

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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PRE-HARVEST FOOD SAFETY
BREAKOUT SESSION

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FRIDAY
SEPTEMBER 23, 2011

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The Advisory Committee met in the Georgetown Room in the Savoy Suites, 2505 Wisconsin Avenue, N.W., Washington, D.C., at 8:00 a.m., Robert Reinhard, Chair, presiding.

MEMBERS PRESENT:

- ROBERT G. REINHARD, Chair, Sara Lee Corporation
- NANCY J. DONLEY, STOP Foodborne Illness
- VENERANDA GAPUD, Fiedale Farms
- HEIDI KASSENBERG, Minnesota Department of Agriculture
- CRAIG E. SHULTZ, Pennsylvania Department of Agriculture
- STANLEY A. STROMBERG, Oklahoma Department of Agriculture, Food, and Forestry
- LEONARD W. WINCHESTER, Public Health - Seattle & King County

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ALSO PRESENT:

JOSHUA HAYES
CRAIG HENRY
JOHN LINVILLE
LEO O'DRUDY
DANAH VETTER

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1 P-R-O-C-E-E-D-I-N-G-S

2 8:00 a.m.

3 CHAIR REINHARD: We have at least a
4 partial group, here.

5 So, what we can do real quick is
6 get through the recommendations, take a look
7 at where we are.

8 We're at number three. I'll make
9 sure no one has any comments about the
10 recommendations. I don't know when the person
11 with the computer is going to be here.

12 So, hopefully, we'll just work off
13 of these, and I can line up -- I'm talking
14 about the one that goes up there, and we'll
15 work our way through this.

16 So, does anybody have any concerns
17 about the first two we put together yesterday?
18 Go ahead.

19 DR. VETTER: I am not, you know, an
20 official member of the committee. So, like
21 Nancy, I try and bite my tongue, some.

22 But I feel like that the

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1 recommendations are full of promise and good
2 intentions, but I just don't feel like they're
3 very realistic.

4 I also think that the intent of
5 this meeting was to hopefully, come up with
6 some things that FSIS either could do for
7 industry, or that we could make
8 recommendations to industry, because those
9 things can be done right now, I believe, to
10 some extent.

11 So, I just feel like, for example -
12 - I wish we had them up there, but I think
13 that testing and then making a disposition is
14 just -- I just don't think that that's
15 something that is realistic.

16 Salmonella is not an adulterant.
17 It's not, and it's not even an adulterant if
18 it has the same PFGE pattern as an illness
19 outbreak.

20 We have to actually show that it is
21 making people sick. That is our current
22 position and policy, and to -- it just seems

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1 like what that is saying is, it's starting to
2 declare, so to speak, adulterants, and say it
3 can't go into commerce.

4 I just don't think that that's a
5 realistic position to take, right now, and I
6 think that if you really want to put something
7 forward that's going to be able to be adopted,
8 it needs to be more realistic, and I do see
9 parts of those recommendations that could be
10 useful.

11 For example, getting data about
12 which Salmonellas affect which classes and
13 species and those types of things, I can see
14 that being very helpful to industry and FSIS,
15 when we talk about pre-harvest, in particular,
16 and also, in-plant Salmonella, because that
17 will help big guys and little guys, when
18 they're doing their food safety hazards, to
19 more realistically address things that could
20 potentially become food safety hazards and
21 make people ill and sick, or adulterant, so to
22 speak.

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1 So, I do see parts of it, that I
2 think are useful and good. I'm just not sure
3 that all of it is very realistic. That's all.

4 CHAIR REINHARD: Thank you.
5 Others? Anybody?

6 So, well, let's go ahead and talk
7 about number three, and it's consider
8 antemortem pre-harvest sampling, when, where
9 and how to determine the presence of select
10 Salmonella strains.

11 Grade of framework, guidance, rules
12 for the disposition of animals found positive,
13 which you just said, you thought wasn't a good
14 approach, and identify those identified in
15 Part 1.

16 So, what about the first sentence.
17 Are we okay, with the first sentence,
18 consider antemortem pre-harvest sampling,
19 when, where and how to determine presence of
20 select Salmonella strains.

21 MR. WINCHESTER: I feel like we've
22 already stated that, though, in the first

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1 sentence, almost in a sense that, you know,
2 we're saying if we're going to go with -- if
3 we follow with what we've already said, here.

4 If the Agency, you know, in the
5 very first part of it, 'to collaborate,' and
6 then to come up with recommendation -- you
7 know, that they are suppose to do, you know,
8 some kind of baseline study, sampling
9 information, I think we've already said that,
10 and I felt that number three, basically, is
11 almost repeating what is part of one, and I
12 just don't --

13 As I went through this more and I
14 read it over again, it seemed like we just --
15 we're -- each of these numbers are just more
16 details of what we're essentially saying in
17 one.

18 If we just took one and two -- you
19 know, actually, part of two, and incorporate
20 that into one, we're basically just making a
21 general overall statement about what we'd
22 recommend doing with this particular position,

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1 and I almost think there is a lot of this that
2 is just, you know, a little tie into add-on.

3 So, it's just -- and I kind of felt
4 bad, I wrote -- reread the question and was
5 thinking, "Well, we didn't really go and
6 directly look at the questions that," -- you
7 know, we basically said, "This isn't kind of
8 going to work." You know, we don't see how
9 this would move forward.

10 So, we had a new idea, new
11 approach, and I think if we want to go that
12 way, maybe we just have a statement, you know,
13 that -- based on the questions that were
14 brought forward to us, we don't know that
15 that's a recommendation or a best approach, or
16 we don't know how that would work, but we feel
17 that, you know, this all in one and two kind
18 of statement would be a way of moving forward,
19 a direction, "Hey, this is a way to
20 potentially bring people together," which is
21 kind of what we said initially.

22 You need to bring a bunch of people

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1 together, to review this issue, that are the
2 stakeholders involved with it.

3 So, I just feel that that part is
4 not there.

5 CHAIR REINHARD: All right, and I
6 agree, and I do want to go back and reread the
7 questions, after we get done with this, and
8 make sure we're -- we'll try to answer them,
9 if we can, and this is our alternative
10 approach, to really, question three, right?

11 MS. GAPUD: Yes, what he said, I
12 don't agree that three is going completely out
13 there, because I think the second sentence
14 will create framework, guidance, rules for the
15 disposition of animals found positive for the
16 strains.

17 I think that has to be done,
18 because it is realistic. If we are talking
19 about something that, hey, if there is some
20 issue with this Salmonella, in talking about,
21 before it enters the establishment, we have to
22 really realistically come up with something,

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1 on what we want to do with those strains of
2 Salmonella and the product, before it comes,
3 you know, but more like Craig was talking,
4 yesterday.

5 CHAIR REINHARD: I just -- I think
6 right now, it's not very practical to come up
7 with that, and there isn't an alternative
8 approach for industry.

9 MS. GAPUD: Yes, but that's very
10 realistic thing. If they're talking all about
11 this -- you know, Salmonella issue.

12 What are we going to do with the
13 product that has some possible Salmonella,
14 because it's all over the place, too.

15 DR. VETTER: I mean, I don't think
16 at this point, it's any different than when we
17 test products coming out of the chiller, and
18 they test positive.

19 We don't stop that product from
20 going into commerce, and I just don't see us
21 changing all of that, based -- and that's --
22 this is -- that's changing an entire world,

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1 and we all know how hard it is, just to pass
2 one regulation.

3 And I mean, we currently have
4 Salmonella positives in ground beef and whole
5 turkey, and I know that we're talking about
6 narrowing the scope and trying to name some
7 specific Salmonellas, and I do think that
8 that's probably somewhere in the future, and
9 as things happen more and we get better at
10 tracing outbreaks back, that may be a reality.

11 But the fact of the matter is, if
12 is not a reality or the world that we live in
13 right now.

14 Right now, we currently have
15 Salmonella positive product every day, in
16 plants, and it moves into commerce.

17 So, I think what we need to be -- I
18 think -- like I said, there is some good
19 intent in there, but I think the approach
20 needs to be, what can FSIS do for industries?

21 Is there information that we can
22 share, or gather for industry, and what can

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1 industry themselves do, pre-harvest, which is
2 somewhere -- a realm that we haven't really
3 been into, to be more preventative and pro-
4 active.

5 And I'm glad you mentioned, going
6 back to the questions, because I wanted to
7 throw some stuff out there, specific to things
8 that could be looked at, because I believe
9 that we've kind of really veered off course,
10 with the intent.

11 CHAIR REINHARD: Let's move
12 quickly, because I think we're going to get
13 through it.

14 So, I'm going to let Heidi go, and
15 I'm going to let Stan go. Craig, if you have
16 anything to say about this specific one, I'll
17 let you, and then we'll decide if we're going
18 to adopt as a committee, or just move on from
19 it, so, we can get to the questions. Heidi?

20 DR. KASSENBERG: I think I agree, a
21 little bit with Dr. Klein, but I don't want to
22 -- because I think -- it needs to be a step-

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1 wise process, and I don't know we're there,
2 either.

3 I also am concerned that, like Dr.
4 Stromberg had mentioned -- talked about, that
5 we don't have good guidance about how to
6 control it.

7 What is industry to do, to try to
8 decrease Salmonella in there? So, without
9 those tools, how are we going to start
10 clamping down on the front -- on the back end?

11 So, I think we need to all go, kind
12 of hand-in-hand, and -- but I don't want to,
13 you know, not knowing what the future of this
14 committee is, as far as meeting in the future
15 about perhaps, this issue, I think we need to
16 move towards, you know, the ultimate goal of
17 trying to eliminate it and remove that
18 product, once we know those -- once those
19 variables get into place, and we have answers
20 for those variables, I think that is a
21 reasonable goal. But I agree, we're not
22 there, yet.

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1 CHAIR REINHARD: Okay, Stan?

2 MR. STROMBERG: Yes, the issue I
3 have with this problem number three is that --
4 the thing that -- FSIS doesn't have the
5 regulatory authority to do antemortem testing,
6 and we're making recommendations to FSIS, and
7 we can't recommend something to them that they
8 don't have the authority to do, and I'm --
9 even thought it's -- it may be a good idea,
10 and it would be a good idea for maybe industry
11 to do it, I don't think we can recommend to
12 FSIS, that they do something that they don't
13 have the regulatory authority to do.

