly join with AMI and Boiler Council
9 and the other groups here in voicing concerns about this
10 because of the international ramifications in trade, but I
11 just want to talk for a minute about our situation.

12 We represent a lot of small and medium sized
13 businesses in the country and I guess the main concern I
14 would have at this point is about what the release of this
15 information in this kind of way is going to mean, depending
16 on how the context is built around it.

17 In a sense maybe we in this room maybe know too
18 much, but when you talk to the average person out there in
19 the street when they hear the word salmonella they think
20 right away food poisoning.

21 I don't think the average person knows that
22 salmonella is present on raw product in a certain quantity.
23 They don't even know that.

24 It's kind of like with the E. coli testing. You
25 know we know that the testing is being done for generic E.

1 coli and that's different from 015787, but the average
2 person doesn't know that. When they hear E. coli they go
3 bananas because that has a certain meaning for them.

4 Getting back to the question I asked before about
5 who is the intended recipient of this information, I think
6 that if the information, the way it's going to be released
7 is going to be very confusing, especially in small
8 communities where there are small plants and people are able
9 to get this information that's publicized in the press or
10 whatever and they hear these numbers or that number.

11 It's not going to have any meaning for them except
12 this is somehow bad and it's going to hurt the product in
13 the long run.

14 In other words, while you're saying it's going to
15 be aimed at process control, the fact is it's going to have
16 ramifications in the area of the final product and it's
17 going to create a very confusing situation.

18 I'm not sure what the solution is to this in terms
19 of context and all that, but having been in the newspaper
20 business before I got into this business I know how hard it
21 is to set context on anything, especially when information
22 becomes public.

23 It's out there and people will make of it what
24 they will and so we have very great concerns about that.

25 MR. BILLY: We'll do Heather and then we'll take a

1 15-minute break.

2 MS. KLINKHAMER: Heather Klinkhamer with STOP. I
3 just want to make a comment that I think that some of these
4 arguments are moot because if the information can be
5 obtained through a FOIA request any person who obtains the
6 information can put it on the Internet and that happens
7 frequently in other areas.

8 For instance, there's a site run by an individual
9 who formerly worked for the FEC who now makes FEC records
10 available to anyone who wants to visit his site. So I don't
11 see why we're even discussing this.

12 MR. BILLY: Okay. Let's break for about 15
13 minutes.

14 (Whereupon, a brief recess was taken.)

15 MR. BILLY: We have scheduled about another hour
16 and I think all of the session to date has provided a
17 background or framework for what I hope in this next item if
18 we can we can think in terms of the way I think about it is
19 a win-win.

20 How can any of us think of a strategy that in the
21 end provides what everyone needs in terms of this particular
22 issue, this type of information?

23 We would be interest in ideas along that line that
24 would help guide us in terms of coming to a final view on
25 how to address this area.

1 So you've heard about the legal requirements under
2 the Freedom of Information. You've heard about the concerns
3 and some hypothetical examples that hopefully provide some
4 context and the technical aspects of this.

5 So I would be very interested in particular if
6 anyone has ideas about an approach that is fair to everyone
7 and consistent with the law.

8 Steve?

9 MR. PRETANIK: This is Steve Pretanik. I would
10 like to raise just one more issue or concern if I may and
11 that is, has any thought been given to how this information
12 would be protected from hackers if that information is
13 available say on the Internet, Worldwide or whatever?

14 MR. BILLY: I assume the context is as an example
15 someone that would go in and change the numbers as one
16 example. They turn negatives into positives so that numbers
17 end up looking different than what they very are. That's a
18 very legitimate question and concern.

19 MR. STAFKO: The plan was to make it a read only
20 kind of disclosure and you know the issues of whether or not
21 people can break into these things are a little beyond the
22 scope of people on this panel, but the intent was to make
23 that so that it would not be possible to --

24 MR. PRETANIK: I only raise it because there has
25 been some press, as you know, FDA, FBI, so forth. It's a

1 possibility.

2 MR. BILLY: I think we need to give that some
3 further thought as we go through this process. That's a
4 good point.

5 Dennis?

6 MR. JOHNSON: Dennis Johnson, Olsson Frank and
7 Weeda. I was thinking of talking to Ralph about this during
8 the break. It seems to me that until I do a lot more legal
9 research I'm going to have to play in his ballpark.

