

UNITED STATES DEPARTMENT OF AGRICULTURE

In the matter of:

NATIONAL CONFERENCE ON
ANIMAL PRODUCTION FOOD SAFETY

Pages: 1 through 341

Place: St. Louis, Missouri

Date: September 6, 2000

HERITAGE REPORTING CORPORATION

Official Reporters

1220 L Street, N.W., Suite 600

Washington, D.C. 20005-4018

(202) 628-4888

hrc@concentric.net

BEFORE THE
UNITED STATES DEPARTMENT OF AGRICULTURE

* * * * *

In the matter of:

NATIONAL CONFERENCE ON
ANIMAL PRODUCTION FOOD SAFETY

Grand Ballroom, A-C, E and F
Hyatt Regency
One St. Louis Union Station
St. Louis, Missouri

Wednesday,
September 6, 2000

The conference was convened at 8:00 a.m.

MODERATORS:

DR. JOHN R. RAGAN
DR. KEN OLSON
DR. ALICE THALER
DR. JERRY GILLESPIE

SPEAKERS :

DR. BONNIE BAUTAIN
DR. DOUGLAS POWELL (Keynote)
DR. STEVEN SUNDLOF
DR. BETH LAUTNER
CAROLINE DEWAAL
DR. JERRY GILLESPIE
DR. GARY COWMAN
DONNA REIFSCHNEIDER
JOHN ADAMS
DR. DAN CUTHERMAN
DR. CINDY WOLF
STEPHEN PRETANIK
DR. ALICE JOHNSON
DR. CATHERINE WOTEKI
AL POPE
DR. CRAIG REED
DR. BARBARA MASTERS
DR. DAVID WHITE
DR. NORMAN STERN
SHANNON JORDRE
DR. WILLIAM LAEGREID
DR. STEVEN LEHOTAY
DR. MONTY KERLEY

I N D E X

<u>SPEAKER</u>	<u>PAGE</u>
John Ragan	4
Bonnie Bautain	8
Douglas Powell	15
Steven Sundlof	34
Beth Lautner	50
Caroline DeWaal	69
Jerry Gillespie	89
Ken Olson	103
Gary Cowman	104
Donna Reifschneider	113
John Adams	121
Dan Cutherman	134
Cindy Wolf	140
Stephen Pretanik	150
Alice Johnson	160
Alice Thaler	166
Catherine Woteki	167
Al Pope	186
Craig Reed	203
Stephen Sundlof	218
Barbara Masters	232
Jerry Gillespie	245
David White	246

<u>SPEAKER</u>	<u>PAGE</u>
Shannon Jordre	274
Norman Stern	287
William Laegreid	300
Steven Lehotay	313
Monty Kerley	326

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

P R O C E E D I N G S

DR. RAGAN: Good morning. It's nice to see a substantial crowd out there all in place and ready to go. We're going to wait another moment here for some of the folks loitering around the registration desk, and then we'll be underway.

(Pause.)

DR. RAGAN: The group came to order so nicely I have the feeling we had better go ahead while we have a quiet room.

I'm John Ragan. I'm National Livestock Program Leader for the Animal Production Food Safety staff at FSIS. And on behalf of the long list of cosponsors, which are on the back of your agenda, I would like to welcome you to the National Conference on Animal Production Food Safety.

We do have a large number of speakers, distinguished speakers, scheduled for today and tomorrow. So one of the things that you will see here is a rather stern set of moderators insisting on keeping the program up to schedule so that we can hear from everyone.

There will be some time as we go along, depending on the flow, for questions. And then, tomorrow, at the breakout session, there will be ample discussion time.

1 As many of you, perhaps most of you, are aware, a
2 meeting somewhat similar to this was convened five years
3 ago, just over five years ago, in College Park, Maryland,
4 dealt with the same subject matter, animal production food
5 safety.

6 Over the last few days, as I reviewed the
7 proceedings from that meeting, I was struck with the number
8 of similarities, first, in the agenda we have for the next
9 two days, and at the same time with a number of differences.

10 A great many things have changed. HACCP was a
11 strange animal that everybody was concerned about and
12 talking about and discussing in 1995. Now it's a process
13 and a watershed change in the way meat and poultry is
14 inspected, and it's largely implemented, depending on whom
15 you speak to.

16 But it's still a large matter of discussion. In
17 fact, I doubt that very many processes and procedures and
18 programs have been so cussed and discussed and analyzed.
19 And I assume that will carry forth.

20 One of the great changes that I realized as I
21 looked at that proceedings is the raising of the bar. I
22 think expectations in our government, in our society at
23 large, are dramatically higher than they were in 1995.

1 Fortunately, some of the answers to the questions
2 that we didn't have then we do have now. And as many of you
3 are aware, there are an awful lot of unanswered questions
4 still, particularly with regard to the on-farm side of food
5 safety. Perhaps we can have some of those answered this
6 week.

7 We have a number of distinguished researchers, we
8 have industry representatives, and we have government agency
9 representatives, as well as consumer representatives.

10 So hopefully, together, with a cooperative
11 spirit, high expectations, we can find the way that we
12 should best go in the future.

13 There are three themes to this meeting: quality
14 assurance, research, and education. And they are somewhat
15 divided in the agenda, but we hope to see them at the end
16 all molded together into a document of proceedings that will
17 give us all some idea of how we should proceed.

18 I have taken the liberty this morning to ask for
19 some remarks from a speaker not on your agenda but known
20 largely to this group and certainly near and dear to those
21 of us in animal production food safety.

22 Dr. Bonnie Bautain was, I think, the moderator at
23 that first session in '95 and introduced the Undersecretary,

1 and was involved heavily throughout.

2 Dr. Bautain, as you may know, got her DVM at
3 Colorado State. She got her master's at the University of
4 Hawaii. She was in private practice in Hawaii up until '89,
5 I believe, and then came to the mainland and has had a
6 number of very productive and relevant positions since then.

7 She has worked for CSREES, FDA, finally for FSIS,
8 was the first director of the Animal Production Food Safety
9 staff and certainly established a sound basis for all of us
10 to work on.

11 Bonnie is going to share just a few remarks with
12 us about how things were in '95 and how they are from her
13 point of view now. Bonnie.

14 DR. BAUTAIN: Good morning. It's a real honor to
15 be here and to see such a distinguished audience.

16 And with John's permission, I was going to tell a
17 little story about John in 1994. He told me he was curious
18 about preharvest food safety, and he wasn't quite sure just
19 how it was going to fit into his job as state veterinarian.

20 And now you can see John is the National Program Leader for
21 Livestock and Food Safety.

22 And I think it represents that we've all changed
23 a little, some of us a lot, since then.

1 And I believe that the past is prologue to the
2 future. There's a lot that we've learned and a lot that's
3 going to be shared today.

4 Six years ago could we have envisioned the most
5 radical shakeup of food safety hygiene rules?

6 Let me read you something. And this is a quote.

7 "The new regulations will merge, harmonize, and simplify
8 food hygiene policy applicable to all food and all food
9 operators, from the farm to the table.

10 "The focus is on setting objectives while leaving
11 business flexibility in deciding the safety measures to take
12 rather than prescribing them in great detail.

13 "On farms codes of good practice are to be used
14 as the safety management instrument given that, for the
15 moment, full HACCP implementation is considered
16 overambitious in the farming context.

17 "Producers must put in place procedures for
18 traceability of all foods and be able to withdraw products
19 presenting a serious risk to consumer health."

20 Six years ago, would this seem like fiction?
21 Well, this quote is from the European community's Health and
22 Consumer Protection Commissioner, David Byrne, as he
23 proposed sweeping regulatory changes in Brussels just a

1 couple of months ago, in July, July 17.

2 My job for the next five minutes is to tell you
3 where we have been in animal production food safety at USDA
4 and leave you at this meeting to determine the future.

5 After the watershed tragic E. coli 0157 event in
6 1994, the Animal Plant Health Inspection Service, APHIS,
7 held the first preharvest food safety national forum.

8 The result was a blueprint for preharvest food
9 safety emphasizing the collaborative veterinary
10 infrastructure available to serve and to build on food
11 safety models such as the Salmonella enteritidis project in
12 Pennsylvania.

13 Later that year Congress reorganized the USDA,
14 and those of us who worked mostly on food safety in APHIS
15 were transferred to FSIS, the Food Safety Inspection
16 Service, along with the Agriculture Marketing Service's Egg
17 Products Inspection program. The Undersecretary for Food
18 Safety position was established in USDA at that time.

19 From 1994 to 1995, APHIS, and later, FSIS
20 supported the Animal Production Technical Analysis Group,
21 the TAG group.

22 These experts analyzed food animal production
23 physical, chemical, and microbial hazards all along the

1 animal production chain and made some very significant
2 recommendations that still are very valuable today.

3 For example, the TAG suggested that food safety
4 control points be developed through research and that HACCP
5 principles be applied to quality assurance programs.

6 As John mentioned, from May 23 to 25 in 1995,
7 FSIS hosted about 300 people in the National Forum on Animal
8 Production Food Safety in College Park in Maryland.

9 Earlier in 1995, FSIS had proposed its first
10 major regulatory change in almost 100 years, the passage and
11 reduction in HACCP system's rule. Needless to say, there
12 was some anxiety in the production community over FSIS's
13 role in animal production.

14 The acting Undersecretary for Food Safety, Mike
15 Taylor, invited all of us, all stakeholders, to focus on the
16 preventive approach to reducing pathogens from farm to
17 slaughter.

18 He asked us all to do several things at this
19 meeting:

20 Define the current status of food safety hazards
21 and possible and promising risk reduction measures in animal
22 production practices; to work toward national consensus on
23 research priorities; to identify partnerships needed for

1 research and education; to recommend effective public and
2 private funding; and to make recommendations for the role of
3 the new Animal Production Food Safety program in FSIS.

4 As its first director and chair of this forum, my
5 staff and I enthusiastically carried out a lot of the
6 recommendations from the forum in our programs.

7 For example, I just wanted to highlight some of
8 the things that happened since the last program and under
9 FSIS's initiatives.

10 The Animal Production Food Safety staff helped to
11 organize and guide the discussions and the recommendations
12 for the World Health Organization Consultation held in
13 Washington, D.C. in July -- or rather, June of 1995. And
14 this consultation was entitled "Economic Implications of
15 Foodborne Diseases and Consequences on Animal Production
16 Food Safety."

17 Some of the important findings from that -- or
18 recommendations from that consultation was that animal
19 production food safety is an integral part of the farm-to-
20 table strategy, that traditional animal disease eradication
21 processes of government regulation, eradication, and
22 compensation does not apply to animal production food safety
23 and microbial pathogens.

1 For pathogens, HACCP is currently most
2 effectively applied at slaughter and processing activities.

3 And there were some research priorities that the
4 international community agreed upon which really reflected
5 much of the information that came out of that '95 forum.

6 We needed ecology and epidemiology of pathogens
7 research, pathogens and virulence in genetics, live animal
8 HACCP models, economic analysis and risk assessment, risk
9 communication and technology transfer, and animal
10 identification enabling case controlled studies.

11 The Animal Production Food Safety staff led
12 initiatives to support 18 state partnerships as a catalyst
13 for sharing information at the local level. Also,
14 recommendations from the forum included a more cooperative
15 role that FSIS could play.

16 And under the brainchild of Dan Vitiello from the
17 Animal Production staff, he led the efforts which resulted
18 in the agency regaining its cooperative agreement authority
19 instead of trying to work through contractual relationships
20 with our partners.

21 In 1996, industry supported and FSIS received the
22 President's Food Safety Initiative funding to fund multi-
23 state epidemiology studies of pathogens in sheep, chicken,

1 swine, and nonfed beef. And currently papers are being
2 presented in the scientific journals as a result of those
3 epidemiology studies.

4 FSIS also funded a national survey of very small
5 producers in economically disadvantaged areas to determine
6 their educational needs and the challenges they are going to
7 face in the HACCP era.

8 FSIS, with the former Livestock Conservation
9 Institute, developed innovative ways for education. We had
10 the Food Safety Digest. We looked at regional -- we had
11 regional conferences on animal production food safety. And
12 then, we also had the Livestock Conservation Institute do a
13 clearing house for industry's educational programs.

14 Currently FSIS is supporting efforts in a virtual
15 university so that we can provide educational information to
16 our schools.

17 What I'm trying to point out is that we listened
18 then, and we'll listen today.

19 A lot has happened since the '95 forum and the
20 World Health Organization Consultation, and we'll hear
21 updates at this conference. I believe that the past is
22 prologue, and you're here to determine our future.

23 So, welcome. Have a great conference, and help

1 define our collaborative future. Thank you.

2 (Applause.)

3 DR. RAGAN: Thank you, Bonnie. The next
4 presentation will be somewhat unique in my experience.
5 Perhaps some of you with more experience will not find it
6 so.

7 But our keynote speaker, Dr. Douglas Powell, is
8 unable to be with us today for an unusual and bizarre reason
9 that we won't go into at the present time, but we would hope
10 to hear from him in person in the near future.

11 Dr. Powell completed his doctorate degree in the
12 Department of Food Science at the University of Guelph and
13 is currently an assistant professor in the Department of
14 Plant Agriculture at the University of Guelph.

15 He continues as a free-lance journalist, and many
16 of you know him for his Web site, FS Net, in which he deals
17 with a number of subjects, including food safety.

18 He produced his first book in 1997, entitled Mad
19 Cows and Mother's Milk. And his next book, entitled
20 Reclaiming Dinner, will be published next year.

21 And before we have a look at Dr. Powell on tape,
22 I would like to thank his wife, Dr. Wendy Powell, also a
23 veterinarian in the food safety agency, for bringing the

1 tape to us last evening.

2 So if we can roll that tape, we will hear from
3 Dr. Doug Powell.

4 (Whereupon, the videotape was played.)

5 DR. POWELL: Oh. Hi. Sorry I couldn't be with
6 you. I was just sitting here editing some news, you know,
7 Animal Net, FS Net, all those good things.

8 If you were at the International Association of
9 Food Protection annual meeting, you may have heard my tale
10 of woe.

11 It seems that 20 years ago -- it doesn't seem --
12 20 years ago I did have a criminal conviction for bad
13 driving. U.S. Customs found out about this a couple of
14 weeks ago and prevented me from going in.

15 So with the help of Kateegy [phonetic] here on
16 the other end of the camera, we sent the talk down.

17 We thought we would have this fixed by today; we
18 haven't. So here we are. We got a little more theatrical
19 this time, give you a little early morning entertainment,
20 because it is only 8:00 in the morning down there, I'm
21 aware.

22 So what are we here to talk about? Why is food
23 safety important, and why is it important on the farm?

1 Well, you can't go anywhere, you know.
2 Newspapers, they're all full of it, of food safety. They
3 may be full of it, too.

4 Why, just on Friday the New York Times had a
5 letter. There's been this argument about, you know, is
6 organic better than conventional and vice versa? You can
7 ask Lester about that one. He may know a little something
8 about it. I think he's supposed to be there.

9 Anyway, on Friday the Times had this letter from
10 a person saying, Look, you know, even if there is bacteria
11 in manure, it doesn't matter, because you can just wash it
12 off the produce. Duh. Not quite.

13 And of course, these things, the trends that are
14 out there and the level of public discussion is actually
15 quite disconcerting.

16 There are real risks out there that need to be
17 reduced. They need to be managed and need to be seen to be
18 managed. At the same time, there is an awful lot of New Age
19 hucksterism going around.

20 Producers, processors, farmers, all of you folks
21 have to be vigilant about enforcing good food safety on the
22 farm. Why? Well, we're going to show you a couple examples
23 over the next half-hour, but the bottom line is, that's

1 where some problems start, and in fact, in some cases, the
2 only place to fix them.

3 Having said that, let's not oversell the things.
4 They're limited in what we can do.

5 But you have to do them. You have to get the
6 right data. You have to make it public so people know
7 you're making an effort. The lawyers call this due
8 diligence, and it will stand up in court. Furthermore, you
9 have to be perceived as doing the right thing.

10 People have an interest in how food is produced.
11 In fact, that interest is maybe at an all time high as so
12 many -- there's so few people involved in food production
13 that people are now interested in how it's produced because
14 they don't have any idea.

15 How do we see this reflected? We see this in all
16 kinds of New Age diets where people are looking to link it
17 to health. We see this in stories about food safety. Every
18 week, on and on and on, there's outbreaks, and they're very
19 nasty outbreaks.

20 We see it in concern about genetic engineering
21 and agricultural biotechnology. We see it in concern about
22 animal welfare standards, a whole array of concerns, even
23 corporate control and concentration in the food supply.

1 Not a day goes by that I don't have to sit here
2 at this computer for two or three hours editing stories that
3 have appeared just that day.

4 So rather than viewing this as, Ooh, this is bad,
5 this is an opportunity. If you've got a good story to tell,
6 get out there and tell it.

7 Now, one of the trends that's out there is where
8 consumers, whether rightly or wrongly, in response to all
9 this they say, Well, I'm going to go for the all natural
10 food because that's better for me.

11 Conversely, people think that food associated
12 with factory farming is bad.

13 Now, you may know, and I'm sure many of you in
14 the audience know, we have had a terrible outbreak of 0157
15 in Walkerton, Ontario this summer.

16 Now, Walkerton is about 50 minutes away from
17 here, north and to the west a bit. One of my best friends
18 is the dairy farmer at the edge of town. And I can't begin
19 to tell you how this has impacted on his life.

20 This is a town of 5,000 people, largely a farming
21 community. They were descended on. They had a media outfit
22 worthy of the Gulf War. CNN had a crew up there. There
23 were helicopters. There were more helicopters for the

1 television stations than there were ferrying kids back and
2 forth to the sick kids' hospital.

3 In the end, six people died and over 2,000 got
4 sickened by 0157 that apparently got into the water supply.

5 Now, a few weeks ago, the Globe and Mail, one of
6 Canada's self-proclaimed national newspapers, came out with
7 the headline on the front page, E. coli linked to cattle.
8 There's something to stop the presses over, cattle shed E.
9 coli.

10 What happened was, because in Canada we have not
11 as open and transparent a system, whether you like it or
12 not -- I mean, you think there are flaws, but it's not as
13 bad as what is in Canada in terms of reporting -- there had
14 been no information on this outbreak, a lot of speculation.

15 What that has led to is, Well, it's factory
16 farms. It's these large hog things.

17 And I mean, factory farms in Ontario, the
18 definition is over 150 cattle, and you've got a factory
19 farm.

20 This is not factory farming like in Iowa or North
21 Carolina, with these thousands of animals. These are
22 actually small operations. I think the biggest feedlot
23 maybe is 5,000 head.

1 Never mind, the story took off that it was
2 factory farming and it was hogs, which of course doesn't
3 really make sense in this context. And these stories
4 proliferated.

5 And others tried to come back and say, Well, hold
6 on, wait a minute, maybe it's not that. You know, it could
7 be anything. It could be deer, it could be cattle, you
8 know. They all shed this thing. Well, that got lost in the
9 noise.

10 So when the story came out a couple of weeks ago,
11 then, the lead was they connected it to a farm, one of the
12 farms in the area tested positive.

13 This is guy, cow cap operation 100 head, hardly a
14 factory farm. In fact, he's a model producer. He does all
15 the right things. He has an environmental farm plan, good
16 containment.

17 The point is we know cattle shed 0157. That's
18 why we chlorinate water. But in the absence of that kind of
19 information, mythologies and rumors and conspiracies take
20 off.

21 This produces a challenge. Furthermore, it
22 produces a real risk, because people become impervious to
23 risk. They think -- and I've heard this so many times this

1 summer I can't begin to tell you -- I don't live near a
2 factory farm, therefore, I'm not at risk.

3 A little girl in Montreal got sick from 0157 a
4 little while ago. Her father wrote in to -- or was quoted
5 in the newspapers saying, Well, we were using frozen
6 patties, so it couldn't have been the hamburger; it must
7 have been the water.

8 Stories like that unfortunately are
9 proliferating, and there's a real danger there. And there's
10 a lot of hucksters, as I said before, about all natural
11 stuff.

12 And I would argue that, for those folks in this
13 room, science has a responsibility, if not to inform, then,
14 to lead that public discussion about where risks are and
15 what we can do to reduce them.

16 Now, when it comes to consumers, that kind of
17 factory farming, what that is is a stigmata, it's a symbol.

18 I don't want to know all the details about how 0157 may get
19 into the water supply and get people sick.

20 I just know, big storm, Oh, I've seen them
21 spreading this stuff out there, therefore it must be factory
22 farming, and therefore, it's bad, and I want to stay away
23 from it.

1 Stigma is a very powerful shortcut that consumers
2 use to view whether we should, you know, worry about risks
3 or not.

4 For example, the most famous case of this, and in
5 fact, why a lot of the on-farm food safety push got started,
6 was these California strawberries. Well, not these
7 strawberries. These were bought at the store down the road.
8 Not bad for this time of the year.

9 In 1996 there was an outbreak of Cyclospora all
10 across North America -- well, on the eastern side of North
11 America. In the end, about a thousand people got sick. You
12 all know the story.

13 And at the time they said, Well, it's California
14 strawberries. Turns out it was probably Guatemalan
15 raspberries. These aren't Guatemalan, but they're
16 raspberries. It's breakfast. You're probably sitting there
17 eating, too, so don't get mad at me eating. And it turns
18 out it was Guatemalan raspberries.

19 No matter. The California strawberry growers
20 lost between 20 and \$40 million largely because their
21 product became stigmatized. The details became irrelevant.
22 The producers were slow to get out there.

23 Look at it this way. Once the fingers start

1 pointing -- and this is what happens all the time. The
2 journalists go and they write the stories, and they say,
3 They say it's you, and they say, It's not us, and the
4 journalists say, Prove it. And they say, It's not us.

5 Eventually they opened their books, but it was
6 too late, and the damage had been done.

7 Today if that happened and you went to the
8 California strawberry growers, they would say, Well, we
9 don't think it's us, but here is everything we do to reduce
10 risks on the farm.

11 And they would show you these neat little hand
12 washing stations that they move around the fields. They
13 would show you these neat little ways that they warm up
14 water so that they can have warm water to wash hands out in
15 the fields -- and it gets cold at night out in the fields in
16 the valley in California -- and so on. And they would be
17 able to document it.

18 Is that risk elimination? No. But is it risk
19 reduction? Yes.

20 Now, this here is a greenhouse tomato. It's very
21 uniform, nice color.

22 Leamington, Ontario has the largest concentration
23 of greenhouses anywhere in North America, and they produce

1 this stuff. And well, with the 65-cent Canadian dollar, we
2 export most of it to the United States, and you guys seem to
3 like it.

4 Now, a couple of years ago I developed an on-farm
5 safety plan for all 220 growers in the province. And it
6 involves water quality checks and employee sanitation, and
7 so on, again, risk reduction. But it's documented, it's on
8 the Web. Consumers can get it if they want, customers can
9 get it if they want.

10 Why am I telling you all this? What's this got
11 to do with animals?

12 Well, in the aftermath of Walkerton this year,
13 every little town in Canada has gone crazy on water testing.

14 We have had more boiled water advisories than you
15 can begin to imagine in Ontario and throughout Canada in the
16 last year because all of a sudden people are realizing, Oh,
17 I thought Canada was pristine. No. It can happen at home.

18 One of the things with on-farm food safety
19 plans -- and I've done a number of them now -- and we survey
20 the producers at the start.

21 And we always ask them, What's the biggest risk
22 to the foods you eat? Just like you do with consumers. And
23 consumers for the last few years would say microorganisms,

1 bacteria, bugs.

2 What do farmers say? It's not bugs, it's not
3 chemicals. Every time we've done this the answer is
4 imports. It's always someone else. My food is clean. It's
5 that bad stuff from somewhere else.

6 And in Canada, we were certainly very guilty of
7 this image of the pristine environment and it couldn't
8 happen here. Guess what, folks? It did.

9 In the aftermath of Walkerton, then, a couple of
10 newspaper reporters actually called up these greenhouse
11 vegetable guys.

12 And they said, Are you concerned that you're
13 using water -- and we use municipal water in Leamington, but
14 it's well water elsewhere. Are you concerned about growing
15 your vegetables in this water that contains E. coli? And
16 that's where the story was going.

17 And the general manager of the greenhouse
18 association said, Well, actually, we are concerned about
19 water quality, and that's why we put in a plan over a year
20 ago where we're testing water quality for every grower, and
21 I can show you all the data that says we're on top of this.

22 And that was the end of the story. It didn't go
23 anywhere. The reason why is the short form for HACCP. Say

1 what you do, do what you say, and be able to prove it, and
2 you'll have some success.

3 But, hey, why just sit here and talk in my
4 office? This is my office. I've got all these computers
5 for the kids. Fortunately, this is the first week of
6 September now, and my kids have gone back to school.

7 Anyway, but if we're going to talk about food
8 safety, I think we had better go to the farm. So we'll see
9 you there.

10 (Pause.)

11 DR. POWELL: Hi, folks. If we're going to talk
12 about on-farm food safety, let's talk on the farm.

13 Now, of course, this is a research facility.
14 This is at the University. We did not have time to go to a
15 couple of friends' farms, but you do what you can do for
16 theatrics.

17 Now, people don't necessarily think of it as
18 food. They think of their dinner plate. But on-farm food
19 safety, this is where it starts. It starts with research
20 and getting that research out into the field and having it
21 make a difference. And that's a real challenge. But
22 there's been a number of successes that have happened.

23 You look at the Nebraska corn-fed beef program.

1 And D. Griff has done a great job getting all those
2 producers on there. And what it really is is a great QA
3 program. The data is there, and they can prove what they're
4 doing. That's the best you can do.

5 People are always going to say, you know, my
6 favorite line from Regis Philben a few years ago on the gab
7 fest with Kathy Lee before she left, Anything from a cow is
8 bad. Well, it's not. But there are risks, and they need to
9 be managed appropriately.

10 But there's a real danger, of course, in
11 overselling these things. You know, why are all these
12 outbreaks happening at HACCP based facilities?

13 HACCP is a great tool to reduce risk, but it's
14 not going to solve all the problems. And we as an industry
15 and as a government have to be very careful not to oversell
16 it, because there's always going to be problems.

17 You can't have real HACCP on the farm. You can
18 have HACCP-like procedures. But remember, human behavior is
19 very unreliable and very difficult to quantify. So don't
20 oversell things.

21 There's an old saying, and you've probably heard
22 me say it before: Bullshit is the grease on the skids of
23 innovation. So be careful about that, because down the line

1 your credibility will be harmed because, remember, there's
2 that consumer interest out there. They don't see this cow.
3 What they see is maybe that broken needle in their steak at
4 home.

5 You know, stigma is an incredibly powerful
6 emotion that consumers use to decide what's real and what's
7 not. They don't want to know all the specifics about bovine
8 encephalopathy and transmissibles and New Variant
9 Kreutzfeld-Jakov disease. They just say British beef is
10 bad. Yuck. I want to stay away from it.

11 A good example is, talking about those California
12 strawberries and raspberries. The poor strawberry growers
13 come back, and you know, six months later they had an
14 outbreak of Hepatitis A in the frozen strawberries. It
15 turned out that they were legally grown in Mexico and sold
16 to the U.S. school lunch program.

17 And they had an outbreak, vaccinated all kinds of
18 kids. Well, of course, strawberry sales collapsed all
19 through North America.

20 I went to the grocery store with a couple of my
21 younger kids who weren't in school at the time. It was
22 during the week. And we found when we shopped, of course,
23 that California strawberries were really cheap, they

1 couldn't give them away. I picked up a couple of pints.

2 And all these people in the produce section, they
3 just stopped and stared at me like I was, you know, a child
4 abuser. And one of them actually came up to me, and she
5 said, Didn't you hear about the strawberries? Don't you
6 know they're poison?

7 So I looked at her, and I said, Gee, you know,
8 I'm a professor in food safety, and blah blah. It didn't
9 matter. She was gone. I had lost her. She had concluded
10 that I was a bad person. All she had heard was that it was
11 bad, and therefore, stay away from it.

12 I walked away. There was no -- she wasn't going
13 to change her mind. I was a child abuser in their minds.
14 And of course, my kids are eating the damn things in the
15 cart because they're animals, nothing but animals.

16 Do they still do jokes about aggies and sheep?

17 (General laughter.)

18 DR. POWELL: Of course, most consumers, they
19 don't go to the farm. They go to the grocery store. They
20 want to buy food they trust. Safety is not negotiable.
21 It's expected.

22 And of course, the other reason to do on-farm
23 food safety is it can be real hard to cook food safely.

1 Dale Hancock is here. He can tell you about hamburgers. He
2 can watch and critique all the mistakes I'm making right
3 now.

4 But the point is, people are not going to be
5 perfect. It's the middle of the day, you know, and what if
6 I've had a few pops and gotten a little sloppy? Is that any
7 reason for someone to get sick? I don't think so.

8 So what we want to do is ensure that we've got
9 risk reduction across the board. By the way, this cloth is
10 just for wiping. It goes into the laundry room. This plate
11 goes straight into the dishwasher. These steaks are pretty
12 good looking.

13 So we want safety across the board because that's
14 what consumers expect. And if there ever is an outbreak,
15 they're going to come back to you and say, What have you
16 done to reduce risks?

17 You know, I really need some corn to go with
18 this. I'll be right back.

19 (Pause.)

20 DR. POWELL: Hi. I'm standing in front of a
21 field of genetically engineered BT sweet corn.

22 This is a farmer friend of mine. His name is
23 Jeff Wilson. He grows about 300 acres of fruits and

1 vegetables.

2 And one of the things we did this year was we
3 grew genetically engineered and -- or Jeff grew genetically
4 engineered and conventional sweet corn and potatoes side by
5 side. And because he has a farm market, we were able to
6 take it right through for consumer testing.

7 In fact, we just finished a press conference
8 which announced the start of the consumer testing, because
9 we got our first harvest. This stuff, oh, it will be
10 another five days or so till it's ready.

11 But the idea is, we're bringing people to the
12 farm. This is no different than any other segment of
13 agriculture. We have to get people more involved in what's
14 going on at the farm. Certainly the interest is out there.

15 And you know, if farmers and the agriculture
16 industry doesn't promote an understanding of what's involved
17 in today's food production in terms of safety, in terms of
18 environmental impact, and in terms of the trade-offs that
19 individual farmers have to make to produce a crop, then
20 others are going to do it for you.

21 And you may not like the results when, say, a
22 particular group goes out and says, This is what's going on
23 at the farm. You're better to take them out.

1 And I've been very fortunate that Jeff has been
2 willing to open up his farm market so that we can do some
3 consumer testing. We've been very open about this project,
4 you know. And in Europe we couldn't do this. I mean, they
5 would come by and cut it all down. I'd be standing in front
6 of a field of corn that was lying on the ground.

7 We actually have a three kilometer walking tour
8 through the corn and potatoes. No one has trampled the
9 crops. In fact, there's been at least a thousand people
10 through over the last month or two.

11 So the idea is, get out there, show people what
12 you're doing, and then let them vote.

13 We were able to show people today -- and this is
14 last Wednesday -- that the genetically engineered corn had
15 one treatment of herbicide, one treatment of nitrogen, no
16 insecticides. The conventional stuff had at least three
17 treatments of furodan [phonetic]. That's a human health
18 issue.

19 As a parent I'm more interested in having my kids
20 eat sweet corn -- which they eat a lot of -- that has the
21 actual 100 percent fewer levels of insecticide on it.

22 Further, we use BT as a spray, same thing, a lot
23 of spraying. And what about the impact on nontarget

1 insects? The environmental aspects are very significant.

2 So bring folks out, show them what's involved in
3 agriculture, and get your side of the story out there.

4 Now, you can see we've got out genetically
5 engineered corn and our safe beef, and we're going to go
6 have lunch. I hope you enjoy your day.

7 This may not be the best food or beverage for
8 eight o'clock in the morning, but you understand I'm taping
9 this.

10 Anyway, I'm really sorry I couldn't be with you.

11 We all miss you. I hope you have a good conference. And
12 we'll see you in the future real soon. Thanks very much.

13 (Applause.)

14 DR. RAGAN: Okay. We do have Dr. Doug Powell on
15 the phone if there are a couple of burning questions that
16 you have for him. I think you can use the mic up here.

17 Now, Doug is going to be really disappointed if
18 somebody doesn't jump on him here, and we do have him on the
19 wire. And we will give you two minutes to indicate that you
20 want to ask questions.

21 (Pause.)

22 DR. RAGAN: Okay. I will tell Dr. Powell that
23 the audience was transfixed.

1 (General laughter.)

2 DR. RAGAN: And we will move ahead.

3 Thank you, Doug, if you're still on the line.

4 DR. POWELL: Oh, I'm here.

5 DR. RAGAN: Okay. Very good. This is a shy
6 group.

7 DR. POWELL: Yes. Apparently. Well, you know,
8 these things work okay. My department thinks I'm in St.
9 Louis, so I got out of the departmental retreat today.

10 DR. RAGAN: Very good.

11 (General laughter.)

12 DR. RAGAN: I think we do have a question in the
13 back of the room. Would you come up to the mic, please?

14 VOICE: Dr. Powell, you had mentioned that on-
15 farm HACCP is not possible but HACCP-like processes is.
16 Could you elaborate on that?

17 DR. POWELL: For the HACCP purists in the crowd,
18 they will say that it's difficult to have critical control
19 points on the farm. It's not like you're in a dairy where
20 you're pasteurizing and you can measure the temperature.
21 But you can have HACCP-like programs.

22 It's the same idea. I don't get too hung up in
23 the words, but some HACCP purists do. So I just wanted to

1 avoid that.

2 DR. RAGAN: Anyone else?

3 (No response.)

4 DR. RAGAN: Okay. I guess we're ready to move
5 along. Dr. Powell, thank you very much for being with us in
6 voice and on the screen.

7 DR. POWELL: Thanks, John. We'll see you later.

8 DR. RAGAN: Okay. At this point we're going to
9 move to looking at the question of where we are with regard
10 to animal production food safety or food safety on the farm.

11 We have three speakers who will address this
12 subject, from the government perspective, from the
13 producer's perspective, and from the consumer's perspective.

14 Our first speaker will bring us the government
15 perspective, Dr. Steve Sundlof, very likely needs no
16 introduction to this group. But I will say a few words
17 about him in any case.

18 He is director, as you know, of the Center for
19 Veterinary Medicine in the Food and Drug Administration;
20 received his DVM and Ph.D. in toxicology from the University
21 of Illinois; is board certified in toxicology; has served on
22 the faculty at the University of Florida, and held the rank
23 of professor there.

1 And as you're well aware, Dr. Sundlof has
2 published numerous articles in scientific journals on drug
3 residues and food safety.

4 He has presented more than 100 invited lectures
5 at national and international meetings. And he presently
6 serves as chairman of the WHO/FAO Codex Alimentarius
7 committee on residues of veterinary drugs in food.

8 He is past president of the American Academy of
9 Veterinary Pharmacology and Therapeutics. Please welcome
10 Dr. Steven Sundlof.

11 (Applause.)

12 DR. SUNDLOF: Thank you. If you can just bear
13 with me for a second while I try and get the computer up and
14 running. Oh. That was easy.

15 Thank you very much. This is the first time that
16 I've ever been asked to represent the entire U.S. government
17 in a public meeting, so I think this is kind of cool.

18 But in the future I think I'm going to do all my
19 presentations by video tape. That looked like it was a lot
20 more fun.

21 Yes. I do want to talk on what the government
22 perspective is on food safety. Within the recent years
23 there has been a great amount of activity at the federal

1 level in focusing attention on food safety and on programs
2 in which to improve food safety.

3 Well, the government, of course, has been
4 involved in food safety. This is one of the primary
5 responsibilities of government, to make sure that the food
6 supply is safe.

7 Although it had been going on even in the 19th
8 Century, it was early in the 20th Century, under President
9 Teddy Roosevelt, that the first Food and Drug Act was passed
10 in 1906.

11 And that was generally looking at certain
12 foodborne issues such as tuberculosis and trichinosis, which
13 were major food problems at the time, still are food
14 problems but not nearly to the extent that they were back
15 then.

16 The major government entities, when we think
17 about food safety and who is responsible, we generally think
18 about the USDA, especially Food Safety and Inspection
19 Service, but also APHIS and CSREES and ARS and ERS and a
20 number of other organizations within USDA that do have some
21 responsibility in food safety.

22 We also think about the Department of Health and
23 Human Services, two cabinet level departments in which HHS

1 has the FDA, including Center for Veterinary Medicine,
2 Center for Food Safety and Applied Nutrition, and the
3 Centers For Disease Control and Prevention.

4 But we are aided by other parts of the federal
5 government, including EPA and the Department of Commerce
6 through the National Marine Fishery Service.

7 But more than a centralized government regulatory
8 control program, we rely extremely heavily on the states, on
9 state and local authorities to carry out these programs.
10 And I don't think those programs get near the credit that
11 they deserve.

12 But without the states and local governments and
13 organizations like AFCO, we wouldn't have the safe food
14 supply that we do. So that's very important.

15 Well, since I am from FDA, I think it's prudent
16 to talk about some of the FDA's programs and some of the
17 statements made. If I was from USDA, I would be quoting
18 Secretary Glickman. But I'm from FDA, so I'll be quoting
19 Dr. Henney.

20 And in a speech last year Commissioner Henney
21 remarked, While the U.S. enjoys one of the safest and most
22 bountiful food supplies in the world, each year in our
23 country millions of people become ill and thousands die due

1 to foodborne illness. We can and must do better.

2 And the government's assumption is that all food
3 should be safe and that the public has the right to the
4 safest food supply that we can possibly give them.

5 And this is occurring at a time when we are
6 seeing new infections, new infectious agents emerging in the
7 food supply and we're more concerned about certain chemical
8 substances.

9 We do have -- much more of our food is imported.
10 To a greater extent we eat outside of the home, and we
11 don't have direct control over food safety.

12 We know of at least five times as many substances
13 and organisms that can cause foodborne disease than we did
14 back in 1942. Some of the more interesting organisms that
15 have developed are things like Salmonella enteritidis, which
16 was not known until recently, transmitted transovarially into
17 the egg. That was a route of transmission that we didn't
18 know about.

19 BSE, it goes without saying, is a new foodborne
20 infection. We just heard about cyclospora as a new
21 foodborne disease. And there are a number of other new
22 organisms that are causing disease.

23 We also are more concerned about naturally

1 occurring and manmade chemicals that pose threats at much
2 lower levels than we thought of in the past. The new EPA
3 risk assessment on dioxin shows that the level of risk of
4 cancer may be anywhere from 1 in 100 to 1 in 1,000, fairly
5 low.

6 We are also concerned about chemicals such as
7 mercury, where new science has shown that the risk may be
8 greater than what we had previously thought.

9 And we can detect these things at much, much
10 lower levels than we could in the past.

11 And in terms of the foodborne pathogens, CDC
12 reports that of all the foodborne pathogens, the diseases
13 that they cause, we don't know what the majority of them
14 are. So we have a lot of work ahead of us in trying to
15 determine just exactly what organisms are responsible for
16 foodborne disease.

17 So what is the Government's approach? Well, we
18 start out by saying enforcement is the bottom line. That is
19 the last resort for us.