14 CHAIR REINHARD: Okay, Nancy?

15 MS. DONLEY: I apologize for being
16 late. I don't know if it's -- you know, I'd
17 like to hear from FSIS, on whether or not that
18 is necessarily true.

19 You know, FSIS's inspection begins
20 with antemortem. They certainly have the
21 right that once, you know, the animals arrive
22 on premises, to do whatever testing.

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1 In fact, they do testing. Maybe
2 not microbial testing, right now, but they
3 certainly inspect the animals.

4 DR. LINVILLE: Okay, I mean, yes,
5 we could do antemortem testing. We could take
6 a test at antemortem, there is no question
7 that we could do that, once it's on the
8 premises.

9 I would, however, say that that's
10 maybe not the only option. I mean, FSIS would
11 not have to be the entity that does the
12 testing.

13 Would it make more sense for
14 industry to do the testing? I mean, that
15 could be an FSIS requirement, if need be, but
16 I'm just throwing that out as an option.

17 Not everything here has to be
18 something that FSIS would have to do. FSIS
19 can still mandate it.

20 CHAIR REINHARD: Okay, so, here is
21 where we are. We're going to decide if the
22 subcommittee wants to adopt number three as

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1 our recommendation.

2 So, are people opposed to number
3 three?

4 Okay, so, we're not going to adopt
5 number three as a recommendation from this
6 subcommittee, because it's divided. It will
7 remain up there for the whole committee to
8 see.

9 MS. DONLEY: Okay.

10 CHAIR REINHARD: And it --

11 MS. DONLEY: We're just -- it won't
12 be put out as a consensus?

13 CHAIR REINHARD: Correct.

14 MS. DONLEY: As is number one and
15 two?

16 CHAIR REINHARD: Correct.

17 MS. DONLEY: Okay.

18 CHAIR REINHARD: All right, moving
19 on to number four.

20 Streamline cooperation among
21 agencies responsible for approving and
22 implementing technologies for pre-harvest.

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1 Heidi?

2 MR. O'DRUDY: Sorry, Mr. Reinhard?

3 CHAIR REINHARD: Yes.

4 MR. O'DRUDY: I missed the final
5 conclusion on recommendation three. Are we
6 skipping it or are we --

7 CHAIR REINHARD: The subcommittee
8 is not going to recommend it as a consensus.

9 MR. O'DRUDY: Okay, thanks.

10 DR. KASSENBERG: I have a comment
11 about four.

12 CHAIR REINHARD: Yes?

13 DR. KASSENBERG: I would say
14 develop and implement metrics to measure
15 cooperation amongst agencies.

16 CHAIR REINHARD: So?

17 DR. KASSENBERG: So, actually, I
18 mean, it's all -- you know, world peace is
19 nice, too, but you know, streamline, unless we
20 have actual measurements in there, I don't
21 know that we're going to get anywhere.

22 CHAIR REINHARD: So, at the end of

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1 that, can we put develop and implement
2 metrics, to measure effectiveness? That's all
3 right.

4 DR. LINVILLE: Yes, I mean, I would
5 kind of like to make one comment on that.

6 I like your world peace comment. I
7 mean, we got a lot of recommendations last
8 year, especially around animal ID, that FSIS
9 really needs to do a bunch of things, and we
10 can work our best towards doing that.

11 But you know, those were things
12 that are completely and totally out of our
13 realm of control.

14 CHAIR REINHARD: I think if you're
15 -- well, okay, that can be your opinion, but
16 truly, if you're going to drive public health,
17 you need to address this, with your sister
18 agencies, and that is your foundation of what
19 you're suppose to do.

20 DR. LINVILLE: Sure, we can work
21 towards that, but if you say streamline
22 cooperation, we can't force anybody else to

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1 cooperate. I mean, that is my point.

2 CHAIR REINHARD: All right.

3 DR. LINVILLE: Not that they're
4 not. I'm just saying, you -- think about how
5 you word your recommendation, I guess.

6 CHAIR REINHARD: Right. Heidi, did
7 you have anything else to say? Anybody have
8 other thoughts about number four?

9 DR. KASSENBERG: If we're going to
10 have number four, it would be just develop and
11 implement metrics, at the beginning of the
12 sentence.

13 (OTR comments)

14 CHAIR REINHARD: Any other thoughts
15 on number four? Stan?

16 MR. STROMBERG: At the very end of
17 the sentence, it should read, "For pre-harvest
18 interventions," not just pre-harvest.

19 DR. LINVILLE: I mean, I just need
20 to ask, how would we measure cooperation?
21 Just give me an idea, how to -- what you mean
22 by that.

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1 DR. KASSENBERG: Well, I think
2 actually, asking them to come together,
3 seeing, you know, are they actually responding
4 to the requests and publishing those?

5 DR. LINVILLE: Okay.

6 DR. KASSENBERG: You know, you made
7 the offer. They didn't or they did.

8 DR. LINVILLE: Okay.

9 DR. KASSENBERG: Yes.

10 DR. LINVILLE: All right.

11 DR. VETTER: I believe further
12 down, there is a statement about putting out a
13 quarterly report on where certain things are
14 in the system.

15 CHAIR REINHARD: So, if we go to
16 number 14, we can show that? Maybe this says
17 what we want to say and we can take the other,
18 out.

19 So, it says, "FSIS has to take the
20 leadership position, evaluating interventions
21 that are currently moving through the
22 regulatory process and on a quarterly basis,

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1 report -- on a quarterly basis, report their
2 movement and what they are doing with their
3 sister agencies, to move them forward." Is
4 that a better statement?

5 MR. STROMBERG: I think so.

6 CHAIR REINHARD: All right, so, if
7 we can put 14 in, for four? Yes, sir?

8 MR. WINCHESTER: I think you just
9 need to make sure to clarify this is like pre-
10 harvest interventions, because I was actually
11 taking four and trying to move it up again
12 with two, trying to consolidate some of these
13 things, because -- but now, I'm actually
14 trying to keep them separate, you know,
15 testing methodologies for rapid
16 identification, and then this is an actually
17 separate area. We're talking about pre-
18 harvest?

19 CHAIR REINHARD: Yes, new
20 technologies and pre-harvest.

21 MR. WINCHESTER: Right, so, I think
22 that you need to make sure that pre-harvest

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1 aspect is added or kept in there.

2 CHAIR REINHARD: All right.

3 MR. WINCHESTER: So, either at the
4 beginning or end.

5 CHAIR REINHARD: Well, leadership
6 position in evaluating, right there, we can
7 put it, right? New technologies in pre-
8 harvest, and then interventions can be in
9 parenthetical, right, and instead of saying
10 their sister agencies, because it's not really
11 that, we should say --

12 (OTR comments)

13 DR. VETTER: I was just going to
14 say, you might want to keep FSIS, take
15 leadership, at the beginning --

16 CHAIR REINHARD: Okay, right.

17 DR. VETTER: -- or it could be FDA.

18 CHAIR REINHARD: Yes.

19 DR. VETTER: See, I guess that is
20 what I kind of have issue with. I don't think
21 they should all be recommendations for FSIS.
22 I think they should be recommendations for

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1 industry and FSIS. That's just my opinion.

2 CHAIR REINHARD: Okay, does the sub
3 -- Heidi?

4 DR. KASSENBERG: I think that
5 having number four through that, too, and if
6 you correlate on -- if you report on a
7 quarterly basis, Dr. Hayes' point, that maybe
8 industry isn't bringing you information or
9 ideas to actually approve, then that will
10 become evident, as well.

11 MR. HAYES: Yes, I think it's
12 really important here to distinguish what type
13 of pre-harvest interventions you're talking
14 about.

15 If you're talking about USDA-
16 regulated products, that is one thing. If
17 you're talking about FDA-regulated products,
18 that would be another.

19 One of the realistic, practical
20 down sides to this proposal, which isn't a bad
21 proposal, if it's kind of a public type of
22 document that's being developed, publically.

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1 However, if it's a proprietary
2 product being brought forward, FDA cannot
3 confirm or deny the existence of any said
4 product, when it's being evaluated, or if it's
5 being evaluated.

6 So, you may get a lot of --

7 PARTICIPANT: No comment.

8 MR. HAYES: -- no comment, right.

9 So, I think the recommendation that we have is
10 whether or not USDA is bound by similar
11 constraints.

12 DR. LINVILLE: I honestly don't
13 know. That's APHIS.

14 MR. HAYES: Okay, and if not, it
15 might do well to parse the two, and it may be
16 worthwhile to explore, you know, possibly
17 doing kind of a public type of -- you know, we
18 have these things called public master files,
19 where information can be put forward in a
20 portfolio that could be used for approval
21 purposes.

22 That sort of information can be

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1 made public, but in general, the development
2 process is -- you know, we have to respect
3 the, you know, proprietary nature of the
4 development plans.

5 DR. VETTER: I just have a
6 question, because it seems like if things are
7 proprietary, is that information shared among
8 agencies, or it's strictly -- because if FSIS
9 doesn't even have access to that information
10 and can't be granted access, how are they
11 going to take the leadership role?

12 MR. HAYES: That's a good question,
13 and I'm not sure exactly what the nature of
14 our memorandum of understanding -- if we have
15 a memorandum of understanding with the USDA,
16 to actually share proprietary information, or
17 if instead, it's restricted to subject areas,
18 where we may develop broadly, you know, kind
19 of success strategies or a pathway for a
20 product to be approved, and whether that would
21 extend all the way to where is a particular
22 product in the development pipeline?

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1 So, you know, I could go back and,
2 you know, find out that information and see
3 what we could do, there.

4 DR. VETTER: So, I would just
5 suggest that maybe you say FSIS take a
6 leadership role and since FSIS has nothing to
7 do with evaluating the new technologies,
8 that's going to be APHIS or that's going to be
9 FDA?

10 Maybe it could be something more
11 realistic that FSIS could do, which is find
12 out information about whether this can be
13 done, and if it can, possibly working to get
14 it done with FDA and APHIS, because those are
15 really going to be the two agencies that have
16 that information, access to it and let us know
17 whether or not FSIS can do that.

18 CHAIR REINHARD: Craig?

19 DR. SHULTZ: That sentence is --
20 you've got a subject predicate issue there,
21 with FSIS taking a leadership role.

22 They're currently moving to a

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1 regulatory process, and on a quarterly basis,
2 report their movement. That doesn't refer
3 back to the subject.