10 What he had indicated the test was for the reading
11 room is that he would anticipate or the Agency would
12 anticipate receiving many subsequent requests for the same
13 records.

14 Now, I see Ralph a lot of times on FOIA matters
15 and I requested more than my share, but it seems to me that
16 most times you don't ask for information on good plants.
17 You don't ask for information when there's no problems.

18 I cannot remember the time I just decided I was
19 going to FOIA the PDR's of a plant. There's just too much
20 information I'm not going to use and I'm not going to bother
21 asking for it.

22 There seems to me that at least in the case of the
23 first series, I mean this whole thing is really three
24 series, first one series of tests, if you flunk then you go
25 to a second and you go to the third.

1 For the first series just because of the bias the
2 Agency built into those performance criteria there's a one
3 in five shot you're going to flunk.

4 If you're in compliance, there's 20 percent chance
5 you're still going to fail that particular test, just
6 because you wanted to make sure for policy reasons that you
7 would cover people who were operating outside that.

8 Pretty soon if that's true I mean I can go to
9 Vegas on those odds and win a lot of money. Everybody is
10 going to be on that list at one point or another.

11 There seems to me that really you're going to get
12 the requests probably for those plants which have been
13 closed. The third strike. Those plants which haven't been
14 able to make the changes sufficient to eliminate that first.

15 The whole incentive and I thought about this
16 coming on the Internet before 1996, so before the statute
17 and it's an incentive program.

18 I mean bottom line is I don't want my name to
19 appear on any list so I'm going to make sure I do better
20 than the industry average. I'm going to ratchet down those
21 numbers as much as I can to stay off the list.

22 But if I'm going to get on that list every time it
23 sort of diminishes the incentive to do that. So I think
24 that as an initial matter I would propose or suggest that
25 for those establishments that had taken the test the first

1 time and passed or those that have taken the first time
2 flunked, but passed the second that those would not be the
3 subject of repeated requests as a general matter.

4 Therefore, those companies would not be on the
5 Internet, albeit they're available for a Freedom of
6 Information Act request, which just goes for the people who
7 got strike two and strike three.

8 Not to speak for the consumer groups, but I think
9 they want to know the plants that struck out the second time
10 and have that very accessible as opposed to those the first
11 time out.

12 It makes the information more manageable and does
13 help to put it in the context and it does provide an
14 incentive that everybody can have, because if you're going
15 to experiment, if you're going to put in a new process,
16 there's a good possibility you're going to flunk the first
17 time until you can fine tune it.

18 Why do you want to keep on changing that? Why do
19 you want to expose yourself to the risk of being on the
20 list? It acts as a disincentive and that's some of my
21 concern with the list.

22 I understand the trade implications and everything
23 else, but as I say, perhaps put the information only on the
24 Internet only widely available for the second and third
25 strike folks.

1 MR. STAFKO: I wish we had our statisticians here.
2 I think I have a little problem with your characterization
3 of a one in five.

4 MR. BILLY: We do.

5 MR. STAFKO: Can you address Mr. Johnson's concern
6 about the probabilities that a plant that is in fact
7 operating at or below baseline level will flunk the test?
8 Is it a one in five?

9 MR. ELDER: Bob Elder, FSIS. It was set up.
10 That's correct. If you are right at the performance
11 standard, you have an 80 percent chance of passing and 20
12 percent chance of failing, but if you do better than
13 performance standard your risk goes down.

14 The better you are the farther below the
15 performance standard you're operating at, the less chance
16 you have of failing.

17 MR. STAFKO: So that's not an across the board. I
18 mean you still have 67 percent plus or minus one standard
19 deviation.

20 MR. ELDER: Well, the bell curve is not relevant
21 here. An individual plant and what the process average is
22 for that plant. That determines how they do on the test.
23 If the standard is 20 percent and you're at ten percent, you
24 have a better chance at passing.