20 We do have the authority to take regulatory
21 action, both on the farm, in the plants, or in the retail
22 establishments, or anyplace in the chain. But we try not to
23 use that except where absolutely necessary. And both the

1 USDA and the FDA strongly believe that education and
2 cooperation is the real key to food safety.

3 This is an interesting debate now that is
4 occurring in the European Union, where they are looking
5 towards a centralized food authority, food safety authority.

6 And one of the criticisms they have received is
7 that, although they have a central authority, they have no
8 direct enforcement authority. And that involves the
9 individual member countries of the European Union. And that
10 is somewhat unsettling to the public.

11 Through cooperation, though, we have had some
12 very successful programs to prevent food safety outbreaks
13 that we've seen in other places. The BSE prevention program
14 is an example of this.

15 And in this program, we work heavily with our
16 state partners in getting out there and inspecting all the
17 rendering facilities, all of the protein blenders and
18 distributors, all of the commercial feed mills, and many on-
19 farm operations, as well, to make sure that they were in
20 compliance with our new feed laws that prohibited the
21 feeding of mammalian proteins back to ruminants.

22 And in the first go-round we decided that this
23 would be an educational. If we found violations of the

1 regulation, we would first try and take an educational
2 approach to get people into compliance, then come back on
3 the second go-round and determine whether or not that had
4 been effective.

5 And in most cases, it has been effective in
6 bringing people into compliance merely through educational
7 efforts.

8 What about seafood? Seafood HACCP is another
9 program in which there has been a great cooperation between
10 the government, in this case the Center for Food Safety and
11 Applied Nutrition, the industry, and academia in developing
12 these HACCP programs.

13 In a survey, 78 percent of processors said they
14 would not have been able to develop a HACCP plan or comply
15 with the HACCP regulation if they had not been through this
16 course developed by the alliance.

17 And the success rate was fairly high. Even
18 before the first inspection, roughly about a quarter of all
19 seafood plants were in compliance. And so this is an
20 ongoing effort to bring more and more people into voluntary
21 compliance. And they expect that this will continue to
22 grow.

23 But it is a tremendous problem. It's a little

1 bit more difficult than trying to inspect in federally
2 regulated plants where you have thousands of people out
3 there producing.

4 We import over 50 percent of all seafood. And to
5 make sure that those other countries are in compliance is
6 also very important.

7 Egg safety is another area that has received a
8 lot of attention lately. There was, in fact, just last
9 July, there was a public meeting to discuss the issue of egg
10 safety.

11 There are some on-farm components to the egg
12 safety plan. This was part of the President's Council on
13 Food Safety. And they identified egg safety as a component
14 of overall food safety and developed an egg safety action
15 plan.

16 And FSIS and FDA have issued some current
17 thinking documents for public discussion, which includes
18 again on-farm actions designed to reduce the levels of
19 Salmonella enteritidis in eggs at the processing level.

20 And there will be another meeting this Friday in
21 Atlanta which will be discussing Salmonella enteritidis
22 research.

23 Milk safety, another component of the

1 government's plan to make sure that the food supply is kept
2 safe. This also emphasizes the importance of states, but
3 also of the dairy industry itself.

4 And it's regulated under a unique kind of a
5 cooperative plan called the Pasteurized Milk Ordinance.

6 And the National Conference on Interstate Milk
7 Shipments meets every two years to discuss changes to
8 Pasteurized Milk Ordinance in order to maintain food safety.

9 But it is a highly participative program that is
10 a government, state, and industry cooperative venture.

11 Well, we think in the government that there are
12 really three major things or areas that we want to emphasize
13 in our approach to food safety.

14 One of them is that it is a science-based
15 approach. Interestingly in the United States, science as an
16 institution is deeply rooted in our food safety programs.

17 This is not the case in many other countries,
18 especially less developed countries where science does not
19 serve as the basis for decisions. Other things that are
20 much more important, political decisions, economic
21 decisions, and trade implications are much more important in
22 developing their regulatory process than science is.

23 In the United States science is very important

1 and as an institution is deeply rooted in food science. The
2 best decisions we feel are made by using an objective,
3 scientific basis for those decisions.

4 And that presents certain problems, because as
5 you know, the area of food safety has become more and more
6 complicated as we learn more and more about these emerging
7 problems. And trying to keep government officials up to
8 speed on the new science can be a very demanding task.

9 But we have a substantial investment in food
10 safety research. And with the food safety initiative, the
11 budget for doing food safety research has doubled within the
12 past four years.

13 The food safety initiative has been a true
14 watershed for the United States in really focusing on the
15 whole issue of food safety.

16 It also means looking outside of the federal
17 government and looking to the scientists in the scientific
18 community, determining where the research priorities ought
19 to be, and making sure that those highest priority research
20 areas get funded and that there is not duplication of
21 efforts.

22 And I think we're going to be hearing from Dr.
23 Jerry Gillespie later on today, this morning, about the

1 Joint Institute for Food Safety Research that grew out of
2 the food safety initiative and the President's Council on
3 Food Safety.

4 So science is one of our basic tenets for our
5 food safety program. The other one is -- Number 2 is risk-
6 based. We want to take a more risk-based approach to
7 dealing with food safety.

8 We want to try and prioritize which are the most
9 imminent threats to public health and make sure that our
10 resources are directed at those.

11 We are instituting risk assessment much more into
12 the regulation of food safety. And we've seen a number of
13 quantitative and qualitative risk assessments that have been
14 published lately to get more of a risk-based approach.

15 We also are using our risk assessment in order to
16 give our risk managers the tools that they need, the
17 information that they need to make the proper risk
18 management decisions.

19 Thirdly, we think that the process needs to be
20 very open and transparent. And this is the area of risk
21 communication which Doug Powell just talked extensively
22 about. And risk communication has become one of the mantras
23 of modern food safety programs.

1 This concept includes telling the public where
2 the risks are, trying to explain those risks and the
3 approaches that are being taken to minimize those risks in a
4 very understandable way.

5 It also means that when we do have a problem we
6 get out there and we let the public know immediately. That
7 is absolutely critical to having a system which has public
8 support. And it means that everybody has a chance to
9 comment, that this is an open public process, that the
10 public is invited to make comments, and that the government
11 is required to respond to those comments in a timely manner.

12 And that's the reason for today's program, is to
13 try and bring in more outside input so that the food safety
14 programs that we're all part of can function better together
15 so that we can meet the expectations of the public.

16 So today's meeting is a focus on food safety,
17 basically on the farm, which is probably one of the areas
18 that gets the least amount of attention and one that is
19 absolutely critical in maintaining the safety of the food
20 supply.

21 We're here to explain what government has done to
22 promote food safety, to find out and document what producers
23 have done, and also to see what more needs to be done.

1 We realize that the responsibility to improve
2 food safety is not vested in one agency or just one
3 government, but we're all involved.

4 So food safety is our common goal. We request
5 and want your thoughts. Your comments and your criticisms
6 are all invited.

7 And we certainly, as Bonnie Bautain indicated
8 earlier, have come a long way in five years, but we need to
9 do a lot more. And we appreciate your willingness to work
10 with us. Thank you very much.

11 (Applause.)

12 DR. RAGAN: While we are changing our gear here,
13 if there is a question for Dr. Sundlof, he will respond.

14 VOICE: Hi. I'm Clarence Surogee [phonetic] from
15 Wisconsin State Veterinarian. And I think the food safety
16 approach on the farm is a very laudable goal, and I think
17 most of us in our states are working very, very hard to get
18 to that goal.

19 But every time I have producers and others sit
20 down and meet and talk about this, the first question they
21 ask is, Well, what's going on with the cooking of food, the
22 preparation of food, and what's the funding like in the
23 inspection on the retail side?

1 I know it's easy to point the finger at the other
2 direction, and I don't really want to do that.

3 But sometimes it helps for me to answer that
4 question if I were to know that there is an equal effort
5 say, for example, in restaurants where there is inspections
6 maybe once a year and some of the places even once every two
7 years, to know what's going on in that end so I can explain
8 to our producers what's happening there.

9 DR. SUNDLOF: Excellent question. Some of the
10 things that are being done under the food safety initiative
11 is that one of the major areas of that is education.

12 There is a program called Fight BAC! which is an
13 educational program to try and get the message down into the
14 elementary school level.

15 There are a number of other educational programs
16 that are going on besides the Fight BAC! to try and get
17 consumers to understand the importance of food hygiene, of
18 safe handling of food. So there are some efforts being made
19 there.

20 In terms of retail establishments, local
21 restaurants, that is a very good question and an
22 interesting -- it's a difficult area to try and regulate,
23 especially in these days where it is becoming increasingly

1 difficult to try and find competent help in those
2 establishments and to make sure that they are conforming to
3 the local and state laws regarding food safety.

4 Most of the retail establishments and
5 restaurants, et cetera are inspected by state and local
6 authorities, and they are strained in their resources to do
7 as adequate a job as we would like to have happen all the
8 time.

9 But there are a number of different areas in the
10 whole area of food safety, on-farm being one of them, public
11 education, retail establishments, testing, et cetera, et
12 cetera that all need to have a lot of interest paid to them.

13 And I think that these are areas that we need to be
14 discussing here at this forum.

15 VOICE: Dr. Ann Rumen [phonetic], Illinois
16 Department of Agriculture, Meat Inspection.

17 I had a question as far as where FDA stands when
18 you speak of risk assessment as far as repeat violators on
19 antibiotic residues when they send them to market.

20 DR. SUNDLOF: Yes. Well, we -- the way we have
21 established our enforcement program is that first-time
22 violators are generally given letters by the Food Safety and
23 Inspection System to let them know that they were in

1 violation.

2 Repeat violators go into a database, which FDA
3 makes sure and ensures follow-up action on the repeat
4 violators. We also sometimes work -- we work with FSIS in
5 order to make sure that we have coverage on those.

6 But for the repeat violators we generally take a
7 more strong enforcement action. Generally it starts out
8 with some warning letters. If that doesn't seem to affect
9 the problem, we get tougher.

10 And right now we have a number of dairies that
11 are under consent decrees that they are not able to market
12 their product. We took legal action against them. There
13 are some individuals actually serving jail time as a result
14 of repeated violation of residues.

15 In most cases -- one of the nice things about it
16 is that, in most cases, the repeat violators are a very,
17 very small proportion of the one-time violators, and that
18 generally means that people made a mistake and they are
19 willing to correct their mistakes.

20 But we're always interested in making sure that
21 if there are egregious violations that we target our
22 enforcement resources on those which are of the greatest
23 magnitude. Okay. Thanks.

1 DR. RAGAN: Thank you, Dr. Sundlof. And now, to
2 bring us the perspective of food animal producers or animal-
3 based food producers, if you will, is Dr. Beth Lautner.

4 Dr. Lautner serves as the vice president of Swine
5 Health and Pork Safety for the National Pork Producers
6 Council.

7 Dr. Lautner got her DVM at Michigan State and her
8 master's at the University of Minnesota, was involved in
9 private practice for some time, joined the National Pork
10 Producers in 1992.

11 She is responsible for the development and
12 coordination of food safety and swine health programs and
13 for information as they relate to pork production and long-
14 range policy planning.

15 Dr. Lautner represents National Pork Producers on
16 the Secretary's advisory on farm animal and poultry
17 diseases.

18 She is the recipient -- was in 1994 -- of the
19 Howard W. Dunn Memorial Award for outstanding service to the
20 American Association of Swine Practitioners and later
21 received the Animal and Plant Health Inspection Service
22 Administrator's Award in recognition for her contribution to
23 the advancement of animal health.

1 Also, as you know, Dr. Lautner has been an
2 integral part of many government/industry collaborative
3 efforts in the area of animal health and food safety.

4 So Dr. Lautner, if you'll bring us the producers'
5 perspective.

6 DR. LAUTNER: Thank you. I appreciate the
7 opportunity to provide overviews of animal production food
8 safety activities since the last conference in 1995.

9 Obviously in the short time period I'm not going
10 to be able to go through all of them. But what I'm trying
11 to do is just give a synopsis of them and an overview in
12 many different areas.

13 Almost every talk on food safety starts out with
14 a picture of the food supply in the continuum. Obviously we
15 understand that producers are at one end, the farming
16 community, and then we go all the way through to the
17 consumers.

18 And the important point with this is that there's
19 impacts all along the chain of activities, and any one
20 segment can influence the safety of the product that's
21 received through all the chain.

22 A lot of attention, I think we all know, since
23 1995 by the producing community, consumers, industry groups,

1 governments, both national and international governments, in
2 food safety.

3 We also recognize, as we said, internationally,
4 for many of the commodity groups export markets are a key
5 part of their profitability and productivity for the future.

6 We recognize as we start having countries replace
7 their domestic supplies with imported supplies they ask a
8 lot of questions about the safety of the product that you're
9 producing and try to make sure that they are providing a
10 very good, safe product to the consumers in their country.

11 So as I said, I'll provide an update since the
12 forum. I did actually last night sit down and read the
13 proceedings, and I think we'll have a lot of new information
14 to add in these areas.

15 I also surveyed the different producer groups for
16 their input into this presentation, as well.

17 It's going to be divided into four very quick
18 areas, looking at activities in the education area,
19 research, monitoring types of programs, policy, and
20 marketing.

21 And actually, this area is a new area that we've
22 had significant activity since actually the last 1995
23 meeting.

1 I'm going to use examples from different
2 industries as I go through this to talk about activities.

3 One of the things that all of the groups have
4 established is producer food safety committees. And these
5 committees consist of producers, practitioners, academia.
6 government is involved in some of those committees, the food
7 industry through to the retailers in some of these cases.

8 They have different subcommittees that operate
9 underneath them that may deal with specific types of issues,
10 the quality assurance programs, the research programs that
11 they have, specific topical areas of pathogens of concern
12 for that industry. There may be working groups in those
13 areas, as well.

14 Obviously QA programs are the flagship programs
15 for all the commodity groups to get food safety information
16 to producers. And they have different types of content.
17 Most of them are based on the residue avoidance.

18 The Turkey Federation had this program that's
19 been out for a period of time, Best Management Practices,
20 that looks at the practices on the farm and looks at some of
21 the pathogen reduction strategies at the farm level as well.

22 As I said, QA programs are really the flagship
23 way to get information to producers in an organized fashion

1 by having key contacts that carry this information out to
2 the producers.

3 You'll see examples, and I think many, many -- I
4 mean, you have catfish, trout -- many, many QA programs out
5 there at the present time.

6 I did see information out there and posters, with
7 a five-star program in the egg industry, on pork quality
8 assurance. I think beef, most people are familiar with the
9 beef program. Sheep, dairy, veal, very active types of
10 programs.

11 And we're going to have updates later this
12 morning also on more specifics of the QA program, so I'm not
13 going to get into those in any more detail.

14 We do definitely recognize when you deal with
15 issues such as Dr. Sundlof mentioned today on drugs residue
16 avoidance that this is a producer responsibility. It is not
17 something which can be fixed or dealt with later in the
18 chain. It's directly an area that the producer has the
19 control over at the farm level.

20 As Dr. Powell mentioned today, there's a lot of
21 discussion of whether you call it HACCP at the farm, you
22 call it good production practices, good management
23 practices, HACCP-like practices, best management practices.

1 I really don't think it's relevant or really
2 pertinent to the discussion to get into a lot of debate of I
3 think of what the terminology is. Many groups use different
4 types of terminology.

5 The important point is looking at what can be
6 done at the producer level, what types of controls can be in
7 place, and how you can implement those.

8 We also know that we're not producing in
9 isolation. Obviously the next step for our animals is to go
10 into the packing and processing side of the industry.

11 And as they have regulatory changes take place
12 there, such as the pathogen reduction and HACCP
13 implementation, that their expectations of producers can
14 increase. And what they're looking for in those animals or
15 the information they want to have about the production
16 practices of those animals can increase, as well.

17 This is information we put together about packing
18 plant changes affecting producers, because even though they
19 do not -- the regulations do not touch specifically at the
20 farm level, the way they are implemented in the plant does
21 require more knowledge about the animals coming into the
22 plant.

23 An area actually that we did not discuss, as I

1 went through the proceedings really didn't see a discussion
2 of, is the antimicrobial resistance topic, which is
3 consuming a lot of time and energy and research dollars and
4 understanding to really look at the potential impacts of
5 antimicrobial resistance at the farm for public health
6 significance.

7 I'm not going to spend a lot of time on it today.
8 There are speakers later this afternoon on this. And as we
9 said, there's been many workshops and conferences on this
10 issue.

11 But it really came to me as I saw that in 1995 we
12 were not having really much discussions of it, it is one
13 area that is going to receive much, much, much more
14 attention in the future.

15 And as information becomes available, you will
16 see more and more information put out to producers on their
17 role in this and into the quality assurance programs.

18 We're seeing some of this now with the judicious
19 use guidelines. The American Veterinary Medical Association
20 has done an excellent job of leading the way for the species
21 specific practitioner groups on developing guidelines for
22 the industries.

23 The Food and Drug Administration is providing

1 funds to have these types of programs developed and
2 information developed for practitioners and producers.

3 It is an area we're going to see, as I said, much
4 more information and be included into quality assurance
5 programs in the future.

6 That's a quick summary of education. And as I
7 said, I think it's important to take a look at the posters
8 and the display booths that provide more information in
9 different areas.

10 Also, I would commend FSIS for the state specific
11 projects that have been funded. As you read through the
12 projects and the results that are coming out of those
13 projects, there's good lessons for all involved in quality
14 assurance programs to look at how we can more effectively
15 reach all producers with those messages.

16 In the research area there has been numerous,
17 numerous meetings since 1995 developing research agendas,
18 both on a broad-based animal production level, processing
19 level, but then, also species specific levels as well.

20 And this is important to come forward and reach
21 agreement on what the research agenda is, how can we move
22 forward in these agendas?

23 We also are seeing the emergence of commodity and

1 pathogen specific working groups that bring together
2 producers, scientists, and government to sit down and look
3 at what we know about a certain pathogen and what we need to
4 know and develop a very good detailed research agenda. Many
5 of these are in place, such as for salmonella,
6 campylobacter, across different industries.

7 Federal funding has increased for research. I
8 think that has been very good. It's been very supported by
9 the commodity groups to put forward more research at the
10 animal production food safety level.

11 We're seeing progress, I think, on research
12 agendas. If I would fault maybe all of us in one area, it
13 would be that we really don't have a good way to communicate
14 how we're making progress on research and answering specific
15 questions.

16 Many times one research project creates new
17 questions. But we are moving forward and developing
18 progress on that research agenda. And I don't think we've
19 developed a good way to communicate that to people, the
20 types of progress being made.

21 Just as a quick example, this is for the pork
22 industry, our research priorities for salmonella. And this
23 is 1999, and this is 2001. And you can see we are starting

1 to hone down and funnel down on the questions.

2 We're starting to ask very specific questions
3 about, how do you define populations, how do you define
4 interventions, how do you show progress in pilot projects?
5 But very clearly moving down from the early work, which was
6 really survey, just how much is out there, what's present,
7 and what can be done?

8 So a lot of progress is being made, but I think
9 we have not found a way to communicate that as well as we
10 could.

11 The beef industry did a nice job of summarizing a
12 research portfolio that they have been involved with with
13 regard to E. coli and putting this information out. And I
14 think that's been a very, very effective way to deliver some
15 of the information.

16 There's many questions that remain, though, as we
17 are making progress, is, can measurable progress be made
18 when we're talking about pathogen reduction at the farm
19 level? What are the costs of this reductions that might be
20 made at the farm level? Presorting, there's interest in how
21 can you presort animals to slaughter? A lot of questions
22 that come up in that area, as well.

23 And then, probably the big question is, can

1 improvements that are made at the farm level, can we
2 translate those to enhance food safety all the way through
3 the food chain? That's the question that in many cases
4 remains to be answered.

5 And it's confusing. And I think research is like
6 that. You're creating new information and trying to
7 understand how that fits with the old information that you
8 had.

9 But for the producer community, as you're trying
10 to develop guidelines and information for producers and take
11 messages that you can take to them and say, These are
12 messages, this is information that you can use and implement
13 and will make a difference, I think it's important to
14 understand that our information is evolving in many areas.

15 And I'll just very quickly go through four quick
16 examples.

17 One of these is in the pork industry on feed
18 formulation on salmonella in swine. As you know, the pellet
19 process for producing feeds will kill the salmonella that
20 might be present in the feed. If there is some there, it
21 will provide temperatures to destroy the salmonella.

22 So the thinking would be, farms that feed
23 pelleted feed should have less prevalence of salmonella in

1 their particular animals.

2 Denmark had moved forward with a salmonella
3 program at the farm, where they actually were recommending
4 to producers to switch to pelleted feeds.

5 But what research has come out, both in the U.S.
6 and Denmark -- and this has been published several times --
7 is actually farms that were feeding pelleted feed had a
8 higher prevalence of salmonella in their animals on the
9 farm.

10 Now, that doesn't mean that you should not feed
11 pelleted feeds. But what it means is there's much more we
12 don't understand yet.

13 The pelleted feeds were free of salmonella. But
14 somehow when they're processed in the gut, in the gastric
15 intestinal tract, the environment there that it creates is
16 more conducive to survival of salmonella that they might
17 pick up through the environment as opposed to meal feeds.

18 And in fact, in Denmark they've gone back to some
19 of their farms that they had switched to pelleted feeds and
20 saying, For salmonella control, we need to go back to meal
21 feeds and mix a percentage of meal ground feed back into the
22 feeds.

23 So just as an example to show that sometimes

1 intuitively what we feel is not necessarily the science will
2 find out as we move through projects.

3 And sometimes you have different goals at
4 different places in the chain. An example would be feed
5 withdrawal in swine.

6 There is some conflicting work of withdrawing
7 feed just prior to shipment, just a few hours prior to
8 shipment, can increase salmonella shedding, might increase
9 antibiotic resistance shedding of certain pathogens as well.

10 However, in the processing plant, animals that
11 have less feed in their stomachs are less likely to have
12 intestinal problems when you're going to process those
13 animals. So sometimes you can have different types of
14 conflicting research results.

15 We've had studies with either increase or
16 decreasing in shedding, but then you also have differences
17 in the next part of the chain of how they handle it.

18 Another example would be a hypothesis that was
19 put forward about increased shedding of salmonella in poorer
20 condition cows. Preliminary results would say that they're
21 not seeing those differences.

22 That doesn't mean you don't want to continue to
23 look at those areas. It means that there's confounders out

1 there, as well.

2 Same, I think there's been different studies on
3 effective diet on E. coli 0157:H7 in cattle.

4 And when information comes out and producers
5 think, Well, this is what I should do, and then conflicting
6 information comes out, this is what someone else's
7 interpretation of that study is, it's very difficult to
8 understand and go back to the farm with real concrete types
9 of recommendations to make for producers.

10 When we talk about research, I think producers
11 definitely understand that we need to support basic
12 research, we need to look at detection strategies,
13 introduction of different types of methodologies, the basic
14 types of understanding virulence and pathogenesis of
15 organisms is very critical.

16 I'm always interested in the applied research.
17 How do you take that research from the lab and take it out
18 and start applying it? And then, with field studies and
19 demonstration projects.

20 Because as we take -- in looking at potential
21 pathogen reduction out at the farm level, we don't operate
22 without other microbiological flora there, as well. And we
23 have definitely learned that when we alter the flora, you

1 can have some unintended consequences, as well.

2 Some of the things that you might do for
3 reduction of salmonella might actually increase
4 campylobacter.

5 So those are the types of things you need to take
6 out to the field out of a laboratory setting.

7 Monitoring programs are very important to
8 understand what's going on in the industry. I hope everyone
9 here is aware of APHIS's national animal health monitoring
10 studies.

11 These studies have been very good to provide
12 descriptive information to industries all across the
13 industries as they do their five-year studies of different
14 industries. The last one was in dairy layers.

15 While they're asking animal health questions,
16 they're also asking food safety questions and investigating
17 potential risk factors as well, and doing biological
18 sampling on the farm.

19 The commodity groups are very involved in the
20 design of these studies and put forward questions that they
21 feel their industry needs to have answers for as far as
22 baseline type of information. This was a 1995 study.

23 A 2000 study for swine is going to expand and

1 address other issues, as well. These types of programs are
2 very important on a national level.

3 It's also important, and I think this is an area
4 we need to spend more time on, the transfer of research
5 results.

6 There's international and national meetings
7 trying to put forward information in food safety. Commodity
8 groups have specific meetings to try to put forward research
9 information. It's always a challenge, I think, to get
10 current information into the hands of people who can act
11 with it.

12 This was a beef safety symposium held in 1997
13 that really brought together not just what was known about
14 the certain pathogens, but as we look ahead, we're always
15 looking over our shoulder at what's emerging as well, some
16 new issues that we need to deal with.

17 This is an example of information we use to
18 communicate with plants to try to help them understand the
19 production food safety information that's out there.

20 As we look at food safety in the future and
21 producers' views of this, it's a very tough area to talk to
22 producers about something that is not causing production
23 problems on their farm, that they may not be aware is even

1 an issue for others, something that is not an issue for
2 them.

3 So many of the foodborne agents produce little or
4 no disease in livestock or poultry. So it's not something
5 they may be sampling for in their normal sampling for their
6 farms.

7 Also, as you look at this, the presence of a
8 potential pathogen on a farm doesn't always mean that's the
9 most effective control point. Those are areas of research
10 that we need to continue to move forward on.

11 Progress can be made in some of these areas, but
12 there's many, many confounders and much work that needs to
13 be done to try to funnel down to keep answering more and
14 more descriptive questions.

15 Just to review again real quickly what FSIS's
16 policy is on animal production food safety -- this is from
17 the pathogen reduction HACCP final rule -- FSIS is
18 cooperating with -- and I think this is a good example of
19 the types of cooperation to help get information out there.

20 And as I said, that as we put forward information
21 about what expectations are of packers and requirements of
22 packers, this is providing an increased interest at the
23 farming level, increased incentives for improving food

1 safety practices at the animal production level, as well.

2 And we are seeing these types of things, and I
3 think you'll hear more about it in the presentations this
4 afternoon, that the changes that have taken place in the
5 packing plants are increasing the expectations of packers of
6 producers.

7 This is an area that was talked about in 1995 as
8 things that are on the horizon of market driven food safety
9 programs that we may see in the future.

10 Value chains are an area. All the producer
11 groups, as they look to where things are going in the
12 future, you're seeing some vertical integration.

13 You're seeing vertical coordination, as well,
14 producers that are being part of a chain that's going to
15 market directly to the consumer and are going together to
16 say, We can describe these types of production practices on
17 the farm. And these are starting to happen now across
18 different industries.

19 We have supplier agreements where suppliers agree
20 to provide a certain type of animal raised under certain
21 types of production practices.

22 And we're seeing, as Dr. Powell mentioned,
23 organic marketing and different types of those. We're

1 seeing some direct consumer marketing.

2 Many people are trying to understand what were
3 considered niche markets, trying to understand what those
4 really mean for the future and how big those markets are.

5 Just a couple quick examples of things that we're
6 seeing in the pork industry. 1995, we reported that, with
7 USDA, ARS, FSIS, and APHIS we were working on a trichinae
8 certification program.

9 This now is going into a pilot stage this fall in
10 packing plants with producers in several states and two
11 plants to try to look at the implementation of this.

12 And while we've been developing this other groups
13 have been saying, What types of things could we put together
14 into a chain concept?

15 Minnesota Certified Pork is a new area that's
16 being worked on to provide the market with quality pork
17 traceable to the farms of origin.

18 It's independent producers going together and
19 guaranteeing certain types of things through audited
20 certified production practices and have different types of
21 areas that they're putting in to try to start testing into
22 their food safety practices, as well, and have picked up
23 some of the things that have been looked at and have been

1 developed.

2 We also are seeing groups that are starting to
3 work with the USDA process verified program. Premium
4 Standard Farms was the first pork unit. Farmland Foods has
5 been right behind them as a cooperative that's looking
6 together to put together certain types of food safety
7 practices and have them audited and verified on the farm.

8 So some of these are being put forward as market
9 driven programs. I expect we're going to see more and more
10 of these. We're seeing them in other commodity groups.

11 And I think probably faster than any type of
12 government regulation at the farm level, I think the market
13 driven programs are sending signals to the industry of areas
14 that need to be addressed.

15 And I would just conclude that as a producer
16 community we do see that we're part of the chain, that we
17 have definite responsibilities at the farm level, that we
18 need to look through what types of areas that we can address
19 at the farm.

20 And to make sure as we look at the farm that the
21 efforts that we do at the farm are practical, economic
22 based, science based, and really produce a real and
23 measurable difference to the final user of the product.

1 Thank you.

2 (Applause.)

3 DR. RAGAN: Okay. While we are working on the
4 mechanics here a little bit, I will go ahead and introduce
5 our next speaker.

6 The third part of this equation is to look at
7 animal production food safety from the consumer standpoint.

8 And to represent that viewpoint is Ms. Caroline Smith
9 DeWaal.

10 Ms. DeWaal is the director of the food safety
11 program for the Center for Science in the Public Interest.
12 She represents CSPI in Congress and in the regulatory arena
13 on such issues as meat and poultry safety, seafood safety,
14 food additives, pesticides, unsustainable agriculture, and
15 animal drugs.

16 She has extensive media exposure in all these
17 areas. And particularly if you live in the Washington area,
18 you will be familiar with Caroline.

19 She is a leading consumer analyst on the reform
20 of laws and regulations governing food safety, especially
21 HACCP. So she can today and in the breakout groups
22 certainly speak HACCP with anyone who is interested.

23 She has substantial experience in testifying

1 before Congressional committees on this subject matter.

2 And prior to coming to CSPI, Caroline was
3 director of legal affairs for Public Voice for food and
4 health policy. She spearheaded the Public Voice lobbying
5 effort on seafood safety in Congress, at the FDA, and in the
6 media.

7 She was chief legislative counsel prior to that
8 for the Massachusetts Commissioner of Insurance.

9 She graduated from the University of Vermont and
10 the Antioch School of Law and is a member of the
11 Massachusetts Bar. Ms. DeWaal.

12 MS. DEWAAL: Good morning. Let me make a few
13 adjustments up here so I can actually give my talk this
14 morning.

15 I must say this is a good size crowd, and this is
16 the second time now that I've seen Doug Powell give a
17 presentation by video tape, and he's getting better at it.
18 He's quite good.

19 I want to just tell you what my speech is going
20 to cover, because once we get in there sometimes it's hard
21 to figure out what I'm talking about.

22 The speech is going to cover two big problems.
23 Then it's going to give us three reasons for hope. And

1 finally, and because it wouldn't be a speech by me if we
2 didn't talk about the role of government and what consumers
3 expect from government.

4 The Center for Science in the Public Interest has
5 been around since 1971. We represent about 800,000
6 consumers, both in the U.S. and Canada.

7 And we're known widely for our work on nutrition.

8 The nutrition label you see on the back of food packages
9 are largely the result of our advocacy, as well as the work
10 we've been doing on food safety and focusing for the last
11 six years, since I've been there, on microbial food safety.

12 We publish a nutrition action health letter.

13 I'm here to give the consumer perspective on why
14 improvements are needed at the animal production level to
15 increase food safety.

16 Food safety is the number one food priority for
17 our members. It tops nutrition, it tops food additives, it
18 tops everything else.

19 But with 75 million illnesses, 325,000
20 hospitalizations, and 5,000 deaths each year which CDC
21 estimates are linked to contaminated food, changes are
22 clearly needed to reduce this terrible toll.

23 Steps need to be taken to improve food safety at

1 the farm level, because these changes will reverberate
2 throughout the entire food supply and result in great
3 reductions in foodborne illnesses. Now, you don't have to
4 believe me. I'm going to give you some evidence later in
5 the talk.

6 But let's just look at it logically. If we can
7 decrease or eliminate the number of chickens contaminated
8 with salmonella -- and I know that's a radical concept, but
9 stick with me for a minute.

10 If we can reduce the number of chickens
11 contaminated with salmonella going home with consumers to
12 their kitchens or going into restaurant kitchens, we're
13 going to reduce the number of illnesses, because there's
14 going to be less salmonella to cross-contaminate with other
15 foods, there's less problems with undercooking.

16 And in fact, CSPI last year, to our somewhat
17 dismay, especially by my boss, we tested 50 turkeys for
18 salmonella and campylobacter, and we didn't find any.

19 And you can check our methods. It was done by a
20 laboratory right outside of Baltimore run by Glen Morris,
21 who has done a lot of this work in the past.

22 But we didn't find any salmonella. We did find
23 some campylobacter, but not a lot.

1 So in fact, when I go -- I give a talk almost
2 every year on turkeys right before Thanksgiving. And it was
3 really a good news talk, that maybe turkeys aren't as
4 contaminated as some of the previous government data tells
5 us.

6 So addressing food safety problems at the source
7 is very important to consumers and will represent a
8 significant step forward in food safety protections.

9 While reducing pathogen levels as early as
10 possible is critical to achieving lower levels of illness,
11 food safety at the animal production level has been a low
12 priority in this country for years.

13 The need to address on-farm practices is now
14 undeniable, particularly the problems of manure
15 contamination and the subtherapeutic use of antibiotics.

16 In the past few years, outbreaks traced to fruits
17 and vegetables contaminated with hazards which are normally
18 associated with food animals have become increasingly
19 common.

20 Recent outbreaks also indicate that the problems
21 linked to environmental contamination of harmful pathogens
22 are becoming more serious.

23 And I'm going to go through here a series of

1 outbreaks.

2 The first one occurred last summer in a New York
3 county fair. About 1,000 attendees were sickened, and two
4 people died; I believe it was one young child and an elderly
5 person.

6 The source for this outbreak was unchlorinated
7 water contaminated with manure runoff from the dairy barn.
8 That's the best suspected source that public health
9 officials were able to identify.

10 This year a similar scenario occurred on a much
11 more frightening scale in a small Ontario farming community.

12 E. coli 0157:H7 literally invaded Walkerton, Ontario
13 through the town's drinking water. The bacterium sickened
14 2,000 residents and killed six.

15 Though the source of the outbreak hasn't been
16 pinpointed, the same strain of bacteria responsible for the
17 outbreak was isolated from cattle near the town, and in
18 particular from a herd next to one of the most contaminated
19 wells. A government report has ordered that that well be
20 capped and abandoned.

21 The Walkerton tragedy shows that producers, their
22 families, and their communities are at risk if they are not
23 vigilant about controlling pathogens on the farm.

1 In fact, one study shows that people living in
2 rural areas with high cattle density are at higher risk of
3 E. coli 0157:H7 infections than people living in urban
4 areas. These tragedies are likely to be repeated unless
5 steps are taken to improve safety at the farm level.

6 For example, there is another outbreak occurring
7 this year at another county fair, this one in Ohio. And
8 contaminated water is the suspected source of this outbreak,
9 as well, although it hasn't been fully investigated yet.

10 Contaminated water is only one of the problems
11 with livestock manure, however. Frequently foodborne
12 illness outbreaks, especially produce outbreaks, are linked
13 to direct manure contamination.

14 And here are several examples. But I grew up in
15 Vermont, and I know very well what we need to do with dairy
16 cattle manure. And it gets spread on the fields. So it's a
17 fairly common practice for people living in rural areas.
18 The key is how that manure is applied and whether it's
19 composted and how adequately it's treated.

20 In July 1995, over 70 Montana residents were
21 sickened by lettuce contaminated with E. coli 0157:H7. The
22 lettuce was most likely from a local farm that used
23 composted dairy manure as fertilizer and kept sheep near the

1 lettuce field.

2 Another possible source for contamination was
3 irrigation water from a pond fed by streams running through
4 cattle pastures.

5 In my next example, it occurred in 1996.
6 Contaminated lettuce from a small California operation
7 caused a multi-state outbreak in which 61 people were
8 sickened, at least 21 were hospitalized, and three people
9 developed serious complications.

10 Investigators found many potential routes for
11 contamination, but one thing was clear, cattle manure was
12 the problem.

13 Some of the lettuce was grown in a field where
14 cattle had grazed the previous winter. Some irrigation
15 water was drawn from a well located in a cattle pasture.
16 The open processing shed was located less than 100 feet from
17 cattle pens, and lettuce was washed with water from a well
18 located 20 feet from the cattle pen.

19 Needless to say, opportunities for manure
20 contamination were ample.

21 In May 1996, over 500 cases of Salmonella
22 Montevideo and 100 cases of Salmonella Meleagridis -- sorry,
23 I'm probably mispronouncing the types, and I'm sorry -- were

1 linked to alfalfa sprouts.

2 The seeds for the sprouts were grown in fields
3 where chicken manure was used as fertilizer. Also, horses
4 were kept, and their manure was stored next to the alfalfa
5 fields.

6 In 1997, a trace-back of an alfalfa sprout
7 outbreak in Michigan and Virginia that sickened over 100
8 people revealed that some of the seeds came from fields next
9 to cattle feedlots, which was the suspected source of
10 contamination.

11 And finally, in May 1998, 27 people were sickened
12 by E. coli 0157:H7 contaminated cole slaw at a Kentucky
13 Fried Chicken restaurant. Investigators traced the cabbage
14 in the cole slaw back to a farm with a cow pasture next to
15 the cabbage patch. The likely source of contamination,
16 fresh manure in the cabbage patch.

17 CSPI compiles a list of outbreaks, and these
18 examples are just the ones which we think provide the best
19 illustration of the problem with manure on produce.

20 Fruits and vegetables came out fourth among the
21 foods most likely to cause a foodborne illness outbreak
22 according to the data we've been able to get from CDC,
23 medical journals, and other sources. So there are a lot of

1 fruit and vegetable outbreaks. These are just a few.

2 These examples demonstrate that manure
3 contamination is a pervasive problem. While there doesn't
4 seem to be an easy answer, the solution clearly has to lie
5 with the producers.

6 It is essential that animal producers control
7 manure so it doesn't contaminate water and crops. In
8 addition, manure must be properly composted to ensure that
9 all pathogens have been killed.

10 Research is urgently needed on composting to
11 determine the correct time, temperatures, and methods to
12 produce safe compost.

13 Antibiotic resistance is the next problem I want
14 to outline.

15 Antibiotic resistance is clearly a problem with
16 human medicines as well, so I want to make clear that CSPI
17 understands that. And in fact, in our report, Crown Jewels,
18 we talk about that extensively.

19 But antibiotic resistance stemming from drug use
20 on the farm is another food safety related public health
21 concern where producers really hold the key.

22 CSPI has been working for years to encourage
23 producers and the government to take strong action to

1 preserve the effectiveness of antibiotics for human use.

2 Although the practice of treating animals with
3 subtherapeutic doses of antibiotics to increase growth rates
4 is widespread, the evidence to show this practice really
5 works is limited in the literature. It probably works,
6 because a lot of people are doing it, but it's really not a
7 well documented practice.

8 What is clear is that the use of antimicrobial
9 agents can help to establish reservoirs of resistant genes
10 in bacteria, both in livestock and on produce where it's
11 applied, that may be passed on to human pathogenic bacteria.

12 To hamper the development of antibiotic-resistant
13 bacteria, CSPI has petitioned the Food and Drug
14 Administration to ban all subtherapeutic uses of
15 antimicrobial agents that are used in human medicine or that
16 might select for cross-resistance to antimicrobial used in
17 human medicine.

18 We have been joined in this effort by 52
19 scientists and health officials.

20 For example, CSPI called upon the FDA to revoke
21 its approvals for subtherapeutic use of penicillin and
22 tetracycline.