4 MR. O'DRUDY: But there is a -- it
5 refers to technologies.

6 DR. SHULTZ: Yes, yes, but it -- as
7 you read it --

8 MR. O'DRUDY: Oh, okay.

9 DR. SHULTZ: -- it seems to refer
10 to FSIS, rather than technology -- or the
11 technologies, rather than FSIS. There you go,
12 that helps.

13 CHAIR REINHARD: Okay, so, is
14 everybody okay with the way it reads, now?
15 All right, fix it, Dr. Henry.

16 Okay, is it the role of the
17 subcommittee to adopt this as a
18 recommendation? Is anyone opposed?

19 All right, I think we could go
20 ahead and bold it.

21 Oh, Nancy is over there. I thought
22 she stepped out. I couldn't see you.

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1 MS. DONLEY: I'm here.

2 CHAIR REINHARD: All right, got
3 you.

4 MS. DONLEY: Sleeping, but I'm
5 here.

6 CHAIR REINHARD: All right.

7 MR. HAYES: Sorry, I hate to go
8 back.

9 CHAIR REINHARD: Yes.

10 MR. HAYES: But the evaluating part
11 that I just read could be a point of
12 contention, there, because we have the
13 regulatory requirements that are established
14 for who evaluates what, and here, you're kind
15 of saying, "Hey," you could read this as, you
16 know, "We want FSIS to regulate."

17 PARTICIPANT: How about monitoring?

18 DR. LINVILLE: Could you say
19 tracking?

20 PARTICIPANT: Yes, tracking.

21 DR. LINVILLE: There you go.

22 MR. HAYES: Fine.

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1 CHAIR REINHARD: Okay, number five,
2 FSIS calling all producing establishments to
3 re-assess they have some plans for Salmonella
4 control. Yes, sir?

5 MR. WINCHESTER: I feel that we
6 just need to put a pre-statement to this,
7 because what are we asking them to do?

8 We don't know, it's a -- so, it's
9 more like once FSIS has Salmonella strains of
10 concern identified, then we could have them
11 call. I just -- to call on it now, we -- what
12 do we have them look for?

13 I mean, we can have them evaluate
14 what they have, but I just feel there needs to
15 be a little -- a beginning sentence to that.

16 CHAIR REINHARD: Dr. Vetter?

17 DR. VETTER: I mean, it could be
18 something similar to what was done, and I know
19 with E. Coli we had a specific sero-type or --
20 you know, sugar toxin producing.

21 But what I'm getting at is that we
22 found out later, you know -- we addressed in

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1 2002, and then in 2007, we realized that there
2 were some holes, that people were not looking
3 at.

4 And so, it could be something
5 similar to that, that establishments go back,
6 and re-assess, based on -- and I think that
7 might be something that would be linked back
8 to when we really answer question number one,
9 about food safety hazards that could
10 specifically be considered at pre-harvest.

11 DR. LINVILLE: Typically, when we
12 do something like that, and I think it's a
13 perfectly good recommendation.

14 Typically, when we do that, it's in
15 light of new information. We -- and I think
16 if you qualified that with that, in light of
17 the recent recalls or something like that,
18 that it would make it clearer.

19 CHAIR REINHARD: Okay, I think we
20 can take out 'as was done for E. Coli
21 0157:H7', and then the second -- number six,
22 that I recommended, which really goes with

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1 this, we ought to just take out, and let it
2 happen naturally, in the first part. Well,
3 but that's okay.

4 DR. HENRY: Question, should we --
5 I don't want to use this.

6 You know, I asked yesterday,
7 whether we may have reason to -- and John, you
8 might comment on this.

9 But you know, try and be specific.

10 I mean, I don't know of a plant that's not
11 considered Salmonella controlled, no matter
12 which way we go. I mean, they're trying to
13 deal with it.

14 We are only being very specific
15 here. Why are we not being specific in this
16 line, and looking at the, you know, multi-drug
17 resistant, and I think we've got to specify.

18 We put strains on -- or we put
19 markers up above, you know, if we drill down,
20 because if they -- if we do this, I think it
21 immediately requires or expects, we would -- I
22 would expect guidance from FSIS, on why it's

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1 reasonably likely to occur.

2 What does the baseline study say?
3 What are the recommendations to fix this, and
4 I think it ties back to the -- the evaluation
5 of the technologies, and thinking back on that
6 one line, not to mess it up, but I -- you
7 know, evaluating is one thing.

8 I think if they take leading role
9 in approval of new technologies, now, we're
10 supporting this part of that, going back
11 through the re-assessment of the HACCP plan,
12 because it's not doing any good to say, yes,
13 I understand it's there, but if I don't have
14 the new technology that's proving it works,
15 how do we move the ball forward? Just two
16 minor points.

17 DR. LINVILLE: And your point on
18 approval, I mean, taking into account that we
19 can only approve new technologies in an in-
20 plant application that have already been
21 approved somewhere else.

22 DR. HENRY: I understand, but I

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1 mean, we had challenges in both areas, and
2 I'll tell you --

3 DR. LINVILLE: Which goes back to
4 the validation issue.

5 DR. HENRY: Right, I mean, and I
6 have -- and I have not had time to check on
7 it, but I know that APHIS/CDM, we had -- there
8 were numerous vaccines in pro-biotics and
9 never got through the approval process.

10 DR. LINVILLE: Yes.

11 DR. HENRY: And they got shot down,
12 and they're critical, and especially if we're
13 -- if we're relating back to Salmonella
14 Enteritidis.

15 So, I think the same situation
16 here, if we're trying to fix a problem in the
17 plant, the port of immune-ability is at the
18 plant, and we're going to look at the HACCP
19 plan for the plant, I think we need to be
20 specific, you know, because we need very
21 specific technologies to fix this at large.
22 If not, we're just back to the 10 percent

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1 indicator that we're using on routine safety.

2 CHAIR REINHARD: I think for this,
3 though, you can let the plants figure out how
4 they're going to re-assess, what Salmonellas
5 they're going to consider.

6 I would rather it be broad --

7 DR. HENRY: Okay.

8 CHAIR REINHARD: -- and let the
9 plant address those different things.

10 I do want to make a change, FSIS
11 calling on all, it should -- maybe we should
12 say FSIS require.

13 DR. HENRY: Yes, okay, so, I mean,
14 let's review the others.

15 So, okay, so, the only place we're
16 really bringing this ABR in, is line two of
17 item one, above?

18 CHAIR REINHARD: Correct.

19 DR. LINVILLE: Well, and we don't
20 have to restrict ourselves to ABR, here, by
21 any means.

22 DR. HENRY: Okay, I was just kind

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1 of relating back to the focus on the
2 questions.

3 I mean, it seems like most all of
4 this is already --

5 DR. LINVILLE: It was -- yes, it's
6 various sero-types and/or antibiotic resistant
7 strains, yes. I mean, it's -- it really is
8 those particular sub-types of public health
9 concern, whatever that may be.

10 CHAIR REINHARD: Dr. Shultz?

11 DR. SHULTZ: Dr. Linville, correct
12 me if I'm wrong here, but with repeated
13 Salmonella set failures, now, doesn't FSIS
14 already have the authority to do food safety
15 assessments?

16 DR. LINVILLE: We do, absolutely.

17 DR. SHULTZ: So, it's already kind
18 of there.

19 DR. LINVILLE: Right, but I mean, I
20 think the -- the thrust of this
21 recommendation, correct me if I'm wrong, is
22 really, that the establishments have to re-

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1 assess.

2 DR. SHULTZ: Okay.

3 DR. LINVILLE: And then we would
4 have the option of going in and doing an FSA,
5 normally -- we have -- right now, we have a
6 directive that outlines when we would normally
7 do the FSA --

8 DR. SHULTZ: Okay.

9 DR. LINVILLE: We can do an FSA
10 whenever it's necessary to do it. This would
11 kind of just --

12 DR. SHULTZ: Okay.

13 DR. LINVILLE: -- bring that to the
14 forefront.

15 DR. SHULTZ: Thank you.

16 CHAIR REINHARD: Any other comments
17 on this one? Is the committee in favor of
18 adopting this, are a recommendation, Nancy?

19 MS. DONLEY: Just a quick question.
20 Did you want to -- when you have -- you have
21 require all producing establishments.

22 CHAIR REINHARD: It could just be

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1 all establishments, right?

2 DR. SHULTZ: Slaughter
3 establishments?

4 DR. LINVILLE: I wouldn't restrict
5 it.

6 MS. DONLEY: I would agree. I'd
7 like to broaden it, if we could.

8 CHAIR REINHARD: Okay, all
9 establishments is fine. Anybody have a
10 concern about it?

11 So, without this, then we'll go
12 ahead and make this a recommendation to the
13 committee?

14 All right, moving on to the next
15 one. The committee did not make that as a
16 recommendation to the subcommittee. You know,
17 it's a descending opinion, or whatever.

18 FSIS develop best practice and
19 compliance guard -- guidelines for pre-harvest
20 producers.

21 Now, just on this, they already
22 have it for O157:H7. They drafted. There

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1 were a lot of comments back, about it.

2 DR. LINVILLE: Well, and we
3 actually do have compliance guidelines.

4 CHAIR REINHARD: For Salmonella in
5 the producing facility, and it does reference
6 some pre-harvest.

7 DR. LINVILLE: And it does
8 reference some of the pre-harvest.

9 So, are you saying that we need to
10 expand on those, that they're not sufficient?

11 I mean, I'm just asking, for clarification on
12 that.

13 MR. STROMBERG: I worked on this a
14 little bit more last night and reworded it,
15 maybe it might be a little bit clearer.

16 But what I came up with, instead of
17 what's up there, I have FSIS should hold
18 public meetings with stakeholders, including
19 APHIS, ARS, FDA, CVN, and develop pre-harvest
20 best practices and compliance guidelines for
21 livestock producers.

22 FSIS should also incorporate the

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1 information about the effectiveness of the
2 interventions they have investigated, and that
3 -- I combined some of the other ones, that we
4 had to make it into --

5 CHAIR REINHARD: Do you want to
6 give them a copy of that --

7 MR. STROMBERG: Sure.

8 CHAIR REINHARD: -- so, we can type
9 it in? Well, that sounded pretty good, to me.
10 Any comments? Are there any comments from
11 the audience, at this point?