25 MR. JOHNSON: But --

1 MR. ELDER: That's just the way it is.

2 MR. JOHNSON: Broad generalities we can at least
3 assume that there is a significant percent of those would be
4 operating under compliance who just through the matter of
5 chance will come up positive or will flunk the test. A good
6 percentage of the plants. A decent percentage. I'm not
7 going to put numbers on these.

8 MR. ELDER: Right. If they do nothing to change.

9 MR. BILLY: That's looking into a crystal ball.
10 We don't have any information to base that on.

11 MR. JOHNSON: My comment though I still think that
12 the first series, the first batteries of tests may not
13 accurately represent so therefore why do them and plus as I
14 say where's the real interest in that first battery.

15 MR. BILLY: Okay. Heather?

16 MR. MAY: I have one comment on that since you
17 brought up statistics. This is Ken May, National Boiler
18 Council.

19 You were running a baseline and I can report to
20 you that individual plants vary a lot over short time
21 periods. A whole lot compared to what their long range
22 average is.

23 As a matter of fact, I think any plant in the
24 United States could be subject to a failure regardless of
25 what their long-term average has been in a specific time

1 period.

2 MR. BILLY: Okay. Heather?

3 MS. KLINKHAMER: Hi. Heather Klinkhamer, STOP.
4 Can you hear me? Okay. I just wanted to make a comment
5 that I'm disappointed that this is being viewed so
6 negatively.

7 It seems to me that a good player would want to be
8 on the list to demonstrate that they're in control and doing
9 a good job and a company would want that kind of information
10 publicly available and would be marketing based on a good
11 safety record. I just think everyone is seeing the glass is
12 half empty.

13 MR. BILLY: Nancy, do you have --

14 MS. DONLEY: Nancy Donley, STOP, Safety Tables Our
15 Priority. A quick question. This preliminary data that you
16 are accumulating right now, when do you think that there
17 might be some kind of a quick litmus test to see just how
18 well things are doing generally to get some kind of a handle
19 on are we looking at an 80/20? What are we looking at?
20 Any --

21 MR. BILLY: I think that would be in the October
22 time period. I think that we targeted that initial sampling
23 to be available so we could look at the results to maximize
24 the value of the public meeting and look at it that way.

25 MS. GLAVIN: Ann Marie jump in if I'm getting this

1 mixed up, but the kind of thing we're doing right now is
2 making sure that our system is working.

3 That samples are getting to the lab on time and in
4 condition that the labs are able to run them at the rate
5 that we've set the labs up to do. So in talking about
6 preliminary data, it's preliminary in that sense.

7 We're trying to shake down our system of
8 collecting and analyzing the samples. So that's what we've
9 got right now and once we go live, which we haven't made the
10 decision to do that yet, we haven't made the decision that
11 our system is looking well enough to do that yet, but we're
12 pushing real hard to get it to that point so that by the
13 time of this fall meeting we've got at least one complete
14 sample data of the product class.

15 MS. DONLEY: Can I take this a little further?
16 I'm talking strictly off the top of my head now. I just
17 want to throw out some suggestions, because listen I want to
18 make it perfectly clear that as a consumer representative
19 and having been through the worst possible experience with a
20 food safety disaster I don't want anyone in this room to
21 think we don't want this to succeed and be really very, very
22 positive.

23 I just want to kind of editorialize this a second
24 and just say hey listen, we're here to work with and not
25 against, but what if between now and October, I'm just going

1 to try and throw this out, we were to take a look at many
2 plant manufacturers and the producers and the processors in
3 here have HACCCP systems already in place, that we put in
4 some sort of a little very pilot type of program between now
5 and October just to get a feel for how things are operating.

6 What kind of a problem do we have. We might find
7 out that there is no problem. The numbers might be even a
8 lot better than we think and just kind of then be able to
9 take that in and get some reassurance between now and
10 October between now and the implementation date of January,
11 1998 and that's very rough, very raw here, but I'm trying to
12 give suggestions so that we're not so scared of the
13 information.

14 Perhaps the information is going to come out to be
15 a heck of a lot better than everyone in this room seems to
16 feel.

17 MR. BILLY: Bob?

18 MR. HIBBERT: I'm interested in getting a better
19 understanding of the extent to which the decisions in this
20 area might reflect broad changes in overall Agency policy.