23 The FDA should also repeal the approval of

1 fluroquinolones in poultry and should only allow additional
2 approvals of fluroquinolones for animals if the drugs'
3 manufacturers can show that these uses would not reduce
4 their effectiveness in human medicine.

5 To increase the options available to producers,
6 the USDA should fund research on alternatives to antibiotics
7 for growth promotion and disease prevention in livestock,
8 including competitive exclusions and vaccinations.

9 The research also should quantify the current
10 benefits of antibiotic use in animal feed, if any, and
11 identify alternate means of providing those benefits.

12 The USDA should then publish practice guidelines
13 to educate producers about alternatives to antibiotics for
14 growth promotion. That information could be disseminated to
15 producers through cooperatives, extension services, and
16 other outreach efforts.

17 Veterinarians can also play a direct role in
18 controlling antibiotic resistance. The FDA should develop a
19 symptom-based formulary for veterinarians that describe
20 appropriate treatment for common livestock infections. The
21 treatment guidelines should be based on current scientific
22 data and susceptibility patterns.

23 Finally, antibiotics should be dispensed to

1 animals only by veterinarian prescription.

2 While these proposals may seem like a dramatic
3 departure from current practices, we believe they are highly
4 appropriate given the problems with antibiotic resistance
5 and the need for effective medicines to treat human illness.

6 Although the concept of on-farm controls, be it
7 through manure management or the appropriate use of
8 antibiotics, may seem daunting, it is feasible.

9 Both traditional risk assessment methodologies
10 and actual on-farm experiences have documented the promise
11 of initiating food safety controls at the farm level.

12 For instance, a Canadian quantitative risk
13 assessment on E. coli 0157:H7 in hamburgers predicted that
14 on-farm controls would be almost three times more effective
15 at reducing illnesses than a consumer education campaign on
16 cooking hamburgers.

17 Now, CSPI does consumer education. We're one of
18 the private sources for information. And we have an article
19 coming out probably in our November issue on practices in
20 consumers' kitchens. So this is our stock and trade, and we
21 believe that consumer education plays a critical role in
22 solving this.

23 But we are also optimistic that controls earlier

1 in the food chain could eliminate many food safety problems
2 before they ever reach consumers.

3 These benefits are not just theoretical. On-farm
4 control programs for Salmonella enteritidis in eggs have
5 proven successful in reducing both salmonella contamination
6 rates in shell eggs in the northeastern United States and
7 also reducing human illnesses linked to SE.

8 In April 1992, USDA began a voluntary pilot
9 program to control Salmonella enteritidis in Pennsylvania
10 with the help of egg producers and state government
11 agencies.

12 The goal was to reduce SE contamination in shell
13 eggs in Pennsylvania, a state that had been particularly
14 hard hit by SE.

15 While no longer funded by the federal government,
16 the Pennsylvania Egg Quality Assurance Program has been very
17 successful. Today about 85 percent of the state's egg
18 producers participate.

19 The voluntary program requires participating egg
20 producers to follow certain practices to identify, reduce,
21 and eliminate Salmonella enteritidis contamination in the
22 flocks.

23 These practices include things like chicks for

1 layer flocks are obtained from SE-free breeder flocks.
2 Manure samples from layer flocks are regularly tested for
3 SE.

4 Where the testing of eggs shows a positive for
5 SE, all eggs from that flock are diverted to pasteurization
6 plants. There are security programs and rodent control
7 measures for the layer houses. And also, eggs are required
8 to be refrigerated at all times.

9 While the program was implemented in 1992, at
10 that time multiple manure and other samples were taken from
11 the houses of 70 laying flocks in Pennsylvania. And here
12 are the results:

13 In 1992, 38 percent of laying houses had at least
14 one SE positive. But by 1995, only 13 percent of flocks had
15 a positive SE sample.

16 In 1992, 23 percent of all the samples taken
17 tested positive for SE, down to only 3.2 percent of the
18 samples in 1995.

19 And human illnesses, the most important measure
20 of all, from SE in the market area for Pennsylvania eggs,
21 which included New York, New Jersey, and Pennsylvania, also
22 decreased between 1992 and 1995.

23 A team of 15 scientists from federal and state

1 government agencies attributed this decrease in part to the
2 Pennsylvania program and recommended that the interventions
3 in the Pennsylvania program be implemented by all egg
4 producers.

5 PEQAP and other on-farm SE programs seem to be
6 continuing to help reduce human illnesses from egg related
7 SE infections.

8 And the Centers for Disease Control and
9 Prevention reported a 48 percent decrease in the number of
10 human illnesses from SE between 1996 and 1999 in it's food
11 net surveillance sites. This reduction also has been
12 attributed in part to the PEQAP program and these other
13 programs.

14 To further this progress, the President's Council
15 on Food Safety developed an egg safety action plan with the
16 ambitious and achievable goals of reducing egg related human
17 SE illnesses by 50 percent by the end of the year 2005, and
18 the elimination of egg related human SE illnesses by 2010.

19 Although the President's plan establishes control
20 measures from the production stage through retail, it
21 emphasizes on-farm control measures similar to the ones used
22 in Pennsylvania.

23 Without on-farm control programs like these, it

1 is unlikely that any national plan could dramatically reduce
2 foodborne illness.

3 The egg industry's example clearly demonstrates
4 that well designed and closely monitored on-farm programs
5 can significantly reduce SE contamination in egg laying
6 flocks, as well as the number of infected shell eggs
7 reaching consumers.

8 This example should be extended to other segments
9 of the food industry where strong on-farm food safety
10 programs will better protect all consumers.

11 And another area where we're very optimistic is
12 newly developed technologies and treatments which will help
13 producers to control hazards on their farm.

14 I've just included a couple of examples here,
15 things like competitive exclusion, the issue of changing the
16 diet of cattle prior to slaughter, removal of water from
17 manure.

18 There are series of different technologies that
19 are becoming available or that are in the works that clearly
20 could be very beneficial for producers.

21 But while these technologies are being developed
22 and soon may exist, better government oversight is needed if
23 we're going to provide incentives for producers to use them.

1 And we run into the problem that we saw also in a
2 meeting I attended just a little over a year ago on egg
3 safety where the producers actually came in and said, Give
4 us an on-farm program. Give us the mandate, because
5 otherwise there isn't a level playing field.

6 And industry needs -- in order to go through the
7 expense of implementing some of these technologies, industry
8 and producers need the government to come in sometimes and
9 give them that kind of a mandate to provide a level playing
10 field for all the producers so everyone is having to face
11 the same expense and the same change in their business
12 plans.

13 government directives can also provide a spur to
14 the faster development of these pathogen reduction
15 technologies -- and I'm again thinking in the egg area -- I
16 see my egg friends sitting right here in the front -- of the
17 development and promotion over the last year of in-shell
18 pasteurization techniques.

19 Okay. My last hope, my last positive hope to
20 leave you with, is the issue of the European Union.

21 And our -- I never know whether to approach this
22 from a competitive standpoint as in, you know, they're doing
23 it so, you know, you guys better get on it, or whether to

1 just approach it from the standpoint that it seems to be
2 working.

3 And I don't care how you want to hear it. The
4 bottom line is the rest of the world is somewhat ahead of
5 us, if not greatly ahead of us, in some of these areas of
6 on-farm food safety.

7 So the EU has published -- and I haven't given
8 you much information on the slide -- but the EU has taken an
9 active interest in controlling pathogens at the animal
10 production level using both new technologies and sound
11 production techniques.

12 The European Commission on Health and Consumer
13 Directorate -- and I think I have that wrong -- has
14 published a series of recommendations called The EU's
15 Measure on Foodborne Zoonoses.

16 The EU's approach to HACCP starts at the feed end
17 farm. A poultry program in Sweden has reduced campylobacter
18 flock prevalence from 50 percent to 10 percent. There is
19 also a program geared towards reducing Salmonella
20 enteritidis in flocks.

21 In many areas of the EU, the reduction in
22 Salmonella enteritidis in flocks has resulted in a
23 significant reduction in human infections, as we've also

1 seen the example in the U.S. I cited earlier.

2 An essential component to the EU poultry program
3 is pathogen-free feed. Producers have also introduced
4 hygiene barriers and on-farm good manufacturing practices
5 such as all in-all out production. They have also used
6 vaccination and competitive exclusion technologies.

7 For E.coli 0157:H7 management, the EU proposes
8 such on-farm controls as manure management to prevent crop
9 and water contamination.

10 It also suggests altered feeding practices to
11 potentially reduce the shedding of E. coli and recommends
12 further research on this topic, as well as on the effective
13 calf management on shedding.

14 The EU's interest in reducing on-farm pathogens
15 has already paid off for SE reduction, and it is clear that
16 they are well on their way to achieving similar goals for
17 other pathogens.

18 The Trans-Atlantic Consumer Dialogue of which
19 CSPI is a member, in conjunction with numerous other
20 American and European consumer groups, has called for
21 broader adoption of the policies included in the zoonosis
22 directive, both in Europe, and it's likely they would be
23 highly beneficial here.

1 As you can see, on-farm programs show great
2 promise in reducing and eliminating foodborne illnesses.
3 The earlier in the food chain that pathogens are controlled,
4 the less chance that consumers will be exposed with the
5 potential for illness or death, regardless of the route of
6 transmission.

7 Put another way, cleaner cows and chickens mean
8 safer consumers.

9 However, producers have few incentives to reduce
10 pathogens unless they cause disease in their own livestock
11 or otherwise impact their ability to sell their products.

12 government action is needed to give farmers the
13 incentives to develop and use technological solutions to
14 food safety problems that originate on the farm. They must
15 be built into a comprehensive on-farm food protection
16 system, which is a key component of a farm-to-table HACCP
17 system.

18 Today farmers are in a Never-Never Land of
19 government food safety regulation. While farmers benefit
20 from government programs ranging from crop insurance to
21 assistance in addressing animal diseases, no federal agency
22 really has oversight to ensure that farmers are minimizing
23 the hazards in their products. This has to change.

1 Consumers are demanding safer foods and have come
2 to realize that only with a single federal food safety
3 agency that has farm-to-table oversight and responsibility
4 will be truly achieve a safer food supply.

5 As you can see from both the U.S. and the
6 European experience, farm-based food safety controls are
7 both effective and feasible.

8 And with the continuation of research and
9 technological development, the benefits of on-farm controls
10 for both consumers and producers will only grow.

11 To ensure their uniform adoption by producers,
12 however, a program of government oversight and incentive-
13 based regulations are clearly needed.

14 And this is currently being recommended, and
15 actually it's being proposed in the area of egg safety. And
16 this trend needs to be brought into other segments of the
17 animal production world, as well.

18 Thank you very much.

19 (Applause.)

20 DR. RAGAN: Thank you, Caroline. Good job.

21 Dr. Gillespie, our next speaker, has graciously
22 suggested that we take a break. And all opposed to that,
23 raise your hand. The others will meet outside.

1 Please be back in 15 minutes. That would make it
2 20 after 10:00 by my watch. Thank you.

3 (Whereupon, a short recess was taken.)

4 DR. RAGAN: If we could come to order, ladies and
5 gentlemen, we'll move on. We are running a little behind.
6 Thank you very much. Except for that one guy in the back,
7 if he could take a seat.

8 Our next speaker, Dr. Jerry Gillespie, is going
9 to speak to the roles of several of the players that have
10 been mentioned already this morning.

11 If I told you all of Dr. Gillespie's credentials,
12 he wouldn't have time to speak himself, so I will just give
13 you an overview.

14 He is the recently appointed Executive Director
15 of the Joint Institutes for Food Safety Research with USDA
16 and HHS. And perhaps he'll take a minute and explain that
17 position and that organization a little further to us.

18 Would somebody at the door over there urge those
19 folks to come on in or else close the door so that the rest
20 of us can go along?

21 (Pause.)

22 DR. RAGAN: A high level of interest and
23 enthusiasm, as reflected by the noise level from the hall.

1 Dr. Gillespie was educated at Oklahoma State
2 University and the University of California. He has a long
3 and distinguished career in research and instruction at the
4 University of California and more recently at Kansas State
5 University from which he came to his new job.

6 Dr. Gillespie has been involved in numerous
7 research related activities, both nationally and
8 internationally, ranging from clinical equine medicine to
9 food safety. And we're fortunate he is now well focused
10 onto the food safety direction.

11 The recipient of numerous awards, is a member of
12 numerous national and international organizations, and will
13 give us a little overview of at least some of the roles in
14 animal production food safety. Dr. Gillespie.

15 DR. GILLESPIE: Thank you, John. Well, I'll
16 spend just a very brief moment talking about the new Joint
17 Institute for Food Safety Research and what is intended for
18 this institute about which I am very excited.

19 If you survey across the federal government,
20 there are at least 19 different agencies having different
21 roles, many of them research, in the area of food safety.

22 And my rather brief experience there is that it
23 is a very dedicated, very intelligent, very motivated group

1 in these agencies in their efforts to improve food safety
2 and quality and keep, first of all, consumers well fed in
3 this country, but also make our producers competitive
4 internationally.

5 My task in the Joint Institute is to really
6 assemble, with the cooperation of these agencies, what
7 they're about in doing research, what are their priorities,
8 what are their needs, link up with industry and find out
9 their needs.

10 And simultaneously find out what the world
11 knowledge is scientifically on the various areas relating to
12 food safety, what the issues are, what the gaps are in our
13 knowledge, what we can do to address those gaps. And many
14 of them I think were well outlined by our speakers earlier
15 this morning.

16 To assemble that together with the 19 different
17 agencies and work with them and industry in setting
18 priorities so that we make the very best use of the money
19 available to us to do research in food safety.

20 And it is also my view that if we do those things
21 and do them well, we will improve the quality of research
22 that's being done, and therefore the efficiency of our
23 efforts to improve the science that underlies our efforts in

1 food safety.

2 So that's what the Institute is about. The
3 Institute was founded on the principle of term limits, so I
4 have a two-year term, and then somebody else will get a
5 chance at doing it. And that's exciting.

6 I intend to make the best use of the time that I
7 have there to do what I can, but I also see a gate out if
8 things go badly.

9 So in any case, I am excited, and I think it's a
10 good thing for all of us to have the Institute.

11 Well, I want to talk to you just a little bit
12 about different roles and the whole issue of on-farm food
13 safety, that I've had a lot of experience, both firsthand,
14 but also as a researcher and also as an educator within the
15 university system.

16 And one of the things that I really think we need
17 to make sure we understand -- and I think many of the
18 speakers have focused on this -- but you can't approach food
19 safety in an isolated way and ignore other issues that are
20 out there confronting the producer. And I want to list some
21 of those and bring up some of those.

22 And the first part of my talk I'm afraid will be
23 just a little bit negative. And then I hope to recoup in

1 the last part in terms of saying there is some hope.

2 But I think I would be really very naive to think
3 the whole issue of addressing on-farm food safety is at all
4 safety, because it's a very complex environment that we're
5 in.

6 And the changes that are going on in production
7 agriculture today and for the last two decades are
8 phenomenal. And I know that you recognize that.

9 But certainly there is a new reality, and there
10 certainly is an issue of globalization. We've talked about
11 where our food comes from and where we need to send our
12 products.

13 There's increased expectation on the consumers'
14 part in terms of safe food and the quality of the food.
15 There's certainly a profitability increasing dependence upon
16 our being able to sell food both locally and
17 internationally.

18 And the market access will increasingly depend
19 upon verification, not just practices, but verification of
20 production and processing practices of safe food.

21 And I think it would be incredibly wrong of us to
22 assume that USA has a place forever in the world marketplace
23 without addressing a number of very complex issues.

1 Well, this list I'm sure you're familiar with.
2 But I want to put it up again to remind ourselves of the
3 complexity of these issues. And when you talk about food
4 safety, you're not just talking about microbes or chemicals
5 or foreign bodies. You're talking about environmental
6 issues that are very, very complex.

7 Now, when you start talking about where water is
8 and where it goes and where it's been in a farm unit, it
9 gets very complex.

10 All of these issues can be focused and have a
11 role in the on-farm, and it certainly is changing the
12 dialogue down on the farm.

13 It's not as though producers aren't aware of
14 these problems and are trying to address them. But it is a
15 complex issue and one that certainly has changed the whole
16 issue of raising food.

17 It's now a matter of an international market,
18 consumer driven, and therefore very complex. It's very
19 competitive. It requires attention be paid to such things
20 as food safety, food quality, environment, animal health and
21 welfare.

22 And again, we need to pause from time to time and
23 think about the complexity of doing and addressing these

1 issues on the farm, and at the same time, it's got to make
2 economic sense. And increasingly in the United States, it
3 just may not.

4 Things are changing in the world environment, and
5 they all affect the production of safe food, for example,
6 increasing disengagement and lack of understanding of
7 consumers of agriculture and food production. That's been
8 mentioned earlier by speakers.

9 But there's a political issue here, because if
10 they're disengaged in terms of how that food is produced and
11 what's needed, then they take on a different attitude in
12 terms of nonagricultural use of land or how land, water, and
13 air are used.

14 And the thing of urban sprawl is not just a
15 California thing or not just a Virginia thing, it's
16 everywhere.

17 And when I survey the county that I was in in
18 Kansas, I can identify three farmers that are legitimate
19 full-time farmers left in that area.

20 Greater conflicts in use and management of
21 resources from nonagriculture sectors result in increased
22 regulatory inclusion and cost in resource management. Make
23 no mistake, no matter where the intervention is, someone

1 will have to pay.

2 Increasing spread between food retail income and
3 production income concurrent with escalating operating costs
4 in production. These are realities that are confronting
5 production agriculture, and they're not exclusive to how we
6 go about addressing food safety.

7 Well, to try to take a more positive approach,
8 what are some things that we can do?

9 Certainly on-farm analysis is needed, and I will
10 make the point a little bit later, is a farm-by-farm
11 analysis, an analysis of the practices and their impact.
12 And we're familiar with that from the HACCP concepts.

13 Risk assessment and analysis. And the more
14 accurate the data that goes into this, the more useful this
15 can be in setting up a program.

16 Implementation of a comprehensive food safety
17 program in a particular unit.

18 Compliance assessment, in other words, evaluating
19 the outcomes of the practices that you've initiated, and
20 verification that the practices are in fact being carried
21 out.

22 Evaluation of new technologies and procedures
23 that come along. And I know a number of instances where

1 good information made available to producers is one of the
2 big gaps that we have to fill. And they need to know about
3 new opportunities for technologies and procedures.

4 Quality safety testing at the end product, what's
5 the total outcome of all of the efforts you've made?

6 Analysis of the outcome assessment must include
7 an economic assessment, adjustments and modifications. And
8 you start at the top again and go back through.

9 Different complexities on farms with different
10 production resources and practices mean that each farm has
11 unique inputs, traffic patterns which impact food quality
12 and production programs.

13 And in our experience at Kansas State, in looking
14 principally at beef operations, the diversity of them really
15 requires that there may be some general principles, but that
16 certainly specific operational food safety and quality
17 programs are often unique for each farm.

18 So if you look at the on-farm analysis, you have
19 to look at all of the inputs and how they mix on the farm.
20 And increasingly there's labor that's coming and going on
21 the farm that impact the inputs and the potential hazards on
22 that farm. So you need to define the potentials and assess
23 the potentials for cross-contamination.

1 Analysis of practices and their impact. And if
2 you were to really carefully analyze the environmental
3 issues, the way animals are managed, the way crops are
4 managed, the way feed is managed, the way other inputs are
5 managed, that's a requirement if you're going to have a good
6 outcome in developing a procedure for that farm, development
7 of good practices, then.

8 Education and implementation, a huge challenge.
9 Telling a producer or their labor what's needed and getting
10 them to do it can be very, very different things, because
11 there's habits that are often difficult to break.

12 Compliance assessment and outcome, how well are
13 they doing? Someone has to look, someone has to measure,
14 someone has to bring back a message of how well they're
15 doing.

16 Finally, you need to test the final outcome.
17 Have you actually done anything with everything that you've
18 tried to do?

19 This can get very complex. And I won't spend a
20 great deal of time. But what you can do is break down a
21 farm in terms of just a particular organism and look at its
22 various risks of spread within the farm. And that's
23 necessary if you're going to make an analysis of that

1 particular pathogen getting off the farm.

2 And if you view A, B, C, D, E, and F as persons
3 on that farm working in different areas, you can assess the
4 sanitation level in those different areas and assess and
5 assign a risk in each of those areas.

6 And so it can get to be very complex in terms of
7 the spread of an organism from a Person A, who is a dominant
8 worker with livestock, throughout the rest of the family or
9 workers. And those are the sorts of assessments that would
10 need to be made and I think are important.

11 So initiating a on-farm plan requires education
12 and explanation of what you're trying to achieve.

13 There has to be buy-in by the owner and managers.
14 And if the top management or the owners are lukewarm,
15 you're not going to achieve it.

16 And of course, that's no different than in any
17 other industry. If the quality assurance programs are not
18 supported by the CEO, they go nowhere.

19 Farm-wide employee training and buy-in, but
20 that's not a one-time deal. It has to be repeated as
21 employee turn-over occurs, which is often quite frequent.

22 So who will carry on the farm safety program?
23 Well, I see it as being principally initiated by a private

1 or public consultant that helps steer the general program
2 and advises it.

3 But it needs the owner, the operator/manager, the
4 inspector or the investigator that's actually going to see
5 that it's operated and do the certification. The
6 veterinarian in the case of livestock operations certainly
7 is important. Employees are absolutely key, and you'll go
8 nowhere unless they have a buy-in and follow the procedures.
9 And the technical suppliers and vendors of all sorts.

10 So how do you get buy-in of all of these people?
11 My own view is that some way or other it's going to have to
12 come out to be profitable. There's too many other things
13 pulling on these producers on a very narrow margin to expect
14 large buy-in unless it can be shown to be profitable. And
15 we'll come back to that in a little bit.

16 I don't think you'll find too many producers. I
17 certainly haven't. And in our research in Kansas and
18 Nebraska we found enormous cooperation with the producers to
19 allow us to do epidemiological studies on foodborne
20 pathogens on their farms. It's the right thing to do, and
21 they want to do that.

22 But one of the scary things is that it's probably
23 a necessity and part of the new reality of agriculture that

1 they will need to have a quality assurance food safety
2 program to market their products. And I think that's
3 increasingly so for all commodities.

4 Well, this is a model that we are beginning to
5 test in Kansas, farm and rural community.

6 We really feel that if you can get a community
7 interested in doing something, and there are definite
8 boundaries to that community, and the
9 university/industry/government coordination of a particular
10 program such that you begin with education, and they begin
11 to help you assess whether or not it's a program that can in
12 fact work in their community.

13 It takes professional leadership, and those
14 leaders have to be in the community. The veterinarians, the
15 extension service, the public health practitioners need to
16 be in the loop. And certainly the community leaders have to
17 be behind it.

18 If the local banker pooh-poohs the idea to the
19 agriculturalists, or if the farm loan credit association is
20 unenthusiastic, and when that farmer goes in for his loan,
21 you're not going anywhere.

22 Outcomes, certainly there is a great opportunity
23 for research in solving some of the problems where the gaps

1 are.

2 There's great educational opportunities, there's
3 innovation opportunities. And I actually believe a lot of
4 the improvement that we will see are innovations that
5 producers make that we later investigate to see how well
6 they work.

7 Improved food safety and public health is an
8 outcome that we've got to aspire to have.

9 So the university can certainly do the data
10 collection and analysis, and they can provide educators and
11 help with implementation.

12 The government can help set standards. And I
13 would take a little different approach than the previous
14 speaker. I think, in fact, that there's motivations
15 otherwise, other than setting regulations on the farm. But
16 if not, they will no doubt come.

17 Practices, economic impact, profit, and pay for
18 system, that's where the industry really has to come to
19 grips.

20 Who pays the extra cost of food safety and
21 quality assurance? And we've got to address that question,
22 and I don't think it's an easy one.

23 The consumer will ultimately be the one that will

1 pay. But the gap between the consumer willingness to pay
2 and paying and what is returned to the producer is a huge
3 gap. And unless there is ways of paying for these
4 initiatives, they probably won't happen.

5 But certainly the consumers drive the system with
6 their demands and practices. And that, by the way, is
7 nationally and internationally. Retailers respond to the
8 consumers' demands.

9 And ATOL [phonetic], the largest international
10 retailer, has made the comment again and again that, as they
11 spread around the world, they will increasingly know
12 everything about every product that goes on their shelves.
13 They intend to control the production through processing and
14 put it on their shelves. So they are responding to
15 consumers' demands.

16 Well, as we go on down through this chain that
17 we've seen, one of the things that will have to probably
18 occur is some sort of agreement with all of the segments of
19 the industry in terms of how they will in fact certify and
20 create a food safety program and what each segment's
21 responsibility will be.

22 But concurrently there's got to be a flow of
23 payments from the consumer down to the producer if it's

1 going to work.

2 Well, in summary, then, I think we need to take a
3 very holistic approach. It is many variables that impact
4 food safety. It's an environmental issue, it's an air,
5 soil, water issue.

6 Investigation, education, and implementation are
7 key. Surveillance with diagnostic tests to know the
8 incidence of disease so you know the standard against which
9 you're measuring. Understand the ecology of pathogens, from
10 whence do they come?

11 It was interesting how wildlife was not mentioned
12 this morning, but it is certainly a part of the mix in terms
13 of keeping these organisms in the rural environment.

14 Investigate implementation of HACCPs on the farm.
15 The health of rural dwellers is a big issue that I think is
16 often neglected. And farm-by-farm approach.

17 So think cost, profit, HACCP, good management
18 practices, education and reeducation, outcome assessment and
19 verification, problem solving with tests and other data.

20 Thank you.

21 (Applause.)

22 DR. RAGAN: Thank you, Dr. Gillespie.

23 And I now turn the moderator's chores over to Dr.

1 Ken Olson, who comes to us from the American Farm Bureau
2 Federation.

3 He is in the public policy division of that
4 national organization and directs the Federation's dairy
5 commodity activities, coordinates animal health work, and
6 acts as secretary and support staff for various commodity
7 committees.

8 Educated at the University of Wisconsin, served
9 on the faculty at the University of Kentucky, and for some
10 years has been active in the area of food animal industry
11 and government. Ken.

12 DR. OLSON: Thank you, John. This session our
13 objective is to provide you with an overview of some of the
14 quality assurance programs of the various livestock species
15 and also how they fit into the food safety efforts.

16 We have a distinguished group of presenters with
17 a limited amount of time for them to make their
18 presentations in. So we'll try and move things along as
19 quickly as possible.

20 Our presenters are all deeply involved in the
21 various quality assurance programs and I think will provide
22 an excellent overview of what is transpiring there.

23 I'll keep my introductions short. If possible

1 we'll have some questions for them at the end of their
2 presentations.

3 However, I think most of our presenters will be
4 here throughout the conference. So if we don't get to ask
5 questions or get your question asked at this time, we can
6 cover them during our breakout sessions or separately in the
7 hall.

8 So without further ado, our first speaker in this
9 panel presentation is Dr. Gary Cowman from the National
10 Cattlemen's Beef Association.

11 Dr. Cowman serves as executive director for the
12 dairy, beef, and veal quality assurance programs. He also
13 works with the animal disease research and quality assurance
14 subcommittees, as well as the quality assurance board for
15 NCBA.

16 So please join me in welcoming Dr. Cowman.

17 (Applause.)

18 DR. COWMAN: Thank you, Ken. And as Ken
19 indicated, there's a lot of us on the program this morning.

20 And the other thing, also, just to forewarn others that
21 will follow me, at least the agenda that John sent me, I was
22 at the bottom of the second page. And it said, the National
23 Cattlemen's Beef Quality Assurance Program, Gary Cowman,

1 10:45 to 12:00, and so consequently I prepared for that.

2 But then, last night I turned to the other page,
3 and there's about six or seven others of you on there.

4 But I'll go through real, real fast and real
5 short. And obviously John Adams and a few of you have been
6 around me before, because when I walked up here, they said,
7 Make it damn short.

8 So, anyhow, the thing is, I thought we had some
9 very interesting presentations and discussions this morning.

10 The thing that I was most impressed with, I think as a body
11 and as a group we have finally come to grips with some
12 reality of the challenges that preharvest, on-farm, this
13 whole food safety face us out at the field level.

14 And the other thing is, I think at least my
15 presentation or our presentation, talking about the
16 industry's quality assurance programs, we're the troops in
17 the field.

18 And we're the troops that have to deliver these
19 education programs and these initiatives and these messages
20 out at the producer and production level. So consequently,
21 we've certainly got a lot of challenges.

22 Real quickly, the beef industry's quality -- we
23 started a quality assurance program in 1987. And we

1 continually face these challenges, getting more people to
2 participate in our program.

3 The one thing that the Cattlemen's program may
4 differ a little than other commodity programs --

5 And the other thing I wanted to point out being
6 the first on this program, we cannot make the error of
7 comparing industry groups' quality assurance programs,
8 because we're all structured -- each of our industries are
9 structured so differently out in the production sector.
10 What works for one commodity group more than like wouldn't
11 fit and be effective at the other level.

12 But our program is implemented on a state-by-
13 state basis.

14 The other point I want to point out, our program,
15 or the beef industry's program, is 100 percent funded by
16 cattlemen's check-off dollars.

17 And the cattlemen feel that is a very important
18 message for the consumer and for the public to be aware of
19 the fact that this is a dollar investment, this is a funded
20 investment by the cattle producers. We do not take allied
21 industry money. This program is supported only by the
22 cattlemen's check off their own dollars.

23 At NCBA, we in essence supervise or are involved

1 in three quality assurance initiatives that relate to beef
2 and beef products.

3 The beef quality assurance, of course, BQA, is
4 from the cow, calf, through the feedlot.

5 The dairy animal, once the hide comes off and
6 those cows go to town, become in our food chain, so we have
7 a dairy beef quality assurance program.

8 And we also, through cattlemen's check-off
9 dollars fund, then, the veal quality assurance program,
10 which Dan will talk about later.

11 But we have one quality assurance initiative at
12 the national level with these three different programs.

13 Some of the challenges we have in getting out in
14 the field and making these things happen is, you know, how
15 do we reach the vast number of cattle producers in our
16 industry?

17 And I go back again. Our industry is structured
18 a little different, at least at this point in time, than so
19 many others. But you know, how do we meet the challenge of
20 reach each and every producer?

21 If we look at the structure of the beef industry,
22 we've got something like 33.7 million cows out there, and
23 more important, 850,000 individual beef producers that we

1 have to get these messages and these guidelines and
2 recommendations out to.

3 And also on the dairy side, from the standpoint
4 of dairy as a meat animal or production of beef and beef
5 products, about 9 million cows, 116,000 or so.

6 So we have a challenge in here of about 1.1
7 million producers, beef cow producers, dairy, and feedlot
8 operators that we have to get to, and a major, major
9 challenge.

10 And I make this point because, with our program,
11 the key to where we're at and where we're going and the
12 opportunities that we have, the key is to build a network.
13 No single entity can reach each and every producer in the
14 beef sector.

15 And we've had to and have been very successful
16 and will continue to build and build and build an army or a
17 network out there of people, through veterinarians, state
18 beef councils, extensions, allied industry, auction markets,
19 media, to help get the message out to the producers, because
20 we're never any stronger than our weakest link.

21 And I always make a point here in working this
22 program, in essence from Day 1, the success that we've had
23 at this point in time with the beef quality assurance

1 program has been greatly the involvement the veterinarian
2 and the extension service.

3 They have given excellent support, the
4 veterinarian profession, of working with producers, helping
5 in getting the quality assurance messages out.

6 At the national level -- because we're structured
7 on a state-by-state basis. And at the national level, we
8 provide national guidelines and get those out to the states,
9 and they get them on, then, out to the various networks.

10 One of the key things or programs that we started
11 in 1991 is developing what we call quality audits or
12 collecting baseline data.

13 And here again I think Dr. Gillespie and Dr.
14 Lautner and all have made a point. You've got to have
15 sound -- the recommendations you take to the field, the
16 production sector, need to be based on sound science or
17 sound data.

18 And we started what we call the quality audits in
19 1991. And from the standpoint of both fed cattle and the
20 market cow side, we repeat those audits every five years.

21 And that, then, gives our producers and our
22 quality assurance initiatives and programs a chance to then
23 benchmark, what different issues and areas have we made

1 improvement in, and where do we need to maybe restructure an
2 educational program?

3 We're in the process right now of doing the 2000
4 national fed cattle quality audit.

5 Back in '95 -- and this is the same protocol --
6 we're looking at auditing about 75 percent of the federally
7 inspected plants on how much bruising, how much hide damage,
8 what are our quality downfalls in that?

9 And from that we produce, then, what we call
10 these executive summary quality audits and get it out.
11 Because as Dr. Gillespie mentioned, we've got a major
12 challenge of getting this information out in educational
13 format to the producers.

14 And these things have been very successful, and
15 some of them that you've seen.

16 One thing we came up with last year on our side
17 of the industry, we got the market cow, and sometimes that
18 doesn't get quite the attention in our initiatives as over
19 on the Fed side. And I think you've got market sows, too,
20 Beth. And so we have the nonfed audit or the market cow
21 audit.

22 But it's still difficult to get producers and
23 cattle and dairymen's attention to an animal they have

1 already made a decision to take out of production.

2 So we had the audit data to show them some of the
3 problems and challenges we had. And we came out with this
4 video. And they're playing that video out in the hall the
5 next couple of days.

6 But what we've done is put together a video
7 showing the producer where this market cow is ending up in
8 today's food chain.

9 And once they saw this and got an idea of where
10 that cow that animal was going -- because most people felt
11 like that the cow was ending up in ground beef, which is not
12 the market today.

13 But it's these kind of educational programs that
14 we've got to constantly explore, I think, to get these
15 messages out to the producer.

16 One other project that we started, was involved
17 in about five years ago, was what we call the quality
18 assurance display, a very extensive, very expensive display.
19 It cost about \$30,000.

20 We had a pilot project in Alabama. And we took
21 this in cooperation with the Alabama Livestock Marketing
22 Association, the LMA, took this display at auction markets,
23 because here again, that's where a lot of producers go once

1 a week, once a month, or whatever.

2 And this has been very, very successful. Many
3 states now have this and are using it in their education
4 program.

5 I was questioning whether I should put this up.
6 But we had an issue in our industry about ten years ago.
7 And we constantly, every quarter, we monitor the progress
8 we're making.

9 And somebody made this statement this morning,
10 You know, HACCP doesn't maybe, in the true definition of
11 HACCP, fit on-farm.

12 But we feel that some of the science-based or the
13 projects or programs that we have are HACCP-based or HACCP-
14 like, because we monitor the progress that we're making.

15 And I use this slide to, in many audiences --
16 voluntary programs will work if you structure the right
17 educational material, have a network to get this out to
18 producers and to veterinarians. And I think that many of
19 the things that we and other quality assurance programs have
20 done will prove that.

21 We are progressing to the point, because we are
22 on a state-by-state basis, where now we have states that are
23 moving into producer certification.

1 Quality assurance at the production level
2 certainly had to and needs to and will continue to go
3 through an evolution period. And we are now seeing states
4 move towards and are implementing producer certification,
5 and some states verification programs at the production
6 level.

7 And as we look in the crystal ball -- and some of
8 you have indicated this also this morning -- this is the
9 direction of the industry.

10 Some of the drivers that we see in the beef
11 quality assurance arena or program, some of the drivers will
12 be the industry is obviously continually consumer focused.

13 And as Dr. Gillespie indicated, there's
14 tremendous changes in our industry and all livestock
15 industries in terms of markets and production and this type
16 of thing.

17 In our industry I think the marketing structures
18 are changing so much these will help drive quality assurance
19 programs.

20 The increase in value-added and branded products
21 are increasing the acceptance and implementation of quality
22 assurance at the production and farm level.

23 And without a doubt, as indicated this morning,

1 the filter-down of the HACCP implementation at the
2 processing plants certainly raises the expectation at the
3 producer level.

4 And I just go back again. We've got a super
5 challenge -- I will challenge the comments or statement that
6 a producer needs an incentive.

7 I think if you own a ranch, own a farm, the
8 investment that livestock people have today, you do have an
9 incentive. You have an incentive that you're going to stay
10 viable. And they realize this. They see the same news, the
11 same everything that we do.

12 And food safety quality assurance is an easy sell
13 at the production level if you go out there with sound
14 recommendations and things that can be applied at the
15 production level. Thank you. I did it pretty short.

16 (Applause.)

17 DR. OLSON: Thank you, Gary.

18 Our next presenter is Ms. Donna Reifschneider.
19 Donna is representing the National Pork Producers Council.
20 She is a past president of the organization. She is a pork
21 producer from Illinois, where she served on the Governor's
22 task force on livestock production.

23 She has also chaired the former Pork Quality

1 Assurance Committee, and so is intimately involved with that
2 activity.

3 So please join me in welcoming Ms. Reifschneider.

4 (Applause.)

5 MS. REIFSCHNEIDER: Good morning. I am Donna
6 Reifschneider, a pork producer from Illinois. In fact, I'm
7 just about 20 miles from home. And we're in the
8 metropolitan area that they were talking about that the city
9 is coming out to visit us.

10 My husband and I, we have a farrowing operation
11 of 600 sows, and we sell about 10,000 wiener pigs a year.
12 That's a ten-pound pig that's farrowed on our farm and
13 finished other places.

14 I think these programs that we have are very
15 important, and it's good that we have these discussions.

16 I would like to caution you and have you
17 certainly remember that, as you are talking about what's
18 happening on the farm, that there are real producers that
19 you're impacting. And certainly we want to send the right
20 messages and the messages that do make a difference. So
21 keep that in mind as we have these discussions in the next
22 day or so.

23 I have a fairly long history with the pork

1 quality assurance program, because I was a member of the
2 first Pork Quality Assurance Committee, and I later chaired
3 that committee, and I have been involved in the Pork Safety
4 Committee since its beginning.

5 Our PQA program began in 1989, and so there's a
6 lot to talk about. But with the time I have today I'd like
7 to tell you what the program is, how it works, and where
8 we're going in the future.

9 First and foremost, the PQA program is a food
10 safety program. It was designed and written to give
11 producers that are responsible for the day-to-day operation
12 the information they need to provide the packer with the
13 safest, highest-quality product available.

14 There is a lot of food safety responsibilities
15 for the packer and others that handle our product from the
16 time it leaves the farm till it gets to the plant.

17 One of the things that they cannot do that we do
18 on the farm is take violative residues of animal health
19 products out of the meat. That is our responsibility, the
20 producers' responsibility, to ensure that everything that we
21 do, that the animal that is delivered does not have
22 violative residues.

23 Providing the producer with the information to

1 get this done was the pre-HACCP focus of the program and is
2 one of the primary objectives, the other being preventing
3 physical hazards.

4 The logistics of the program go this way: The
5 producer contacts a verifier, usually a veterinarian, and
6 tells that they are interested in the PQA program.

7 Our verifiers are mostly veterinarians, but it
8 could be an ag educator such as from a community college or
9 an extension agent.

10 The idea is for the verifier to be able to go
11 through the program with the producer and give them the
12 expert advice about drug and animal health product use in
13 the operation.

14 The producer and verifier get together and go
15 through PQA book and the ten good production practices.
16 These are presented in a way that facilitates interaction
17 and discussion.

18 And I can tell you, being through it many, many
19 times, it is a good discussion period between you and your
20 vet. And you sit down from an hour to even four hours,
21 talking about what you're doing on your farm.