12 All right, I haven't called on them
13 yet.

14 MR. STROMBERG: I have one.

15 CHAIR REINHARD: Yes.

16 MR. GOLTRY: I just -- Scott
17 Goltry, MI. I guess a question that was
18 raised earlier about E. Coli compliance
19 guidelines, and that was kind of tabled, I
20 guess, a little bit, for this last statement.

21 But where are we at on that E. Coli
22 compliance guide? It's a draft. There have

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1 been comments. Is there going to be response
2 to the comments or is there anybody that can
3 respond on that?

4 DR. LINVILLE: I honestly can't
5 tell you, Scott, where the E. Coli one is.

6 As I said yesterday, the Salmonella
7 guide, I -- obviously, if there were comments,
8 they would be -- they're being reviewed, and I
9 would assume that any significant comment that
10 was made, would be taken in account and
11 included in the compliance guideline, before
12 they're final.

13 MR. GOLTRY: I think the other
14 comment is, I think there is maybe reference,
15 maybe reference about a possible public
16 meeting on pre-harvest --

17 DR. LINVILLE: There is --

18 MR. GOLTRY: -- and talk about it.

19 DR. LINVILLE: Yes, there is an
20 upcoming one. We are planning on doing a
21 series of public meetings. The first one will
22 be some time this Fall. I don't have a date

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1 for it, starting with cattle.

2 MR. GOLTRY: Right.

3 DR. LINVILLE: And will be dealing
4 with under -- other -- among other things,
5 O157.

6 MR. GOLTRY: I think that would be
7 a good place to include all these other
8 stakeholder regulatory groups, because truly,
9 it's a -- it's a situation where the packer --
10 you know, the packer receives cattle.

11 We expect these cattle to be in
12 regulatory compliance. I mean, that's really
13 what the FSIS role is, and our role is, is to
14 make sure they're in regulatory requirements
15 with rules that APHIS and FDA and all those
16 people do.

17 So, I think having those people in
18 that room would speed up the process, because
19 if you don't have them there, you're going to
20 say, "Well, let's have another meeting with
21 those other people."

22 CHAIR REINHARD: Thank you, Scott.

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1 Dr. Vetter, I want to ask you, number nine,
2 does this cover you for number -- so, we can
3 take number nine off?

4 DR. VETTER: Yes, I think it's also
5 --

6 CHAIR REINHARD: Microphone, and
7 eight can also be --

8 DR. VETTER: Yes, eight and nine
9 can both go. We've covered those, previously.

10 MR. STROMBERG: And I actually took
11 number 15 and incorporated it into that, too.

12
13 CHAIR REINHARD: So, it would be a
14 different number, now?

15 MR. STROMBERG: Yes, sorry.

16 CHAIR REINHARD: Which was 11, now.

17 MR. STROMBERG: Right.

18 CHAIR REINHARD: Okay, yes?

19 MS. GAPUD: The public meeting --

20 COURT REPORTER: Microphone.

21 MS. GAPUD: The public meeting that
22 we talked about earlier, that was being part

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1 of the recommendation in 2010, isn't it, with
2 what Dr. Linville is talking about?

3 CHAIR REINHARD: It was -- it is
4 similar to the recommendation of 2010, but
5 there is no reason why we can't restate it,
6 and that add-on is, is that the effectiveness
7 of interventions, from what they've found in
8 visiting facilities, should be shared.

9 MS. GAPUD: Okay.

10 DR. LINVILLE: And I think it's
11 fair.

12 CHAIR REINHARD: Okay.

13 DR. LINVILLE: I mean, we are
14 planning on doing the public meeting, but this
15 just helps put the --

16 MS. GAPUD: Yes, so, I think it
17 should enforce the importance of doing
18 something quickly on poultry, also. Yes,
19 thank you.

20 CHAIR REINHARD: Heidi?

21 DR. KASSENBERG: I think we can
22 combine, down the road -- have -- show best

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1 practices, down the road a little bit. You
2 can probably put that up with another
3 recommendation, of FDA implementing SCE rules,
4 and put that together with --

5 CHAIR REINHARD: Put that last
6 statement, correct?

7 DR. KASSENBERG: Yes.

8 CHAIR REINHARD: Okay, does anybody
9 object to that?

10 DR. KASSENBERG: So, that I think,
11 might expand it beyond CVM, because I don't
12 think CVM is the one that's implementing the
13 rules. So, it needs to be more expansive than
14 FDA, maybe just FDA, in general, make is
15 aside.

16 CHAIR REINHARD: And instead of add
17 lessons learned, it would be to include?

18 PARTICIPANT: Yes.

19 CHAIR REINHARD: So, any other
20 comments about this one, number six?

21 DR. SHULTZ: Only, to just throw
22 this out, maybe it's not a good idea.

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1 But the fact that pre-harvest
2 interventions would have to be plant specific
3 and tailored to the HACCP plan and a plant,
4 and would probably vary, depending upon the
5 post-harvest interventions that were present
6 in that facility.

7 So, I don't know if we need to talk
8 about that or not, but I do think that it --
9 it's important that it's -- it's not -- there
10 will just be a list of pre-harvest
11 interventions, that would be applied across
12 the industry, in all situations that will --
13 that FSIS will either recommend or enforce, or
14 regulate.

15 CHAIR REINHARD: Okay.

16 MR. STROMBERG: That wasn't my
17 intent, that we put out a laundry list that
18 they'd have to follow.

19 What I'm really thinking about is,
20 I think larger plants already have a pretty
21 good handle on this, but the smaller plants
22 probably need some help.

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1 They don't have the expertise to
2 think about, what can I do, and it may not be
3 a poultry plant. It may be a hog plant that -
4 - where you have these small plants and they
5 don't have the staff there to do this kind of
6 work for them.

7 Where, if the agency provides them
8 with some guidance and says, "Here is what we
9 think will work. These are some ideas that we
10 think will help you improve the reduction of
11 Salmonella," and that was my -- kind of where
12 I was trying to go with that.

13 DR. LINVILLE: So, can I ask one
14 clarification, as well, then, because you do
15 say livestock producers, and when I think of
16 livestock, I really do think of more red meat.

17 So, you are wanting poultry
18 included in this?

19 MR. STROMBERG: Yes, I forgot about
20 the definition of poultry, it's not livestock.
21 It's -- I thought it had ignored poultry,
22 anyway, but that's --

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1 DR. LINVILLE: You're a good man.

2 CHAIR REINHARD: Very good. Any
3 other comments about this one?

4 Is the subcommittee in favor of
5 adopting this as a recommendation? Is anybody
6 opposed? Okay, bold it.

7 Considering enumeration of
8 Salmonella and set up thresholds.

9 MS. GAPUD: The reason for --

10 COURT REPORTER: Microphone.

11 MS. GAPUD: Yes, because like we
12 talked about yesterday, about qualitative and
13 quantitative, and I think it's also, I think,
14 fair to know, again, looking at when we talk
15 about Salmonella and how -- you know,
16 shouldn't it just be qualitative, whether it's
17 there or not?

18 Also, we have to look at the
19 strains. Again, some are really very, very, I
20 would say potent strains and some may not be.

21 So, I think it's worth looking at
22 that, and setting up some thresholds.

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1 DR. HENRY: And I just need to ask
2 this question, because I've been out, and I
3 apologize to the subcommittee.

4 But when we're -- you know, when
5 we're going to consider it, what do we -- who
6 is considering, what do we do with this? Is
7 this between industry considering, I haven't -
8 - again, unfortunately, I wasn't here
9 yesterday morning to get the overview.

10 But what do we have on the baseline
11 on this? Who has it been shared with? What
12 do the FSIS samples look like?

13 I know industry looks for certain
14 ones. Certainly, the step up for antibiotic
15 resistant ones are there, for multiple
16 reasons. This is not a new occurrence.

17 So, help me out. What are you
18 thinking, there?

19 MS. GAPUD: Well, like what I said,
20 you know, we're just looking at, again, giving
21 priority to those that are really important,
22 or really bad strains, and then if you have

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1 something that is not really -- something that
2 is not on that same category as this is, for
3 example, I think -- you see, the way industry
4 sees it, it's like, well, it's like we are
5 bad, because we have possibly one positive
6 Salmonella, okay.

7 But whether that is really a bad
8 strain or not, it's different story from the
9 industry side.

10 Again, that's why I look at --
11 well, how much Salmonella is really in there,
12 and again, looking at the -- doing evaluation
13 of Salmonella and then bringing in product,
14 you know, there, from the farm, I think it
15 could also help us.

16 It's just a thought, because nobody
17 talk about enumerating Salmonella, always just
18 qualitative, all the time. It's like talking
19 about Listeria, for example.

20 Listeria, of course, we have a
21 specific pathogen, that one, and again, of
22 course, here, it's zero tolerance, but other

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1 places, they have like 100, you know, cells
2 tolerant.

3 So, I am just looking at that, from
4 that perspective, and why we cannot do it also
5 in Salmonella.

6 CHAIR REINHARD: Okay, Nancy?

7 MS. DONLEY: I just want to make a
8 point that particularly with the more variant
9 strains, we don't know -- we don't have good
10 information on, you know, dose -- you know, a
11 threshold, as far as, you know, what makes a
12 person sick.

13 So, you're now looking at, you --
14 we can't establish -- unless we go to a zero
15 tolerance period. That would be the -- then,
16 just bringing that up, that it would have to
17 go to zero tolerance.

18 CHAIR REINHARD: Okay, so --

19 MS. GAPUD: I just put this on the
20 table, you know, because, again, it's just
21 like always qualitative. Let's look at what -
22 - how -- what the numbers of the micro-

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1 organism, also, and looking at the body
2 strains, the very, very body strains.

3 CHAIR REINHARD: So, Dr. Vetter?

4 DR. VETTER: I guess it goes back
5 to what Dr. Henry was saying, like what -- who
6 is doing this, because FSIS is currently doing
7 sero-typing and PFGE patterns.

8 I don't foresee that turning into
9 enumeration, and so, would this be the
10 industry doing this, and what would they do
11 with it?

12 I'm just not really sure where it
13 could be used.

14 CHAIR REINHARD: I'm going to try
15 to answer it, and I really want us to move
16 forward, because I want to get to the
17 questions, in the last hour, so, we can answer
18 the questions.

19 This would be FSIS consider
20 enumeration of Salmonella and set up
21 thresholds.

22 So, if the subcommittee feels like

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1 that's a little bit broad, and it's not
2 directional and it's not of value, then let's
3 just pass on it and move on, which is what it
4 sounds like.