21 As I understand, the Internet issues aside, this
22 is driven initially by the Agency's decision to disseminate
23 the data, first of all, to the plant.

24 It seems to me the logic behind that is look while
25 these data could in some circumstances support an

1 enforcement action, we think it's better to get you this
2 information now because you may be able to fix the process
3 and eliminate the problem.

4 Now, it seems to me that that logic applies
5 equally in other situations, but it's never been the
6 Agency's policy to share that information.

7 I have had experiences in enforcement situations
8 with compliance for example where compliance has taken
9 samples, there's some indication that there's a problem, we
10 have gone to compliance and said, look. Give us this
11 information.

12 We'll look into this. We don't see a problem. If
13 there's a problem we want to fix it. If you get us the
14 information it will help us and the Agency policy has been
15 no, we're not going to share that information, because it
16 might somehow hurt us in an enforcement action a year or two
17 down the road.

18 We said fine. If you want to enforce something
19 that's a year or two down the road, give it to us, but the
20 bigger problem now is why don't you give us the information
21 so that we can fix the process and the Agency policy has
22 been no.

23 It seems to me that given the same logic we're
24 hearing today that philosophy ought to apply to other Agency
25 laboratory sampling activities.

1 MR. BILLY: Let me say something about that in
2 terms of the contrast. You put your finger on what is in
3 fact a very large transition that's under way.

4 In the context of HACCCP, HACCCP by its nature,
5 its design, is the system where industry develops a plan and
6 follows that plan and then when something goes wrong part of
7 HACCCP is correction.

8 There's a process that occurs there and so we want
9 to remain true to what that's about and in that context then
10 we have to deal with the information, the results that we're
11 generating in a context where the firms are allowed that
12 opportunity to make HACCCP work.

13 So I'm worried about casting some of this data as
14 compliance to the extent that I think I understand what
15 you're saying, because what I'm most interested in is having
16 effective HACCCP programs working all the time in these
17 plants.

18 That's what we want to have. We want the right
19 incentives so that if something isn't working right the
20 company recognizes that and makes adjustments as appropriate
21 and have that work and not have what I will call a more
22 traditional context where we're focusing on the product
23 coming out of a plant for example and whether that product
24 meets a particular standard.

25 This is about process control and so I think

1 that's requiring all of us to make this kind of adjustment
2 to how to manage this effectively so that we do accomplish
3 what the objective is. We're all working at that trying to
4 make that work.

5 MR. HIBBERT: I think the only point I'm trying to
6 make is given that philosophy that outside the salmonella
7 program there are other Agency practices which are
8 inconsistent with that philosophy and might make me
9 candidate for some reexamination in view of that philosophy.

10 MR. BILLY: Caroline?

11 MS. DeWAAL: I want to start with helping the
12 Agency define how to deliver that data, given that that was
13 one of the questions on the table.

14 We would clearly like data delivered in a format
15 that clearly gives us the plant name and location and
16 product line as well as the sample results.

17 We would also like a comparison to whatever is the
18 applicable standard. Government standard that's being used
19 right on the sample results so people don't have to go
20 searching through and trying to figure out whether this
21 company do they meet the standard, do they not meet the
22 standard, are they way off, are they close. I mean just
23 give them the data so they can evaluate it clearly.

24 Also, I think the point has been made here that
25 people really should look at data over time. You're

1 providing one set of data, but that if there are multiple
2 sets of data available on the same plant or the same plant
3 product line, that that should be readily accessible once
4 you get one sample set.

5 You should clearly indicate whether there are
6 additional sample sets available and people should be
7 instructed to look at the results over time and to
8 definitely get the most recent set of sampling data that's
9 available.

10 I think this data once it is available will be
11 tremendously valuable. Both the data on the good plants and
12 the bad plants. I think it would be valuable to
13 researchers.

14 I think it will be valuable to a lot of people who
15 evaluate how to make products safer and I think we want all
16 of the data, not as Dennis has suggested, you know maybe we
17 should just publish some of the data. Let's just get all
18 the data out.

19 I do think there are issues around consumers
20 understanding what the data means. I recall a situation
21 where a major meat packing plant started sending me their
22 newsletter and in their newsletter they published E. coli
23 test results.