22 And it's good for the producers to go through
23 that process periodically to say, Oh, yes, that's why I do

1 that, or, Yes, I better firm that up a little bit.

2 The verifier and the producer both sign a card,
3 an enrollment card, and the producer says that we understand
4 the good production practices, and the verifier says that
5 they have brought it to our attention and we have talked.

6 The card is sent to NPPC, then, in Des Moines,
7 and a certificate and wallet card are sent back to the
8 producer. And it's the goal of NPPC to have that turnaround
9 time in two weeks.

10 The PQA program currently has over 75,600 people
11 that have gone through the program.

12 NPPC gets about 1,500 PQA cards per week. And
13 the quality controls that they have in place includes
14 automated detection of partial addresses or duplicate names
15 or addresses and adequate address entry.

16 And I can tell you they spend a lot of time
17 making sure we don't double up on producers and we certainly
18 don't lose producers in the process.

19 I mentioned the ten good production practices.
20 They are divided into two sections. The first six deal with
21 food safety and violative residue avoidance, and the last
22 four address issues to help keep our pigs healthy and
23 productive, which hopefully decreases the need for use of

1 therapeutic antibiotics.

2 To support this educational effort, NPPC has
3 produced quite a number of supporting materials. Videos
4 explain the program and its importance. Proper injection
5 techniques, drug storage and drug handling, animal handling
6 and transport, and needle strength research are a few of the
7 subjects available to producers and verifiers.

8 And from a producer perspective, these have been
9 very helpful. As you get new employees, you tend to go over
10 things and over things, and you might miss something. But
11 by putting a video and having posters and other things, it
12 makes sure that you go through all the points.

13 And we've used them for ourselves, to remind
14 ourselves, and certainly have sent them home with our
15 employees, that they are up to speed on what we are doing
16 and why we are doing it.

17 NPPC also has written materials showing proper
18 injection sites and needle and drug use information listing
19 withdrawal times of some of the antibiotic products.

20 They explain HACCP and how producers are
21 affected, and explain principles of judicious use of
22 antibiotics to address the selection of resistant bacteria.
23 Those are also available and being distributed.

1 We've had a lot of support in promoting the
2 importance of PQA to the producer, also. Our packers have
3 told producers that this program is so important in
4 addressing HACCP responsibilities that they either have to
5 go through the program or are very strongly encouraged to go
6 through them.

7 And I belong to a coop marketing group. And part
8 of that is we have to turn in our PQA card as they come due
9 to make sure that we continue to be part of that coop.

10 This packer support has helped demonstrate the
11 importance of the program. It also has, though, made us
12 aware that there is a need to help youth that handle pigs
13 through such as 4-H and FFA projects to understand HACCPs
14 and their responsibilities.

15 With the input of veterinarians and educators, we
16 have developed a youth PQA program that can be delivered to
17 these young producers. Some of them are our future in our
18 industry, and it is important to make sure they understand
19 the importance of doing things right.

20 As of today, about 25,000 of our over 75,000
21 producers have completed the program there in the youth
22 category.

23 So how about the future of the PQA program?

1 That, like it has always been, is in the hands of us
2 producers. Producers like me have directed the program from
3 the start through our Pork Quality Assurance Committee, with
4 experts, and now through the Producer Education and Pork
5 Safety committees.

6 We're having a PQA advisory group later this
7 month that will be again revising the PQA and looking at it
8 and making sure that we're current and having our next
9 revision and delivery.

10 At this meeting we will be considering additional
11 information about topics such as rodent control,
12 biosecurity, animal welfare, needle use and broken needle
13 prevention, antibiotic resistance, judicious use principles,
14 and how PQA relates to meat quality characteristics and how
15 a producer can use a self-assessment to see how their
16 production stacks up with the good production practices that
17 could be included in the next PQA revision.

18 We will be discussing possible ways to help
19 standardize delivery to the program to the verifier,
20 something that we always need to keep on top of.

21 PQA continues to be a work in progress. We
22 aren't finished. We know we have other things. And it's
23 certainly not an end point.

1 I hope this has given you a brief overview of
2 what we've done and what we're trying to do. It's something
3 that producers, we've funded through our check-off program,
4 and we think it's very important for our industry. And it
5 certainly is an accepted way of doing businesses.

6 And as these vertical integrations and these
7 marketing groups, PQA is certainly a basis for all of those.

8 Thank you very much.

9 (Applause.)

10 DR. OLSON: I believe we'll keep moving along
11 with our presentations here.

12 Our next presenter is John Adams from the
13 National Milk Producers Federation. John is director of
14 animal health and farm services for the organization.

15 He has been involved with development of the
16 dairy quality assurance program; the milk and dairy beef
17 residue avoidance program, which is known as the Ten Point
18 program; also involved in a pilot project in the Northeast
19 working on overall quality assurance.

20 Additionally, he works with such things as the
21 National Johne's Work Group and the Animal Health Emergency
22 Management Steering Committee. So without further ado,
23 let's welcome John Adams.

1 (Applause.)

2 MR. ADAMS: Thank you, Ken. And while we are
3 getting changed up here, let me compliment John Ragan and
4 his team for this pictorial on the front of your agenda
5 here.

6 Finally, John, you got dairy where it belongs,
7 right up on top. Okay? The only thing I'm wondering about,
8 though, is that a new strain, a holstein, you've got there,
9 or where did you come up with that?

10 You know, in preparation for this very important
11 conference this week, I couldn't help but think how
12 fortunate I am to be up here representing the dairy industry
13 and not Firestone Rubber with all the problems they have, so
14 it's somewhat reassuring that we're not the only industry
15 with challenges at the farm level.

16 Well, I'm here today to talk about dairy animal
17 production food safety and what the dairy industry is doing.

18 Our goal, if we have one major goal, is to
19 constantly produce the safest and highest quality milk and
20 dairy beef possible by integrating the best science,
21 technology, and management practices, including alternative
22 organic and sustainable agricultural practices, thereby
23 enhancing animal health, welfare, and environmental quality.

1 That's quite a challenge.

2 I think we all agree that food safety begins on
3 the farm. And we began to roll out our first initiative on
4 a HACCP-based principled on-farm quality assurance program
5 in 1993.

6 But I would point out to the audience that we
7 actually started this initiative in 1987, long before the
8 crisis hit us in the early '90s with regard to residues in
9 the milk supply.

10 So this is a program that's been in existence now
11 formally since 1993 and has become a benchmark for residue
12 avoidance in the dairy industry and is still being widely
13 used as an educational program.

14 Our major dairy animal production food safety
15 focus for 2000 and beyond is in keeping with what you've
16 heard earlier today by other speakers.

17 Food safety has to be on top of the list, animal
18 welfare issues and concerns, environmental issues and
19 concerns, and international market expectations.

20 Now, when we look at on-farm food safety issues,
21 there is a myriad of issues to deal with. Here's a list
22 that's been prepared by the University of California team at
23 Davis, and it's pretty comprehensive, but it's not all-

1 inclusive.

2 If you look at the issues that are confronting us
3 from a zoonotic public health standpoint, the list is
4 challenging.

5 And as you can see on this list, it's somewhat
6 prioritized. But if you go down to the bottom of the list,
7 I think you can see that a major effort is going forward on
8 Johne's. We've had a major effort on listeria
9 monocytogenes. And certainly the staph aureus problem and
10 the Brucella problem have been well captured or at least the
11 risk greatly minimized.

12 And some of the other diseases you see on this
13 list, the challenges remain.

14 Well, how to build a program that's going to
15 address this myriad challenges is before us. And I think
16 where we start in the dairy industry is to build on existing
17 programs. And I think we're fortunate in the dairy industry
18 to have a number of programs to build on.

19 First of all, let me say that without extension
20 we couldn't hope to address these many issues. And we
21 believe that it's very unfortunate that extension is not
22 getting the funding support that it deserves at the federal
23 level.

1 The Grade A Pasteurized Milk Ordinance was
2 mentioned earlier by Dr. Sundlof. You know, food safety in
3 the dairy industry on the farm is not new, folks. We've
4 been with this since 1950. We've had inspectors on our
5 farms twice a year since 1950.

6 So a lot of the concepts and principles that
7 we're talking about today have been longstanding issues with
8 the dairy industry. And dairy farmers are acclimated to on-
9 farm food safety through the Grade A Pasteurized Milk
10 Ordinance.

11 The milk and dairy beef residue prevention
12 program I have mentioned.

13 We have also developed pro-milk and mastitis
14 quality programs, farm assist, and now nutrient management
15 programs to deal with runoff of manure and control of
16 manure; Dairy Breakthrough Management, which is a California
17 program; and the New York State Cattle Health Assurance
18 Program, which I am going to talk more about today.

19 I think one of the important realizations for us
20 in the dairy industry is that we couldn't begin to deal with
21 all the myriad of challenges without putting a regional
22 focus on it.

23 There are just too many differences from region

1 to region, cultural differences, management practices, and
2 so forth.

3 So our focus is going to be on best management
4 practices that directly impact herd health, food safety,
5 animal welfare, and environmental stewardship.

6 We want to keep the program voluntary to
7 encourage producer adoption, we want to emphasize herd
8 biosecurity as a core focus, and we want to develop resource
9 networks to deliver the technical support and science base
10 that we need to build on.

11 We want to keep it simple. We want to utilize
12 existing programs. We don't want to necessarily reinvent
13 the wheel. We've got a lot of resources out there to call
14 upon.

15 We want to develop a farm herd health plan based
16 on risk assessment, which you've heard other speakers
17 mention.

18 We want the focus on integrating practical best
19 management practices, and we want to emphasize quality
20 management and validate the use of BMPs, which is a huge
21 challenge. And we want to keep the overall focus through
22 all this on food safety.

23 One of the models that we are looking at very

1 carefully in a pilot program in the Northeast through 13
2 states in the Mid-Atlantic and Northeast region is NYSCHAP,
3 the New York State Cattle Health Assurance Program.

4 This model was developed by Dr. John Huntly
5 [phonetic], who is the state veterinarian in New York.

6 Another similar program has been developed by the
7 University of California at Davis, at the Tulary [phonetic]
8 Center, by Dr. Jim Culler [phonetic] and his colleagues,
9 called Breakthrough Management.

10 In many ways these programs are similar, with a
11 slightly different focus.

12 The NYSCHAP goals are to identify key livestock
13 health, consumer, and food safety issues affecting livestock
14 and establish and implement preventive intervention
15 strategies that will enhance production and product quality,
16 right along the lines of things we've been talking about.

17 The BTM mission is a little more sophisticated in
18 that they've broken it out into an internal and external
19 mission statement.

20 But essentially what it's trying to do is
21 systematize good management practices on a daily basis to
22 account for all the critical control points in the dairy
23 operations. And it's primarily aimed at the large dairy

1 enterprises that have developed in the West and now in the
2 Midwest.

3 Dairy BTM, how do you do the BTM program? It's
4 pretty simple. You start with the economic impact on animal
5 health on the dairy industry or on the dairy itself, and you
6 discuss the public health, the environmental health, and
7 economic well-being issues.

8 Then you build your BTM team, which is your
9 veterinarian, your herd management group, your employees,
10 all of the other people that have been mentioned by Dr.
11 Gillespie in his talk.

12 You then discuss the goals, create the mission
13 statement, develop standard operating procedures, training
14 form, evaluation form, and monitoring form.

15 So you can begin to see here that we begin to get
16 a little more sophisticated in our implementation process in
17 terms of transferring some of the principles of HACCP into
18 standard operating procedures that we can utilize each and
19 every day.

20 And then, finally, implement training, and then
21 introduce your individual modules.

22 So what is dairy BTM? Simply put, it's team
23 building, it's proactive listening to employees, it's

1 problem solving, it's process management. It's a dynamic
2 process that's ongoing to create a specific plan for that
3 enterprise.

4 The NYSCHAP is a similar approach, utilizing the
5 team approach. But it's a program that can address any size
6 farm, because it's less sophisticated in terms of involving
7 facilitators and other people in the team process.

8 But essentially again we're seeking to coordinate
9 and focus the combined efforts of the producer, the herd
10 veterinarian, agribusiness, university, government extension
11 consultants, and a lot of other people that get involved.

12 Some of the key issues can be diagramed when you
13 look at this. We're looking at animal health, we're looking
14 at environmental stewardship, we're looking at public
15 health. And those are all of the issues that we have to
16 address in any program today of a comprehensive nature on
17 the farm.

18 The NYSCHAP concept is pretty simple. You have
19 this core module that's a biosecurity module. And around
20 that biosecurity module, you build in these other modules
21 that can be developed and are in the process of being
22 developed to focus in on specific animal health issues that
23 are having an economic well-being impact on the producer.

1 The NYSCHAP approach, again, you look at the farm
2 process as a dynamic equilibrium. And you then propose
3 intervention strategies to enhance animal health by
4 considering the areas that I've talked about previously.

5 Now, this is really, I think, one of the diagrams
6 that shows the progress we've made, because now we're beyond
7 the PMO in that we're not looking at problems after the
8 fact. We're not measuring bacteria count and then going
9 back to the farm and trying to correct the problem.

10 We're looking at the whole process as a dynamic
11 process on an equilibrium base and looking at all the
12 inputs, how those inputs are processed, and then, of course,
13 the outputs.

14 The producers have the responsibility of choosing
15 to participate and implement the best management practices
16 and implement the herd plan.

17 The veterinarian enrolls the producer, develops
18 the herd plan, and evaluates progress.

19 The university is responsible for helping with
20 the diagnosis and laboratory support that's necessary.

21 And in New York, the Agriculture Department
22 validates, maintains a herd file, a database, and helps with
23 the development of the program.

1 So it's really a partnership here that makes this
2 kind of an effort at the farm level possible.

3 Two basic elements, again, the core program and
4 the specific modules that I've mentioned. In the California
5 plan, of course, and in the NYSCHAP plan both, the
6 biosecurity is central, because you go in as a team, you do
7 your risk assessment, and you're looking at all the
8 management practices that impact that operation from an
9 overall biosecurity standpoint.

10 And of course mastitis is one of the most
11 important issues facing the dairy industry from a cost
12 impact standpoint. And we have still challenges in the
13 staph aureus and E. coli area. And E. coli-form mastitis
14 remains one of our major challenges.

15 But we're looking at it from a milk quality and
16 public health standpoint as well as an environmental health
17 standpoint.

18 Another module under the Breakthrough Management
19 is a milking parlor module where we get into specifics of
20 milk quality, milk hygiene, prior preparation of the animal,
21 udder preparation, a good milking time practices, proper
22 equipment maintenance, and post-milking hygiene.

23 Another module gets into calf raising. There are

1 other similar modules for raising heifers. But here we get
2 into the feeding, the housing, the disease prevention
3 factors that are very important as far as preventing
4 antibiotic use and so forth.

5 The concept in the pilot program that we're
6 initiating in the Northeast and Mid-Atlantic region is to
7 take the NYSCHAP model and begin to regionalize it.

8 These are some of the modules that have been
9 developed in cooperation with Cornell University: the core
10 module, the Johne's Disease module, bovine viral diarrhea,
11 salmonella, mastitis, milk quality, bovine leucosis virus,
12 and hoof health.

13 Again, the core module, as I said earlier, has
14 minimum enrollment requirements. Unique animal
15 identification is absolutely critical, and we will insist on
16 it.

17 Herd health record system is very important. If
18 the producer isn't interested in maintaining herd health
19 records, we're not interested in having his involvement.

20 Goal setting, risk assessment, the herd plan
21 based on the best management practices, and finally a
22 contract with the State Department of Agriculture.

23 The program sort of can be diagramed in this

1 fashion as a program flow from goal setting through risk
2 assessment and planning to execution and then quarterly
3 evaluation.

4 When we do the baseline assessment, we're looking
5 at the farm description, of course. We're looking at herd
6 inventory. We want to be sure we know where the animals are
7 coming from.

8 We want to look at milk quality and udder health,
9 the history of treatment of those animals with regard to
10 mastitis, reproduction issues that could impact the quality
11 of the product. Culling is certainly a very important area,
12 and lameness is another important challenging area.

13 The risk assessment gets into maternity. The
14 maternity pen is probably the most critical control point on
15 any dairy farm, and that's where we spend a lot of time.

16 The calf, the heifer, the pre-fresh stage, the
17 lactating cow, the dry cows hospital. And other risk
18 factors include the animals, the manure, the feed, the
19 water, the facilities, the equipment, the people, and the
20 risk modifiers.

21 The intervention strategies are very important
22 after all this is done. We want to address identified risk.
23 We want to present an outline, a spreadsheet to arrange the

1 risk factors in a usable form or guide for the producer.

2 And here you can see an example of that, where
3 the risk factors are listed on the right, the risk
4 information is in the next column, then the risk factors on
5 this particular farm and whether or not there's a
6 feasibility for addressing those factors.

7 Best management practice outlines for the
8 producer to guide the producers, the veterinarians, and the
9 advisors in developing the individual herd farm plan.

10 And finally, the herd plan itself, with farm
11 specific goals, summary of priorities, and a tactical plan
12 form that can be reviewed quarterly.

13 And then, a detailed fact sheet with in-depth
14 presentation of management practices, the testing procedures
15 that are necessary to support those practices, disease
16 control.

17 And of course part of the challenge is to
18 catalogue what we need for this specific farm from what's
19 available in the literature.

20 And finally, an annual evaluation, which I've
21 talked about earlier, which is extremely important. And I
22 think one of the most important aspects of the annual
23 evaluation is not only what you're doing wrong, but what

1 you're doing right, and then setting some goals for the
2 future and then, utilizing proper teaching materials.

3 Here's an example of a case study that's been
4 used as a type of teaching material.

5 And finally, a certification process to give some
6 validation to the producers, some reward to the producers.

7 We have other components of each of the modules.

8 Here's an example of some of the module components that
9 help support implementation of these modules.

10 And we're doing this now, beginning to
11 regionalize this, as I said, through a 13-state area,
12 developing the science-based modules to be applied on a
13 regional basis.

14 I think one of the advantages of doing this on a
15 regional basis is to share resources and expertise.

16 We're developing a regional implementation plan,
17 and then, also the financial support that's very necessary.

18 We want to regionally be able to integrate
19 elements of the Grade PMO, what we have in existence today,
20 and the milk and dairy beef quality assurance program and
21 the other programs I have talked about to assure marketing
22 opportunities for the U.S. dairy industry, both domestically
23 and internationally.

1 So in summary, our organization, as a national
2 commodity organization, supports the development of on-farm
3 dairy quality management programs that address consumer
4 needs, validate best management practices that assure food
5 safety, animal welfare and environmental quality, thus
6 enhancing global marketing opportunities for the U.S. dairy
7 industry.

8 And we have some major challenges ahead. But we
9 believe we have developed some models and modules to begin
10 to address these on-farm issues. Thank you very much.

11 (Applause.)

12 DR. OLSON: Thank you, John.

13 We're now moving to the younger animals. And our
14 next presenter is Dr. Dan Cutherman, director of technical
15 services for Strauss Veal Feeds.

16 Dr. Cutherman is a member of the board of
17 directors of the American Veal Association and also chair of
18 the Veal Quality Assurance Committee. Did his graduate work
19 at the University of Kentucky.

20 And so we'll now ask him to fill us in on what's
21 going on in the veal area. Dr. Cutherman.

22 DR. CUTHERMAN: Got too many wires here. What
23 ever happened to the good old days of slides? Hopefully we

1 have power.

2 Okay. Now that we've got the big guys out of the
3 way, we'll get down to the little ones here.

4 I hope I'm not going to be asleep on this. Now
5 we're coming back.

6 I do have Laura Kwisnek [phonetic] with me, as
7 well, on this trip to St. Louis. She's our veal quality
8 assurance coordinator, recently hired at our office. And
9 she'll be attending our booth out here. So if there are any
10 questions after the fact, she can certainly help out and can
11 be located at the booth, I suspect.

12 I wanted to just give you just a brief overview
13 of the veal industry. Primarily the American Veal
14 Association and the veal quality assurance program, we
15 primarily deal with the special-fed veal industry. It's a
16 very specialized market.

17 We're looking at -- I think my mouse is locked,
18 so unless there's a keyboard way to get down to here, it's
19 not going to go. Like I said, what happened to the good old
20 days of slides? Get back on track here.

21 Basically we're looking at harvesting
22 approximately 650- to 700,000 calves annually. These are
23 primarily nearly all holstein bull calves. We raise them to

1 a weight of approximately 450 pounds using about 600 pounds
2 of feed, creating a 275-pound carcass on the end.

3 This meat is probably 95 percent going to the
4 white tablecloth industry, not a lot of it going to the
5 retail chain through the grocery markets.

6 And one important issue that we have to deal with
7 is we have very little to no control over our source
8 animals. Where 99 percent of them come are going to come
9 from sale barns. We have no control over the genetics over
10 those animals.

11 In our industry we have approximately five to six
12 major feed companies and ten or 12 smaller ones, eight or
13 nine major packers and probably half-a-dozen or a little
14 better minor packers, smaller packers.

15 With considerable integration within the
16 business, we're headed towards a trend, I think, as most
17 industries are, or most livestock industries are, of fewer,
18 larger growers.

19 And we do have one company that is completely
20 vertically integrated, from sourcing the animals through the
21 feed, through the meat, and through the meat sales to the
22 retailer.

23 We have put together the veal quality assurance

1 program. It's pretty much a voluntary program that we've
2 got put out. Our goal is market assurance through quality
3 assurance.

4 We've developed a two-level program. Level 1 is
5 essentially a temporary program that essentially holds that
6 producer for a period of about six months until they
7 complete the requirements for Level 2 certification. That
8 is a two-year duration program.

9 In Level 1 the producer agrees to certain issues:
10 Number 1, that they maintain adequate records; that they
11 maintain an adequate or a valid veterinary client patient
12 relationship, which is something I've personally struggled
13 with and the definition of what is a valid VCPR?

14 Myself and as a committee, we've had trouble with
15 that in, what is a veterinary visit? I'd like to see that
16 addressed at some point down the road.

17 We also put in there a proper use of animal
18 health care products; proper management practices, best
19 management practices, if you will; and finally, a review of
20 facilities and management practices to be sure that that
21 producer is on the right track.

22 For Level 2 certification, the producer needs to
23 reaffirm or reconfirm the Level 1 qualifications. There is

1 a -- we've put together a farm plan self-assessment test
2 that's done with the veterinarian.

3 We also ask that the VCPR is confirmed in
4 writing, and that is backtracked through the veterinarian to
5 make sure that he does have a valid VCPR with that producer.

6 And finally, we put together a VQA educational
7 seminar which walks the producer through animal health care
8 product use issues, residue issues, best management
9 practices. That's usually performed by a verified trainer
10 and a veterinarian, as well. And we usually feed them, so
11 that tends to bring people in.

12 After the two-year period, the certification
13 program can be -- or you can be recertified by either
14 reattending one of the certification educational programs or
15 through a written test.

16 And if anybody in the crowd is ever interested in
17 looking at doing something through a written test, my first
18 recommendation would be, make it simply multiple choice or
19 true and false, no essay questions. That can be
20 problematic.

21 The results of the program so far, we have 867
22 Level 1 producers or people that have gone through the Level
23 1 program to date. Level 2 producers, we're at 716.

1 I'm always asked the question, what percentage of
2 the industry are we reaching? And we estimate that's about
3 90 to 95 percent of them.

4 It's a little difficult to get a handle on
5 whether we're getting them all. We do have a lot of people,
6 multiple people registered or certified through the same
7 farm.

8 The meat packers have helped tremendously in this
9 issue. The first of last year, they vowed to only accept
10 Level 1 certified calves, and the first of this year, they
11 vowed to take only Level 2 certified calves. So it's put a
12 lot of teeth into our program, and it's certainly helped us
13 out a lot.

14 The ultimate goal that we've been looking for is
15 on violative residues, and we've seen that drop from .86
16 percent to .075, so from roughly one in 100 carcasses to
17 less than one in 1,000. So I believe we're getting very
18 close to that.

19 As Gary Cowman had mentioned, we are working
20 through the Cattlemen's Beef Association for check-off
21 dollars. This is a 100 percent check-off funded program, so
22 we need to abide by the same rules that the Beef Association
23 has to, as well.

1 We do have a Level 3 certification program that
2 we're currently working on. It is more for the people that
3 are advising the producers. We have a lot of people that
4 are onto producers' farms on a daily basis giving them
5 recommendations, and we're trying to find a way to certify
6 those people, as well.

7 We do have a certified supplier program that the
8 suppliers need to go through. That goes anywhere from feed
9 to medication to equipment to sanitizing agents.

10 And we ask that they go through that so they
11 understand what the recommendations or what the requirements
12 are on our growers so that they can also be certified.

13 And I believe that is all I have. I will be
14 around later if there's any questions. Thank you.

15 (Applause.)

16 DR. OLSON: Thank you, Dan.

17 Our next presenter is Dr. Cindy Wolf. Dr. Wolf
18 is a member of the faculty of the College of Veterinary
19 Medicine at the University of Minnesota, where she is a
20 small ruminant specialist.

21 She chairs the Animal Health Committee for the
22 American Sheep Industry Association and is actively involved
23 in updating the sheep quality assurance program.

1 She also is the chair of the Sheep Health
2 Committee for the National Institute for Animal Agriculture.

3 So we'll now call on Dr. Wolf to provide us an
4 update on what's going on in sheep quality assurance.
5 Cindy.

6 DR. WOLF: I'm not a very good joke teller, but
7 we could make a fair bid to subsidize this meeting. Anybody
8 want to run off with these computers?

9 (Pause.)

10 DR. WOLF: Okay. Well, thank you very much for
11 having me.

12 My job this morning is to bring you up to speed
13 with what's been happening regarding sheep quality assurance
14 activities.

15 And I'll just give you a little warning that two
16 of my daughters are very upset that their mother wasn't
17 going to be there to take them to school for their first day
18 at a new school today, so they got to choose the background.

19 And they don't know it, but I took the sound away.

20 (General laughter.)

21 DR. WOLF: Sheep quality assurance is an
22 interesting topic to me because I work for the University of
23 Minnesota and do some volunteer work for the sheep industry.

1 But I and my husband also raise 1,800 commercial
2 ewes in two states. And so whenever we come back from
3 meetings, he wants to know, Well, what's new? What do I
4 need to know?

5 And those of you who are involved in agriculture
6 on a day-to-day basis realize, that the farmer and the
7 rancher are always the strongest critic of what's happening
8 in these meetings. So it keeps me honest.

9 In 1995, the American Sheep Industry published
10 what I'm going to refer to today as the Green Book. And
11 this book was put out similar to the other quality assurance
12 efforts for other species. The goal is very similar as
13 other programs.

14 Basically we have some recommended on-farm
15 management practices referenced in this book, preventive
16 flock health programs, some detail there, some detail left
17 out on purpose because sheep production really varies
18 depending on the size of the flock and the area of the
19 country.

20 And as Dr. Cowman mentioned, that's similar to
21 the beef industry.

22 And then, we have some detail provided on the
23 kind of record keeping that really needs to be in practice

1 on the farm level.

2 So I brought some copies of this Green Book for
3 any of you who are interested and will leave them out on one
4 of the tables.

5 We chose green on purpose because we feel like
6 producers need to sit up and take notice of quality
7 assurance programs, and so this was a good color to help
8 them do that. And if you raise sheep, green is also an
9 important color, because most of the sheep in this country
10 derive a fair amount of nutrition from grass.

11 As Dr. Cowman mentioned, the information in our
12 book is again based on published information, and a lot of
13 that comes from a quality audit that was done in the early
14 '90s.

15 The book has been reviewed a number of times and
16 has been commended for being presented in a producer-
17 friendly manner.

18 This book was a joint activity between the
19 extension service, the College of Veterinary Medicine and
20 Department of Animal Science at Colorado State University,
21 the American Sheep Industry Association, and the University
22 of Minnesota.

23 And it looks like a sort of small and simple

1 book, but I think that that, too, has been brought out
2 today, that when preparing things that we want producers to
3 use, we need to keep it simple so it will be adopted.

4 Different than some other industries, the packers
5 have not required or strongly encouraged sheep producers to
6 participate in this program. And let me flip that around
7 and tell you that they haven't discouraged it, either.

8 And I think the sheep industry is entering a new
9 era in that producers and packers are now having more
10 dialogue than ever before.

11 And some of that is because of a 201 trade action
12 case that was brought forward and won by the American Sheep
13 Industry, and it requires that producers and packers stay in
14 a little closer dialogue than they had in the past and work
15 together.

16 And I think that, as this is happening and will
17 continue to happen quite aggressively over the next two
18 years, we're going to see more packers looking for lambs
19 produced out of flocks that are actively engaged in a
20 quality assurance program.

21 The other edge that it will give us is that the
22 lamb industry faces a lot of challenge from imported lamb
23 meat, and we as a national industry should be proud if we

1 can get more and more packers onboard that the lamb produced
2 in this country is produced under a bona fide quality
3 assurance program.

4 I'm not saying that all imports that come in are
5 not, but certainly it's not something that's aggressively
6 marketed today by imported lamb.

7 Just as other quality assurance programs, we go
8 through, as I mentioned, some of the management practices.
9 So I thought you were probably getting tired of looking at
10 word slides, so feeding management, facilities, handling,
11 and transportation.

12 And I just want to digress for a minute. We're
13 really proud in the sheep industry and perhaps a bit
14 fortunate at the same time in that pathogens were not a
15 major defect found at the quality audit. And the major
16 defect is bruising.

17 And sheep are a little unique in that many times
18 they come from small farms that don't have nice handling
19 setups. And the other feature that's unique is that they
20 have wool. And while we shouldn't handle them by using
21 their wool as handles, it occasionally happens.

22 So we just made sure we really focused and tried
23 to give people good information on how to improve their

1 handling and minimize bruising to make that quality defect
2 go down in prevalence.

3 We also touched on the milking area. Certainly
4 milk sheep are not a big aspect of our industry, but they do
5 contribute human products, and it needs to be addressed and
6 will continue to be addressed.

7 And then, in the feedlot I'm bringing a little
8 new information -- about a year old -- to you today. This
9 would be a feedlot probably out in the Colorado area.

10 And we had a study done by Dr. Steve Lavalley
11 [phonetic] and some graduate students; he's from Colorado
12 State University. And they looked at a combination of 12
13 treatments in feeder lambs in feedlots. And this actually
14 wasn't done at a university setting. This was done in a
15 feedlot.

16 And basically the treatments were shorn versus
17 unshorn lambs; crutched versus not crutched; and then,
18 environmental manipulation, bedding with primarily straw
19 bedding versus not bedded, and wet versus dry, because those
20 of us who come from more high rainfall areas like myself
21 can't always control how much rain we get when these lambs
22 are in the feedlot.

23 And we found something quite interesting -- and

1 it's also been found in other countries -- is there were
2 actually no differences between treatments on the carcass
3 bacterial load at slaughter.

4 On the other hand, the producers have had to
5 adopt the strategy that the majority of lambs sold today are
6 shorn, and that's a management practice that's in place
7 primarily because the packer can make more money off the
8 pelt if it's been shorn about three to six weeks prior to
9 the lamb being marketed.

10 So that's interesting how things come together
11 whether they have scientific basis or not. And that's what
12 sometimes feedlots can look like even with fairly regular
13 scraping. Like I said, we could get days and days of rain.

14 Okay. We also have a section on shearing. I
15 thought that since this is about food safety we wouldn't
16 spend much time on wool quality. And also have a section on
17 flock health, injections, use of drugs.

18 We are expanding that section to include an area
19 on judicious use of antimicrobial and resistance. That
20 section also has some detail on record keeping and some
21 other basic flock health procedures.

22 The sheep industry is fairly well positioned when
23 it comes to individual animal identification in that the

1 APHIS voluntary flock identification program mandates
2 individual animal ID. And so we've had probably about six
3 years now of trial and error of, what's a good form of ID in
4 sheep?

5 And while this is not a picture of the tamper-
6 proof ear tag that's been developed for this program, it's a
7 prompt to remind me to discuss that.

8 And so this ear tag is very producer-friendly in
9 that the numbers are big enough that you can read them
10 without glasses. They have very good retention rate in the
11 sheep, and they are difficult for producers to remove.
12 Nothing is impossible for the producer to remove.

13 The other two aspects that are somewhat unique to
14 sheep production is the majority of sheep going to slaughter
15 in this country never eat out of a feeder for very long, and
16 so we have very good retention rate of ear tags in general.

17 And lastly, we have something called wool, which
18 means that if we have animals that have been treated and for
19 some reason are not ear-tagged, we have wool-friendly paints
20 that can be applied to those sheep.

21 And the way we use it in our feedlot, for
22 example, we keep a hard copy of which animals have been
23 treated, but we also spray paint the last date that animal

1 was treated, and then, there's a code of which antimicrobial
2 was used in that animal so that anybody can look at that
3 lamb when they're sorting for lambs going to market and not
4 by accident put that lamb on the trailer.

5 Okay. That's a little bit of where we are today.

6 And now, where are we going?

7 Well, at the moment, the Green Book is under
8 revision to bring it up to date. And we expect to have that
9 new edition published in the next few months.

10 And sometime later this year or early next year,
11 additional training materials will be developed to do a
12 number of things: 1) to encourage more producer
13 participation; and 2) to allow that we have standardized
14 training not only of producers, but of the trainers.

15 And those trainers, just as it is true for other
16 programs, will be a combination of extension personnel and
17 veterinarians.

18 So there is just some of the format that is going
19 to be used. CD Rom, video, standardized training sessions.

20 A Web Site is being developed.

21 And we need to get into third-party verification.

22 It's not something that's required at the moment in our
23 program, but we're moving in that direction and expect to

1 have that component onboard in 2001. With that component,
2 it will be a database development such as was talked about
3 with PQA. And they are to be commended on what they have
4 done.

5 In the verification area, we have heard from our
6 other species groups that there is definitely a need to have
7 standardized training with your trainers.

8 So we have talked a little bit with the American
9 Association of Small Ruminant Practitioners and the AVMA to
10 work in conjunction with us so that we have some
11 standardized training of the third-party verifiers.

12 And I think the net result is fairly obvious, is
13 that we'll have a more credible program to everybody who
14 examines it.

15 Who is updating our program for the American
16 Sheep Industry Association? Really it's a team effort. The
17 National Institute for Animal Agriculture, under the
18 leadership of Glenn Slack, and Colorado State, under the
19 leadership of Dr. Gary Smith.

20 I'm not really sure why I put this over here.
21 But anyway, we as an industry continue to encourage people
22 to keep their records out in front of them, and that's
23 something we're going to push harder in our new program.

1 Something that's a little different than some
2 industries perhaps is we have to focus fairly heavily on
3 parasite control.

4 And while I don't believe FSIS looks hard for
5 residues at Antalmentix [phonetic], it's probably one of the
6 most common products used in sheep, way above antimicrobial.

7 So again we're trying to tie management and responsible use
8 of these drugs together.

9 We are real serious to have a strong producer
10 campaign and get more producers onboard. And this is
11 probably going to happen through multiple methods.

12 And lastly, I'd like to thank the number of
13 people who have been working on this updated effort in the
14 last several months.

15 And with that, thank you.

16 (Applause.)

17 DR. OLSON: Okay. Thank you, Cindy.

18 We're now moving to the poultry side. And our
19 first presenter is Steve Pretanik, who comes to us from the
20 National Chicken Council, where he is director of science
21 and technology.

22 Steve's current responsibilities include
23 addressing food safety issues, both in live production and

1 in the processing area.

2 So please join me in welcoming Steve Pretanik.

3 (Applause.)

4 MR. PRETANIK: I want to thank all of you for
5 this opportunity to share with you some of the programs that
6 our industry has adopted to address food safety at the
7 production level.

8 Our industry is a little unique in that we are
9 structured as a vertically integrated industry. What this
10 means from a food safety point of view is that we have
11 control of all of the inputs affecting our finished product,
12 all the way from the breeder farms through processing, and
13 again, to the finished product.

14 For those of you who are not familiar with the
15 structure of our industry, a typical operation would consist
16 of the integrated company owns the feed mill, hatchery,
17 processing facilities. They'll contract with local farmers
18 to produce the hatching eggs, and the breeders are company
19 owned, generally purchased from a primary breeder.

20 The eggs after hatch go to a local farmer where
21 they're generally grown under contract until market age and
22 then to the plant for processing.

23 Feed is provided to both operations and the

1 companies also provide veterinary care to the breeder farm
2 operations and the grow-out.

3 So you can see we pretty much have control over
4 all aspects over all elements affecting our product.

5 Because of these controls, our industry felt that
6 the best way to address food safety issues was to put
7 together, develop, and adopt industry-wide good
8 manufacturing practices which encompass the whole spectrum
9 of our industry, again, all the way from the breeder
10 operation to the finished product.

11 In the interest of time, I'm going to briefly go
12 over those elements that apply to the live production side
13 and highlight those that are specifically designed to
14 address food safety concerns.

15 Management practices, as everybody has noted,
16 play a very important role in addressing food safety issues.

17 Our industry provides breeder broiler production
18 manuals to their growers. These manuals spell out in
19 detail specifications with respect to things such as
20 pesticide usage.

21 And I'd like to point out that growers are not
22 permitted to use any type of pesticide or insecticide
23 without the express approval of the company. If they do use

1 them, they must then certify that they have been used in
2 accordance with all regulatory requirements.

3 And we missed a slide. Backing up, facility
4 standards. This is also an important element and has food
5 safety implications not only with respect to the type of
6 equipment that's used, location of the facilities, it
7 addresses ventilation, water supply, and even physical pest
8 control measures.

9 Biosecurity is also another important element of
10 these programs. The intent here, of course, is to minimize
11 contact with the flocks with the diseases that may affect
12 the flock, but also vectors that may introduce foodborne
13 pathogens such as salmonella and campylobacter.

14 And again, these standards are developed strictly
15 enforced.

16 Animal health care is another important aspect of
17 these production practices. And here we have standards,
18 strict standards for pharmaceutical use.

19 Again I'd like you to note that the growers are
20 not allowed to use any pharmaceutical that have not been
21 provided by the company. If the company determines that
22 such usage is necessary, it's generally provided in the form
23 of medicated feed that's delivered to the grower, or in some

1 cases it may be administered in the drinking water.

2 Again, also -- well, okay, we'll get more into
3 the pharmaceutical later in the other operations.

4 Specific to the breeder operations, you can see
5 feed again plays a very important part not only with respect
6 to formulation to meet nutritional profile, but also we're
7 concerned with the controls that address pharmaceutical,
8 microbiological, and chemical residues. These are all part
9 of a company program.

10 Monitoring breeder flock health is also another
11 important aspect with respect to food safety, since some
12 diseases are zoonotic.

13 And here we have specific programs for
14 controlling pathogens. And these are generally dealt with
15 through the National Poultry Improvement Plan which the
16 companies participate in.

17 And also, that program has taken on great
18 importance with respect to our exports to other countries.
19 They're relying on this program for us to meet disease-free
20 certifications.

21 Another important element are procedures to
22 interrupt eggborne poultry disease transmission. This area
23 is likely to be expanded in the near future, as new

1 information is being developed which suggests that some
2 foodborne pathogens such as campylobacter may be transmitted
3 to the flocks, and this may be a major source of that
4 organism in the flocks.