5 But I want to verify that, and then
6 we can just go ahead. We do address sampling
7 and testing methodologies and doing a bunch of
8 work in number two.

9 So, FSIS does enumerate, when they
10 do some things. So, it will be incorporated,
11 probably where it's appropriate, already, and
12 we'll just move on.

13 MR. GOLTRY: Bob, can I?

14 CHAIR REINHARD: Yes.

15 MR. GOLTRY: I guess I have a
16 compromising point, there.

17 Maybe you can consider using
18 quantitative levels, if there is -- and there
19 should be --

20 CHAIR REINHARD: Yes.

21 MR. GOLTRY: -- some risk
22 assessments completed on this.

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1 CHAIR REINHARD: Okay.

2 MR. GOLTRY: In other words, when
3 you do the risk assessment, you would have
4 quantifiable data from the risk assessment.

5 CHAIR REINHARD: Right, so, does
6 the subcommittee feel like that changes it?
7 So, we would want to consider adopting it, or
8 do we want to move on?

9 MR. WINCHESTER: I have no problem
10 putting it in. You know, now, I mean, it's
11 additional data, but it would -- you know,
12 funding, we'll just have to see how it's --
13 how it's applied.

14 It may have value, certainly, when
15 you look at the technologies to control, you
16 know, and -- but it would take another step.

17 You'd have to qualify again and re-
18 evaluate sampling, etcetera.

19 CHAIR REINHARD: So, if we took out
20 'and set up thresholds', would that be better,
21 for Nancy? Dr. Hayes?

22 MR. HAYES: Sorry, just listening

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1 to what is being said, here, I think one of
2 the things that could improve this is, again,
3 where do you want this applied?

4 Do you want it applied into your
5 risk assessment, when you -- do you want it
6 applied when you're identifying the select
7 strains of Salmonella that you're going after?

8 Do you want it considered when it's
9 a compliance guide? So, where specifically do
10 you want this information, or do you want it
11 generally, into all of these things?

12 CHAIR REINHARD: Any other
13 comments? Nancy?

14 MS. DONLEY: Yes, I do have a
15 problem with this. I don't see what -- unless
16 I'm missing something here, what the benefit
17 would be, at all.

18 We have a huge problem with
19 Salmonella, what the public health benefits
20 would be, here, and setting a tolerance level
21 -- I don't think the system is broken, right
22 now. I don't know.

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1 CHAIR REINHARD: Okay, so, we'll go
2 ahead and move on, as we don't have unanimous
3 consent, it will be a recommendation for the
4 subcommittee, and get to the next one.

5 So, the next one is on public
6 posting systems for producers, comments of the
7 subcommittee? Dr. Shultz?

8 DR. SHULTZ: The only concern here
9 is what we've discussed yesterday, about
10 individually sourcing animals and the fact
11 that traceability is a real serious issue
12 there.

13 We would not be able to
14 definitively associate a pathogen with a
15 producer, when we're doing testing upon
16 receipt at the plant.

17 CHAIR REINHARD: Stan?

18 MR. STROMBERG: My concern with
19 this is that from -- and I'm not a Salmonella
20 expert, but from what I heard yesterday, you
21 can follow best practices and do everything
22 you're suppose to do, and this will still show

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1 up, and particularly, in the case of people
2 that own poultry houses, I don't think you
3 should put someone out of their livelihood,
4 because they followed all the best practices
5 and by some fluke, Salmonella showed up and
6 now, they've got a \$200,000 poultry house
7 they've got to pay for and no income.

8 I just -- that really concerns me
9 and it's that -- it's like you're going to
10 pillar somebody for something that they did
11 everything they could, and this just happened,
12 and now, you're going to punish them for it,
13 and that is what concerns me about the public
14 posting system.

15 CHAIR REINHARD: Dr. Henry?

16 DR. HENRY: One, I assume producer
17 means the farmer, Nancy?

18 MS. DONLEY: It could be -- it
19 could -- well, it can also -- I mean, it's got
20 to go through the system.

21 So, in the case of cattle, you've
22 got, you know, coming out of various feed

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1 lots, and however it's done at auctions, you
2 know, that type of thing.

3 However, this is kind of -- what
4 this -- and you weren't here, Craig, is how --
5 yesterday, is -- this is based on the model
6 that is done now for drug residues.

7 DR. HENRY: Yes, I heard.

8 MS. DONLEY: And so, I think the
9 bottom line, to me, is that this is
10 transparency, transparency is going to push
11 efforts back to strengthen public health.

12 DR. HENRY: And I just -- that is
13 good, I appreciate that. So, it's everything
14 pre-harvest outside amenability of a plant,
15 per se, unless it's the holding yards at the
16 slaughter house.

17 However, I would be fully
18 supportive of this, if we could show the
19 similar relationship, as we do with antibiotic
20 testing.

21 So, if you can show me the cause
22 and effect relationship, as far as the

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1 technology, I'd be fully supportive.

2 So, in antibiotic testing, in that
3 program, which I think has immediate merit, if
4 you knowingly abuse an improperly withdrawal
5 antibiotics being used in livestock or flocks
6 intended for human consumption, then that is
7 pretty straight forward.

8 You can control that and get a
9 response. Nancy, if you can embellish upon
10 that, and clarify the action the producer
11 should take, to minimize, control, reduce or
12 eliminate horizontal transmission and the
13 presence of Salmonella strains at large, where
14 the public health concern, we know, continues
15 to grow, then I think we should put that up
16 there, and then have it reviewed.

17 MS. DONLEY: Well, speaking about
18 the antibiotic issue, I mean, that is
19 something here, that -- maybe you can
20 elaborate a little bit.

21 So, what are you suggesting? How
22 would you suggest tweaking that?

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1 DR. HENRY: I don't know, that's
2 why I -- I'm saying, you know, if you can tell
3 me what the producer should do to eliminate
4 the threat, the hazard, then we should specify
5 it.

6 I mean, all the rest of the work
7 above, I mean, that is the problem, is if you
8 -- you know, we put somebody out there, and I
9 concur with Stan.

10 You know, if I put it out there and
11 say that somebody has got Salmonella on their
12 farm, we're implying that they haven't done
13 anything about it.

14 So, now, the question is, what
15 should I do about it?

16 DR. LINVILLE: So, can you take a
17 step back from that and say, okay, we will
18 encourage that that producer take these steps,
19 and we can -- we can somehow or another,
20 reward that particular producer for taking
21 those steps.

22 If it comes up, it comes up, but at

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1 least, we know it's coming up, or the
2 establishment knows it's coming up and can
3 take appropriate actions, based on that.

4 I mean, at this point in time, no
5 one really knows what is going on out there.
6 At least if they do, they're not letting us at
7 FSIS know they know.

8 DR. HENRY: Well, but I disagree,
9 John.

10 DR. LINVILLE: Okay.

11 DR. HENRY: Strictly because, now,
12 I'm going to go back to my original call-out.

13 DR. LINVILLE: Okay.

14 DR. HENRY: Everybody in the room,
15 including all FSIS establishments and
16 personnel, know that all livestock come in
17 with Salmonella.

18 Now, are they coming in with
19 antibiotic resistant Salmonella, that is a
20 question I raised yesterday, about where the
21 baseline is. What is the frequency --

22 DR. LINVILLE: Well, and it's not

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1 just --

2 DR. HENRY: The occurrence --

3 DR. LINVILLE: It's not just
4 antibiotic resistant Salmonella.

5 DR. HENRY: Okay.

6 DR. LINVILLE: It's any sub-type of
7 human health concern.

8 DR. HENRY: So, but I haven't seen
9 that complete list, and what list over what
10 period of time, based on what threshold
11 studies?

12 MS. DONLEY: Well, I think that is
13 going to be a moving target. I mean, there are
14 certain things that we can identify now, but
15 you know, as we have emerging pathogens and
16 issues of public health concern, that is going
17 to necessarily change.

18 DR. HENRY: I'm with you. So, what
19 is the fix?

20 MS. DONLEY: We set up there,
21 strains of public health concern.

22 DR. HENRY: No, no, no, Nancy, what

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1 I'm asking for, how do I prevent that from
2 happening? Not, which strains am I looking
3 at.

4 We can create a list, and I'll tell
5 you, the list will be really long, if you're
6 going to start doing that sampling.

7 So, I mean, you know, you've got to
8 have -- to the point, you put the name up
9 there and you put it out there, okay, I
10 understand that.

11 That means you're really trying to
12 bring public pressure, which could impact the
13 livelihood, as Stan said, or the outcome of
14 that producer. What is the producer going to
15 use? What guidance? What specific fix are we
16 going to tell that person, besides, "Clean
17 your drinkers. You know, don't co-mingle, all
18 in, all out," that's already there.

19 I want to see a very close
20 relationship between the cause and effect.

21 MS. DONLEY: Well --

22 DR. HENRY: Does it use a vaccine?

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1 You know, is it to select a different style
2 of livestock or birds? You know, what is it?

3 MS. DONLEY: Well, I don't think
4 we're telling them, necessarily, what to do,
5 and I don't think that -- that this committee
6 should be saying very specific things, and I
7 know FSIS has certainly tried to not be
8 prescriptive.

9 So, it's something that, hey,
10 obviously, you know, some of them do a better
11 job of it now, and do clean -- do better --
12 better animal husbandry procedures in place.

13 What this is, is the -- what this
14 is just showing, it is going to be, frankly, a
15 way of again, putting downward pressure, it's
16 transparent.

17 At the end of the day, it's the
18 companies that are producing -- are purchasing
19 these -- who will understand that yes or no,
20 maybe this is something I should be concerned
21 with, or maybe this is something I don't need
22 to be concerned with.

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1 DR. HENRY: Yes, well, I'm not
2 comfortable with that clause.

3 CHAIR REINHARD: Okay, so, here is,
4 I'm going to say, two things, and then,
5 because I don't think it matters, I think
6 we're not going to come to consensus, we can
7 move on.

8 The first thing is, I do not
9 believe there is a lot of data to post. So,
10 there wouldn't be much, here, even if they did
11 post.

12 The second thing is, is based of
13 our meeting last time, the National Academy of
14 Science's, yesterday and today, are putting
15 out their recommendations for FSIS to post
16 data and be transparent, and this may just get
17 taken care of with that.