24 They just published it. They did samples on their
25 plants and they published that in their little newsletter

1 and I started collecting this and at one point I brought it
2 over to the department and said, hey, you know well this
3 company publishes their results and I alerted the company I
4 was doing it.

5 It's not the person I was dealing with, but
6 someone else got concerned that I misunderstood the data as
7 being E. coli 015787 data when it was generic E. coli data.
8 Well, I didn't misunderstand it and their scientists knew
9 that.

10 I mean we need to be very, very clear that we are
11 looking at salmonella data, but that salmonella may be at
12 extremely low levels and it may not be at levels that are
13 enough at the plant to make people sick.

14 I mean we can explain that to consumers and I
15 think they can understand that, but nonetheless, salmonella
16 is a human pathogen and at some point that salmonella at a
17 very low level could be sufficient after certain time and
18 temperature abuse to make someone sick.

19 So I think that kind of information can be
20 explained very easily in a single document that contains the
21 sample result.

22 As a document, as a screen on your computer, as a
23 single data set, I think this stuff is easy to deliver to
24 consumers through FOIA or to researchers or whoever needs it
25 and in a way that's capable of being understood.

1 MR. BILLY: Joe?

2 MR. POCIUS: Joe Pocius of Montclair Foods. Just
3 as a matter of comment to what was just said. One issue of
4 providing this information boiled down and distilled so that
5 it's easily understood.

6 Currently when an FOIA request is made the raw
7 data that's accumulated by the Agency provide a PDR.
8 Request PDR from time X to time Y you get copies of the
9 PDR's.

10 The recipient it's their responsibility to do with
11 that what they will. To collate it. Treat it
12 statistically. Do whatever. Draw what conclusions they
13 may.

14 I would highly disagree with the Agency putting
15 this in such a user friendly manner. You say that you are
16 bound by the rule to provide the information. That's one
17 thing.

18 But to analyze it and provide it so that it's user
19 friendly for any particular user, I think is just beyond the
20 scope of your duties or requirements frankly.

21 In terms of how to provide this again, just to
22 repeat myself, I would recommend that you consider using
23 E-mail instead of the Internet. E-mail is controllable.

24 You're not going to have hacker break in. It's
25 going right to whomever the requestor is. It's not a list

1 serve that can be played with.

2 It may end up on the Internet anyway, but you
3 can't do anything about that. Anything that's put up on the
4 Internet through other means and other ways is disputable.

5 MR. BILLY: Okay. Other comments? Other
6 suggestions? One thought that's occurred to me in terms of
7 the context again as we've been talking here this morning is
8 whether language to characterize the data might best be
9 framed in a HACCCP context.

10 Maybe that's a way of making a distinction about
11 this that's important and putting it in a context that is in
12 fact what it's about.

13 All of us have this tendency to drop back into
14 data that sounds like we keep saying numbers and data and so
15 forth rather than what it actually is in the context and
16 qualifications around it in terms of verification of a
17 HACCCP system in terms of process control.

18 Just another thought about providing the best
19 possible context, which is one of the things we're
20 interested in.

21 MR. STAFKO: Can I follow up on that, Tom? I'm
22 just kind of following up on Bob's comment before about the
23 distinction between the purposes for which we are gathering
24 this data which is largely as you described them and the
25 kind of data that is collected expressly for the purpose of

1 developing a case against a suspected violator of a law are
2 really very different kinds of data collection activities.

3 In those situations where data is gathered with
4 the intent of building such a record, that is the kind of
5 information that is often not disclosed under that exemption
6 seven I spoke of.

7 MS. DeWAAL: I'm confused. Caroline Smith DeWaal
8 again. Does that mean that at some point you would stop
9 disclosing this data if you were beginning to consider
10 enforcement action on a company?

11 MR. STAFKO: If we went into a plant where we're
12 taking samples for any potential violation of the law,
13 bringing in dead and diseased animals or using marketing
14 devices after hours or something like that.

15 In the case of gross insanitation we might take
16 samples of pathogens that might be running rampant around
17 those kinds of things, but I already established a suspicion
18 the plant is violating the law and is producing adulterated
19 product.