5 So we will be expanding this area as new
6 information and interventions come along.

7 Monitoring and controlling egg cleanliness of
8 course also is important.

9 And here's another important element from a food
10 safety point of view, and this is specifically targeted at
11 Salmonella enteritidis.

12 And the broiler industry does not offer, for
13 human or animal usage, eggs that have not been pasteurized.

14 If they're not going to pasteurize them, they go to some
15 other nonfood use. This is strictly adhered to within the
16 industry.

17 Within the hatchery operations, sanitation and
18 cleaning are also very important with respect to food safety
19 concerns. Again, monitoring programs are in place.

20 Specifically, we have microbiological testing
21 programs in the hatchery, not only in the general facility,
22 but equipment surfaces as well. And we also monitor air,
23 again all with the intent of trying to minimize the

1 introduction of foodborne pathogens at the hatchery level.

2 Disposal of eggs is also another important issue.

3 And again, grow-out feed preparation, this is probably one
4 of the most important areas on the grow-out side, the feed
5 provided to the birds. And here we're going to get into
6 some of the quality programs that are adopted and used in
7 the feed mills.

8 And you'll note that each company has
9 specifications with respect to microbiological quality in
10 their feed ingredients. They sample these ingredients to
11 ensure that they meet their specifications. They also test
12 and sample ingredients for pesticide and other chemical
13 residues.

14 And records are maintained of all of these
15 activities. A typical broiler flock going to a processing
16 plant has a flock history that accompanies it which details
17 all of the medications, the type of feed, batch of feed, et
18 cetera.

19 So we can pretty well go back to any part, if a
20 problem should ever develop, and trace where it may have
21 occurred.

22 Pharmaceutical inventory on site again is another
23 important element. This is to ensure that pharmaceutical

1 are used properly and not inadvertently added to a batch
2 when they shouldn't be.

3 Again, only FDA approved pharmaceutical are used,
4 and then only in an approved manner.

5 And the industry does not use growth promotion
6 hormones, and we have continued that position since the late
7 1950s.

8 Sanitation and dust control are also important
9 elements with respect to contamination in the feed mill.

10 Pelleting of grow-out feeds we feel is beneficial
11 in reducing the level of microorganisms in the feed. And of
12 course, we find that the birds do perform better on pelleted
13 feed.

14 We also have testing programs for finished feed
15 with respect to again the pharmaceutical, residues,
16 chemicals, et cetera.

17 And cleaning of equipment after batches are made
18 of course are very important so that you don't get
19 contamination in the next batch, particularly with respect
20 to drug usage.

21 Environmental conditions are also element of
22 concern, particularly with respect to water quality and air
23 quality.

1 On the grow-out side again, control of feral
2 animals. This is not only to keep diseases out of the
3 flocks, but also foodborne pathogens, which a lot of these
4 animals can serve as vectors.

5 Again, pesticide usage can only be -- is only
6 done in accordance with company instructions.

7 Litter selection programs and management programs
8 are also very important, particularly with respect to any
9 residues that may be present in wood shavings or other
10 litter materials.

11 And an ongoing daily assessment, culling of sick
12 birds, and alerting of the company if there's anything
13 unusual that requires a veterinary investigation.

14 Preslaughter chemical residue testing and
15 monitoring is also another element in our industry, as well
16 as ensuring proper drug withdrawal procedures and proper
17 feed and water withdrawal prior to the birds being delivered
18 to the plant to help minimize fecal contamination when the
19 birds are processed.

20 Transport of birds for slaughter is another
21 consideration. This is a recommendation, really.

22 And the problem the industry faces here, even
23 though we recognize this could really help us improve the

1 micro profile of the birds coming to the plant, currently
2 there are no effective cleaning and sanitizing systems
3 available to the industry.

4 So from a practical sense, this application
5 really does not exist. Those that are in existence don't do
6 a very good job at all.

7 I would like to take a few minutes to talk about
8 a new program that we initiated last year and which has been
9 adopted by our industry. And this is our Food Safety
10 Enhancement Program, and it addresses both the live
11 production level and the processing level.

12 And the intent of this program is to have a
13 continuous ongoing program to have real improvements in the
14 microbiological profile of the raw poultry products.

15 Industry has committed itself to adopt
16 interventions, both at the live production and processing
17 level. And presently we have companies representing over 90
18 percent of the U.S. broiler production have agreed to
19 participate in this program. We hope to get the others
20 onboard pretty soon.

21 Some of the interventions that are being tested
22 by the industry, and if shown to be effective, adopted
23 throughout the company include various hatchery

1 disinfectants such as formaldehyde, peroxide, quaternary
2 ammonia compounds, litter treatment primarily to address the
3 moisture issue, and the PH, which helps to reduce the level
4 of foodborne pathogens that might be found in the litter.

5 Various organic feed additives, organic acids
6 added to the feed, again trying to reduce the micro level in
7 the feeds.

8 Treatment of drinking water with chlorination,
9 organic acids, ozonation, peroxide. Again we're trying to
10 address potential foodborne pathogens that may be
11 transmitted through the watering system.

12 And the use of competitive exclusion products.
13 We hope to see a lot more in this last area. Currently only
14 one product has been approved for use. There are several in
15 the pipeline at FDA, and we hope to see them come onboard
16 shortly so we can see how they work under actual field
17 conditions.

18 And that pretty well wraps up what we're doing in
19 our industry. I'll be glad to answer questions later on.

20 Thank you.

21 (Applause.)

22 DR. OLSON: Thank you, Steve.

23 We are going to make one adjustment in our

1 program this afternoon since we are pushing up on the lunch
2 hour. And our final speaker, Al Pope, will be on the
3 program later in the afternoon.

4 So our final presenter for this session will be
5 Dr. Alice Johnson, vice president of scientific and
6 regulatory affairs for the National Turkey Federation.

7 Dr. Johnson comes with a background from
8 veterinary medicine, as well as from the regulatory side.

9 She works with regulatory impacts on producers
10 and provides technical information on food safety.

11 And we're pleased to have her talking about the
12 quality assurance on the turkey side.

13 DR. JOHNSON: I thought that the only thing
14 standing between you and lunch would be Al Pope and me, but
15 now they've got it down to where it's just between lunch and
16 me. So I'm going to go pretty quick through this, and I'll
17 spare some of my slides.

18 I'd like to thank Dr. Ragan and his staff on
19 behalf of the National Turkey Federation for putting on this
20 conference. It is a wonderful conference, and we appreciate
21 the opportunity to walk through what we've done with our
22 best management practices.

23 The Turkey Federation started in 1996 looking at

1 what they call the food safety best management practices.
2 In 1997, the first edition of the best management practices
3 were published.

4 We had said at the time that this would be a
5 changing document, and it needed to keep up with new
6 technology. Little did we realize that it would need to be
7 changed so quickly.

8 And in 1999, we started working on the second
9 edition for publication in the year 2000, which is what we
10 have today that we have made available.

11 It's available to all of our turkey company
12 members, turkey processors, and turkey growers, as well as
13 the allied industries associated with turkeys and the
14 extension and universities.

15 There are special acknowledgements to Dr. Peter
16 Poss; Dr. Steven Clark; Roche Vitamins, now Alpharma,
17 provided us the support to put our best management practices
18 on CD Rom, which has worked out real well; and Dr. Allan
19 Rain from Michigan. More acknowledgments.

20 The best management practices started from the
21 turkey industry and one of the live production meetings in
22 which there was a workshop, an all-day workshop, where all
23 the growers got together and started talking about what they

1 do within their grow-out facilities that work and what they
2 have found out that doesn't work.

3 Part of the food safety best management practices
4 that NTF has put out, we talk about HACCP and the definition
5 of HACCP.

6 As I said, it was developed by the turkey
7 industry. It identifies the live production CCP's and is
8 used to enhance food safety.

9 We've had a lot of the state federations as well
10 as the extension agents associated with the counties and the
11 universities who have gone out and used the best management
12 practices to help work through some training courses.

13 We have several different modules that I'll talk
14 about in just a minute.

15 But all the modules are equipped with the flow
16 process chart, how you establish critical limits, critical
17 control points, monitoring, and documentation and the need
18 for documentation and the awareness of what the
19 documentation means, that you're not just documenting for
20 the sake of documenting.

21 We do emphasize that this is a voluntary on-farm
22 program. But we've had good success with the growers
23 adopting this program because they've found out that it does

1 improve the flock health and performance.

2 And as I said, it does emphasize education and
3 documentation. And again, you're not just documenting for
4 the sake of documentation. You're documenting so that you
5 can go back and look and see what works and what doesn't.

6 There are five modules, foundation multiplier
7 breeding, the commercial hatchery, the meat bird production
8 grow-out, live haul transportation, and then, feed
9 manufacturing and delivering.

10 In each module they talk about the ways to
11 prevent, eliminate, or reduce physical, chemical, and
12 microbiological hazards.

13 In 1992, the Turkey Federation did put out a
14 chemical residue avoidance program that has been put into
15 the food safety best management practices.

16 As I said, there's a flow chart, talk about
17 control steps, monitoring, and then, documentation.

18 And this is what the flow chart looks like for
19 the meat bird production and grow-out module.

20 I know this is hard to read. But as you can see,
21 you have on one side is your flow chart; in the middle are
22 what we call the control points, the critical control
23 points; and then, what is referred to as M, the monitoring

1 the feed back. It includes such things as sampling, your
2 environmental cultures, disease diagnosis, and then,
3 documentation is included within that.

4 And here's just a closeup of some of what we
5 consider: your vector control, drinking water sanitation,
6 litter management, feed management, and then, disease
7 diagnosis.

8 We're going to go pretty quick, I think, if I can
9 here.

10 The purpose of the food safety best management
11 practices is to produce the safest turkey or broiler for
12 food consumption that is possible with today's technology.

13 And as we try to emphasize to everyone who sits
14 through any of these training classes or who uses the CD
15 Rom, that this will change.

16 And you're going to have to keep your programs
17 updated. You're going to have to sit down every once in a
18 while and look to see what's changed within your facility.

19 I won't go through this in detail. We do go into
20 specifics about certain areas, as far as making a diagnosis,
21 what you need to do. You can see you have the control
22 points, and then, your monitoring and feedback.

23 The importance of biosecurity; vaccinations; the

1 chlorination of your water system; the importance of
2 ventilation in your houses; medication.

3 And then there is actually a BMP checklist that,
4 Have you done all these? Do you have them documented? Do
5 you have a program that you can pull out and review?

6 And can you look at your documentation and
7 determine where you might have problems, and is there
8 anything that leads up to what the problems possibly were
9 based on your documentation?

10 I'm going to end the slide presentations right
11 there.

12 But I would like to say that we've talked several
13 times today about litter management for turkeys, manure
14 management in the cattle industry.

15 And as a part of the food safety best management
16 practices, when the growers get a copy of the disk or the
17 hard copy they also get a copy of what NTF put out late last
18 year, which is the environmental guidelines.

19 While this is basically litter management,
20 comprehensive nutritional management programs, and
21 phosphorous nitrogen testing, it also includes part of
22 proper litter storage and application to prevent, you know,
23 any possible runoff that may occur.

1 And thank you again for the opportunity.

2 (Applause.)

3 DR. OLSON: I would like to thank all of our
4 speakers again this morning for their presentations. I
5 apologize that we didn't have time to ask questions of them
6 individually. Again, we will have the final presentation
7 from this session later in the afternoon.

8 But I think that the depth of the presentations
9 you saw today, the difficulty of fitting them into a ten-
10 minute slot shows the commitment that industry has and the
11 importance that we place on quality assurance and food
12 safety.

13 I encourage you to find the speakers during the
14 breaks or in the breakout sessions tomorrow to ask
15 questions. But do thank you for your attention.

16 And now I believe we're to adjourn for lunch,
17 which is down the hallway in Ballrooms A and C. So, thank
18 you.

19 (Whereupon, at 12:23 p.m., the meeting was
20 adjourned for lunch, with a presentation to be given at
21 lunch.)

22 //

23 //

1 L U N C H E O N P R E S E N T A T I O N

2 DR. THALER: I'm Dr. Alice Thaler. I'm the
3 director for the Animal Production Food Safety staff for the
4 Food Safety and Inspection Service, USDA.

5 And it's my pleasure to introduce our luncheon
6 speaker.

7 To summarize our luncheon speaker's career in a
8 few words, one could say that Dr. Catherine Woteki has
9 devoted her career to food.

10 Her education in biology and chemistry includes a
11 Ph.D. in human nutrition.

12 She worked early in her career at USDA and then
13 returned to us. Her earlier experience was in the area of
14 human nutrition.

15 She has served in several high profile positions,
16 including Acting Undersecretary for Research, Education, and
17 Economics; Deputy to the Associate Director of Science of
18 the Office of Science and Technology Policy; and Director of
19 the Food Nutrition Board.

20 Since 1997, Dr. Woteki has been Undersecretary
21 for Food Safety for the U.S. Department of Agriculture.

22 She is here today to share her unique perspective
23 on how we can achieve our food safety goals.

1 (Applause.)

2 DR. WOTEKI: Thank you very much, Dr. Thaler.

3 And it is really a pleasure for me to be with
4 this group today. I am really pleased at how many people
5 have showed up for a, for me, very interesting day-and-a-
6 half meeting.

7 It really, I think, indicates the level of
8 interest in animal production and the contributions that can
9 be made by focusing on animal production towards improving
10 the safety of our food supply and ultimately the health of
11 our population.

12 I want to thank all of you, then, for
13 participating in this meeting.

14 We're expecting, out of the breakout sessions
15 tomorrow, to gain some additional insights into research
16 that is needed to answer unanswered questions, and also as
17 far as educational activities that will help the producers
18 here in the United States in furthering the safety of food
19 safety at the animal production level.

20 I would also like to extend to you greetings from
21 the Secretary of Agriculture, Dan Glickman.

22 He has had food safety as one of his primary
23 priorities, really top priorities, during the five years

1 that he has been Secretary of Agriculture. And he is very
2 interested as well in the outcome of this meeting.

3 I've been asked to talk about, how can we achieve
4 our food safety goals?

5 And I think it's worthwhile to consider that it's
6 only been five years since the Food Safety and Inspection
7 Service first articulated its food safety goals and a
8 strategy to achieve them.

9 To refresh your memory, that strategy was part of
10 the 1995 proposed rule on pathogen reduction and HACCP
11 systems.

12 And one element of that strategy was the need to
13 approach food safety broadly and to address potential
14 hazards that arise throughout the food production and
15 delivery system, including before animals enter FSIS
16 inspected establishments and after meat and poultry products
17 have left those establishments.

18 While FSIS articulated the strategy, it was by no
19 means a job that FSIS could carry out alone. It required a
20 team effort among government agencies, including those that
21 are represented here and that are cosponsors of this
22 meeting, the industry, academics, and consumers. And each
23 had an important role to play in achieving the goals through

1 that strategy.

2 Nor could all of these changes be made at once.
3 FSIS chose to focus most intensely at first -- and I believe
4 appropriately so -- on regulatory oversight of slaughter and
5 processing establishments.

6 The pathogen reduction and HACCP rule, which
7 mandated HACCP and set performance standards for salmonella
8 that plants have to meet, has now been implemented in all of
9 the federally inspected and all of the state-inspected
10 plants across the country.

11 I think this has been a major achievement, and
12 thanks to the very hard work of industry as well as of our
13 own employees in the Food Safety and Inspection Service.

14 HACCP implementation from my perspective has gone
15 very smoothly, and it has also accomplished some dramatic
16 reductions in salmonella prevalence in meat and poultry
17 products.

18 Now I believe we're seeing the progress we've
19 made at the in-plant level spreading to other segments of
20 the farm-to-table chain.

21 Certainly the strategies developed for use in
22 slaughter and processing plants are not the same strategies
23 that are appropriate for animal production.

1 We've all known from the very beginning, five
2 years ago, that a different approach would be needed,
3 basically one that would be focusing on voluntary quality
4 assurance programs coupled to very research base and
5 educational outreach, all of these carried out through
6 partnerships.

7 And I think we're now beginning to see the fruits
8 of that labor, as you're hearing during this conference from
9 the various presentations.

10 Certainly many challenges remain, but I believe
11 we're in a better place than we were five years ago when the
12 strategy was first articulated.

13 Now, this progress is timely, because we're
14 seeing increased attention being focused on hazards to human
15 health that can arise because of practices carried out at
16 the animal production level.

17 Examples include the focus on animal
18 agriculture's role in antimicrobial resistance, agricultural
19 runoff from the farm and its effects on water as well as
20 food safety.

21 And very recently, environmental hazards have
22 resurfaced once again as an area of primary interest with
23 the release of the new risk assessment on dioxin that

1 indicates that this is a problem in concentration in animal
2 tissues.

3 The experience in Europe with BSE, the Mad Cow
4 Disease, also has focused additional attention on animal
5 production as a source of food safety problems.

6 At the recent international conference on
7 emerging infections that was held just this past July, it
8 was reported that three out of every four recent emerging
9 diseases of importance to human health arose from animal
10 infections. In other words, most new human diseases are of
11 animal origin.

12 An example is the Nepa [phonetic] virus that
13 killed 105 people in Malaysia last year and destroyed the
14 country's swine industry.

15 Thus the animal production community has an
16 important role in protecting public health more broadly.
17 And also, there is increased pressure on the animal
18 production community as well as processors, transporters,
19 and retailers, to take whatever steps they can in order to
20 do so.

21 I believe the growing attention to food safety at
22 the animal production level reflects the fact that food
23 safety problems are multifactorial in origin, and therefore,

1 the solutions have to be multifactorial as well.

2 As products traverse through the farm-to-table
3 continuum, there are many opportunities for contamination to
4 occur, and many opportunities as well for it to be checked.

5 This becomes very clear when you look at several
6 of the outbreaks related to E. coli 0157:H7 that occurred
7 just this past summer.

8 The outbreaks are still under investigation in
9 many cases. No definitive causes have been identified. But
10 it is possible that causes of illness that are still under
11 investigation have included the following:

12 Children petting farm animals without washing
13 their hands before they then went to eat; contaminated
14 product leaving an inspected establishment; and also a very
15 large outbreak has been associated with poor preparation and
16 cross-contamination in a restaurant setting.

17 Just as you wouldn't expect to prevent a robbery
18 if you locked just one door in your house and left all of
19 the windows open, one intervention along the farm-to-table
20 continuum isn't going to work to prevent all food safety
21 problems, either.

22 So to prevent hazards to human health,
23 interventions are often going to be needed at several points

1 in the farm-to-table chain, and we all need to step up and
2 do our part.

3 With that challenge before us today, I'd like to
4 focus on three questions. First to talk about what are our
5 food safety goals, and have they changed over the past five
6 years? Secondly, what progress have we achieved so far?
7 And lastly, what remains to be done?

8 First let's look at the food safety goals. We
9 know from foodborne illness data that are frequently quoted
10 now, recently released from the Centers for Disease Control,
11 that an estimated 76 million illnesses, 325,000
12 hospitalizations, and 5,000 deaths a year occur in the
13 United States, and that this burden of foodborne illness is
14 therefore very significant.

15 One major way that food safety goals have been
16 set in this country is through the Healthy People
17 initiative. It's a national health promotion and disease
18 prevention program that sets objectives every ten years for
19 a variety of health concerns. And food safety is one of the
20 major areas of the Healthy People initiative.

21 The success of improvements in food production,
22 processing, distribution, and preparation can be measured,
23 then, through the reduction in outbreaks of disease caused

1 by foodborne pathogens.

2 Fortunately we are seeing progress in meeting the
3 Healthy People goals.

4 Surveillance data show us that we have already
5 met our year 2000 targets for the reduction of foodborne
6 illnesses caused by four key pathogens: salmonella,
7 campylobacter, E. coli 0157:H7, and Listeria monocytogenes.

8 The Healthy People objectives for the year 2010
9 are the ones that we're working on now, and they set a very
10 ambitious target of an additional reduction of 50 percent in
11 each of these illnesses.

12 In order to meet these Healthy People objectives,
13 a number of government-wide activities are ongoing.

14 In 1997, the President announced the food safety
15 initiative. And this initiative was very significant in
16 that it provided funds to fill existing gaps in the food
17 safety system; it certainly raised the visibility nationally
18 of food safety; and it improved coordination among the
19 various government agencies with food safety
20 responsibilities at the federal, state, and local levels.

21 It also was significant in that it provided a
22 comprehensive framework for making significant improvements
23 in food safety, a framework that encompasses surveillance,

1 outbreak response, risk assessment, voluntary as well as
2 regulatory approaches such as inspections, and also research
3 and education.

4 Now, the food safety initiative's efforts have
5 focused really on a half-dozen pathogens that are the
6 primary causes of foodborne illnesses in the United States.

7 In 1998, President Clinton announced formation of
8 his Council on Food Safety which, among other things, was
9 charged with developing a more comprehensive strategy for
10 federal food safety activities.

11 A strategic plan, then, is the one of the
12 objectives of the council. And the plan is broader than the
13 food safety initiative in that it addresses all hazards
14 associated with food, not just pathogens.

15 We've held numerous public meetings to gain a
16 variety of viewpoints and insights to help in the
17 development of the plan, and we expect that the council is
18 going to present the draft strategic plan to the President
19 in the very near future.

20 The plan provides goals, objectives, and actions
21 for the U.S. food safety system and evaluation strategies to
22 determine whether our public health goals are being met.

23 Now, what progress have we made through these

1 various initiatives? I think the answer is we've made quite
2 a lot of progress. And let me briefly give you just a few
3 examples of that.

4 In the area of foodborne disease surveillance,
5 the existing network, called Foodnet, has been expanded to
6 provide better data on the incidents of foodborne illness.

7 Foodnet began with data collection in five areas
8 of the country in 1995. Today there are eight sites that
9 are in place. Colorado will be added in the year 2001, so
10 very soon. And the total U.S. population that is now
11 covered by the Foodnet system is about 25 million people, or
12 about 10 percent of our population.

13 In the area of outbreak response, FSIS has joined
14 with other public health agencies such as the Food and Drug
15 Administration and the Centers for Disease Control to form
16 the interagency Foodborne Outbreak Response Coordination
17 Group, or it goes by the acronym FORCE G.

18 Because we work so closely with the states in
19 outbreak response, one of our major goals has been to
20 strengthen the infrastructure at the state level,
21 particularly through the state health departments.

22 Another important development also in
23 collaboration with the public health agencies in the states

1 is the Pulsenet national laboratories that perform DNA
2 fingerprinting on foodborne bacteria.

3 Pulsenet has enabled us to many times now, since
4 it's been in place, link outbreaks of illnesses with
5 specific food products.

6 What took us weeks to accomplish just seven years
7 ago, in 1993, as far as linking illnesses with common food
8 sources now is taking as little as 48 hours with Pulsenet
9 being widely in place and being widely used.

10 Risk assessment is another important area of
11 emphasis where we're making, I believe, some very
12 substantial progress.

13 Risk assessments are being looked to play an
14 increasing role in establishing public policy for food
15 safety here in the U.S. as well as internationally.

16 In 1998, USDA completed our first ever farm-to-
17 table quantitative risk assessment for a pathogen in a food
18 product. It was the risk assessment for Salmonella
19 enteritidis in eggs and egg products.

20 And that risk assessment is being used as a major
21 resource in the development of improvements in egg safety
22 that we've articulated in an egg safety action plan.

23 FDA has also been leading in developing a risk

1 ranking for *Listeria monocytogenes* in ready-to-eat food
2 products and will soon be releasing that risk assessment.

3 FSIS is also completing work on a risk assessment
4 of *E. coli* 0157:H7 in ground beef.

5 And with help from researchers in industry, we've
6 also been making progress in designing voluntary as well as
7 mandatory regulatory approaches such as HACCP in meat and
8 poultry plants and the voluntary quality assurance programs
9 at the animal production level.

10 Designing and implementing these approaches from
11 farm to table necessitates a very close working relationship
12 among federal, state, and government agencies, along with
13 the producer community and the academic community.

14 I believe we've made quite a bit of progress in
15 working among those communities all along this farm-to-table
16 continuum.

17 Research is another area of emphasis because it
18 provides us with information and tools that we really need
19 in order to continue to make progress on food safety.

20 This afternoon we're going to be hearing from a
21 variety of researchers -- and I'm really looking forward to
22 these presentations -- about the progress related to animal
23 production food safety.

1 Food Safety and Inspection Service, for which I
2 have oversight, is not a research agency, but we are a
3 research reliant organization that has long been interested
4 in encouraging food safety research to answer the very
5 specific questions that the agency has.

6 FSIS began in 1996 to articulate very clearly its
7 research needs and its food safety research agenda.

8 Now, the President's food safety initiative has
9 provided very substantial funding increases for research to
10 federal agencies and through them also to academic
11 scientists.

12 It's also established the Joint Institute for
13 Food Safety Research that you heard a little bit about this
14 morning from Mr. Gillespie.

15 The Institute is charged with developing a
16 strategic plan for conducting food safety research and
17 coordinating the federal food safety research activities.

18 And it also has a very broad mandate to also work
19 closely with the private sector and with academic scientists
20 in the development and coordination of that research agenda.

21 We're certainly looking forward to the
22 Institute's feedback on the status of the research that has
23 been conducted to date that relates to FSIS's food safety

1 research agenda. And we're also looking forward to your
2 comments today as far as providing further indications of
3 directions that the federal research portfolio should be
4 taking.

5 We've also made some progress in education at all
6 levels. The Fight BAC! campaign, the result of the public-
7 private partnership for food safety education, is spreading
8 the word to consumers about taking some fairly basic steps
9 in sanitation and food handling to protect themselves and
10 their families from foodborne illnesses.

11 And at the animal production level, information
12 delivery systems have been developed to reach producers,
13 especially those that are not parts of a commodity
14 organization or another industry group.

15 The implementation of HACCP within slaughter and
16 processing plants necessitated a very extensive education
17 and outreach program, especially for the small, and most
18 especially for the very small plants that did not have much
19 experience with HACCP.

20 Now, lastly, let's look a little bit to the
21 future. I think we do face some major challenges for the
22 future, and the first is that we have to continue progress
23 in all areas of research and risk assessment along this

1 farm-to-table continuum.

2 For example, in animal production we need to
3 identify what I would call cost effective practices that can
4 be carried out on the farm to reduce food safety hazards.

5 These practices can then be incorporated into
6 quality assurance and production control programs that can
7 be then widely used by producers.

8 In addition, I think government agencies need to
9 get more experienced in using risk assessment to guide our
10 risk management strategies.

11 I think this is happening. We are, as I told
12 you, developing a number of new risk assessments, and I
13 think it's going to naturally follow that we will gain more
14 experience in how to use this relatively new tool in
15 formulating risk management strategies.

16 Secondly, I think we also need to recognize the
17 links between these various segments in the farm-to-table
18 continuum so that that chain of responsibility is also felt.

19 I still am somewhat disheartened at times that
20 segments within this continuum continue to express lack of
21 responsibility.

22 The producers say, particularly if referring to
23 pathogens, You know, it's not my problem, it's natural. God

1 made these organisms. There's not much I can do about it.

2 The slaughter processing companies say, You know,
3 I got bad product to begin with. It's not my
4 responsibility. If only the consumers would cook their
5 product.

6 And sometimes the consumers say, It's not my
7 fault, and it's true. And sometimes they say, It's not my
8 fault, when there were some steps that they should have and
9 they could have taken in order to properly prepare and even
10 store foods.

11 Now, I'm not saying that these attitudes are
12 widely pervasive these days. I think there has been an
13 enormous change in attitude towards food safety among all of
14 those segments that I have just mentioned. But there are
15 still some who express these attitudes.

16 So one approach that I think that we need to take
17 is to recognize and to accept that there is interdependency
18 among the different segments in terms of both industry's
19 responsibilities, government's responsibilities, and
20 consumers' responsibilities.

21 One example of this is that FSIS is pilot testing
22 a project wherein our inspectors will be able to move more
23 freely between their responsibilities in-plant and oversight

1 of product, meat and poultry product, that is in
2 distribution locations in order to ensure the integrity of
3 the marks of inspection on meat and poultry products.

4 That approach also requires that federal, state,
5 and local government officials work together better to
6 coordinate their own resources and to make sure that in
7 following product as it moves from plants through
8 distribution that we're making effective use of what are
9 very limited inspection resources at local, state, as well
10 as federal levels.

11 Thirdly, I want to encourage the animal
12 production community to continue to look beyond its own
13 immediate sphere of interest and expertise and to
14 participate in food issues at a much broader level.

15 The adage, Think globally and act locally,
16 probably applies here.

17 For example, I encourage industry representatives
18 at all levels to participate in the activities of the Codex
19 Alimentarius Commission.

20 The animal health and food safety standards that
21 are set by the commission really do have broad ranging
22 implications for animal production practices as well as for
23 overall public health improvement, and they also have

1 impacts on our economy as well as on our international
2 trade. So it's important that we participate in the Codex
3 Alimentarius.

4 Fourthly, I think we have to continue to
5 strengthen the partnerships between government and industry
6 in order to continue the progress that we've seen so far.

7 I believe we've made progress in animal
8 production food safety. I think we've heard evidence of
9 that already in presentations this morning. And much of
10 that is attributable to the voluntary quality assurance
11 programs that we heard about just before lunch.

12 Now, the topic I was asked to talk about was, how
13 can we achieve our food safety goals? And I think the take-
14 away message that I would leave you with is that we need to
15 keep our focus on farm-to-table, cost effective
16 interventions.

17 Clearly there are going to be a lot of obstacles
18 that will be encountered in the development of that very
19 simply articulated but very complex goal.

20 But in closing, I'd like to remind you of the
21 words of Henry Ford, who said that obstacles are those
22 frightful things that you see when you take your eyes off
23 your goal.

1 So I'm confident that, if we remain focused on
2 our goal of improving food safety, that we can succeed.
3 We've got good evidence that so far that has served us very
4 well.

5 And your recommendations on research and
6 education I think are going to be very important in moving
7 us forward.

8 So I look forward to the presentations this
9 afternoon. And I thank you very much for your active
10 participation in this meeting. Thank you.

11 (Applause.)

12 DR. THALER: Okay. Well, that will pretty much
13 wrap up lunch.

14 The message I have is we're going to try to
15 squeeze a little more time. I have about 1:20 on my watch.
16 We want to be 1:30 in the room to start again. And Al
17 Pope, you get to go first.

18 We'll wrap that up and then move on, pretty close
19 to what our agenda is.

20 //

21 //

22 //

23 //

1 //
2 //
3 //
4 //
5 //
6 //
7 //
8 //
9 //
10 //
11 //
12 //
13 //
14 //
15 //

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

A F T E R N O O N S E S S I O N

1:37 p.m.

DR. THALER: Good afternoon. We're going to go ahead and start this session.

We're going to follow up by finishing out our updates on quality assurance activities.

The last speaker, that was kind enough to wait until after lunch, is Mr. Al Pope, United Egg Producers. He joined the UEP in 1974 as the general manager. UEP in general represents 80 percent of total U.S. egg production. He has been president since 1978.

He is also president and founder of the United Egg Association, who represents 90 percent of the further processors and major suppliers to egg industry of services and equipment.

He is a council member and past chairman of the International Egg Commission, so he reaches out very broadly in the world of eggs.

And I don't think he needs any more introduction. He wanted to save the introduction so he would have a couple of extra minutes to speak, so I will honor that. Mr. Al Pope.

(Applause.)

1 MR. POPE: Thank you, Alice.

2 Well, it looks like we lost about half of the
3 group. So if I could get you folks at the door to come in,
4 please, or we're going to call you out by name.

5 If you'll humor me for just a minute, if
6 everybody would just stand up one more time. There's a few
7 coming in yet. So would everybody just stand up for a
8 moment, please? This is just for, you know, our newsletter
9 type thing, you know. So --

10 (General laughter.)

11 MR. POPE: No, no, no, no. Now, I can't -- I
12 don't have the opportunity, as much as I'd like to, to shake
13 everybody's hand, so if you would just -- we'll do this in
14 the film. Okay? So if you would like shake my hand. Okay.

15 Now, put your other hand out there, too. I want
16 to see that. Okay. Get it all in here. Okay. All right.

17 Now, everybody has been so nice so far. I'm not
18 as nice as they are.

19 Well, the first thing I wanted to do today was to
20 thank everybody and thank especially the staff and John for
21 inviting us to participate with the groups this morning.
22 And I really look forward to the opportunity of sharing a
23 few words with you.

1 But before I get started, one of the things that
2 I need to tell you about is how tough egg producers are.

3 Now, if I was on Johnny Carson's program and I
4 said that, Egg producers are really tough --

5 VOICES: How tough are they?

6 MR. POPE: How tough are they? Okay. Well, we
7 have a tradition. On our board we have a sheriff. And this
8 sheriff makes sure that everybody comes in on time and no
9 cell phones go off during the board meeting. He makes sure
10 they come back from break on time, and he finds them all if
11 they're late and so on and so forth. This is a tradition
12 we've had for 25 years. And it just works great.

13 The problem is that there's also another
14 tradition that comes with it. Our sheriff -- his name is Ed
15 Houseton [phonetic], and he's from a little town in south
16 Georgia called Lumber City, Georgia.

17 And I've known Ed for 30 years, and he still
18 doesn't know my first name. He calls me Pope, Pope, you
19 know, that's it. He says, Pope, what are you doing here or
20 what are you doing there?

21 Well, egg producers are so tough that I get paid
22 once a week. I get paid on Friday based on what I've done
23 that week. I mean, that's tough. How many of you do that?

1 So every week, Ed Houseton calls me on Friday.
2 This Friday, actually, I'm going to be with him.

3 And once again he'll say, Pope, how has your week
4 gone this week? And I'll say, Great. Of course, we were
5 off Monday, didn't get down there, but I still went into the
6 office, and I went through my presentation so that I'd make
7 sure I was timed right and everything.

8 And I said, Then I went to St. Louis. And I
9 said, I was on the program. And I said, Man, there was 250
10 people in the audience or something like that.

11 And he says, Well, what was it about? And I say,
12 It was about food safety and eggs.

13 And he said, Well, we've had a lot of problems
14 there. He said, How well did you do?

15 I said, Do? I said, It was great. I got a
16 standing ovation. Look at these pictures.

17 (General laughter.)

18 MR. POPE: So I hope that I get paid a little bit
19 more this week for this.

20 First of all, I want to start by saying eggs have
21 been the poster child. I don't know how many of you agree
22 with that, but certainly our egg producers feel like they've
23 been a poster child on food safety. And I think we were

1 kind of the first ones on the block.

2 And this year, so far this year, our industry has
3 lost an estimated 175- to \$200 million through the end of
4 August. Very hard to implement food safety programs, animal
5 welfare programs, environmental programs, because you can
6 only do that to the extent that you have resources
7 available. So as a poster child, we've been picked on.

8 Now, my associate down here, Ken Clippen
9 [phonetic], I said, I'm going to tell them who has abused me
10 here, how many people have abused me. And he's going to
11 say, No. Challenged you, Al; how many have challenged you?

12 Well, I said, No. I said, I'll give you credit,
13 and I'll say that you said challenged, but I'm going to use
14 the word, abused.

15 Secretary Kessler abused me and abused UEP. My
16 good friend is here in the audience today, Joe Madden. Joe
17 Madden has abused me. Caroline has abused us. Secretary
18 Billy [phonetic] has abused us.

19 And you know what? The last straw was the
20 Saturday morning address, two weeks in a row, President
21 Clinton abuses us.

22 Well, we're not down and out, and we want to come
23 roaring back.

1 And so I'd like to share with you today how they
2 brought us to the water trough, and how we felt like we went
3 there, and how this partnership has worked, and what have
4 the results been? Because that's what the bottom line is.

5 It is not all peaches and cream, because you have
6 to fight not only with your administration, with your staff,
7 but with your members as well, and trying to keep your
8 consumer uppermost in your mind, your customer.

9 So these are all things that I think are really
10 tough. And I'd like to share with you today, I think, where
11 we were, what happened to us, and where we've been.

12 Well, first of all, we got our wake-up call in
13 1988, so that's 12 years ago. CDC came out with this
14 report. I couldn't even say Salmonella enteritidis. And
15 then, transovarian transmission was completely out, and we
16 didn't even know what that was.

17 And we had to look those things up, we had to
18 call our vets, we had to find out what all that meant, and
19 we didn't believe it.

20 So the producers' reaction was, I think,
21 expected. They were alarmed, they were in denial. They
22 said, No way. There's no way you could have transovarian
23 transmission. It's impossible. Until Charlie Baird

1 explained to us that it was possible.

2 We were depressed. I mean, we'd just come off of
3 20 years on the cholesterol issue and were just making some
4 big science-based roads back, where the egg was being
5 redeemed, and all a sudden, it's getting beat up again.

6 So we had a lot of things we felt like we had to
7 do. And so it took a team effort. And I'm going to talk
8 about that team in a little bit.

9 But it reminded me in the beginning of this.
10 Remember the old dealy on Abbot and Costello, Who's on
11 First, What's on Second, and Why is on Third? Well, that's
12 the way we felt back in 1988. And we had to do something.

13 It was confusing, and it was chaos, and it had
14 many, many questions we didn't have any answers to, and
15 there was no one single answer. You couldn't put your
16 finger on it.

17 So unlike Abbott and Costello's comic relief, it
18 was no laughing matter to us, because we could see what kind
19 of damage it might do to our industry.

20 So we started doing some things in the beginning.
21 We felt like we were proactive. But still we had an
22 adversarial relationship -- I'll be honest with you -- with
23 the administration, and we didn't see eye to eye. And we

1 were the first ones they were targeting in some respects.
2 And so we were both learning as we went along.

3 We did go to Congress, and we got money from
4 Congress to set up the pilot project in Pennsylvania.

5 We developed a food safety quality assurance
6 program, which is our five-star program. And I want to just
7 mention it a minute, because we've expanded dramatically
8 what comes under the five-star program. It has a number of
9 other components to it.

10 It has, of course, the food safety component. It
11 has an environmental component.

12 And the environmental component has just -- we
13 have just signed a historic agreement with EPA to do a
14 better job through an Excel project that's going to be
15 proposed hopefully and developed by November 1 of this year
16 and then will be rolled out across the country to those that
17 want it.

18 It's a voluntary program. It's a tough one to
19 meet. But we've worked with EPA on that to demonstrate our
20 proactiveness.

21 On the animal welfare issue, I would challenge
22 any commodity in the United States, or in Europe, as far as
23 that goes, that has gone as far as the egg industry has

1 gone.

2 We put together an animal welfare committee, had
3 no producers on it. It was only scientists, and we only
4 selected one of those. You had to start somewhere. And we
5 had no limits on them.

6 They have presented their paper to the UEP Board,
7 who has adopted it in total. It will be a dramatic change
8 over the next ten or 15 years.

9 But I'm just trying to demonstrate how proactive
10 the egg industry has been.

11 We have GMPs developed. And, of course, today I
12 want to focus on food safety.

13 On our five-star program, which we have copies
14 out at the booth today, and we have added since we have
15 started third-party monitoring, both APHIS and AMS have
16 offered that service to us, and we really appreciate it.

17 We have added a validation or a testing procedure
18 to it, and I'll get on that a little bit more later.

19 But we've worked with the Department, worked with
20 the stakeholders, all the stakeholders, consumers alike.
21 And I think we've come up with to agreement on what we think
22 a good food safety program for eggs can really entail.