18 And so, just because we don't push
19 the requirement here, it's already being
20 considered elsewhere.

21 MS. DONLEY: Okay, I would -- I am
22 going to bring us back to what FSIS gave us as

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1 questions. So, this is going to come up in
2 that.

3 So, if it's all right with the
4 subcommittee, I'd like to just leave it up
5 there, not as a consensus statement.

6 CHAIR REINHARD: Of course.

7 MS. DONLEY: Okay, all right.

8 CHAIR REINHARD: Okay, are there
9 anymore, down below? Anymore topics?

10 So, this is the vaccine, and I
11 think we pulled this up into number one and
12 four. So, are you okay, Craig, that we go on
13 from this?

14 DR. HENRY: Yes, the only thing I
15 didn't see above was looking at the external
16 experiences, with foreign entities. Is there
17 a reason we did not adopt that?

18 CHAIR REINHARD: Can we add it to
19 the public -- to the one that we have?

20 DR. HENRY: Because correct me if
21 I'm wrong, but Caroline, I think, has brought
22 up very good data from multiple countries.

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1 CHAIR REINHARD: Okay.

2 DR. HENRY: And if we're not global
3 on this, then we're really not doing the --

4 MS. DONLEY: Oh, I'm with you.

5 CHAIR REINHARD: So, right there,
6 number six? We can add it to the end?

7 DR. HENRY: Correct.

8 CHAIR REINHARD: Okay.

9 PARTICIPANT: It was just oversight,
10 that we didn't include it.

11 CHAIR REINHARD: Yes, okay.

12 DR. HENRY: Yes, we need to know
13 lessons learned, what is working and what's
14 not working. Thank you.

15 CHAIR REINHARD: Okay, so, that
16 doesn't really change number six. Is there
17 any heartburn on that? I don't want to have
18 to go back and reconsider it.

19 All right, let's go to the bottom
20 and see if there is anything else.

21 That's it. So, here is what we're
22 going to do. We're going to take a couple of

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1 minutes. I am going to clean this up, put it
2 back up for everybody to see, then we're going
3 to type the questions in, and answer the
4 questions. Dr. Shultz?

5 DR. SHULTZ: Just, do we want to
6 make some kind of a follow up statement to the
7 last meeting, on animal traceability, because
8 all of this, food product traceability hinges
9 on animal traceability, and we don't -- we're
10 not completing the circle there, I fear.

11 MS. DONLEY: It was on there.

12 CHAIR REINHARD: Subcommittee, does
13 anybody want to say anything about animal
14 traceability?

15 DR. LINVILLE: I would just request
16 that if you do, that you give some specific
17 guidance on what you think FSIS can do about
18 it.

19 DR. SHULTZ: Well, I think that the
20 collection of ID devices at slaughter, and
21 their retirement at slaughter is critical to
22 the new animal disease traceability system,

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1 and it will require FSIS and APHIS
2 cooperation.

3 MS. DONLEY: If I could just add to
4 that, you know, Craig's thing about lessons
5 learned from other countries, as well, who
6 have traceability, animal traceability systems
7 in place.

8 DR. HENRY: Just a question, again,
9 I apologize, what is our status on the
10 national program right now?

11 I mean, it's been up and down and
12 all around, so, I didn't know that I'd seen
13 anything forward on that, and we're really
14 looking at livestock, right? I mean, that is
15 what we're talking about?

16 DR. LINVILLE: I'm sorry, I really
17 can't tell you.

18 DR. HENRY: Yes, well, I think it's
19 fair to put it up there. It's a great thing,
20 because we're behind the rest of the developed
21 countries on this issue, just flat out.

22 DR. LINVILLE: Right, and my only

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1 point was, I'm in full agreement that it needs
2 to move forward.

3 I just -- if you're going to put up
4 there, that FSIS needs to do something, I just
5 would ask what that would be.

6 CHAIR REINHARD: I would actually
7 prefer we don't, even though I think it's a
8 great idea and it needs to be done.

9 I think it's beyond the questions
10 that we were asked, and it's a whole big mess.

11 DR. HENRY: Don't candy coat it,
12 please, please.

13 CHAIR REINHARD: And we could spend
14 hours talking about it, right, and so, I don't
15 want to get into all these details around
16 specifics of how we do animal ID and how we do
17 tracing, that type of stuff.

18 So, I think it's a great note.
19 It's in the minutes, and we can move forward
20 with it. Dr. Hayes, did you want to say
21 anything?

22 MR. HAYES: I was just going to

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1 say, I mean, I'm sure it's going to be a
2 component, when it goes to feasibility.

3 CHAIR REINHARD: Okay, we're going
4 to take ten minutes. I'm going to work to
5 clean this up.

6 So, we're on break for ten minutes.
7 We'll come back at 9:10 a.m. We're going to
8 add the questions in and we're going to make
9 sure we tried to answer them. Thanks,
10 everybody.

11 (Whereupon, the above-entitled
12 matter went off the record at approximately
13 9:00 a.m. and resumed at approximately 9:10
14 a.m.)

15 CHAIR REINHARD: Okay, we'll go
16 ahead and get started with the questions, just
17 to make sure we don't want to specifically
18 answer any of them, and where appropriate,
19 we'll refer to our -- we'll refer to what we
20 agreed to, on our recommendations, which
21 really applies to a lot of them.

22 So, the first question was on

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1 verifying factors, such as sub-type or drug
2 resistance of historically -- played an
3 important role, and it asked about what we
4 would recommend before entering it into an
5 official establishment.

6 So, I'm going to let anybody
7 comment on the first one, and then we'll go
8 from there. Dr. Vetter?

9 DR. VETTER: These may already be
10 in the current guidance, I'm not sure. But
11 I'm just going to throw some recommendations
12 out there, and I know that to some extent,
13 industry is doing some of this.

14 But I think where the changes need
15 to be is maybe, they're reacting to some of
16 this information, and what I'm referring to is
17 the testing of feed, whether it's Salmonella
18 positive or not, and possibly, even sero-
19 typing.

20 Those type -- that type of
21 information, because I do believe that this is
22 -- can be a very likely entry point for

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1 Salmonella into a flock, and I'm speaking
2 about what I know most, which is poultry.

3 But I think maybe to some extent,
4 it could be applied, particularly maybe to
5 hogs, and that type of thing.

6 So, I would suggest that that's
7 something that needs to be looked at by
8 industry.

9 I know with poultry, there are a
10 lot of companies or farms that are involved in
11 the NPIP, and they are sero-typing those
12 results, and I believe that when those come
13 back positive, particularly for Salmonella
14 types of public health concern, and we know
15 we've got the top 20 list. We know what
16 plants are also getting back in their
17 Salmonella set results.

18 I think that plants need to be
19 looking at that information, and reacting to
20 it, when they get those types of sero-types,
21 because they're not, always.

22 CHAIR REINHARD: Okay, so, my

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1 comments will be, did we address it in our
2 recommendation number one and our
3 recommendation for FSIS, to require the plants
4 to re-assess, because when they re-assess,
5 this is part of the regulation. You have to
6 consider it.

7 So, did we kind of already address
8 this question, with our recommendations that
9 we had? Any public comment?

10 Okay, so, I'll take it that the
11 committee feels like we addressed this with
12 our recommendations, and we don't have to put
13 something specifically under the question, and
14 go forward to number two, which is what
15 innovative steps can the agency take to assist
16 industry?

17 So, we can comment on this. We did
18 call on them to do a couple of different
19 things with stakeholders in our comments,
20 already. Stan?

21 MR. STROMBERG: I agree, I think
22 that we have addressed this question number

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1 two, and in several of the statements that we
2 have already approved, and again, I don't
3 think that we need to add any additional
4 information, unless there is some other stuff
5 that someone would just want to add.

6 CHAIR REINHARD: Craig?

7 (OTR comments)

8 CHAIR REINHARD: Okay, then the
9 next one is number three, which really drove
10 us to answer all of our recommendations,
11 anyhow.

12 So, that was, what do we think of
13 an approach similar to the residue violator's
14 program, which we did talk through in detail.

15 In essence, we took a different
16 approach than the residue violator's program,
17 and made different recommendations.

18 So, if everyone is comfortable with
19 that, and doesn't think anything else needs to
20 be discussed, we'll move to the last one,
21 which we didn't discuss, which we will have to
22 discuss.

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1 So, the last one is about end of
2 letter sets, including PFGE patterns and drug
3 resistance data, and FSIS is going to start
4 sending this information to facilities and
5 giving them information.

6 Now, I had to go back and figure
7 out what this meant, after they presented it.

8 So, I did go ask, so, what is going to
9 happen?

10 And so, my understanding is, FSIS
11 will send -- currently sends plants end of
12 sample sets, with this sero-type, so, you get
13 your number of positives and their sero-type.

14 In addition, FSIS is looking to
15 provide with the sero-type, if the PFGE
16 pattern single enzyme cut has been seen in
17 Pulse Net, first, ever, if the PFGE pattern
18 has been seen in Pulse Net in the last 90
19 days. So, you would get more information.

20 Then finally, if the sero-type is
21 drug resistant, so, information about multi-
22 drug resistance, of that specific sero-type,

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1 whether it be three, four or five, the way
2 FSIS does it.

3 So, that is my understanding. So,
4 it's basically more information to the
5 facility, for them to do what they need to do.

6 The reality of it is, more information is
7 always good. I don't have -- I don't think we
8 should have an objection to it.

9 What they can do with it, I don't
10 know, yet. But that will come in time.

11 I do have one suggestion, though.
12 The way FSIS does multi-drug resistant data
13 now, it isn't as helpful as if they focused on
14 the four specific FDA critical drug resistant
15 --

16 DR. LINVILLE: And that is the
17 plan.

18 CHAIR REINHARD: Okay.

19 DR. LINVILLE: Let me add just a
20 little bit. What you said is basically
21 correct.

22 CHAIR REINHARD: Okay.

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1 DR. LINVILLE: Currently, the way
2 that it works is that the end of the set,
3 there is a letter that goes back to the
4 establishment, that just says, "You passed,"
5 or, "You failed," and it gives you some basic
6 information on sero-types, but it doesn't
7 include all of the sero-types for the
8 positives, that goes out individually, so,
9 it's not compiled.

10 So, that is the first step. That
11 is the one thing that we can easily fix, right
12 now.

13 The other piece is including, to
14 start with, just PFGE based information.
15 About the best we're going to be able to do,
16 until we get connectivity to the CDC and to
17 Pulse Net, is say, "This particular strain has
18 showed up more than once in your establishment
19 over, say, the past year."