20 In those cases, the information we gather with a
21 view towards imposing some kind of a sanction is information
22 we would want to keep protected until we have our case
23 finalized.

24 MR. BILLY: That's an important contrast there
25 under the HACCCP rule to the provisions regarding sample set

1 that fails to meet the performance standard for that product
2 class or so-called strike one.

3 The way that is constructed is to provide an
4 opportunity for the system to be corrected. For the
5 situation to be corrected. It's about making it work.

6 That's why in fact then there's another
7 opportunity and it's about process control and making
8 process control work.

9 So I see a real distinction between that and what
10 Ralph just talked about. There's a whole different mind
11 set. A whole different situation involved in those two
12 situations.

13 Dennis?

14 MR. JOHNSON: I think Bob will carry it on. I
15 will let him.

16 MR. HIBBERT: I will try first. This is Bob
17 Hibbert. I guess I see a little bit less of a distinction
18 than you might.

19 First of all I'm sure Ralph mis-spoke when he said
20 that when you're investigating someone you've already
21 determined that they've broken the law. There's a
22 possibility.

23 MR. STAFKO: If I said that then I clearly
24 mis-spoke.

25 MR. HIBBERT: You have a situation where there's a

1 problem. You're looking into it. It may be a process
2 control problem. It may be a potential violation of law.
3 It may be something else. There's a whole range of
4 activities.

5 What makes it a little more similar on the other
6 side is that the Agency, as far as I know, while it has
7 other implications, is not willing to abandon the
8 enforcement consequence.

9 While it might not be your lead item, there are
10 enforcement consequences to this activity. So I guess I
11 would say that in this hypothetical enforcement situation
12 you can't assume on the front end that it's a cut and dried
13 violation of the law nor on the salmonella situation can you
14 assume, given your regulation, that it is not enforcement
15 related.

16 MR. BILLY: Do you see any difference between that
17 and the PDR in that sense?

18 MR. HIBBERT: I'm not sure I understand the
19 question.

20 MR. BILLY: Well, what may eventually happen with
21 regard to a PDR, although in the context of how they're made
22 available.

23 MR. HIBBERT: No. I mean I guess going back to my
24 earlier point, I think probably what I want to try to
25 salvage out of this discussion if nothing else is a

1 recognition that in many instances your compliance activity
2 is foregoing the opportunity to get information to a plant
3 which might help that plant fix a process because it is so
4 dedicated at the front end of the process to hanging onto
5 sort of maximum protection from enforcement action.

6 That is the Agency's longstanding policy and I
7 believe that it is inconsistent with much of what we've
8 heard this morning.

9 MR. BILLY: Ralph?

10 MR. STAFKO: Okay.

11 MR. BILLY: I understand your point. I think most
12 of us do. I would like to move on because I want to more
13 broadly explore any ideas that anyone has in terms of how we
14 can make this work effectively for everyone.

15 MR. DOPP: This is Mark Dopp, Hogan and Hartson.
16 I wanted to raise largely what Bob said because he wasn't in
17 the room when Ralph was answering the question.

18 MR. BILLY: Okay.

19 MR. DOPP: I'm sure that you would recognize that
20 the application of the exemption from disclosure under FOIA
21 is discretionary so that the policies that you may have, I
22 mean the application of the exemptions that you regularly
23 and I've been in the same circumstances, Bob and Dennis and
24 others, you know the application of that policy that that
25 information will not be disclosed is not something that you

1 are required to do.

2 I mean the application of the exemption is
3 discretionary with the Agency and my suggestion is
4 consistent with Bob's that given what you said and the fact
5 that the disclosure is not necessarily or prevention of
6 disclosure is not necessarily required that you revisit that
7 issue in that policy with respect to the type of
8 circumstance that Bob was describing.

9 We've got a problem. Tell us what it is. No, we
10 won't give you the test results. I understand where you're
11 coming from, but let's make sure we're consistent.

12 MR. BILLY: Other ideas? Thoughts? Ken?

13 MR. MAY: Ken May of the National Boiler Council.
14 We are talking about the Pathogen Reduction Act and I think
15 it would be certainly a thing to do to publish on a
16 continuous basis what sort of percentage industry wide
17 you're getting of positives and also publish industry wide
18 the percentage of sets that fail or passing in an industry,
19 because hopefully we are all going to see a reduction over
20 time as we all do everything we all know how to do or learn
21 how to do to do a better job.