23 We called for breeder testing through MPIP. You

1 heard that earlier. We supported eggs being on the FDA high
2 risk -- I forgot what the name of it is called right now.
3 Let me go back there. Just a minute here.

4 (Pause.)

5 MR. POPE: Yes. The hazardous food list. We
6 proposed and supported a national refrigeration law, which
7 many of you know. We established a SE assessment working
8 group.

9 Our American Egg Board became a founding member
10 of the partnership with the White House on President
11 Clinton's food safety initiative.

12 We recommended that liquid pasteurized egg
13 product be used in food service and especially institutional
14 settings with immuno-compromised patients.

15 If you look at the outbreak records and look --
16 this is the most critical area. We think that the
17 Department has not given enough credit to looking at the
18 developments that have been made on vaccines and the
19 important role that they can play in any quality assurance
20 program.

21 We need to work hard on that. And during this
22 regulatory process that's coming up, we'll certainly focus
23 on that.

1 We have sponsored HACCP workshops for the egg
2 industry, both production and processing. We established
3 egg handling and preparation tips for food service and
4 consumers.

5 You know, I heard a comment earlier which is
6 true. Our producers were in that group that first said,
7 Well, you know, these consumers have a responsibility, too.
8 And I think we all agree with that.

9 But it's our product. And if we don't want them
10 to stop eating our product, then we also have a major
11 responsibility at the consumer level.

12 Now, I was real pleased. You heard there were
13 some hearings last month where they delivered the current
14 thinking papers. I was delighted to see there that they
15 focused on what needed to be done on the education part with
16 the consumer, too. And I applaud the Department for that.

17 But we have the major responsibility. If we want
18 them to eat eggs, they've got to feel like eggs are safe.
19 So we tried to put a teamwork approach together.

20 And I share this with you because it's just kind
21 of our way of presenting it, I guess, and we think it's an
22 easy way to do it.

23 You see our five-star program is on the left, our

1 logo there. And here's who we have as our players.

2 We have on first base we have the producer-
3 processor, and marketer. On Second Base, we have the
4 industry organizations, Third Base, government. And then,
5 in the outfield there's just a tremendous number of support
6 team members. And then, certainly at the Home Plate we have
7 the consumer. And I'd like to take a look at each.

8 On First Base, we have the producer-processors.
9 And we heard this earlier. They have to, first of all,
10 recognize the challenge. And then, after that, they have to
11 make a commitment. It's a state of mind. They have to be
12 obsessed over this.

13 They have to be obsessed when they see rodents in
14 their facilities. They have to be obsessed to get them out.

15 They have to be obsessed about the water and the testing.
16 And they just have to -- it's just something that has to
17 happen, and it just doesn't happen in every operation. And
18 you can imagine how hard it is.

19 I was listening to John Adams this morning
20 talking about how many he had to go out, how many farms and
21 so forth and so on. And I'm glad we're not faced with that.

22 And then, you have to have people to implement
23 them. You have to come up with a quality assurance program.

1 You have to have record keeping so that they know exactly
2 what their responsibilities are and what records they need
3 to keep. And we gave them all of that.

4 In our five-star book out there, it has the
5 actual records for the producers and processors to use.

6 And then, the resolve and determination to the
7 programs. And then, of course, the research, identifying
8 the research.

9 And then, on Second Base, we have the industry
10 organizations. We have to, in our membership -- and this is
11 where it is really difficult. And I can share the
12 frustration.

13 But by the way, you notice I didn't have one of
14 the people that picked on me was Dr. Woteki. She didn't
15 pick on me. She's been very nice to me. So I appreciate it
16 a lot. I just want you to know that. And the others have
17 all become friends, I hope. I hope I haven't alienated them
18 too bad.

19 But you have to be tough on this. You have to be
20 tough on it, we have to be tough on it. Our producers
21 expect it, your administration expects it, your school
22 expects it. We all have to be tough. We have to hang in
23 tough.

1 And so our responsibility was to get our
2 membership up to date on the issue, recognize that there's a
3 problem, and then try to be proactive.

4 Try to develop uniform programs for our members
5 so that we don't have an uncompetitive or a competitive
6 advantage or disadvantage by geographic area, by state, by
7 whatever. And that's very difficult to do.

8 You seek input from all stakeholders. And I
9 think that we've all tried to do that. Certainly I don't
10 know that I've ever seen really government try harder to get
11 input from all stakeholders.

12 Identify the research needs and find available
13 funding, not an easy project. You know, it's programs like
14 this and animal welfare and the others that are burdensome
15 to the agriculture community.

16 We have an economy that is just steaming along
17 here. But I'd like to have anybody hands raised in
18 agriculture, are we sharing any part of it or a big part of
19 it or a little part of it or any part of it?

20 We're not really sharing in any part of it, are
21 we? If you ask any agriculture people, they're not.

22 And one of the reasons they're not is that during
23 these times consumers are very receptive to these kinds of

1 social programs, and yet we've got to try to come up with
2 the money to afford them, not an easy project. So we need
3 to identify the research.

4 We need to work with the government agencies that
5 have the authority. And then we need to communicate in
6 public relations efforts.

7 This has been hard for us. We haven't done as
8 good a job as we would have liked to have done. But, you
9 know, you see Jill, and you see Ken and myself, and Gene
10 down in Atlanta, and you're looking at 50 percent of our
11 staff.

12 So you know, it's kind of hard to expect a great
13 public relations program and a great communications program.
14 You've got four people running around trying to just
15 respond to regulatory challenges.

16 So this is one that we're weak on, and we'd like
17 to strengthen it up. We need to do that to educate our
18 stakeholders, and that means our own members, too.

19 Third Base, obviously this is the government part
20 of the team. They have an obligation to protect the
21 consumer interests. They also have an obligation to be
22 even-handed.

23 They have a major obligation in education, of

1 course. They need to work with the industry and all
2 stakeholders. They need to provide some resources and
3 research assistance to us. And we still need help in this
4 area.

5 And we hope we can help here at the meeting, and
6 we hope we can help Friday down in Atlanta, where they're
7 specifically going to look at SE.

8 If appropriate, develop uniform food safety
9 programs with input from all stakeholders. Now, we're in
10 the process of doing that now with the Department.

11 We didn't think we'd get to that point, quite
12 frankly. But if we're going to have a program, then it only
13 makes sense that everybody in the country be on a level
14 playing field. So we're trying to be as least intrusive as
15 possible with a maximum amount of effectiveness.

16 So that's what our goals are. And it's a
17 multiagency effort, and we're all interested in that.

18 In the outfield -- and this is just a short list.
19 I mean, CDC; academia; vaccine manufacturers; chemical
20 cleaning; disinfecting; rodent specialists; testing labs;
21 communications; food safety consultants.

22 Congress has to get involved or has gotten
23 involved; other regulatory agencies that are affected by

1 this; Food Market Institute; National Restaurant
2 Association. All of these organizations need to be
3 involved.

4 How do you get over and visit all of these? It's
5 tough to do. The health care industry deserves to know that
6 their eggs are safe. And so it's a real challenge for us.

7 And so we've picked up the slogan, Eggs, Safe at
8 the plate. And it takes this team to really make this
9 possible, to have eggs safe at the plate.

10 So what are the results so far? This team has
11 been working for a pretty short period of time, to tell you
12 the truth. I mean, even though we've been working on it ten
13 years in different aspects, the team has been only working
14 the last three or four years, in fact, maybe the last year-
15 and-a-half really closely together.

16 So the SE scoreboard -- now, this is all SE, of
17 course. The total outbreaks have gone from 85 to 44; the
18 illnesses have gone from 2,600 down to 1,080; the health
19 care facilities have gone from 12 outbreaks in '90 to two in
20 1999. So that's the good news.

21 I mean, we have a lot more that we can do, and we
22 are going to do a lot more.

23 These statistics are based on CDC's outbreaks.

1 They're not all egg related.

2 Here is the egg SE scoreboard. Basically out of
3 those outbreaks that we had in 1990, 26 of them were egg
4 related, and in 1998, there were 15. The illnesses went
5 from 1,059 to 369; the health care facilities, down to one.

6 It's kind of interesting on the bottom here. And
7 I want to point out Rick Bretmyer [phonetic] is here from
8 California. They have a terrific program in California.
9 There's a terrific program in Ohio; there's one up in Maine.

10 I don't mean to overlook anybody's state program,
11 because they're all based on the same principles that the
12 five-star program is on. They all deserve credit for what
13 they've done.

14 But if you look at the percentage of producers on
15 the program, we had nothing in 1990 practically, or you
16 could say that. And in eight years, we're up to 84 percent.
17 Now, under the administration's program, we'll be at 100
18 percent.

19 And obviously our outbreaks are going to continue
20 down. We know that's going to happen. That's just the way
21 it's going to be.

22 So here is basically what's happened on the
23 Foodnet score. From '96 to '99, we've already had a 48

1 percent reduction. And if you'll look back, you'll see that
2 that increase, of course, was -- where am I here?

3 The increase is this 5 percent to 84 percent, so
4 obviously that had something to do with this 48 reduction.
5 It does demonstrate that those are on quality assurance
6 programs.

7 Are they doing as good as they ought to? No.
8 Are they record keeping as good as they ought to? No.

9 You know, I can do all those things. But if you
10 look and you look at how many are on the program now, and
11 you look at the results of it, I think you've got to say
12 this thing really works.

13 So it takes this team effort to hit a homer, and
14 our homer is -- who is our homer here? We all know who that
15 is. Here he goes, BAC; so to knock bacteria out of the
16 park.

17 And on behalf of United Egg Producers, we want to
18 thank the egg organizations and the support folks on this
19 team who contributed to making eggs safer at the plate.
20 Thank you.

21 (Applause.)

22 MS. THALER: And then, I'll call your attention
23 to just one small change in the program. Dr. Reed will go

1 next, and then, Dr. Sundlof has asked to be moved up so he
2 can make his plane.

3 Dr. Craig Reed is the administrator for the U.S.
4 Department of Agriculture's Animal and Plant Health
5 Inspection Service.

6 APHIS conducts domestic disease programs and also
7 protects the nation's agriculture from dangerous foreign
8 animal, plant, pests, and diseases.

9 Before coming to APHIS, Dr. Reed served as deputy
10 administrator of the office of field operations at USDA Food
11 Safety and Inspection Service and director of the
12 Agricultural Marketing Service's science division, and dealt
13 with food safety matters.

14 He was also in private veterinary practice at one
15 point, so hopefully he has a real strong tie back to
16 producers prior to joining USDA.

17 His topic today is APHIS's supportive role in
18 animal production food safety.

19 DR. REED: You've got to love all these Power
20 Points, don't you?

21 Thank you, Alice. And thank you, everyone, for
22 inviting me here today.

23 I'm glad I wasn't the first one without a Power

1 Point. I've been inundated by the technology today. I must
2 say directly following Al was not in my plan. It's kind of
3 hard to follow, Safe at the plate. But I felt like I was in
4 the on-deck circle over here.

5 (General laughter.)

6 DR. REED: And Al talks about being tough. It's
7 easy for the egg guys to talk tough. They've got a shell;
8 the rest of us have skin.

9 (General laughter.)

10 DR. REED: After that, I have to say that Al
11 saved me one time from being hit with a pitch back in '95,
12 when FSIS took over the egg products inspection program.

13 I was down in Atlanta with a bunch of angry egg
14 products producers, and Al pulled me off to the side and
15 said, You're going to get nailed here, so be ready. So I
16 appreciate that, Al.

17 Well, I've had 27 years in the food safety
18 business in one way, shape, or form. And it's a pleasure to
19 have worked in FSIS and AMS.

20 Now I'm the administrator of APHIS. And I need
21 to tell you a little bit about what we're doing as a support
22 agency. But before I do, I think it's important for all of
23 us to put a little of perspective on what we just finished,

1 and that was lunch.

2 And despite what anybody says, that chicken and
3 those potatoes, the apples, the whipped cream and other
4 dairy products, everything on those tables we took for
5 granted as being safe.

6 Some of us might have given it a little bit of
7 thought, but not long after the fork reached the lips.

8 I also need to give a lot of credit to other
9 players in the food safety arena, including producers,
10 veterinarians, most importantly, state officials, and of
11 course everybody at USDA. These people work hard every day
12 to keep our animals and food safe.

13 And integral part of maintaining animal health is
14 preventing entry of exotic pest and disease threats. That's
15 probably the main theme of the Animal and Plant Health
16 Inspection Service duties, although we have others.

17 Through our veterinary services program, we work
18 to make sure that the livestock industries get protected
19 from foreign animal diseases and pests. And we also work to
20 eradicate domestic livestock diseases and conduct animal
21 health certification programs and do quarantines to
22 facilitate trade.

23 If you don't think trade is important -- hasn't

1 come up but a few times. I noticed John Adams' presentation
2 did identify that. And most of us need to know that
3 probably 30 percent or more of our local production is
4 dependent on moving it abroad.

5 We've saturated consumption here in this country,
6 so the only way our producers are going to stay viable is to
7 ship it overseas.

8 One of the first things I'd like to mention is
9 our joint operations with the Agricultural Research Service,
10 ARS, and others.

11 We have three locations that I'd like to bring to
12 your attention today: Ames, Iowa; Plum Island, New York;
13 and Fort Collins, Colorado.

14 Plum Island is home to the Plum Island Animal
15 Disease Center. And although ARS is the primary agency in
16 charge of the center, the director shares responsibility
17 with our agency's chief of the foreign animal disease
18 diagnostic lab, also located at Plum Island.

19 In Fort Collins, we have our home of our Centers
20 for Epidemiology and Animal Health. Our agency's lab have a
21 close relationship of working with ARS, the primary research
22 arm of USDA. This close relationship enables us to actively
23 exchange data and information with ARS officials as they

1 study a variety of ag subjects, including those involving
2 animal production food safety.

3 What I'd like to do now is talk a little more in-
4 depth about our facilities.

5 First, our national vet services lab in Ames'
6 main charge is to protect the health of animals and
7 contribute to public health by providing timely, accurate,
8 and reliable lab work to our customers.

9 Our customers include local and state government
10 agencies and labs, other federal agencies, educational
11 institutions, foreign governments, and, of course,
12 producers.

13 We normally focus our efforts on diagnosing
14 pathogens that cause disease in animals. However, we can
15 and do lend ourselves to institutions studying zoonotic
16 agents, which are those that affect humans and animals both.

17 Last year, when crows in the New York City area
18 started dying from a mysterious illness, our agency
19 scientists at NVSL took samples from birds and isolated the
20 virus.

21 They sent those samples to the U.S. Department of
22 Health Human Services Centers for Disease Control and
23 Prevention, and it was confirmed that it was the West Nile

1 virus.

2 This disease that affects both humans and animals
3 and was responsible for the deaths of seven people in New
4 York City in 1999.

5 At our NVSL facilities in Ames, our agency has
6 been involved with several projects that have had an impact
7 on animal production food safety.

8 Among other things, we have aided in the study of
9 transmissible spongiform encephalopathies and salmonella.

10 Lately TSE's have been receiving a great deal of
11 media attention. I won't talk about Vermont today. These
12 degenerative neurological diseases, which include scrapie
13 and bovine spongiform encephalopathy, or Mad Cow Disease,
14 are characterized by very long incubation periods and 100
15 percent mortality.

16 In Great Britain, BSE has been linked to the
17 deaths of at least 48 people from New Variant Kreutzfeld-
18 Jacov disease and has caused over \$6 billion damage to the
19 livestock industry.

20 Right now in Vermont our agency is working hard
21 to acquire the last two flocks of three after four animals
22 were confirmed positive for TSE.

23 Unfortunately, when we did our Western Blood

1 analysis, Western Blood indicated it wasn't quite scrapie,
2 and it wasn't quite BSE.

3 If it was just scrapie, we would have handled it
4 strictly as an animal disease, but we're seizing the flocks
5 to make sure that nothing gets into the human food chain.

6 Our agency also works with ARS to learn more
7 about TSE so we can enhance current diagnostics and develop
8 new diagnostics for live animals.

9 Since the mid-'90s, when Mad Cow Disease came
10 onto the national scene, we have been performing
11 surveillance and exclusion activities for TSE's.

12 Our scientists have trained employees of state
13 labs across the country in diagnosing these diseases, and we
14 have provided samples from high risk or affected flocks to
15 research scientists.

16 We have also helped researchers determine if
17 certain tests are practical or if they detect a certain
18 percentage of cases.

19 NVSL, along with our Centers for Epidemiology and
20 Animal Health, which I will talk more about shortly, have
21 played an instrumental part in testing two experimental
22 diagnostic procedures that may become standard soon, the
23 third eyelid test used for diagnosing scrapie, and the

1 capillary electrophoresis test used in diagnosing BSE.

2 By providing such support to ARS researchers, we
3 are helping to enhance testing and diagnostic methods. We
4 believe this will lead to healthier animals and ultimately a
5 safer food supply.

6 In addition to the work we do with TSE's, NVSL
7 has also cooperated with researchers studying salmonella in
8 poultry.

9 CDC officials have used the data we gather from
10 testing poultry to determine the dispersal and infection
11 rate of different strains of salmonella.

12 NVSL performs the diagnostic tests on the poultry
13 samples. CDC then uses that information to project where
14 the disease might be thriving and the areas in the country
15 where it will be most likely to infect human populations.

16 Again the work we do at NVSL is used to support
17 another agency and their work concerning animal food safety.

18 And I'm not sure whether the lab still does the
19 typing for salmonella strains for the egg products
20 inspection program. Most of that work was screened at
21 Gastonia in North Carolina and then sent on to Ames if there
22 was a salmonella positive.

23 As part of NVSL, our diagnostic facility at Plum

1 Island, the foreign animal disease diagnostic lab, shares
2 its goal of protecting the health of animals and
3 contributing to public health by providing reliable lab
4 support to our customers.

5 While the Ames facility's main focus is domestic
6 animal disease issues, FADDL, as we call it, works with
7 diagnosing exotic pathogens that must be worked with under
8 biocontainment conditions.

9 Currently the majority of agents that we deal
10 with here, like Foot and Mouth Disease and African Swine
11 Fever Virus, do not affect human health.

12 However, if Plum Island's biosecurity level is
13 upgraded, we may begin to study zoonotic agents. I'll be
14 discussing this possible upgrade a little bit later.

15 Right now on Plum Island our agency is
16 responsible for testing imported animals, biological
17 products, and some animal products to ensure they are free
18 of foreign animal disease agents.

19 We're also involved in the production of reagents
20 used in diagnostic tests for foreign animal disease and the
21 testing and evaluation of vaccines for these diseases.

22 Our other efforts on Plum Island include training
23 other veterinarians and animal health professionals to

1 recognize and diagnose foreign animal diseases.

2 Through our work at this facility, we again are
3 helping to keep the country free of foreign diseases and in
4 the end ensure safer products for U.S. consumers.

5 Our Centers for Epidemiology and Animal Health,
6 as another part of our agency, is responsible for generating
7 studies and gathering and distributing information about
8 animal health and other agricultural issues.

9 Here we gather information about animal health,
10 animal production, animal product wholesomeness, animal
11 welfare, and the environment.

12 Through our national animal health monitoring
13 system, CEAH, as we call it, works closely with federal and
14 state animal and public health agencies, universities,
15 diagnostic labs, producer groups, and private interest
16 groups.

17 Working with these groups, CEAH officials
18 identify key information gaps facing those in animal
19 production. They then design studies to fill these gaps and
20 gather data through state and veterinary services employees
21 in the field.

22 After analyzing gathered data, CEAH officials
23 compile statistics and estimate risk factors affecting

1 animal health, food safety, public health, and the viability
2 of U.S. agriculture.

3 Once completed, the studies are widely
4 distributed electronically and as hard copy.

5 In summary, CEAH many times poses the question
6 that needs to be answered by the researchers. What is the
7 researchable question?

8 For example, CEAH officials have published
9 several reports with regard to animal production food
10 safety, including studies of the prevalence of E. coli and
11 salmonella in U.S. dairy operations. They have also worked
12 with the swine, poultry, equine, and beef industries to
13 determine the prevalence of these and other microbial
14 pathogens.

15 By compiling such data, CEAH gives animal health
16 experts and producers information that may help them reduce
17 risk factors in animal food production.

18 Our Center for Veterinary Biologics contributes
19 to American agriculture by not only being responsible for
20 helping diagnose animal diseases and distributing
21 information about them, but also ensuring that veterinary
22 biologics are pure, safe, potent, and effective.

23 Our Center for Vet Biologic ensures that the

1 quality of vaccines, commercial diagnostics, and
2 immunotherapeutics have the quality that we need in the
3 animal industries.

4 We set standards, license product, inspect
5 manufacturing plants, and perform confirmatory testing.

6 Although we are mainly concerned with preventing
7 and treating animal diseases, the work we do at the Center
8 for Veterinary Biologics can and does affect animal
9 production food safety. After all, if we can prevent a
10 disease, it's one less that we have to treat.

11 For instance, CVB licenses test kits for bovine
12 TB, which is used conclusively to diagnose this disease in
13 livestock herds.

14 There are other safeguards in place to prevent
15 bovine TB from entering the food supply. Milk is
16 pasteurized and cows are inspected at slaughter facilities.

17 However, diagnosing an animal before it even
18 enters the production process is the best way to prevent it
19 from affecting the general public.

20 We also license the Salmonella enteritidis
21 vaccine. The purpose of this vaccine is not to control the
22 disease in birds, but to reduce the potential risk of egg
23 contamination. You could say it's a vaccine for food

1 safety.

2 In addition to licensing veterinary biologics and
3 performing confirmatory testing, Center for Biologics
4 officials are also involved in the research and testing of
5 plant-derived biologics. This is an exciting new area of
6 study that may soon have major ramifications on animals as
7 well as human health.

8 Plant-derived biologics are plants genetically
9 engineered to produce immunogens of disease agents.

10 With this new technology, feeding animals
11 modified corn, potatoes, or soybeans would produce the same
12 effect as administering them with an oral vaccinations. In
13 some cases producers would no longer be required to treat
14 their animal feed with antibiotics.

15 As an example of one that's currently under field
16 test, there is a corn that's been engineered with the rabies
17 attenuated virus as part of the corn. And when animals eat
18 the corn, they vaccinate themselves for rabies. I don't
19 know what could be a better deal.

20 The study and testing of plant-derived biologics
21 is very exciting but is still in its infancy.

22 Since our agency regulates vet biologics as well
23 as the production of genetically modified plant and plant

1 products, we feel a great responsibility to the American
2 public to ensure that this new technology and these products
3 are as safe to use as the products produced through
4 traditional methods.

5 Towards this end we are working closely with the
6 Food and Drug Administration, various state Departments of
7 Agriculture, and the EPA to prepare our regulations that
8 satisfy everyone's first need for safety.

9 Let me talk a little bit about proposed upgrades
10 to Ames and Plum Island facilities. Since I've got you
11 here, you get to hear the sermon.

12 As you can see, our agency is doing a lot of good
13 work across the country in conjunction with ARS, the CDC,
14 FDA, and other agencies.

15 To further this good work we have undertaken two
16 important initiatives that will improve our diagnostic
17 research and vaccine evaluation capacities.

18 These two initiatives will strengthen our
19 relationship with ARS and allow us to provide even more
20 support to their research efforts into animal production and
21 food safety issues.

22 Currently our two agencies are developing plans
23 to construct a world-class facility for biocontainment

1 research, diagnostics, and vaccine evaluation in Ames. ARS
2 budget for fiscal year 2001 includes a request for \$9
3 million to begin designing this facility.

4 Plans include the construction of a laboratory
5 building to be shared between ARS and APHIS, renovation of
6 our current National Veterinary Services lab. And our
7 Center for Veterinary Biologics will be used as a joint
8 administration building, and construction of joint animal
9 biocontainment facilities would occur.

10 This new construction would strengthen our
11 readiness for possible animal disease outbreaks, a threat to
12 us all, and improve customer service and enhance the overall
13 lab environment.

14 USDA is also considering upgrading the biosafety
15 level at the Plum Island Animal Disease Center. Some of you
16 have read about this in the paper.

17 The center is the only place in the United States
18 where scientists can conduct research and diagnostic work on
19 highly contagious exotic animal diseases.

20 The facilities on Plum Island currently operate
21 at the Biosafety Level 3. This means that they are equipped
22 to handle microorganisms that are highly contagious to
23 animals and could cause them serious illness or even death.

1 The proposed upgrade of the facilities at Plum
2 would allow us to conduct research and diagnostic work on
3 Biosafety Level 4 agents that affect both humans and
4 animals. By definition, the Level 4 agent is a dangerous or
5 exotic agent that poses a high risk of life-threatening
6 disease for humans and for which there is no cure or
7 vaccine.

8 However, I must point out again that we would
9 only work on those Level 4 agents that can affect both
10 humans and animals. Such an agent would pose a serious
11 threat not only to our ag industries, but also to human
12 populations.

13 We would not work on Level 4 agents that infect
14 only humans, such as Ebola. That's best done at Atlanta or
15 at USAMRID.

16 The proposed upgrade would improve our ability to
17 evaluate the impact of emerging or foreign diseases and
18 develop new strategies for disease diagnosis, prevention,
19 and control. This in turn would enhance animal production
20 and food safety efforts.

21 In conclusion, the prevention and detection of
22 animal diseases, even if they're not transmissible to
23 humans, helps to ensure a predictable and safe food supply.

1 Our agency stops problems before they start
2 through a variety of programs, most notably our veterinary
3 services program on both Ames and Plum Island.

4 However, I would like to point out -- and it was
5 only touched upon by one other presenter -- there is an
6 increasing threat from wildlife populations, whether it's
7 birds and Avian Influenza and New Castle Disease, whether
8 it's Hog Cholera in the swine industry, Foot and Mouth
9 Disease, and a number of other agents that are easily
10 transmitted from foreign animal populations.

11 And whether it's coincidence or whether it's
12 something we can expect to see, the outbreaks of Foot and
13 Mouth Disease in South America which we expected would be
14 free of Foot and Mouth Disease in the relative next few
15 months are not going to happen.

16 We also see more and more Foot and Mouth Disease
17 in countries surrounding and in China. So all of the
18 countries, Malaysia, Taiwan, Korea, China, Russia,
19 everything around China seems to have Foot and Mouth Disease
20 all of a sudden.

21 We're also worried about the United Kingdom,
22 where Classical Swine Fever or what we know as Hog Cholera
23 has popped up, and it's been relatively absent in the United

1 Kingdom for a long time. We've got a lot of spare ribs that
2 used to come into this country until a couple weeks ago from
3 the United Kingdom.

4 And don't discount Cuba. It's only 90 miles
5 away. The small boat traffic is almost uncontrollable no
6 matter what you do. Don't ask me. Ask ATF and DEA.

7 But all of these are threats to our animal
8 industry. And even though it's an animal pathogen, it's got
9 to be wholesome before you can put it on the table.

10 Thank you.

11 (Applause.)

12 DR. THALER: Okay. And our next speaker again is
13 Dr. Stephen Sundlof again, who has already been introduced,
14 so I won't do that again.

15 He is going to speak on the importance of sound
16 scientific research to support animal production food safety
17 decisions. And it will just take him a moment to get hooked
18 up here.

19 (Pause.)

20 DR. SUNDLOF: Well, thank you. And I want to
21 thank especially Dr. Masters for trading places with me. I
22 do have a short connection to my airline.

23 I also want to say thank you to John Shide

1 [phonetic], who has been instrumental in putting together my
2 presentations for today.

3 And again I want to compliment the people who
4 have put this program together. It's truly an excellent
5 program, and the attendance is wonderful.

6 I want to talk about some of the interesting
7 scientific issues.

8 We see in the paper a lot about the negative
9 parts about food safety, the threat of food safety
10 incidences.

11 And I want to talk about some of the other kinds
12 of science that we're seeing that is at least coming through
13 the FDA on an everyday basis.

14 I want to talk about some of the interesting
15 advances in science that are being presented to us. Not all
16 of this is on food safety. But just to kind of give you a
17 flavor for the things that we are starting to see.

18 These are some of the things that FDA is faced
19 with having to come up with the scientific expertise to
20 start regulating in some of these areas.

21 This is a polymer scaffold on which they are
22 growing live endothelial cells now. In the future we will
23 be growing our own tissues. And some interesting work has

1 already been conducted. It's not too far off where we're
2 going to be able to grow some of the tissues that we need
3 for replacements in people.

4 FDA's building, the one that I'm in, is actually
5 in the shadow of Solara, the company that, along with the
6 human genome project, has now unraveled the expressed human
7 genome.

8 And all kinds of wonderful things and interesting
9 things are going to evolve from this. And we're already
10 seeing being able to screen patients who have genetic
11 deficiencies. We can look at how drugs interact with these
12 people.

13 We're going to be looking in the future about --
14 this will be an active area for food safety research. All
15 kinds of interesting things will be coming as a result of
16 our understanding of the genome, and I think most people
17 recognize that.

18 Other interesting things that have just happened
19 within the last few months: We're starting to see things
20 like robotic surgeries where the physician is in a different
21 city from the patient, and yet, through these approved
22 products and procedures, are able to do intricate surgical
23 procedures through the use of these medical robots.

1 And even more futuristic now is the
2 nanotechnologies. We're starting to see these nanomachines,
3 extremely small microscopic machines that actually can move
4 around and do things.

5 This is a nanobot. It is not a real product yet.
6 But in the near future, we're going to be able to develop
7 these machines that will actually be injectable, and they
8 can roam around in your body and report out good information
9 to the physician.

10 So all kinds of interesting things that are
11 happening as we see a convergence of all these new sciences,
12 the genomics and proteomics and information sciences and
13 biochemistry and a lot of different things all of a sudden
14 starting to coalesce and give us these wonderful products
15 that we're going to have to somehow figure out how to
16 regulate.

17 Because oftentimes the science that goes into
18 making these things possible is not the science that allows
19 us to make determinations as to whether they're going to be
20 safe or effective for their intended purposes.

21 Here's one that's been developed recently in FDA,
22 I think with some outside help, as well. But it's the Fresh
23 Tag Biosensor. This is a food safety issue.

1 And you can put this biosensor on a package
2 that's used now for fish, and if you get a reading of 4, 3
3 to 4, you know that that fish is not safe to eat anymore.

4 So now we're starting to see real sensors. And
5 these things are becoming economical enough that you can
6 actually put these on the package, and they will give you
7 some indication about the freshness of the product and the
8 wholesomeness of the product.

9 Okay. Last, and again back to the genomics
10 issue. These are some of these DNA array microchip
11 technologies that are quickly being developed.

12 Within about the next year or two, we will be
13 able to see the entire genome being placed on a microchip
14 the size of a postage stamp. And the limits are just about
15 boundless about all the different things you can do.

16 And of course the human genome will be shortly
17 followed by many of the animal genomes. So again an area
18 where we're going to see lots and lots of things happening
19 in the future.

20 Again, these kinds sensors can be used for
21 disease diagnostic purposes, for food safety, for
22 bioterrorism, for epidemiology, all kinds of interesting
23 things. We can also look at gene sequences, in my case, for

1 antimicrobial resistance.

2 So what are the public's expectations in light of
3 all of this new science and technology that they're being
4 confronted with?

5 And our Commissioner has said that the public
6 trusts the FDA to safeguard their health by making timely
7 and credible independent scientific judgements, no matter
8 how complex the circumstances.

9 And as I talked about a little this morning, we
10 are constantly trying to catch up with all of this new
11 science that's being presented to us, and we're constantly
12 looking for outside help to help us make these kinds of
13 very, very important decisions from the public's point of
14 view.

15 Dr. Woteki talked about this at lunchtime, at
16 least two of these surveillance systems. We're recognizing
17 how important it is to have good surveillance systems for
18 foodborne diseases.

19 She talked about Foodnet and Pulsenet. And
20 there's another one up there, NARMS, the National
21 Antimicrobial Resistance Monitoring System.

22 Without these kinds of systems, without these
23 kinds of on-the-ground intelligence systems out there for

1 surveillance, from a regulatory standpoint we're basically
2 flying blind. We don't have any idea of whatever regulatory
3 action we might take.

4 What is the outcome of that? If you don't have
5 some way of monitoring, continuously getting feedback and
6 information back from the actual field, you don't have much
7 of a food safety program.

8 So sometimes these are not as glamorous as some
9 of the other new sciences coming out. But they're
10 absolutely critical in our ability to do our job in
11 protecting the public.

12 Foodnet is the foodborne disease active
13 surveillance network. And its an active system gathering
14 information from patients, actual human patients, in
15 catchment areas around the United States that represents 10
16 percent of the population.

17 So Foodnet presently samples from about 10
18 percent of the population to give us a fairly good sampling
19 of what is actually happening in terms of foodborne
20 diseases.

21 As Dr. Woteki mentioned, it is growing, so that
22 there will be new active surveillance sites as time goes on
23 taking into account more diseases, getting better

1 information from the patients to try and link that back to
2 the source and the practices that may have caused that
3 disease.

4 The goals of it is to describe the epidemiology
5 of new and emerging bacterial, parasitic, and foodborne
6 pathogens; estimate the frequency of foodborne diseases in
7 the United States; and determine how much foodborne illness
8 results from eating specific foods such as meat and poultry
9 and eggs.

10 The other exciting area, and one that does take
11 advantage of the new science and biotechnology, is Pulsenet.

12 And Dr. Woteki also talked about that.

13 It's a national computer surveillance network of
14 public health laboratories developed by CDC in conjunction
15 with FDA and USDA and state health laboratories.

16 And it uses DNA fingerprinting in order to make
17 the connections between foods and the disease caused in
18 people.

19 So if you see, this is a pulse gel
20 electrophoretogram. You can see that the two lanes on the,
21 I guess it would be on your left side, pretty much match up.

22 The first one is from a patient; the second one
23 is actually from -- this is Salmonella Agona from cereal,

1 from a commercially prepared breakfast cereal, which is not
2 a place you would normally think of looking for salmonella,
3 but there it was.

4 The third lane is an isolate that is not related
5 to the two. So you can see how these two match up.

6 The interesting thing is that this is all
7 Internet based so that anybody at a Pulsenet site around the
8 country can scan their gel into the system, and it will
9 match it up to any other gel that's in the system from
10 anywhere in the country.

11 And this has been instrumental in making some
12 outbreaks of as little as two people. You can have outbreak
13 detections with as little as two people coming from
14 different states or even from across the ocean. So, amazing
15 system.

16 This is a CDC slide that Joe Lovett [phonetic]
17 from Sissan [phonetic] likes to use a lot. And it's kind of
18 a what-if. This is a, What if we would have had Pulsenet
19 back in 1993, when we had the Jack-in-the-Box incidents with
20 E. coli 0157:H7?

21 As it turned out, we had 726 cases back in 1993
22 because we didn't understand the outbreak at the time.

23 If we had had Pulsenet, it's estimated, in

1 hindsight, that there would have only been 235 cases of E.
2 coli 0157.

3 So having this technology and looking at it in
4 these kinds of what-if situations really gives you a flavor
5 of how much we've accomplished in really a relatively short
6 period of time.

7 NARMS is the National Antimicrobial Resistance
8 Monitoring System. And again, it is a collaborative program
9 with the Centers for Disease Control using Foodnet.

10 It's also a collaborative association with USDA
11 looking at their slaughter samples through the HACCP
12 programs and trying to find out where antimicrobial
13 resistance is, measuring it in animals and also in the
14 public. And you can make that association.

15 We're using NARMS in order to set a regulatory
16 course for dealing antimicrobial.

17 Science and risk assessment: I talked earlier
18 this morning about the importance of risk assessment, that
19 this is a more -- it's a less subjective way of analyzing
20 information and making sound regulatory decisions.

21 It still is in I would consider it to be a very
22 rudimentary state. As we learn more about risk assessment
23 I'm sure our risk assessment models will get a lot better.

1 But even now, even in their infancy, they are
2 providing us with a much better picture of what is causing
3 foodborne diseases.

4 And here are just some examples of how these are
5 being all done through the regulatory agencies.

6 And we have microbial. Dr. Woteki talked about
7 E. coli 0157:H7 risk assessment. There's also a Salmonella
8 enteritidis risk assessment that's been conducted. Listeria
9 monocytogenes, which she also mentioned, will be released
10 fairly soon from Sissan.

11 We recently have completed a campylobacter risk
12 assessment looking at the incidence of resistance to
13 fluroquinolones and campylobacteriosis in humans.

14 In addition to microbial risk assessments, which
15 I maintain are the most difficult to conduct, there have
16 also been recent risk assessments on dioxin, mercury, and
17 other agents such as BSE.

18 So risk assessments are becoming part of the
19 landscape for regulatory work.

20 Our campylobacter risk assessment that I
21 mentioned earlier looks at basically chickens that were
22 given a fluroquinolone antibiotic and developed
23 fluroquinolone-resistant campylobacter, and what is the

1 impact on public health?

2 And the impact that we're looking at is people
3 who have campylobacteriosis are prescribed a fluroquinolone
4 to treat the disease and don't respond to the treatment.
5 And we estimate somewhere around 5,000 people per year are
6 affected by that.

7 And we can just go on from there. A little
8 cartoon that's come up lately: Sometimes I hate being an
9 antibiotic. What doesn't kill me only serves to make me
10 stronger.

11 And that's one of the real problems that we face,
12 is that the microbes seem to have a mind of their own.

13 An area that we're rapidly becoming more and more
14 engaged in is the area of transgenic animals. And this is
15 the kind of -- you heard about eggs being the poster child
16 for food safety. Well, this is the poster child for
17 genetically modified animals.

18 And this shows a salmon and its sibling,
19 virtually, being born or hatched on the same day. But one
20 of them has been transgenically modified to insert growth
21 hormone genes. And so this fish is producing growth
22 hormones at a faster rate than the one on the bottom.

23 And the results of that are very, very

1 impressive. And it's hard not to get excited when you're a
2 fish producer and you see the kinds of benefits that modern
3 biotechnology may be able to provide.

4 But it raises all kinds of public issues, the
5 Frankenfood, and Frankenfish in this case. You've all heard
6 about it.

7 So fish are the first transgenic animal that
8 we're having to deal with at the FDA. But there are a
9 number of other ones that we're sure are coming because the
10 industries are in there talking to us about pigs and
11 chickens and other animals that are now being genetically
12 modified.

13 And we must as regulators be prepared to apply
14 science to determine whether a product produced by
15 biotechnology is safe, not an easy thing to do.

16 First of all, we have to determine, Is it
17 different? Is that food different from the food that would
18 be derived from an animal that wasn't genetically modified?
19 Will inserted genes turn into silence genes or block needed
20 genes?

21 There's all kinds of questions about, once you
22 insert these genes, how do you know what's going to happen?
23 How do you know if they're going to affect other genes or

1 turn into something that has unintended effects?

2 And so there's a lot of interesting very
3 technical scientific questions that we don't have all the
4 answers to yet. But we're rapidly attacking some of these
5 issues.

6 Biotechnology can simply provide alternative
7 methods to deliver a drug substance to animals. That was
8 the case of the transgenic salmon.

9 We have approved BST, bovine somatotropin, for
10 cattle as a drug. Now that you've put the genes in the
11 animal to create the growth hormone, we're trying to
12 regulate that also as a drug, and it seems to make sense for
13 us.

14 For us it's just another drug delivery system.
15 And we have to make sure, again, that all of that is safe.

16 In terms of transgenic animals, we're really
17 looking at two different kinds of biopharm animals. There's
18 been a lot of efforts and now some products coming to market
19 from food animals that are genetically modified to produce
20 pharmaceutical drugs.