20 That is the first step.
21 Ultimately, we want to get to where you are,
22 but that is going to require a little more

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1 work.

2 Multi-drug resistance, we would
3 provide the resistance patterns, but we would
4 also classify it according to the FDA
5 classification, and the worse case scenario,
6 if one of them is a critical and the rest of
7 them are just highly important, then we would
8 say, overall, you've got a critical issue.
9 So, yes.

10 CHAIR REINHARD: I'll try to go in
11 order. Stan?

12 MR. STROMBERG: I agree with Robert
13 about the benefit of this. I think the more
14 information you can provide to industry, the
15 better position they're going to be in.

16 I think from the poultry producers,
17 and I'm talking about the slaughter operation
18 or the one that is actually slaughtering the
19 chickens, if they have some information ahead
20 of time, that one of these strains of
21 Salmonella is showing up, that they need to be
22 concerned about, it's much better for them to

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1 learn about it then, and try to take some
2 corrective actions before they find out from
3 CDC that they've got an outbreak and it's tied
4 to their product.

5 And so, I think that again, like
6 Robert said, the more information and the
7 quicker you can get it to them, then industry
8 is going to be able to use this and hopefully,
9 use it in a way that will benefit the public
10 health.

11 DR. LINVILLE: Well, and part of
12 the question is, and it may get lost in all of
13 the detail, it's because it, right now, takes
14 a long time to correlate the PFGE and the
15 drug-resistance information, is that we might
16 have to send two separate letters.

17 And whether -- I mean, whether you
18 see that as an issue, should we hold off and
19 send everything in one letter? Does it make
20 more sense --

21 I mean, so, that is kind of getting
22 at it, as well, as part of the question.

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1 MR. STROMBERG: I'll just add, I
2 think again, in the -- probably better to send
3 two letters and get it to them quicker, than
4 later, because that is --

5 CHAIR REINHARD: Right, yes.

6 05 I mean, the whole key is, I
7 mean, we understand, it would be great if we
8 had a five-hour screening test that we could
9 do for this, but it doesn't work that way, and
10 so, by the time you're going to find this out,
11 it's all probably been consumed, anyway, but
12 at least you know that this showed up and you
13 -- hopefully, the plant will know where that
14 product came from, and let's say that, you
15 know, we had a problem with that house of
16 chickens, and what do we need to do about
17 that?

18 Hopefully, they can go back and
19 start looking at it, but you know, it would be
20 great if you had this real-time thing, where
21 you could just say, "Yes, we must stop
22 everything right now," but it just doesn't

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1 work that way, at this point.

2 CHAIR REINHARD: Okay, Dr. Hayes?

3 MR. HAYES: Yes, I think that
4 addresses the first part of question four,
5 about whether it would be better to have
6 separate mailings or just wait for everything,
7 and I think most people agree, yes, get us the
8 information as it comes.

9 Also, speaking specifically to
10 providing the resistance information, that
11 three, four and five, or more, or less, it
12 depends on what you're testing, and it isn't
13 very useful per se, and I definitely support
14 the idea of having actual specific drugs
15 listed, because it's important, and it's worth
16 knowing.

17 But my question is, the ones that
18 you're talking about of FDA importance, I
19 assume you're talking about of critical health
20 importance to humans?

21 DR. LINVILLE: Right.

22 MR. HAYES: Speaking to guidance

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1 152?

2 DR. LINVILLE: Right.

3 MR. HAYES: Okay, thank you.

4 CHAIR REINHARD: And we can type
5 that in our answer, so, that it would be
6 those, because those are the ones that are
7 important, I believe, and I want to make sure
8 we don't get lost in the -- the three, you
9 know, it's resistant to three drugs, that are
10 from 1940, and it's of no real value, when the
11 things we really want to change are the ones
12 of critical health importance.

13 DR. LINVILLE: I believe you have
14 last year's presentation in your books. If
15 you go back in there, there is actually, a
16 slide that shows the table that we would use
17 for that classification.

18 MR. HAYES: In that table, just as
19 a guidance, it's publically available, as
20 well?

21 DR. LINVILLE: Right.

22 MR. HAYES: On FDA's website?

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1 DR. LINVILLE: Right.

2 CHAIR REINHARD: Okay.

3 MS. GAPUD: Just do what you are
4 doing right now, because of course, that's
5 appropriate industry, as a poultry supplier.

6 Yes, we do receive the results and
7 then we put already -- if it's whatever sero-
8 type it is, but I think it would be better if
9 you continue what you're doing and somehow,
10 send them out there, another email or another
11 mail, to let us know, in case it's the --

12 DR. LINVILLE: No, I mean, we would
13 not discontinue the sample by sample
14 notification, by any means. This would be in
15 addition to it.

16 MS. GAPUD: Yes, yes, it's
17 beneficial because the plant, they usually --
18 they are in need of it, immediately. Thank
19 you.

20 CHAIR REINHARD: Nancy?

21 MS. DONLEY: I definitely agree
22 that more information is key and would be

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1 helpful to industry.

2 But I have a question for you,
3 John. In the other areas, you know, you post
4 Salmonella on the FSIS, Salmonella results and
5 testing on the websites.

6 DR. LINVILLE: We have a quarterly
7 report and an annual report, yes.

8 MS. DONLEY: Do you -- and I should
9 know this, but I don't.

10 Do you post any of these PFGE
11 results --

12 DR. LINVILLE: No.

13 MS. DONLEY: -- on the website?

14 DR. LINVILLE: Not currently.

15 MS. DONLEY: Not currently?

16 DR. LINVILLE: No.

17 MS. DONLEY: Has there been any
18 internal discussions on that?

19 DR. LINVILLE: Again, well, the
20 answer to your question there is yes, there
21 have been internal discussions on that, and a
22 lot of that still is dependent on us gaining

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1 more real-time access to the data.

2 Right now, like I said, it really
3 is a manual pool. We have to go through ARS,
4 and individually, for a sample by sample, pull
5 those results, which is a very time consuming
6 process.

7 So, realistically, we -- at this
8 point, we can't do that.

9 We have an MOU with ARS. We're
10 going to get a live data feed, where we can --
11 in real-time, send -- connect those two -- the
12 FSIS database and the Vet Net database at ARS,
13 and then we'll be able to do things like that,
14 and yes, we are discussing that.

15 MS. DONLEY: Good, thank you.

16 CHAIR REINHARD: So, if we want to
17 go ahead and type in here, that the committee
18 supports FSIS going forward with their
19 proposal, and understand -- and believes that
20 two letters would be appropriate, to get
21 information out as quickly as possible.

22 Then do we want to say the

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1 committee recommends that FSIS focus on giving
2 drug-resistance information, based off the --
3 based off the critical health importance, not
4 just the three, four, five? So, how would we
5 say that? Does anybody have a --

6 The committee recommends, FSIS --
7 do we want to say focus on supplying the
8 producing establishment with drug-resistant
9 information --

10 MS. DONLEY: Focus establishment.

11 CHAIR REINHARD: Okay.

12 MS. DONLEY: I say that only
13 because they do testing, obviously, in not
14 just the producing establishments, but they do
15 it in further processing.

16 CHAIR REINHARD: Okay, right,
17 right, the establishment, yes.

18 On the four -- do we call them
19 drugs of critical health importance?

20 DR. LINVILLE: It's the
21 classification. It's a classification system.

22 MR. HAYES: I don't think that

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1 there are four, by the way.

2 CHAIR REINHARD: Okay.

3 DR. LINVILLE: It's important,
4 highly important and critical, I think, right?

5 MR. HAYES: Important, highly and
6 critical, right.

7 DR. LINVILLE: Important and
8 critical, yes. So, it's actually three.

9 MR. HAYES: Right.

10 CHAIR REINHARD: Okay, and then --

11 DR. LINVILLE: You could say the
12 three FDA risk classifications, if you wanted
13 to do that.

14 MS. DONLEY: Do we want to
15 restrict? I mean, that is what it is, now,
16 but this is going to be, you know, again, this
17 is not -- that is -- this is a snapshot in
18 time that we're talking, but we want this to
19 live on, correct?

20 So, I question limiting it, in our
21 recommendations, just saying maybe the -- of
22 the -- the FDA, just get rid of the word

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1 'three', risk -- on the FDA risk
2 classifications of critical health and
3 importance to -- is that -- critical health
4 importance to humans, yes.

5 CHAIR REINHARD: Okay, that is
6 fine, and then I have one more question,
7 because I guess, I was thinking we're going to
8 provide the information about what is in Pulse
9 Net, and then you more indicated you weren't,
10 because you didn't have access right now.

11 DR. LINVILLE: No, we -- okay, we
12 will provide it. There is no question that we
13 will be providing -- not the actual
14 information that is in Pulse Net, but we will
15 be providing information, as to whether it's
16 part of an active cluster, whether it's been
17 seen over time, things like that.

18 But that can only happen when our
19 MOU with the CDC has been finalized, and we
20 have connectivity between FSIS and Pulse Net,
21 and ARS. I mean, it's actually a three-tiered
22 system, then, and it gets even more

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1 complicated.

2 CHAIR REINHARD: So, do we want to
3 recommend that they complete their MOU with
4 CDC and ARS --

5 DR. LINVILLE: Any help with that
6 one --

7 CHAIR REINHARD: -- as quickly as
8 possible?

9 DR. LINVILLE: Yes.

10 CHAIR REINHARD: Okay.

11 MR. HAYES: I'm just curious about
12 these letters. Are they hard copy letters or
13 are these emails?

14 DR. LINVILLE: They are hard copy
15 letters to the establishment, that come
16 through the District Office and are signed by
17 the District Manager.

18 It really is -- it is information
19 sharing, but it's part of due process.

20 CHAIR REINHARD: Dr. Vetter?

21 DR. VETTER: It's not an MOU with
22 FDA? It's ARS and CDC?

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1 DR. LINVILLE: Correct.

2 DR. KASSENBERG: And do you want to
3 be -- do you want to specify a little bit more
4 about what MOU?

5 CHAIR REINHARD: Memorandum of
6 understanding.

7 DR. KASSENBERG: But in regards to
8 sharing of the information.

9 DR. LINVILLE: Yes, you can just
10 say data sharing MOU.

11 DR. KASSENBERG: Okay.

12 DR. LINVILLE: I mean, we'll know
13 what you're talking about.

14 DR. KASSENBERG: Okay.

15 CHAIR REINHARD: Go ahead.

16 DR. HENRY: John, a lot has
17 happened since I was in my plants. It's been
18 a few years, now.

19 But on pre-requisite programs or
20 anything else, is FSIS collecting anything, or
21 what type of any history are you collecting on
22 the flocks right now, especially on broilers,

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1 more than livestock? Antibiotic use?