22 I think that might be a good thing to do.

23 MR. BILLY: Okay. Jim?

24 MR. HODGES: Jim Hodges, American Meat Institute.
25 Again, I agree with Ken. It seems to me that there is an

1 implication on the table here that we want to rank order
2 plants from good to bad, based upon salmonella test results
3 and ultimately publish the list so that the good plants get
4 better through commercial trade practices, media publicity
5 or pressure in the foreign markets.

6 It certainly seems to me that that's outside the
7 scope of the Agency when in fact all of these plants may be
8 fully in compliance and complying with the law.

9 I don't think we can get away regardless of where
10 you're trying to take us. I don't think we can get away
11 from the fact that there is an enforcement provision set in
12 the salmonella rules and it would certainly seem to me
13 inappropriate for the Agency if you're proceeding for
14 withdrawal actions on a plant just as you would today for
15 any other kinds of violations. Withdrawal actions or
16 suspensions.

17 That that's probably information that in the
18 public arena has some useful meaning and understanding, even
19 though the plants that are on that list is clearly not
20 wanting that data published, but I think from at least my
21 point of view that's the cut off point.

22 Is are you complying or are you not complying with
23 this rule, because the plants themselves are going to get
24 the data that can make a determination of whether or not
25 they're going to improve or not improve.

1 If your objective is to have process control in
2 the plants, it's only the plant that can do that and they're
3 going to get that data and the real bottom line question is
4 what other use does the Agency plan or see that this
5 information is going to help move the industry forward.

6 MS. GLAVIN: So what is your proposal on how to
7 deal with the data then? I'm not sure I'm following what
8 you're --

9 MR. HODGES: The proposal is to publish whether
10 you're in compliance or not compliant.

11 MR. BILLY: Nancy?

12 MS. DONLEY: Nancy Donley, Safe Tables Our
13 Priority. If an airline has a plane that goes down in a
14 tragic air accident, it doesn't necessarily mean that that
15 particular airline is going to go out of business if it has
16 a good track record.

17 The public has the opportunity then though to know
18 that this has indeed occurred. Many have had good
19 experiences and they choose to remain using that airline.

20 An airline that has consistent problems and has
21 many disasters will go out of business and should go out of
22 business. I don't see where it's much different with what
23 we're doing here.

24 If companies have good trends and there happens to
25 be something, accidents do happen, I think the public is

1 used to dealing with these types of situations in other
2 industries and I think they are astute enough and savvy
3 enough, but they have the right to know and base their
4 decisions accordingly.

5 MR. BILLY: Ellis?

6 MR. BRANTON: Ellis Branton with Tyson Foods.
7 Picking back up on what Jim Hodges and others had said and
8 Tom you asked the question earlier about the concern of
9 putting this information out and I know all the enforcement
10 and performance standards and so on we have concern about
11 that, but one thing and I want to emphasize and I speak from
12 some experience from international microbial specifications
13 I can tell you with a high degree of certainty that numbers,
14 although the base data is qualitative it is quantitative
15 from the standpoint we're going to come up with numbers in a
16 number of plants and all plants that are well within
17 compliance, meeting performance standards, there is a
18 qualitative measurement.

19 Going back to your plant X and Y, you have five
20 instances out of 50 versus eight. My real concern is that
21 those numbers and again I can tell you with a high degree of
22 certainty will be used by the international community to
23 make judgments and it's going to put a lot of companies at a
24 commercial disadvantage.

25 I heard that term and that is the reality of the

1 situation. There's no difference between those two plants
2 based upon the five out of 50 and the eight out of 50, but
3 that judgment will be made.

4 MR. BILLY: Okay. I would like to thank everyone
5 for coming to participate. I think it's been a good
6 discussion and some important new information has been made
7 available to us that will help us in terms of sorting out
8 this issue.

9 Again, thank you very much for participating this
10 morning.

11 (Whereupon, at 11:14 a.m., the hearing was
12 adjourned.)

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