21 What happens to those animals once they're no
22 longer little drug factories? Where do they go?

23 Well, the FDA has to answer those questions. Can

1 they may be used in animal feeds? Can they be used for
2 human feeds? What about the animals that are considered no-
3 takes, in other words, you tried to genetically modify them,
4 but it didn't work? Are those animals safe to go into the
5 food supply?

6 So we're constantly being asked to address those
7 questions as to whether or not those animals can be
8 eventually used as food or animal feeds.

9 The ag biotech ones I've already talked about.
10 Those are animals that are genetically engineered to either
11 resist disease or produce a pharmacologically active
12 substance or grow faster or knock out some gene that
13 prevents growth, a lot of different things. So they all
14 have food safety implications.

15 And a lot of our future, we believe, is going to
16 be trying to address some of these very difficult issues.

17 But we believe that science will always underpin
18 everything that the federal regulators do in food safety.
19 We are committed to staying on that path of science and that
20 the future of food safety must be built on that kind of
21 science in order to provide the public with the assurance
22 that it needs to feel safe about the food supply.

23 So, thank you very much.

1 (Applause.)

2 DR. THALER: Next I want to introduce Dr. Barbara
3 Masters. She got her Doctor of Veterinary Medicine from
4 Mississippi State University and did a food animal
5 internship at Kansas State University.

6 She has been with the Food Safety and Inspection
7 Service for eleven years and is currently the director of
8 the slaughter operations staff at the technical service
9 center in Omaha, Nebraska.

10 The slaughter operations staff provides services
11 related to all aspects of meat and poultry slaughter,
12 pathology correlations, and residue information.

13 And she's going to talk some today on the FSIS
14 implementation of the National Residue Program.

15 DR. MASTERS: Good afternoon. I, too, appreciate
16 the opportunity to be here. I'm not sure if Mr. Pope is a
17 harder person to follow or Dr. Sundlof.

18 I certainly have nothing as exciting as nanobots
19 or little stickers you can put on your fish to get 4s and
20 not eat them. I think that's pretty cool.

21 But I am pretty excited about my topic, our
22 National Residue Program. And I think it provides an
23 excellent example of exactly what we heard about at lunch

1 today.

2 And it's an example of a good cooperative program
3 that requires cooperation amongst all the federal agencies,
4 as well as the industry, as well as the animal production
5 folks. So I think it's a good example of a lot of
6 cooperation.

7 I want to talk about some of our current
8 initiatives and some of the things we're working on for the
9 future. But to get there I wanted to provide at least an
10 overview of our National Residue Program so that we would
11 all kind of be on the same page as I talked about some of
12 the things that we're moving to in the future with our
13 National Residue Program.

14 Basically what we do within FSIS is we test meat,
15 poultry, and egg products for violative residues from
16 pesticides, animal drugs, and potentially hazardous
17 chemicals.

18 Under HACCP, that is now mandatory in all of our
19 meat and poultry establishments, the industry has become
20 responsible for preventing violative residues in their
21 products.

22 If violative residues are considered reasonably
23 likely to occur in their operations, then they must address

1 drug residues in their HACCP plan.

2 That certainly does not mean every establishment
3 out there has a critical control point for drug residues.
4 That is going to depend on the type of animals they
5 slaughter and the incidence of drug violations in those
6 animals.

7 We've had a good example in some of our cull cow
8 establishments, where in fact they do consider drug residues
9 reasonably likely to occur, and they have addressed those in
10 a critical control point at the receiving step in their
11 process.

12 They then rely on information feedback and
13 education to the producers to ensure that they don't get
14 repeat violators bringing those animals back into their
15 establishment.

16 They send letters to those producers when they
17 get violative drug residues.

18 They provide that information to our agency,
19 which in turn could be provided to the FDA so that cases can
20 be written up on these producers to ensure that we're all
21 working together to help this producer understand the
22 responsibility they have in bringing animals that are free
23 from drug residues to the slaughter establishment.

1 Our National Residue Program basically is
2 designed to provide us a structured process for identifying
3 and evaluating compounds of concern by production class.

4 I think Dr. Wolf talked about, for example, in
5 sheep Antalmentix might be a bigger concern than antibiotic
6 residues.

7 So we try to look across the production classes
8 and make some assessment of which drug residues we should be
9 testing for in the different classes of animals.

10 We also have a program that is intended to be
11 designed to provide us the capability to analyze for those
12 compounds of concern.

13 We want to ensure that we can have appropriate
14 regulatory follow-up, as well as having a system to provide
15 for collection, analysis, and reporting of that data.

16 I put in a little bit of information on residue
17 violations from 1/99 through 11/30/99, so almost the entire
18 year last year, for 1999.

19 And I did that because I wanted to demonstrate
20 that, in spite of all the excellent work that we heard about
21 this morning with these on-farm quality assurance programs,
22 there's still work to do.

23 There is still a level of residue violations that

1 we are picking up at the slaughter establishment level,
2 primarily in dairy cows, but also in some of the other
3 classes of animals. So a lot of good work going on, and a
4 lot more work to do.

5 The regulatory component for residues is in fact
6 a shared responsibility across the spectrum of federal
7 agencies.

8 The Food Safety Inspection Service works very
9 closely with the FDA, also with EPA, GIPSA, and the state
10 governments in enforcing our National Residue Program.

11 To kind of give you a little better sense
12 particularly on FDA and FSIS and their roles, FDA plays the
13 primary role in determining drug dosages, routes of
14 administration, duration of treatment, withdrawal time, and
15 residue tolerances.

16 So when FSIS in fact detects a residue, it is in
17 turn determined how much of that residue exists, and that is
18 then compared to the residue tolerance that has been set by
19 FDA. If it exceeds the tolerance by FDA, that is when an
20 enforcement action will take place.

21 The enforcement by our agency goes towards the
22 establishment that is in fact slaughtering animals with
23 residue violations. The information from our agency is also

1 turned over to FDA so that FDA in turn can write up cases on
2 these producers.

3 I think we learned from Dr. Sundlof this morning
4 that they primarily start with information and education to
5 a person that has presented a violative animal, and then
6 after that move through the enforcement levels, all the way
7 up to imprisonment for in fact producing animals with
8 violative drug residues.

9 At FSIS, our National Residue Program consists of
10 several different types of testing programs. We have
11 monitoring testing, contamination response, special projects
12 and surveillance, and enforcement or inspector sampling.

13 Our monitoring program is our random sampling.
14 We in fact look at healthy animals, randomly select those
15 animals, and try to get some sense of the level of
16 violations that are occurring for particular compounds
17 throughout a year's time.

18 Those animals are randomly selected based on
19 directions to our inspection personnel to take those samples
20 from a healthy animal to give us some sense of whether or
21 not those residues are occurring in healthy animals.

22 We do pick up a very low level of violations
23 through our national monitoring program, and that again does

1 give us a sense of what kind of violations we're getting in
2 particular compounds.

3 Special projects are more information gathering
4 studies. They might not be conducted for 12 months, for
5 example. They might be done where we don't have precise
6 slaughter volume data. We might in fact do them where we
7 don't have violative levels set, or we could even do them to
8 develop information on the frequency and concentration at
9 which residues occur.

10 Surveillance sampling is actually a type of a
11 special project, but it's a little more defined in that it's
12 actually a targeted sampling with the intent to distinguish
13 compounds where we have residue problems existing, measure
14 the extent of the problem, and evaluate the impact of
15 actions taken to reduce the occurrence of the residues.

16 I want to talk about one example of a
17 surveillance project.

18 Very timely, I spent yesterday putting gel packs
19 into sample boxes to ship out to the field. We are starting
20 a Phenylbutazone cull cow surveillance project. It is an
21 example of a surveillance project that was started by our
22 agency due to potential abuse of Phenylbutazone in food-
23 producing animals.

1 Phenylbutazone, as we all know, is a compound
2 that is not permitted for use in food-producing animals. We
3 have considerable concern about the use of this compound in
4 animals because it does in fact cause a potential public
5 health concern where there is a residue.

6 Because it's an illegal compound to use in food-
7 producing animals, any level that is found in these animals
8 is considered violative, and that carcass would be
9 condemned.

10 We did a pre-pilot study to get some sense of how
11 we might in fact go out and do this special project.

12 In that pre-pilot study, we looked at about 285
13 animals, and we did detect Phenylbutazone violations at
14 about 2.8 percent, which is a fairly high percentage of
15 animals that in fact did have Phenylbutazone in their
16 system, and those carcasses were condemned.

17 That has a direct impact on our agency in trying
18 to protect public health, it has a direct impact on those
19 establishments slaughtering those animals from a cost
20 perspective, and certainly an area where the people that are
21 producing animals can have a direct impact in stopping that
22 residue from occurring.

23 So I wanted to point that out because we will be

1 starting that project next week. Very timely, and a very
2 good example of how animal production does play a direct
3 role in what we are doing from the Food Safety Inspection
4 Service.

5 Our enforcement sampling or inspector generated
6 sampling is that sampling that is done at the inspection
7 establishments in which the inspector detects some
8 abnormality either on antemortem or postmortem inspection or
9 based on a herd history.

10 They also will take inspector generated samples
11 as a follow-up when animals are marketed by a producer that
12 had a previous residue violation. And they also do drug
13 residue testing to verify industries' HACCP programs.

14 I do want to comment that, in regards to our
15 follow-up on animals where we do testing on these animals,
16 our agency very recently received a request that was signed
17 by five major trade associations requesting that our agency
18 consider working hand-in-hand with FDA to provide a repeat
19 violator list that would in fact provide the names of those
20 violators confirmed by FDA.

21 And that our agency would put those confirmed
22 violators on our Internet for public access so that the
23 establishments would have access to the names of individuals

1 that were repeat violators so they can make more informed
2 decisions in purchasing of that livestock.

3 The agency has a small work group working on a
4 response to that request, and we expect to have a response
5 very soon.

6 But I think it's a fairly significant request by
7 the industry to make that information public so that they
8 can in fact make very informed decisions in regards to their
9 HACCP program.

10 From the technical service center, where I am
11 located, some of the initiatives that we're working on:

12 We are currently doing pathology residue
13 correlation sessions, trying to emphasize uniform
14 application of our cattle residue testing program.

15 We recently, in the last year or so, made some
16 changes to our residue testing program.

17 It was brought to our attention by one of our
18 very astute inspectors in charge that they were finding
19 higher levels of drug residue based on postmortem pathology
20 findings than they were based on the antemortem findings
21 that we in the agency had traditionally used to select
22 carcasses for residue testing.

23 We implemented a notice that described those

1 conditions that our inspectors should be looking for to do
2 residue testing.

3 And since we did not have training for that, we
4 instituted these correlation sessions at the tech center
5 where we bring in animal tissues and correlate with our
6 veterinary medical officers to help them better understand
7 which animals we believe are most at risk for violative drug
8 residues.

9 In addition to that, we are in the process of
10 completing a report on the National Residue Program, and we
11 titled it, Uniform Application in Cull Cow Plants.

12 Basically we're developing this report in an
13 attempt to ensure that we are, in fact, uniformly applying
14 our residue program in the cull cow plants.

15 In response to doing these correlations, we
16 started wondering, How effective are our correlations? Are
17 we in fact uniformly implementing our program? Is our
18 correlation effective in helping us to do that?

19 We began this project the week of July 12. We
20 have a final draft due to Headquarters within 90 days of
21 starting the project. And if you have your calendars out,
22 you can quickly calculate that I have a draft report due to
23 Headquarters next Monday.

1 And that will go through a clearance process.
2 And then we will have a public report that will document our
3 findings from the survey.

4 Basically we got a group together that tried to
5 come up with the questions we would ask to determine whether
6 or not we were uniformly applying our program. We developed
7 survey instruments, and sent a team of folks out to go into
8 some of the top 40 cull cow plants to do some actual on-site
9 visits.

10 They interviewed the veterinary medical officer,
11 they observed the veterinary medical officer performing the
12 screening tests, and they also observed the veterinary
13 medical officer select those carcasses that they believed to
14 be at risk for drug residue.

15 They recorded their responses, and we are in the
16 process of evaluating those and formulating some
17 recommendations to our Headquarters management on some
18 things that we think might be appropriate to ensure that we
19 are in fact uniformly implementing our residue program.

20 Some of the things our policy office is working
21 on related to drug residues is they are working on some
22 initiatives to implement a target tissue market residue
23 policy. It's been in the news a lot lately.

1 Basically what they are considering is
2 implementing a policy that would in fact require the
3 condemnation of carcasses based on target tissues.

4 Currently within FSIS we test carcasses through a
5 screening test at the in-plant level. If there is a
6 positive on the screening test, then there are tissues sent
7 to our laboratory for confirmatory analysis.

8 We at our agency will currently test both the
9 target tissue, which might be, for example, the kidney, the
10 liver, and we will also test muscle tissue, and we will use
11 both of those to look at FDA tolerances.

12 FDA regulations currently set target tissues as a
13 means of determining whether edible tissues should be used.

14 Their target tissues are typically things like the liver,
15 kidney, or fat. And basically if the level of drug residue
16 is exceeded in the marker or target tissue, that would
17 result in condemnation of the carcass for edible food.

18 So that's one initiative that our policy office
19 is considering.

20 And the other initiative that they're working on
21 is publishing a Federal Register notice and holding a public
22 meeting to really discuss the effect of full HACCP
23 implementation on our residue program.

1 I talked about one example that's been very
2 effective in a cull cow establishment related to dealing
3 with drug residues.

4 But I think we all recognize the difficulty when
5 we hear the animal production folks talking about drug
6 residue avoidance in their quality assurance programs, you
7 hear the industry talking about trying to address it through
8 their critical control points in their HACCP plans, and we
9 as a federal agency working in conjunction with our other
10 agencies to enforce it.

11 It really is a multi-pronged approach, and
12 there's a lot of discussion that we believe needs to take
13 place on that topic.

14 So we hope to hold a public meeting in the near
15 future so that we can all discuss it and come up with the
16 best policies to ensure that in fact we are considering
17 residues appropriately in a HACCP environment.

18 I hope, in summary, that you can understand
19 FSIS's role in the National Residue Program and some of the
20 challenges we're going through in ensuring that we're in
21 fact uniformly implementing our program.

22 I hope you also understand the challenges to the
23 animal production side and that, to really produce the

1 safest food possible, it does require the animal production
2 folks implementing the quality assurance programs that we
3 heard about this morning, the industry addressing drug
4 residues and ensuring they're only accepting those animals
5 free of drug residues to in fact ensure that we do have safe
6 food available.

7 I appreciate your time, and I'll be available
8 this afternoon for any questions. Thank you.

9 (Applause.)

10 DR. THALER: All right. Moving on, I have to
11 point out that Dr. Eileen Kennedy was unable to be with us,
12 so Dr. Jerry Gillespie has offered to be the moderator from
13 here on. And he'll be starting with food safety research in
14 support of animal production practices.

15 DR. GILLESPIE: Those of you who know Dr. Kennedy
16 know that she is very disappointed that she could not be
17 here. And those of you that know her know how dedicated she
18 is and what an asset she is to have as a leader in the area
19 of research, education, and economics in the USDA.

20 Now, she has provided a message for the group
21 that, because of time constraints that we now have for the
22 session, I will simply capsule, because many of the points
23 that she has raised in her text I think have been covered.

1 And in essence, she sends, first of all, her best
2 regards to all of you and congratulates your participation
3 in this program. And she also highlights some of the
4 progress, as other speakers have, that has been made between
5 this and the previous meeting of this sort. And she also
6 predicts that we'll be doing this again to continue to
7 monitor our progress.

8 And finally, she wishes the sessions good
9 success, which again I know that she sincerely means. And
10 I've had the pleasure of getting to know her well, and again
11 I want to emphasize how lucky we are to have someone so
12 dedicated to the research enterprise.

13 What I'd like to do is move on to our next
14 speaker, who is Dr. David White, who is going to speak to us
15 about antibiotic drug resistance.

16 Dr. White has traveled from Massachusetts through
17 Vermont, Kentucky, Penn State, Tufts, North Dakota State
18 University, to his present position. And in 1999 he
19 accepted a position as a senior research microbiologist for
20 the Office of Research Center for Veterinary Medicine, FDA.

21 The purpose of his research program at CVM is to
22 collect and scrutinize data concerning the prevalence of
23 multiple antibiotic resistance among various bacterial

1 pathogens, certainly a very timely, very important area.

2 And I would like now to invite Dr. White to the
3 podium to make his presentation.

4 (Applause.)

5 DR. WHITE: I think a few things came unplugged
6 when my boss had his spill up here before, so we have to
7 replugin everything in.

8 (Pause.)

9 DR. WHITE: Well, a pleasure to be here, and I'm
10 sure right about this time everyone is having that post-
11 lunch tiredness right now. So I'll try to move this along.

12 I've been working in this field for a while in
13 antibiotic resistance, and it's pretty ironic that I have,
14 because I found out a few years ago from my mother that I
15 had meningitis when I was about two years old, and the only
16 thing that saved me was penicillin.

17 So it's very ironic that -- I wish I could say
18 that I knew at two years of age that I was going to go into
19 this field. But it is ironic that I'm back into this. And
20 I want to kill these little buggers to make sure they don't
21 do the same thing to somebody else.

22 Now, antimicrobials have been around for over 50
23 years now. They came into commercial use about 1945, near

1 the end of World War II. And they were considered miracle
2 drugs. They were also hailed as the magic bullets.

3 When antibiotics were introduced, they seriously
4 decreased morbidity and mortality associated with many
5 infectious diseases where, at that time, if you came down
6 with it, the only solution was to pray and hope you got
7 better. There was no treatment whatsoever.

8 As you can see in this picture from World War II,
9 Thanks to penicillin, he will come home.

10 However, what we're seeing more and more these
11 days is pictures like this on both laymen's journals and
12 scientific journals. And what we're seeing is that the
13 efficacy of antimicrobials is dwindling down rapidly.

14 We have reports now of bacteria that are only
15 susceptible to one antibiotic, that's it.

16 If you've heard of the acronyms VRE or MRSA, they
17 stand for Vancomycin-resistant enterococcus and Methicillin-
18 resistant staph aureus.

19 In some of these cases, these bacteria are
20 resistant to almost every single antimicrobial we have. So
21 it's almost returning back to a pre-antibiotic era where, if
22 you do come down with that in a bacteremia, the only way to
23 survive is to pray.

1 Now, resistance is not a new phenomenon. If we
2 remember back to our introductory biology class and remember
3 about Dr. Charles Darwin, the origin of species, it's a
4 process of natural selection, survival of the fittest.

5 In any population of cells, be it bacterial or
6 eucaryotic, there's a small proportion that have mutations.
7 It's intrinsic.

8 It's estimated in bacteria, for instance, that
9 are resistant to quinolones that one out of 10^7 , 10^8
10 organisms is naturally resistant. That's just the mutation
11 rate. So resistance can happen that way.

12 We also have antimicrobial resistance that is due
13 to intrinsic resistance. And what that means is that the
14 bacteria are normally resistant to that drug.

15 For instance E. coli, salmonella are
16 intrinsically resistant to, say, erythromycin, and that's
17 because the drug can't get through the LPS of the outer
18 barrier.

19 We also have external acquisition of resistance
20 genes. And this is where we're seeing more of our
21 resistance coming from, is the acquisition of DNA on mobile
22 transmissible elements.

23 And the way to think about this, believe it or

1 not, is bacterial sex. They can exchange genes all over the
2 bacterial genera. It's not anymore from E. coli to E. coli;
3 it can be from E. coli to enterococcus, believe it or not.
4 They don't really care what that other bacteria is they're
5 giving their genes to.

6 Now, we can also have selection of resistant
7 variants from within an animal within a patient. So what
8 this means is that we have a preexisting pool of resistants,
9 maybe a small percentage of the normal flora. But when you
10 are confronted with selection pressure, we kill off the
11 susceptible bacteria, and your resistant bacteria overgrows.

12 And lastly, we can have cross-infection, which
13 another term would be nosocomial infections you may have
14 heard in the hospitals, where you go in there for, say, a
15 knee surgery, and you come down with enterococcus
16 bacteremia. You acquired that in the hospital.

17 Now, what's amazing is, though, even though we
18 have hundreds of antibiotics in both human and veterinary
19 medicine, they only work by inhibiting one of four steps in
20 bacterial growth. That's it: one of four steps.

21 These include inhibiting cell wall synthesis of
22 the bacteria, and the drugs that are most known to do that
23 are the betalactiums like ampicillin, penicillin,

1 bacitracin, and vancomycin.

2 Those antibiotics that inhibit some type of step
3 in nucleic acid synthesis are the fluroquinolones like
4 superfloxicin or efampin [phonetic].

5 The antimicrobials that inhibit some type of step
6 in bacterial growth. That would be the sulfa drugs like
7 sulfamethoxazole and the potentiated sulfonamides,
8 trimethoprim sulfa.

9 Lastly, the greatest number of antimicrobials
10 that we have are aimed at inhibiting some step in protein
11 synthesis of the bacteria. And these are the amino
12 glycosides, your phenicols like chloramphenicol and
13 fluoramphenicol, tetracycline, macrolides, glucosamides,
14 streptogrammins [phonetic].

15 So it's amazing, though. Like I said, there's
16 all these antimicrobials. They only work by inhibiting one
17 of these four steps. And how they do this, remember, is a
18 concept called selective toxicity.

19 We're trying to find a drug that exerts its
20 effect on a procaryotic cell but leaving our eucaryotic
21 cells alone. So over time what's happened is bacteria have
22 evolved ways to circumvent the activity of antimicrobials.

23 And just like the antibiotics have four main

1 mechanisms of action, bacteria circumvent the effects of
2 antibiotics by one of four ways.

3 One is through inactivating the antibiotic. And
4 this is how bacteria survive in the presence of
5 betalactams, aminoglycosides, chloramphenicol, and
6 streptogramins, as they produce an enzyme that either
7 inactivates or degrades the antibiotic.

8 We also can have alteration of the target enzyme
9 or the target binding site. And this is usually due to
10 mutation.

11 For instance, the fluoroquinolones are due to
12 mutations. One base permutation in the DNA gyrase gene is
13 enough to allow bacteria to survive in increased
14 concentrations of the drug.

15 We also have now more cases of reduced cellular
16 uptake and active efflux. What's happening here is the cell
17 has these mechanisms turned on where the antibiotic can't
18 get into the cell anymore, and if it does, it's pumped right
19 back out, like a sump pump in your house. So the drug never
20 reaches its target.

21 Just to show you an example, here's a bacterial
22 cell, and in white is something called a plasmid, which is
23 an extrachromosomal DNA element.

1 Most of the time we have a lot of resistance
2 genes on here. In this case, we have three genes of
3 different color, green, purple, and yellow.

4 The green gene here on this plasmid encodes an
5 efflux pump. So what happens, here is our antibiotic trying
6 to get into the cell. When this efflux pump is made, it
7 just pumps it right back out, so the drug never reaches its
8 target.

9 In purple here we have a gene that, say, encodes
10 an antibiotic-degrading enzyme. As the antibiotic gets into
11 the cell, this enzyme chews it up, making it ineffective.

12 And lastly, we can have a gene here that can be
13 an antibiotic-altering enzyme. This is like through
14 adenotransferase or acetyltransferase, where they add a
15 group to the antibiotic, rendering it ineffective.

16 And you can see in this case there's three. And
17 this will be a point I'll make later on, is that multi-drug
18 resistance is the rule these days rather than the exception.

19 Now, when we're talking about potential transfer
20 of antimicrobial resistance determinants, you have to
21 remember that all of the ecosystems are linked, be it
22 agriculture, veterinary medicine, or human medicine.

23 And if we're going to do something to stop this

1 resistance development, we're going to have to take steps in
2 each one of these three areas because they're all linked.
3 As you can see, the arrow goes both ways. It's not solely
4 from animal to human. There are cases actually of going
5 back from human pathogens infecting animals.

6 And agriculture is not an area that we're going
7 to really touch on. But they use quite a bit of
8 Streptomycin as a spray to treat bacterial diseases of
9 plants.

10 So in terms of our focus at CVM and a lot of
11 other people in this room, as well, what are the potential
12 consequences of antimicrobial use in animals?

13 And as we know, this is not a new issue. It
14 actually first raised its head in 1969 with the release of
15 the Swann report in Great Britain.

16 If you can go back to that initial report and
17 take out some quotes, and if I put it up on the screen here,
18 you would think they were something that we talked about
19 today, but they're actually almost 30 years old.

20 First, one of the consequences, of course,
21 increase in the prevalence of resistant bacteria.

22 Secondly, transfer of these resistant bacteria,
23 be it pathogens or commensals. And the commensals is fairly

1 new. We're starting to think about commensal bacteria as
2 potential reservoirs of resistance genes. So even though
3 they don't cause disease, they still carry like suitcases
4 the resistance genes that can transfer to other bacteria.

5 And this transfer is either via direct contact
6 with animals or through consumption of contaminated food or
7 water.

8 We then could have transfer of the bacterial
9 resistance genes to other bacterial genera and species
10 inside us. We then see an increase in incidence of human
11 infections caused by resistant pathogens, and lastly,
12 potential therapeutic failures in animals and humans.
13 That's the scenario we have to follow.

14 Now, when you try to look at this and say, Yes.
15 Indeed this resistant salmonella we have come from an animal
16 or this resistant enterococcus came from an animal, there
17 are certain things we have to follow.

18 And first of all, we have to determine if the
19 genes are identical or not. And we do this by either DNA
20 sequencing a gene or determining the genetic organization of
21 the resistance determinants. Before we can make any claims,
22 we need to make sure that those genes are identical. If
23 they're separate genes, well, they're separate.

1 So we need to do a little bit of molecular
2 biology to determine the relatedness between an animal
3 strain and a human strain.

4 Next we also have to determine if we can transfer
5 it, because that's one way how we want to see a resistance
6 occurs is to transfer it between a resistant bacteria and a
7 susceptible bacteria.

8 And usually it's in vitro, meaning we do this in
9 the laboratory. We take a strain that has, say, a
10 resistance gene on a plasmid, we do a conjugation study
11 where we actually mix it together with a susceptible, and we
12 see if transfer occurred.

13 One thing we're lacking, though, is in vivo
14 studies, actually what happens in the animal. And I think
15 we need some future focus in this area to see if resistance
16 transfer is occurring inside the animal.

17 Now, there have been many cases actually of
18 resistance gene transfers being documented between bacteria
19 of different genera, for example, tetracycline, in three
20 different cases where they found the exact same tetracycline
21 resistance gene in very diverse bacteria.

22 They found the tet resistance gene, enterococcus,
23 which of course is in both the animal and human intestines.

1 They found the exact same gene in Streptococcus pneumonia
2 and Listeria gonorrhoea.

3 And how they document this is the same gene, it
4 has 99 percent DNA sequence identity. So you're only
5 talking a couple bases different between these.

6 Now, we don't know, of course, which way that
7 gene transferred. But what this does show is that the gene
8 did transfer. We just don't know the direction.

9 Likewise with erythromycin, which is very
10 interesting. You're talking the RNG gene found in Bacillus
11 verrucosus, which is a normal soil organism. They found the
12 exact same gene in Bacteroides fragilis, a clinical isolate in
13 humans; the exact same gene.

14 Once again we don't know the mechanism of
15 transfer, how it got there or which way it went. But we
16 know we can document it.

17 So how are these resistance genes transferring?
18 Okay. There's three main mechanisms how resistance genes
19 can transfer. One, of course, is through transformation,
20 number one. And this is the uptake of naked DNA.

21 So what happens, of course, when bacteria die,
22 they release their DNA into the environment. What can happen
23 is that a cell in the immediate environment can actually

1 uptake DNA and incorporate it into its genome.

2 So when people think a dead bacteria is a good
3 thing, that's not always the case, because even dead
4 bacteria can transmit their resistance genes.

5 Secondly, we have conjugation. This is plasmid
6 transfer, where we have a bacteria that has a plasmid that
7 can duplicate it and give it to another strain that does not
8 have it, but then making that resistant.

9 This is also known, as we said, bacterial sex,
10 because there has to be a sex pilus formed between the two.

11 They have to come into close proximity with each other, and
12 they can exchange resistance genes.

13 Lastly, they can exchange genes by a method
14 called transduction. This is via a bacterial virus. Those
15 of you who do not know, yes. There are viruses that even
16 infect bacteria.

17 And this is how the shigatoxin supposedly arose
18 in E. coli, is that they were caught on a bacterial virus
19 that picked it up from shigella and infected an E. coli,
20 bringing over the toxin.

21 So these are the three main mechanisms how
22 resistance genes can transfer.

23 Now, there is a cycle of antibiotic resistance

1 that I think if we can interrupt any one of these steps,
2 then we can reduce the impact of antibiotic resistance.

3 The first one starts off with a preexisting pool
4 of antibiotic-resistant bacteria.

5 And if you go back in the literature, they've
6 actually found antibiotic-resistant bacteria from glacial
7 ice in the Arctic that they've dated to over 2,000 years
8 ago. That's a little bit before we invented antibiotics.
9 Also, they've found resistance in preexisting historical
10 cultures before antibiotics were used.

11 So antibiotic resistance, like I said, is not a
12 new thing. It's out there. There's a preexisting pool.

13 And one thing to think about is, before we
14 started inventing all these synthetic antimicrobials, a lot
15 of our antibiotics that were discovered by the
16 pharmaceutical companies, do you remember where they came
17 from? They came from soil organisms: Actinomyces,
18 Chlormycetes. So these exist in the soil. They produce
19 crude forms of the antibiotic.

20 Well, a lot of our bacteria, of course, exists in
21 this environment, as well: E. coli enterococcus.

22 And what they've found is, if you look at some of
23 these resistance genes over time, and you do a genetic

1 search on them, they actually have similarity to genes found
2 in the actual antibiotic-producing organism.

3 Think about it. If an organism is producing an
4 antibiotic, it doesn't want to kill itself, so it needs to
5 have a mechanism to protect itself.

6 So what's happened over time is that those genes
7 have evolved into what we see today. So there's a
8 preexisting pool already out there.

9 Well, what can happen is this gene gets
10 incorporated onto this plasmid. Like I said, it's a mobile
11 DNA element. Pathogen picks up this plasmid here. The
12 yellow is the gene.

13 These bacteria come in contact with some type of
14 selection pressure. And it doesn't have to be an
15 antibiotic, we're finding out. It could be a heavy metal,
16 it could be disinfectant, because I'll show you later on is
17 that sometimes all three of these are all linked together.

18 So it has to be an antibiotic that's selecting
19 for resistance. It can be a disinfectant or even a heavy
20 metal.

21 What happens is the selection pressure kills off
22 the susceptible bacteria. The one that has this gene that
23 confers resistance is able to divide and proliferate, and

1 the whole cycle starts up again.

2 So if we can somehow interrupt these steps, we
3 can reduce the impact of resistance.

4 So what's responsible for the widespread
5 dissemination and diversity of resistance phenotype small
6 bacteria?

7 And it's really due, I think, to these
8 transmissible elements, these transferrable elements that
9 can move from bacteria to bacteria, that confers resistance.

10 And the three major players are plasmids,
11 transposons, and integrons. The last two sound like
12 something out of Star Trek. And I'll try to explain these
13 to you in a little bit.

14 Plasmids I'm sure you've all heard of. They've
15 been around a long time. Initially discovered in 1959 in
16 Japan in shigella. Okay. So we've known about these for a
17 long time.

18 They were initially called R factors. I think
19 you can take a guess what the R stands for. It's not Ragu.
20 It's resistance. Right?

21 This is an interactive talk. Sorry.

22 They can possess multiple antibiotic resistance
23 genes. And they are conjugated, meaning they can mediate

1 their own transfer from a resistant strain, donating that
2 plasmid to a susceptible strain.

3 We also have transposons. And transposons, the
4 layman's term is jumping genes. These are segments of DNA
5 that can jump from the chromosome to a plasmid and from one
6 strain to another. They also can possess multiple
7 antibiotic resistance genes.

8 But what's interesting about the transposons
9 sometimes is that they have toxin genes interspersed in
10 between.

11 So in that case, if you have an antibiotic
12 resistance gene next to a toxin gene, think about what's
13 happening. Using an antibiotic is selecting for virulence
14 in that case.

15 These can also move, like I said, back and forth
16 from plasmid to chromosome.

17 The last mechanism is something called an
18 integron. And this is a fairly new DNA mobile element.
19 It's been described in the past ten years or so. And they
20 can possess single or groups of mobile gene cassettes.

21 And these gene cassettes are interesting. Each
22 gene cassette is an antibiotic resistance gene.

23 So far they've found 50 different antibiotic

1 resistance gene cassettes in these integrons. And they
2 include such diverse resistances as those to betalactimases,
3 aminoglycosides, sulfa trimethoprim, and chloramphenicol
4 resistance.

5 We can find these integrons on plasmids and
6 chromosomes. They are in pretty much every gram-negative
7 bacterial species there are. And they definitely contribute
8 to the dissemination of antibiotic resistance.

9 Right now they've been grouped into four classes.
10 Class 1, 2, and 3 are primarily found in the gram negatives
11 like E. coli and salmonella. Class 4 has only been found in
12 vibrio.

13 Just to give you kind of a simple schematic of
14 what an integron looks like, there is two conserve
15 segments -- that's what the CS stands for -- a five-prime
16 conserve segment and a three-prime conserve segment.

17 The five-prime conserve segment encodes an enzyme
18 called integrase which allows for the combination of
19 resistance genes into this fragment.

20 The three-prime conserve segment -- now, this is
21 the backbone. Okay. Every Class 1 integron has this. The
22 three-prime conserve segment has two genes in it, one called
23 Quack Delta E. This is the gene that actually confers

1 resistance to quaternary ammonia disinfectants. The Cell 1
2 gene encodes resistance to sulfonamides.

3 So in the backbone of the integron we already
4 have resistance to sulfa drugs and quats.

5 And what can happen here is we get insertion of
6 an antibiotic resistance genes in between these.

7 And it's like molecular flypaper. These
8 integrons can start catching other genes and put them right
9 next to each other. And I'll try to demonstrate how this
10 happens.

11 So here's our typical integron here. There's
12 nothing in between. It comes in contact with a gene
13 cassette. Okay. This is just a gene here that confers,
14 say, resistance to chloramphenicol.

15 And what happens is the gene gets inserted in
16 between the two conserve segments, and the gene is
17 expressed. So now this bacteria is resistant to
18 chloramphenicol.

19 So from the last picture, here is our gene
20 cassette, now with chloramphenicol resistance. Another guy
21 comes along, another gene cassette, and what happens, it's
22 put right next to it. Okay. So it starts accumulating
23 genes right next to each other.

1 And the biggest one they've found so far is six
2 antibiotic resistance genes back to back to back to back to
3 back.

4 So in that case you're talking one antibiotic can
5 select for resistance to six, because they're all linked to
6 each other.

7 Just to show you that these things are real, you
8 can make up PCR primers to the conserve segments and
9 amplify. And what you do is, you purify the DNA, and you
10 send it out for DNA sequencing, and it determines what the
11 genes are.

12 So here are just some examples. Here's
13 Salmonella Typhimurium. When we do PCR with the conserve
14 segments for integrons, we get two bands, and it's
15 characteristic of DT104. And here's some Salmonella Derby,
16 Salmonella Natum [phonetic].

17 This is interesting here. When we sequenced all
18 these bands, they were all identical. So we found the same
19 gene in very much diverse, different salmonella species,
20 which is pretty common.

21 An interesting story here is this integron in an
22 isolate of Salmonella Brandenburg, when we sequenced it, we
23 identified it as a gene that conferred resistance to

1 norciathricin. This is an antibiotic that is not used in
2 North America. It was actually used in East Germany years
3 ago.

4 And I thought that was kind of weird until I
5 figured out what the name of the salmonella was. If you
6 think about it, it's Salmonella Brandenburg, originally
7 identified, guess where? In Germany.

8 So it makes sense even though this strain we
9 isolated it in the United States, it originated in Germany.
10 And it took with it a resistance gene from the antibiotic
11 that was used in East Germany 15 years ago.

12 So what we're finding out now is that, in terms
13 of transferrable drug resistances, it's pretty much every
14 single drug we have out there, except for quinolones; for
15 those of you who are familiar with fluroquinolones,
16 resistances due to chromosomal mutations.

17 However, there was a report two years ago of
18 plasmid-mediated fluroquinolone resistance. However, they
19 have not gone into detail yet on the mechanism, so that's
20 still a question mark.

21 Now, as I said before, multi-drug resistance is
22 the rule, not the exception. And I'm trying to create a
23 little pictograph here. With selection pressure and the

1 environment increased over time, we already have a strain of
2 bacteria that has a plasmid in it for a resistance gene.
3 It's preexisting, as we talked about.

4 When you introduce -- this arrow denotes an
5 antibiotic selection pressure. When we introduce a new
6 selection pressure, say, another antibiotic, what happens is
7 these bacteria accumulate another resistance gene. Okay.
8 So now they're resistant to two antimicrobials.

9 And into that environment comes another
10 antimicrobial. And guess what happens? It picks it up
11 again.

12 So these bacteria are accumulating resistance
13 genes in a scientific phenomenon that I like to call
14 snowball-rolling-downhill effect; not the most scientific
15 term, but it's really the best way to describe how
16 resistance genes are accumulated.

17 Remember the snowball down the hill, it gets
18 bigger and bigger and bigger? The same thing happens with
19 these bacteria when they accumulate resistance genes.

20 Now, how do we go about stopping this or reducing
21 the evolution of resistance?

22 One way, of course, is to get out there the
23 message of using antimicrobials prudently.

1 And this is a message put out by the Academy of
2 Veterinary Pharmacology and Therapeutics. And their
3 statement is, The use that maximizes health benefits and
4 minimizes the development of resistance and prevents the
5 occurrence of unsafe residues.

6 So that's three main factors in there: maximize
7 health benefits, minimize resistance, and prevent the
8 occurrence of unsafe residues.

9 This is what we want to do, but sometimes these
10 don't all merge with one. For instance, like pushing on one
11 end of a balloon, the other end gets bigger.

12 So if we're going to fulfill this, we're going to
13 have to take a closer look at all of these things.

14 Now, one way to show you judicious use is to show
15 you some inappropriate use or injudicious use.

16 When I was in North Dakota, I was head of
17 diagnostic microbiology. And North Dakota is mostly a
18 cow/calf operation state. And we have a lot of old-timers
19 that -- well, calf scours is the number one disease.

20 And we have these cows, you know, one to two days
21 of age with diarrhea. And they usually don't come into the
22 diagnostic lab to determine what antimicrobial.

23 So what they do is something called the shotgun

1 approach. And what that is here is, they would give them
2 these gelatin capsules full of pills. And they would come
3 up, and they would go, Oh, Doc, here's what I'm giving them.

4 And I'm like, What the hell is that? You know,
5 it's definitely not prudent use.

6 So what we would do -- it was Mike Appley
7 [phonetic] and I. And I asked him to take it apart and
8 identify it. And this is what we found in this gelatin
9 capsule they were giving to two-day-old calves:

10 Okay. First of all, we had an antihistamine; we
11 had sulfamethoxazole trimethoprim; Vitamin C; kephalexin;
12 tetracycline; and a couple of other tablets we had no idea
13 what they were.