2 DR. LINVILLE: You mean, what
3 information is FSIS collecting?

4 DR. HENRY: Yes, yes, because you
5 know, when you look at the antibiotic testing,
6 I mean, there was a point in time when I used
7 to supply, when I would assume antibiotic
8 residues, you know, we would say, "Here is
9 what we're using."

10 But what are you collecting now,
11 especially on livestock, because you know,
12 they tend to be the bigger challenge.

13 DR. LINVILLE: The only information
14 that I'm aware of, that we're routinely
15 collecting at this point in time, is the
16 collection -- the information that we collect
17 when we take a sample.

18 With PHIS, the plant profile is
19 greatly expanded and information on those pre-
20 requisite programs and things are greatly
21 expanded.

22 The proprietary information, as

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1 such, is not put in there, but the
2 availability of it is there.

3 DR. HENRY: Okay, that is good. I
4 mean, you know, I saw the quick update here on
5 PHIS, but I'd like to -- I think it's really
6 important to see what we get, going down the
7 road, because I know so much of the poultry
8 industry has eliminated therapeutic -- or non-
9 therapeutic promoting of antibiotics, and I
10 think in time here, especially with all in,
11 all out, you know, we need to look at what
12 Mother Nature is doing out there, in the
13 industry, as far as getting these multi-drug
14 resistant strains, against what we think is
15 going on, or can confirm what is going on, as
16 far as the husbandry techniques, because they
17 can still occur out there, and there is no
18 intrusion or circumvention of programs.

19 DR. LINVILLE: And you weren't here
20 yesterday when I did the presentation. That
21 is part of the reason that we're going back in
22 time, over the entire history of our database,

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1 and we will be providing the -- what we call
2 prep data, the verification results, back to
3 every active establishment over that entire
4 history, as a one-time catch-up.

5 When it's available, we will be
6 providing also, the PFGE and drug-resistance
7 information that goes along with that, but
8 it's going to -- that is a huge undertaking,
9 and it's going to take some time for us to do
10 that.

11 DR. HENRY: I think, when we look
12 at the -- certainly, the poultry industry,
13 with the livestock industry, right now, I
14 mean, for years, we have talked about the
15 concern of transitioning from non-therapeutic
16 use to therapeutic use, when you take out
17 growth promoting especially non-absorbing
18 antibiotics, and now, you see flocks that
19 become, or animals that become morbid and you
20 use therapeutic antibiotics, I mean, the
21 profile changes.

22 So, I think this is good

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1 information for industry to have, and try to
2 reach back and figure out what were we doing
3 ten years ago versus five years ago, versus
4 just looking at data we have now.

5 DR. LINVILLE: All right, right.

6 CHAIR REINHARD: Nancy?

7 MS. DONLEY: I know this isn't
8 directly to this question, but it is something
9 that I was asking John about, a little bit
10 earlier.

11 This is FSIS information and I
12 think it should be public and transparent,
13 until -- the public should be able to have
14 this information, as well, as far as plants
15 and this.

16 Now, I don't know if the
17 subcommittee wants to -- I want to put it out
18 there, but I think that another statement
19 might be to take this further, is that -- and
20 that FSIS should post this with their
21 Salmonella results --

22 DR. LINVILLE: Okay, Nancy, post

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1 what, exactly? I'm not sure --

2 MS. DONLEY: Post -- right now, you
3 give, you know, Salmonella --

4 DR. LINVILLE: Trends.

5 MS. DONLEY: -- trends.

6 DR. LINVILLE: Right.

7 MS. DONLEY: Well, but you also --
8 you also put out reports by plant number, not
9 establishment number.

10 DR. LINVILLE: Just based on the
11 categorization, whether they're -- if they're
12 category three or not?

13 CHAIR REINHARD: I believe it's now
14 just if they fail.

15 DR. LINVILLE: Which is category
16 three, right.

17 CHAIR REINHARD: Right.

18 DR. LINVILLE: Yes.

19 MS. DONLEY: Well, I think this is
20 important information, this -- I haven't
21 really thought this through, and I apologize
22 for that.

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1 But I just want to get on record
2 that I think that this is information that
3 would be helpful for the public to know, as
4 well, that there are -- again, shedding light
5 on the fact that there is a problem out there
6 and that there are -- you know, industry is
7 dealing with these ABR strains and public
8 health strains, and that transparency is the
9 best way --

10 I guess, you know, I guess I can
11 take this up with my colleagues and figure
12 something out, as far as that goes, but --

13 DR. LINVILLE: Yes, I would be more
14 than happy to talk to you on it, Nancy, once
15 you get your thoughts around it.

16 MS. DONLEY: Yes.

17 DR. LINVILLE: But yes, I think --

18 MS. GAPUD: Well, I think the most
19 important thing that we have to realize, there
20 are so many issues that are really quite
21 different with antibiotics, okay.

22 Again, the antibiotics, you can --

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1 if you -- if the producers wants to use
2 antibiotics, that is fine. He can do it. He
3 has the choice.

4 But with Salmonella, like we
5 discussed yesterday and today, you can do
6 everything you can and you still have
7 Salmonella, and again, like what Stanley said
8 earlier, if -- like, when we were talking
9 about transparency, putting the names of those
10 producers with Salmonella positive, etcetera,
11 I think we are pushing those people to go to
12 bankruptcy.

13 Again, the main thing that I'm
14 trying to drive here, the Salmonella is
15 different from the antibiotic issue.

16 CHAIR REINHARD: Okay, Dr. Vetter?

17 MS. DONLEY: And I understand, and
18 that's a good point.

19 However, the facilities that are
20 failing the Salmonella sets, which are the
21 ones that -- failing those sets, I think --
22 and that information is being made public. It

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1 stands to reason that they failed their
2 Salmonella sets, and it was also found that
3 they did or did not have, you know, these
4 public health issues of concern.

5 It's just additional layer of
6 information.

7 CHAIR REINHARD: Dr. Vetter?

8 DR. VETTER: One quick comment. I
9 think if you were to link it with category
10 three plant specifically, that that might be
11 useful.

12 But I don't -- because we do have
13 category one and category two plants that
14 possibly had one positive out of 50 of what
15 have you, and it may have been a public health
16 concern sero-type, and we expect them to react
17 to that, within their food safety system.

18 But if you were to just kind of put
19 it all out there, it would go against what we
20 currently do with categorization.

21 So, I think when you flush the idea
22 out, to stick to those category three

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1 establishments, that that might work better.

2 CHAIR REINHARD: Okay, so,
3 procedurally, now, the whole committee will
4 come back together, and I assume, I go over
5 what we came up with? Is that how that works?

6 And so, I will go over what we came
7 up with and we'll have a full committee
8 discussion, and depending on the will of the
9 committee, they may dive right down into
10 everything we did and that is the way it will
11 be.

12 So, at this point in time before we
13 break and get ready for the 10 o'clock full
14 committee, I'll call, if there are any public
15 comments, or anybody in the public who wants
16 to make any -- say anything, in addition?
17 Okay, yes?

18 MR. GOLTRY: Could I comment on
19 that?

20 CHAIR REINHARD: Yes.

21 MR. GOLTRY: I don't know if this
22 is the right time --

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1 CHAIR REINHARD: Thanks, Scott.

2 MR. GOLTRY: -- but thanks for
3 letting me comment.

4 Scott Goltry, MI. Yesterday, and I
5 was in the validation meeting, and I -- and
6 maybe this was discussed a little bit, but on
7 the chart, the beef anti-microbial resistant
8 pathogen beef products chart, and I don't want
9 to sound like any time the meat companies get
10 up and question data, that we've got our heads
11 in the sand.

12 Actually, we're trying to be
13 proactive and look at this data the best we
14 can, because we like to be led by good
15 science.

16 We make a lot of decisions based on
17 science, and we want to make sure the science
18 is right, so, we don't make the wrong decision
19 that could impact public health.

20 Regarding this beef product chart,
21 you look at it, and I don't know if you have
22 it in front of you.

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1 In 2005, there seemed to be a
2 reduction in improvement. I'd like to
3 understand more, what caused that improved,
4 and maybe circle that and use that as some
5 learning that -- what happened to cause this
6 to be an improvement?

7 Also, on this beef chart, you have
8 35 percent. I don't know what that is. I
9 assume that's 35 percent of the Salmonella?

10 DR. LINVILLE: It's the positives
11 for carcass and ground beef testing.

12 MR. GOLTRY: Okay, you know, and
13 you can slice and dice this information, and
14 if we look at this, maybe we need to ask more
15 questions about where this information came
16 from? Was it--

17 DR. LINVILLE: It's NORS data and
18 it's anything -- it's any beef carcass testing
19 or ground beef testing.

20 MR. GOLTRY: So, we don't have any
21 way to look at it any better, so, we can't
22 focus our corrective actions on any one class?

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1 DR. LINVILLE: Unfortunately, no.

2 MR. GOLTRY: Okay, I would say that
3 is a concern. We need to know more about some
4 of this data.

5 The other thing is, although -- and
6 you probably have this similar concerns over
7 chicken and turkey, but one thing that is
8 missing is pork data.

9 Is pork data really good, and maybe
10 we need to learn more from what the pork
11 people are doing, or what?

12 DR. LINVILLE: It was in the
13 presentation on this slide.

14 Pork actually is relatively flat
15 over time.

16 MR. GOLTRY: Okay.

17 DR. LINVILLE: So, they seem to be
18 doing -- if you look at just the trends over
19 time, they seem to be doing something right.
20 What that is would be a good question to
21 answer, absolutely.

22 MR. GOLTRY: Okay, thank you.

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1 CHAIR REINHARD: Thank you, Scott.

2 Does anyone else have comments?

3 So, okay, at this point then, if
4 it's the will of the subcommittee, we'll
5 adjourn until 10 o'clock? All right, thanks,
6 everyone.

7 (Whereupon, the above-entitled
8 matter went off the record at approximately
9 9:40 a.m. and resumed at approximately 10:00
10 a.m.)

11

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