14 So this is what they were giving two-day-old
15 calves in an attempt to cure the diarrhea. That definitely,
16 I think, falls under the definition of inappropriate use.

17 One thing to keep in mind, too, is that
18 antibiotic resistance does not respect national boundaries.

19 Whatever we do in the United States has to be
20 done globally, as well, because resistance that develops in
21 Mexico or Canada, as we know, can come here very quickly due
22 to travel and importation of food.

23 This is a picture from my old technician, who

1 went down to Mexico on a trip, as you can see. This is
2 over-the-counter availability of antibiotics. You could
3 just walk in and buy any antibiotic over the counter.

4 So if you have the sniffles, you go buy an
5 antibiotic, that's definitely inappropriate use, as well.

6 As you can see here, Amoxicillin, 50 percent off.
7 They had a big sale. One thing I notice as well here,
8 though, is Prozac was 28 percent off.

9 (General laughter.)

10 DR. WHITE: So you can get a bunch of stuff down
11 there in Mexico.

12 So how do we promote the prudent use of
13 antimicrobials in ag? I think first of all is through
14 improved surveillance of bacterial antimicrobial
15 susceptibility and resistance. And this is being done by
16 the NARMS program, Foodnet, Pulsenet.

17 I think we also need to focus on improved
18 antimicrobial administration and maybe look at short-term
19 narrow spectrum high dose therapies, and also start
20 implementing correct PK/PD parameters.

21 This was mentioned before, but I think we need to
22 encourage research into antimicrobial alternatives. We know
23 that antimicrobials promote growth. But there's got to be a

1 way to get that effect without using an antibiotic.

2 And also, increased education of all involved
3 groups. This includes physicians, veterinarians, clinical
4 labs, ag producers, pharmaceutical companies. And of
5 course, encourage always the appropriate use of these
6 agents.

7 And I figure at the type of meeting we're at,
8 that we need to put some ideas for the future and maybe to
9 think about for tomorrow, as well.

10 I think there are some future research needs that
11 need to be addressed if we're going to conquer this
12 antibiotic resistance dilemma. And one, of course, is a
13 growing area of research is, what is the contribution of the
14 normal flora to antimicrobial resistance? That is, are
15 there innocent bystanders?

16 Even our simple E. coli, are they reservoirs of
17 resistance genes for other bacterial pathogens? More people
18 that are publishing are suggesting that is indeed the fact.

19 Now, what factors contribute to the selection of
20 resistant microbes?

21 So I think we need more researchers in this area
22 in veterinary medicine looking at pharmaco-kinetics,
23 pharmaco-dynamics, and looking at those parameters on the

1 selection dissemination of resistance.

2 And this is looking at the dose, frequency,
3 duration, exposure, and the environment.

4 Also, what is the frequency of selection for
5 resistance-specific antimicrobials? Are there some
6 antimicrobials that resistance evolves faster to over
7 another?

8 How do these mechanisms evolve? Are there other
9 sources of resistance genes and organisms out there? Are
10 there other reservoirs that we don't know about yet? And
11 are there other selection pressures out there?

12 There are some cases where we still see
13 chloramphenicol resistance in E. coli, after this drug was
14 banned 15 years ago. What's happening there? Is there
15 something else? In every one of those strains that's
16 chloramphenicol resistant, they're also tetracycline
17 resistant.

18 There's a possibility that those genes are linked
19 now so that the use of tetracycline is selecting for
20 chloramphenicol resistance.

21 And lastly, of course, how is resistance
22 transferred and how often?

23 These are simple questions, but in vet med and

1 agriculture, we don't really have that many answers yet.

2 We need to know how much transposable elements
3 contributes to resistance, and like I said, the gene linkage
4 aspect.

5 When we see multi-drug resistance, we need to see
6 if these genes are linked to each other or if they're
7 independent.

8 Now, in summary, I'd like to conclude with an
9 analogy that may be applicable to our situation.

10 For those of you that remember, or at least those
11 of you who saw that Tom Hanks film a couple years ago,
12 Apollo 13 mission going to the moon had a few problems on
13 its way. They had a catastrophic explosion, and they were
14 losing their oxygen and their energy, and it was a great
15 possibility they were going to die up there.

16 And what happened at NASA is, a diverse group of
17 scientists, be it engineers, technicians, they got together,
18 put their heads together to try to get these guys home. The
19 end result was a good thing. They made it home.

20 What I'm trying to get at here is we face a
21 similar situation, one maybe not as dramatic as the Apollo
22 13 mission, but one that has significant impact both in
23 human and animal health. And that is the emergence of

1 bacteria that are multi-drug resistant.

2 So our challenge is, can we put our heads
3 together, all groups involved, put on our thinking caps,
4 draw up plans, develop and implement intervention strategies
5 that reduce the public health impact of antibiotic
6 resistance?

7 Thank you.

8 (Applause.)

9 DR. GILLESPIE: Mary Torrence had an emergency
10 and was unable to come. And so her paper on epidemiology
11 will not be given.

12 So we'll go immediately to the break, which will
13 be ten minutes -- ho, ho, ho. And we'll be back as close as
14 we can to 3:45 to start the next session.

15 (Whereupon, a short recess was taken.)

16 DR. GILLESPIE: While people are making their way
17 back in, I would like to begin the introduction, if I could,
18 of Dr. Norman Stern, who will be our presenter this
19 afternoon.

20 And he's going to speak to us about the
21 strategies and successes in pathogen control during poultry
22 production and processing.

23 Dr. Stern serves as research leader of the

1 Poultry Microbiological Safety Research Unit, USDA
2 Agriculture Research Service, Athens, Georgia.

3 In this capacity he directs a major research
4 program with emphasis on developing knowledge and
5 technologies which will prevent or control the prevalence of
6 human bacterial pathogens in eggs and on-farm chickens.

7 The program consists of two primary areas,
8 controlling colonization of poultry by campylobacter and
9 controlling colonization by salmonella.

10 Dr. Stern has approximately 25 years of research
11 experience in microbiological safety of foods.

12 Dr. Stern.

13 DR. STERN: Thank you, Mr. Chairman. Ladies and
14 gentlemen, good afternoon.

15 I'm happy to say we're having technical
16 difficulties. With that, we will work through this.
17 Really, I can either dance or sing a song. The CD is being
18 loaded. Let's see how this goes.

19 (Pause.)

20 DR. STERN: I think I'll just start by saying
21 that it's not the government that makes food safe. There, I
22 said it. It really is the industry.

23 And happily, I've gotten terrific cooperation

1 from a number of my industry colleagues to work together.

2 And these colleagues really are the folks who
3 have stepped up -- is that me? This is unacceptable.

4 These people have stepped forward, and they're
5 probably the top 10 percent. They're proactive individuals.

6 And I figure that's as good as I can do, because
7 if we can get the top 10 percent of the proactive parts of
8 the industry working together to resolve the problems, then
9 the rest of the 90 percent will come along, or else they'll
10 go out of business. And that's okay with me, too.

11 We've got four laptop computers here.

12 (Pause.)

13 DR. STERN: You know, you plan the talk, and you
14 have the presentation, and you kind of want to go with the
15 slides. So I could muddle about.

16 (Pause.)

17 DR. GILLESPIE: Surely someone today has said
18 something about you need to be flexible. And we're going to
19 be that. And I appreciate our speakers' willingness to
20 reschedule themselves.

21 And Shannon Jordre has agreed to move his
22 presentation up. And he's going to talk about feed
23 contamination.

1 He is the commercial feed and animal remedies
2 specialist with the South Dakota Department of Agriculture
3 and has worked in that position since 1990.

4 He has had experience with USDA Meat Animal
5 Research Center at Clay Center, Nebraska and holds a
6 baccalaureate degree in microbiology from South Dakota State
7 University.

8 And he is currently the president of AAFCO,
9 Association of American Feed Control Officers, and is active
10 in the South Dakota Environmental Health Association.

11 Shannon, I appreciate your moving up in the
12 schedule.

13 MR. JORDRE: I was a little intimidated this
14 morning watching everybody come up here with these really
15 nice, slick Power Point and electronic presentations. And
16 I'm thinking, Here I've got the old fashioned, low tech
17 overheads.

18 But it's nice to be useful, and if for nothing
19 else, I'll be remembered as the odd man out, so to speak,
20 somebody who didn't use an electronic presentation.

21 Just to briefly explain: Yes. I'm with the
22 South Dakota Department of Agriculture. I'm the feed and
23 animal remedies specialist there.

1 It's my job to regulate the commercial feed and
2 the animal drug manufacturers that do business in the state.

3 And the way we do this is through collecting samples, by
4 analyzing for guarantees, nutrient guarantees, as well as
5 possible contaminants at times.

6 We do feed mill inspections, monitor for good
7 manufacturing practices. We monitor ingredients that are
8 going into the feed supply.

9 And so if you look at my first overhead here, Oh,
10 boy, it's dog food again, it really does kind of illustrate
11 or it makes a point why we regulate the feed industry.

12 In the case of pets, it's not uncommon for the
13 pet to eat the same diet for years, and so you want to make
14 sure that that diet is both safe and nutritionally balanced.

15 In the case of food animals, we want to be able
16 to eat those animals once they reach their physical
17 maturity, and thus we want to make sure that the feed that
18 they're eating is safe.

19 I've been asked to speak about contamination.
20 And I'm not a researcher, and I don't represent a research
21 association. So what I'm going to do is provide it from
22 more of a regulatory type perspective. And to do that, I'm
23 going to explain what AAFCO is.

1 AAFCO is the Association of American Feed Control
2 Officials. And this is a quote that's out of our
3 association philosophy:

4 The purposes of the corporation shall be to
5 establish and maintain an association through which
6 officials of any state, dominion, federal or other
7 governmental agency charged with enforcing the laws
8 regulating the production -- on and on and on about animal
9 feeds and livestock remedies -- may unite to explore the
10 problems encountered.

11 The following page just follows up on that. A
12 basic goal of AAFCO is to provide a mechanism for developing
13 and implementing uniform and equitable laws, regulations,
14 standards, definitions, and enforcement policies for
15 regulating the manufacturing, labeling, and distribution, et
16 cetera of feed.

17 The association promotes new ideas and innovative
18 procedures and urges their adoption by member agencies for
19 uniformity.

20 In other words, one of our projects is to come up
21 with model feed labeling standards which the various
22 states -- because the states do most of the regulation of
23 the feed industry -- the states can adopt a uniform

1 standard.

2 Companies can devise a label that works
3 nationwide so they don't have to, in most cases anyway, come
4 up with state-by-state labeling.

5 AAFCO consists of 23 committees, task force.
6 These committees and task force work year-round on projects.

7 We have 28 feed ingredient investigators, and
8 there are 40 agencies represented on committees or as
9 investigators.

10 And I should back up and say first that AAFCO is
11 now over 90 years old. It's an international association.
12 All 50 states are members; USDA, FDA, EPA are members;
13 Puerto Rico is a member; and we have international
14 membership as well. Canada has been a member for many
15 years, and more recently, Costa Rica is also a member.

16 So we do have a large group that's active. And
17 so we've got something like 60 different members. And 40 of
18 those members do get involved in some of the committee and
19 investigator work.

20 Our committees, we have, as I said, 23
21 committees. A couple of them that are of primary interest
22 probably to this group.

23 The Feed Manufacturing Committee, they set up

1 good manufacturing practices for feed mills. They are also
2 working on a voluntary self-inspection program for medicated
3 feed mills.

4 What our hope is is that, if we can install some
5 sort of voluntary self-inspection for that segment of the
6 industry that really doesn't need much help, we can spend
7 more time working with the other segments of the industry
8 that really do need some help.

9 And then, because the current good manufacturing
10 practices are designed for those feed mills that make
11 medicated feeds, and we realize that medicated feeds present
12 only one type of contamination risk, we've also started the
13 process to look at devising some good manufacturing
14 practices for feed mills that manufacture feeds that don't
15 contain medications.

16 There's all kinds of problems that you can get
17 into in a feed mill setting. You can have copper carry over
18 between a hog feed and a sheep feed. That's probably more
19 of a threat than an antibiotic residue would be.

20 Another committee that's highly involved in feed
21 safety and contamination, the Ingredient Definitions
22 Committee. This is the committee that works on establishing
23 new feed ingredient definitions.

1 We work very closely with the FDA to establish a
2 definition. And if there are some safety issues or
3 contaminant issues with a feed ingredient or potential feed
4 ingredient, we would incorporate some either labeling
5 guidance, manufacturing guidance, or some other type of
6 guidance into the definition that would address
7 contamination or safety issue.

8 A couple of other committees that are involved.
9 The Environmental Issues Committee is looking at
10 contamination due to environmental factors. Lab Methods and
11 Services, working on new laboratory techniques that could be
12 useful in contaminant analysis.

13 And we recently established the Feed Safety
14 Steering Committee to help organize all of our feed and food
15 safety efforts.

16 The purpose of this slide is just to advertise
17 our Web site. In case you want to know who your local state
18 contact is or a federal contact, you can look up on our Web
19 site there.

20 Like I say, our group is primarily made up of
21 regulators either at the state or local level -- or state or
22 federal level. And so the way we deal with contamination is
23 to try and regulate it, which is not always easy to do. But

1 that's the framework that we have, and so that's what we try
2 to use.

3 Everybody is familiar with mycotoxins. There's a
4 variety of mycotoxins; we have aflatoxin, vomitoxin.
5 Fumonicin [phonetic] is the new one.

6 There's been a fair amount of research on the
7 aflatoxin and vomitoxin.

8 And what we've been able to do, then, in the
9 regulatory process is establish some kind of guidelines or
10 framework that says if you've got an animal such as a dairy
11 cow, for example, that you want to be very careful about how
12 much aflatoxin you're feeding the dairy cow, because there
13 is a pretty good transfer of aflatoxin from the feed into
14 the milk.

15 So you feed the dairy cow a low level of
16 aflatoxin or not at all. But you want to keep it to a low
17 level.

18 On the other hand, if you have a feed that's
19 contaminated with vomitoxin, for example, and you're in the
20 business of feeding cattle in a feedlot, the cattle are
21 fairly tolerant of vomitoxin, and so you can feed a higher
22 level.

23 And that's the advantage of having research to

1 fall back on. You can establish a science-based, reasonable
2 way to regulate some of these contamination problems.

3 Fumonisin is the new mycotoxin on the block. And
4 we don't have a real lot of information about that one yet,
5 but likely it will probably follow the same concept in terms
6 of regulation as the other mycotoxins do.

7 And there are well over 100 other kinds of
8 mycotoxins that we can identify. We can't quantitate them
9 all, and we don't know necessarily which ones are problems.

10 But likely there will be additional mycotoxins identified
11 down the road that we would like to try and control.

12 Drug residues, we had some discussion already
13 today about the drug residues, tissue residues.

14 I think we're all agreed that the number of
15 violative animals is down. In large part this is probably
16 due to QA programs sponsored by the producer groups.

17 Sort of the new interest in drug residues has to
18 do with antibiotic resistance development. And we've heard
19 some excellent points about that today.

20 Likely, as more research unfolds, this may result
21 in some additional regulations, in which case we'll have to
22 incorporate those.

23 The third point, mistakes, environment vandalism.

1 In a feed manufacturing setting you have ample opportunity
2 to make mistakes. Hopefully, you have adopted good
3 manufacturing practices that try and help keep those to a
4 minimum.

5 But you get into situations sometimes where
6 there's some -- as I alluded to earlier -- where there's
7 some copper in the -- you made a swine feed, for example,
8 that contained a high level of copper, and you followed that
9 with a sheep feed. Sheep aren't very tolerant of copper.
10 So you have to deal with issues like that.

11 Sometimes you have a case where you've
12 manufactured a cattle feed, you've labeled it as a cattle
13 feed, and then somebody takes it home and feeds it to their
14 sheep anyway. It's not really a contamination, but that's
15 the type of accident that happens occasionally.

16 All kinds of environmental issues come into play,
17 poisonous plants. Where I'm from, in central South Dakota,
18 we have high levels of naturally occurring selenium in the
19 soil and in the plants. You have to deal with factors like
20 that.

21 And occasionally you hear about some incidents of
22 vandalism or negligence or some other things that cause
23 contamination events.

1 Some emerging issues that we're dealing with:
2 BSE is one; dioxin is another. And we're waiting for
3 additional science before we move on those issues, or move
4 on those issues beyond what we've done so far, I guess.

5 Another emerging issue, we've heard several
6 speakers talk about animal waste. It's another issue that
7 we need to watch.

8 Some of the agencies that regulate animal waste
9 are advising or suggesting to the people that they deal with
10 that feeding is one option for disposal of their animal
11 waste. And while that may be true, it's not something
12 that's simple to do in all cases. I mean, it's something
13 that has to be managed very carefully.

14 And then, the bottom point here is economics.
15 Let's not forget that there is an economic factor to many,
16 many kinds of contamination.

17 You've got a farmer who has harvested his wheat,
18 and he's got a bin full of wheat, and it's got too much
19 vomitoxin to go to the food market. He still needs
20 someplace to dispose of that.

21 In the case of wheat, most of that is geared to
22 go to food manufacturing first and foremost. If it's not
23 good enough for food manufacturing, then, the feed market is

1 the next most likely outlet.

2 If it can be used as feed, let's use it for feed.

3 But if it's not, let's be very careful about how it's
4 handled. Let's find some other way to use it.

5 There's always an economic incentive, and the
6 feed and the livestock industry have become very dependent
7 on byproducts of manufacturing.

8 And it's pretty normal for me to get a call
9 probably once a week or every couple weeks, anyway, from
10 some food manufacturer who has got some byproduct that
11 they're trying to find a use for. Rather than sending it to
12 the waste water treatment plant or to the landfill, they
13 would like to explore the idea of livestock feeding.

14 In many cases, it's a viable option. In some
15 other cases, it's not. But we need to be very careful about
16 doing some of that.

17 Well, how do we handle these issues? AAFCO would
18 like to propose three different approaches: research,
19 education, and regulation.

20 Research, we would like some additional research
21 on animal nutrition. We know a lot about nutrition, but we
22 don't know everything. There are some frontiers yet, and
23 especially as we deal with some of these byproduct feeds.

1 There's all kinds of geographic issues that come
2 into play, weather factors, lots of different things.

3 We need some additional research on analytical
4 methods. We all know that there is a wide variety of
5 contaminants out there. Many of them we can qualitatively
6 analyze but we can't quantitate. And if we can't quantitate
7 them, it's hard to manage them. And we need some additional
8 research on the contaminants themselves.

9 The next slide that I've got here comes from the
10 Arizona Department of Ag newsletter. And they're reporting
11 on some ARS research regarding aflatoxin in cottonseed. And
12 it's just a good example of how we can make the food supply
13 a little safer.

14 We also want some education. We need to educate
15 the producers, the livestock producers in particular, but
16 also some of the people that are providing these ingredients
17 to the livestock producers and to the feed industry.

18 Here's a good article out of Feedstuffs just a
19 couple of weeks ago, "Tradeoffs Evaluated When Pricing
20 Byproduct Feeds." It's all about the economics of using
21 byproduct feeds. And it's a very good article, and
22 economics are very important to livestock producers.

23 The article does indicate that, if you do feed a

1 byproduct, for example, you might lose a little bit of your
2 rate of gain.

3 It doesn't say anything -- so it does advise the
4 producer that his performance might be affected a little
5 bit. But it doesn't say anything about possible safety
6 concerns or the fact that there might be some additional
7 vitamin or supplementation necessary if you do choose to use
8 some of these byproducts in your feeds.

9 So we would like to see some additional education
10 to the feeders as well as industry.

11 And, yes. We do think that regulation is
12 necessary. I think that's probably not a surprise to you
13 coming from me, a regulator.

14 But the regulations that we do have now, they do
15 allow for good uniform labeling, product identity. There
16 are some standards for manufacturing process control; there
17 are some standards for contaminant levels. And these only
18 serve to help the people who are using the products and to
19 make a more level playing field for the industry.

20 We do want that regulation to be flexible. And
21 there is a need for the local agencies to have some of the
22 regulatory authority and flexibility to deal with some of
23 these local issues. The regulation does need to be science-

1 based.

2 What does the future hold? As several of the
3 other speakers have already said, there's been a huge amount
4 of attention to the area of animal feeds in the news. You
5 see it in the newspapers, people's Web sites; lots of
6 attention to animal feed safety. A lot of it is driven by
7 the BSE issue, the more recent dioxin issues.

8 And there is a huge amount of international trade
9 involved, which means that something that the Europeans want
10 typically is something, then, people in America start to try
11 and achieve. So you have that international trade aspect
12 also involved.

13 Recently there was a new Codex task force, a task
14 force on animal feeding. AAFCO has made a big step, and we
15 are participating in that task force. And they're looking
16 at trying to establish some worldwide standards for
17 livestock feeding.

18 Some of these possible standards might include
19 on-farm inspections, additional restrictions on ingredients
20 that are usable.

21 And speaking on behalf of AAFCO, we're very
22 interested in getting feedback from the groups represented
23 here in terms of what your thoughts are on some of these

1 issues.

2 In conclusion, contamination is a huge topic. We
3 could talk about contamination all week and barely scratch
4 the surface.

5 I hope the presentation I have given today has
6 identified some areas of research that we as the regulatory
7 community think would be helpful, some areas of education
8 that we see there needs to be some more emphasis placed on,
9 and also some regulatory issues that we feel are important,
10 as well.

11 And I also hope that I've provided a little bit
12 of information on AAFCO for those of you who aren't familiar
13 with our group. Thank you.

14 (Applause.)

15 DR. STERN: Thank you, again. Do you want to
16 hear the introduction?

17 In addition to the individuals listed on the
18 screen, I do want to acknowledge that the National Chicken
19 Council, individuals, various individual companies were
20 involved, as well as the people who are listed here were
21 primarily involved in much of the work that I'm presenting
22 today.

23 I also think that the Food Safety Inspection

1 Service has worked cooperatively with the Agriculture
2 Research Service to gather some of the data. So, I thank
3 you.

4 Okay. As said already today, the Year 1 was a
5 terrific success story on the part of the industry in
6 reducing the presence of salmonella in the broiler
7 carcasses. And you know, I think we don't want to
8 shortchange that.

9 Before, we had in excess of 20 percent of our
10 carcasses positive, and really the industry worked very hard
11 to reduce that level substantially.

12 So I think the industry should be applauded. And
13 I hope Caroline appreciates all the hard work that the
14 industry has done.

15 All right. Now, controlling pathogens in poultry
16 products reduces human health hazards, but it does not
17 enhance poultry production.

18 Basically, as we've heard already, the industry
19 has to make money. And just because the chicken does or
20 does not have salmonella or campylobacter does not change
21 their bottom lines.

22 Consumers do want safer food, but the industry
23 really was stopped short, because the only effective

1 intervention that was available to them was the use of
2 disinfectants during the processing of the birds.

3 So, indeed, we have to just recognize that our
4 consumers and really even in international trades, places
5 such as China, as Japan, and Great Britain will not allow
6 disinfected poultry to be shipped to their countries. And
7 if we want to continue expanding our international trade, we
8 will have to deal with these.

9 I don't believe that disinfection is a long-term
10 solution, so we do need to create these pathogen control
11 points during production.

12 And so the question is, how are we going to get
13 there? This is a pinata, and the kid is aiming, blinded, at
14 the target. We all want to get there, but we best take off
15 our blindfolds. And that's the goal.

16 So what we want to do is to identify the
17 representative poultry operations, and we have done that in
18 this country. We want to determine where contamination
19 comes from during the production all the way through to the
20 consumer and then gather information without the constraint
21 of adverse litigation.

22 And this I believe is a scale of justice. So we
23 don't want to have to deal with justice in this particular

1 case. I think it's fair to give us a chance to identify
2 where the problems come from rather than just say we've got
3 to fix it.

4 Yes. We've got to fix it, but it does take time,
5 and we don't need lawyers to tell us that we're not there
6 yet. We're not there yet.

7 All right. What have we been doing within the
8 United States? And the question is, how does government and
9 industry work together?

10 And part of our responsibility in agricultural
11 research is to come up with ideas that perhaps do
12 effectively reduce the pathogens.

13 So what we did in the poultry industry was to
14 work together very closely with the companies around the
15 United States.

16 And we just created this particular epidemiologic
17 study to look at 32 different flocks around the country from
18 two farms per location, a high and low production facility,
19 and these were sampled through all the four seasons of the
20 year, to give us 32 flocks.

21 And so I know that's not representative of the
22 entire industry, but it took an enormous amount of work to
23 get that done.

1 But what kind of things did we learn? Well, we
2 looked at each of these items here on the board insofar as
3 production, just about everything that you can imagine. And
4 we sampled approximately 350 samples per flock in post-
5 production, transport crates, all the way through to carcass
6 rinses, which really represents the consumer exposure.

7 So we went through this in great detail. And it
8 was quite an endeavor, but I'm pleased that we learned a
9 fair amount out of that particular study.

10 What we learned in part was that some of the
11 sources of salmonella in operations can come all the way
12 from the breeder stock through to the broiler and on to the
13 processed carcasses. Other strains came from a variety of
14 other environmental sources.

15 And these data really enabled us to come up with
16 a large-scale proposal for on-farm intervention. We're not
17 there yet. But indeed now we think that it is plausible to
18 go forward and begin controlling salmonella in production,
19 or at least making a dent in this particular arena.

20 Shifting a little bit, I want to tell you a
21 little bit about campylobacter, because 20 years ago nobody
22 could pronounce it, and now everybody can pronounce it. But
23 let me just briefly go through.

1 The organism distinguishes itself from salmonella
2 in that it's a sporadic outbreak transmission primarily.

3 I will say that raw milk certainly has been the
4 most frequent vehicle for outbreaks of campylobacter. But
5 there are a number of very large outbreaks documented being
6 waterborne. And I will say that approximately 30 percent of
7 transmission to humans does come from pets. So again we
8 have some complications.

9 So how do we go about tracking campylobacters?
10 Well, there actually are a number of different ways of
11 tracking campylobacter, and each one is appropriate for
12 their own situation, but my laboratory has come up with a
13 particular method that's involving a gene sequencing. And
14 just a very brief description:

15 We discovered on the flagellan genome if the Y
16 axis is variation in campylobacter strains, we have a
17 terrific amount of variation in the short variable region,
18 the SVR, that is flanked by highly conserved regions.

19 So if we take each of these nucleotide sequences,
20 we can compare one campylobacter to the next much in the
21 same way as you compare people around the room, with hair,
22 without hair, height, you know, any number of comparisons.

23 And this gives us a fairly inexpensive, fairly

1 rapid means of comparing one campylobacter with the next so
2 that we know if we're tracking one through a system.

3 So using this system, we conduct our polymerase
4 chain reaction, run it through a DNA sequencer, and analyze
5 the results.

6 And of course, A and C are very closely related;
7 D is just several base pair differences and likely to come
8 from the same sources; but B is very different. So I'm just
9 showing this as an example as we look at one example of our
10 U.S. epidemiology study for campylobacter.

11 Used to be that you if you would get 100 isolates
12 around the pie-shaped chart, you would have such
13 information. And you wouldn't be surprised to have
14 campylobacter in fecal droppings, in carcass rinses, on
15 crates; all of these are possible.

16 But the question that would be unanswered is,
17 what role did this wild bird feces have on the contamination
18 of the carcasses?

19 And so to answer that question, we used DNA
20 sequencing to obtain these data.

21 And what you can tell in this particular flock is
22 that the bird droppings were the same as the wild swabs, as
23 the mouse intestines, as the boot swabs, as we found on the

1 carcasses and so forth. And these were all really very
2 closely, maybe one base pair different from one another. So
3 we would conclude they were all the same.

4 However, when we got out to 1-1/2 percent
5 difference and 2 percent difference, that's enough to
6 suggest strongly that they likely have a different point
7 origin.

8 And so it gives us the ability to see where the
9 campylobacters are coming from.

10 Of course, the other element of this is, if we
11 only found that the mouse intestinal dropping was
12 positive -- or the mouse intestine was positive after the
13 birds began excreting, it would tell us that the birds gave
14 it to the mouse. Right? So temporal relations are
15 important.

16 So, you wonder, Why Iceland? Right? Why is that
17 they produce 100 percent of their poultry that they consume;
18 we have a bead on the breeder eggs, all originating from
19 Sweden; and many similarities exist between the countries.

20 But I found it very interesting that they would
21 have rates of even 158 per 100,000 persons while we had
22 rates of only 20 per 100,000 in the United States, although
23 they consumed only one-fourth the poultry.

1 And so this enabled us to have a prospective
2 study on the flow of campylobacter to humans.

3 So what we did was to gather three months of
4 poultry isolates, as well as we excluded all human isolates
5 that were in that country from people who were on foreign
6 travel so that we knew that it was not obtained from foreign
7 travel.

8 And then we sequenced them and compared the
9 clones of the poultry isolates with the human isolates.

10 And what did we find? The different colors
11 indicate what we found. The yellow match with the blue
12 isolate at the very top, and that was a distinctive clone,
13 as did this large group in between. These are all a
14 particular clone. But again we had isolates from poultry
15 and the same clones really found in humans.

16 Another flock of birds were found to be identical
17 with the human strains. And then, we had a number that were
18 not associated with poultry isolations.

19 So really Iceland allows us to have a country
20 that's 1/1,000 the United States that enables us to have a
21 very detailed epidemiologic study that we could never do in
22 the States.

23 So, then, how do we wind up controlling

1 campylobacter? Well, we would like to see that the temporal
2 relationship between isolates from the environment to the
3 excretion of the pathogen in chickens.

4 We would like to determine the levels of
5 isolates, because certainly we want to address sources that
6 have higher levels of campylobacter or more consistent
7 sources of campylobacter. And we would like to create
8 interventions.

9 What I have here is something really quite
10 remarkable, and that is, in Iceland, we have identified the
11 flow of campylobacter in the poultry production of Iceland.

12 And you could draw another box up here where the
13 eggs come from Sweden. We know the egg producers in Sweden.

14 And then, we have another box down here which is
15 the human incidence of campylobacter.

16 So we can trace campylobacter very carefully in
17 Iceland. And at every level, we'll be able to isolate
18 campylobacter and determine clonality, which is really an
19 exciting opportunity such that we will take this
20 information, whatever we learn, and see whether it holds for
21 the United States.

22 And of course, if we were to find interventions
23 that apply and effectively reduce campylobacter in the

1 humans, we would say this is a pretty good model for us to
2 use.

3 All right. I think we found a pretty interesting
4 observation on the transmission of campylobacter from the
5 breeders to broilers.

6 In the past, because we couldn't isolate
7 campylobacter from hatching debris, we wound up concluding
8 that campylobacter never came from the breeders.

9 So what we did was to obtain droppings both on
10 the breeder flocks as well as in the broiler flocks, and
11 then we went about our DNA sequencing as well as ribotyping.

12 So in this study we used two. And actually, we also did
13 pulse-field gel electrophoresis and obtained the following
14 types of data:

15 In our ribotyping analysis, in Arkansas the
16 breeders had campylobacter with exactly the same pattern as
17 did the broilers, and those flocks were 20 miles apart.

18 Again, the breeders manifested -- here we had a
19 breeder pattern for ribotyping that was exactly the same as
20 the broilers.

21 And we had a third isolate in this breeder that
22 was precisely the same as the broilers.

23 We analyzed all these again by sequencing, and we

1 found the relationship that -- oh, this -- you can't see the
2 relationship. That's curious. But anyway, the breeders
3 again were very closely matched or identical with the
4 broilers in spite of the breeders and broilers being 20
5 miles apart.

6 This one shows it a little better. And of course
7 these breeder isolates are precisely the same as the broiler
8 isolate.

9 All right. So we believe that campylobacter can
10 be transmitted from breeders to broilers. We don't know how
11 important that is yet, although in our national study in the
12 States, we did not find environmental contamination before
13 we found the birds excreting. So we think we've come onto
14 an important potential source, and we'd like to follow that
15 through.

16 The last topic I want to talk about is
17 competitive exclusion.

18 This is a train in Tokyo. This guy is
19 salmonella, these people are the competitive exclusion, and
20 this train is the intestinal tract.

21 I want you to remember that by nature birds are
22 coprophagic, and they used to live in nests. And what does
23 that mean? That means the little chicks used to eat mama's

1 droppings in the nest. We now remove those eggs from the
2 hen, and we hatch those birds out in large hatcheries.

3 So what we intend on doing with competitive
4 exclusion is to provide normal flora from healthy mature
5 donor birds, and we then subculture that.

6 And this was patented by ARS, originally patented
7 as mucosal competitive exclusion flora. Continental Grain
8 licensed this as mucosal starter culture. And this is a
9 diverse natural microflora from the adult birds.

10 Although it was originally created for
11 campylobacter, it really does work better against
12 salmonella.

13 We have a number of commercial field trials that
14 we have already run in Puerto Rico, Georgia, Arkansas,
15 Alabama, Brazil, and Japan. And each of those have
16 demonstrated efficacy in controlling salmonella.

17 So salmonella was reduced both on the farm and,
18 happily, all the way through to the processed carcass. And
19 that is something important.

20 So to conclude the talk, really microbiological
21 safety does depend on the poultry industry. I don't think
22 we can create illusions.

23 We need to have cooperation with the industry and

1 Agricultural Research, and this has been mutually
2 beneficial.

3 Again I want to applaud industry for subjecting
4 themselves to self-evaluation so that risk factors can be
5 identified and suggest intervention strategies that will
6 work, especially for salmonella control.

7 Campylobacter can come through the egg to seed
8 the broiler flocks.

9 And international cooperation seems to be
10 important here in identifying risk factors for
11 campylobacter.

12 And I think that salmonella can be reduced, in
13 any case, by measures of competitive exclusion.

14 So I thank you for your attention. And we'll
15 take your leave.

16 (Applause.)

17 DR. GILLESPIE: Thank you very much. Our next
18 speaker is Dr. William Laegreid.

19 Dr. Laegreid obtained his veterinary and Ph.D.
20 degrees from Washington State University, and he is
21 currently research leader of the Animal Health Research Unit
22 at the USDA ARS U.S. Meat Animal Research Center in Clay
23 Center, Nebraska.

1 His research interests include pathogenesis of
2 viral and bacterial infections and hosts to infection, as
3 well as transmission agents within and between livestock
4 populations.

5 He's going to discuss with us today a very
6 important topic, pathogen detection and sampling, which I
7 think is a very crucial area.

8 DR. LAEGREID: Thanks, Dr. Gillespie. If we can
9 hold on for just a second here, I'll be up and running.

10 (Pause.)

11 DR. LAEGREID: When I was asked to give this
12 talk, I had a bit of a pause, because pathogen detection is
13 a huge problem.

14 There are a number of ways to detect pathogens.
15 There's, you know, a huge number of diagnostic platforms out
16 there right now. There's a whole bunch of issues associated
17 with each one, what targets, what approaches to use to
18 detect a given pathogen in a given sample.

19 And when I started to put that together it was
20 very clear that that was more than probably anyone wanted to
21 see even before I knew it was going to be 4:30, five o'clock
22 in the afternoon.

23 So I decided to take and look at one issue that

1 is really important in terms of all diagnostic tests, and
2 that's how we evaluate them and how we know whether they're
3 actually telling us the information that we think they're
4 telling us.

5 Now, underlying the entire field of preharvest
6 food safety is this hypothesis, and that is that the
7 prevalence of these bacteria on carcasses or in product is
8 somehow related to the prevalence of infection in the live
9 animal.

10 Now, that seems very intuitive, and in some ways
11 it is. But in fact, there was damn little data for it in
12 terms of cattle up until recently, when we've shown that
13 there is in fact -- at least for 0157:H7, and we would
14 assume for other fecal bacteria -- a very good correlation
15 between prevalence in the live animal and carcass
16 contamination at slaughter.

17 Again, that's intuitive, but it's also something
18 we knew before. That's really the basis for our original
19 food inspection systems in this country.

20 Historically we knew that sick animals probably
21 had things that could be transmitted to people. So if we
22 saw enlarged lymph nodes or we knew an animal was sick when
23 it walked in the door, those animals were condemned or

1 routed some other way.

2 And that was based on the fact that a
3 contaminated animal was likely to -- or an infected animal
4 was likely to contaminate product and thus cause a human
5 health problem.

6 Recently, though, we're dealing with agents that
7 don't cause disease in livestock in most cases. Most
8 salmonella cases, certainly all enterhemorrhagic E. coli
9 cases in cattle, are subclinical. There's no disease.
10 There's nothing to see. Those animals are perfectly
11 healthy.

12 And we've looked at a lot of parameters to try
13 and show that there was some disease aspect to, for example,
14 O157:H7 infection in cattle, and in fact there is nothing.
15 There's nothing to see.

16 So we're dealing, then, strictly with a
17 laboratory approach to diagnosis. There's no other way to
18 know if an animal is infected other than to do some sort of
19 laboratory test.

20 Now, we are actually talking here about
21 diagnosis. And in a live animal it's a little different
22 than swabbing a carcass or looking at some other
23 environmental contamination. We're actually diagnosing

1 whether an animal is infected or not infected.

2 And diagnosis is not just the test result. The
3 test result is part of what goes into making a diagnosis.
4 But it really has to be an interpretation of all the
5 available data to give us a probability of whether an animal
6 is infected or not infected.

7 And like any interpretation, there is an error
8 rate associated with it. That's partly of the function of
9 the test, partly a function of the people doing the
10 interpretation.

11 Now, those of you that are Star Trek fans will
12 recognize this right away. But this is the ideal. This is
13 what we're all shooting for, is the tricorder, the little
14 thing that they wave over the patients and it automatically
15 diagnoses whatever strange virus they've gotten on Planet X.

16 It's fast, it's noninvasive, it's portable. This
17 is what we're looking for. And nobody is even close,
18 despite what some of the salesmen will tell you.

19 All of the tests we have have some error rate
20 associated with them. And we have to have some criteria for
21 evaluating whether a diagnostic test is likely to give us
22 the right answer or not.

23 We use a series of measures to evaluate

1 diagnostic tests. Sensitivity and specificity are commonly
2 used, and these are just the probability that a test will
3 give us the correct answer in either an infected or a
4 noninfected animal.

5 Sounds very simple. It is mathematically quite
6 simple. But the interpretation of this is very difficult,
7 because in order to derive sensitivity and specificity in
8 most cases, you have to already know whether the animal is
9 infected or not.

10 We do that in the cases of cancer and some other
11 a little bit more readily diagnosed diseases on the basis of
12 some gold standard test.

13 If you're developing a test for a particular form
14 of cancer, you'll have a biopsy; you can look at it under a
15 microscope; you can say, yes, that's an adenocarcinoma, and
16 yes, it correlates with this serum test or whatever other
17 diagnostic test you're trying to evaluate.

18 It's fairly straightforward to classify
19 individuals into diseased or not diseased or infected or not
20 infected.

21 For infectious diseases in general, there are no
22 gold standard tests. So it makes it very, very difficult to
23 evaluate diagnostic tests, and this has led to a lot of

1 confusion in the literature and a lot of confusion out in
2 the research community in general.

3 For tests where there is no gold standard, all
4 you can really generate is a relative sensitivity and
5 specificity. You can compare one test to another and say
6 it's either better or worse, and that's about as good as you
7 can get with them.

8 And when you do that, it's very, very important
9 that the populations that are being tested, the samples that
10 are being tested, and the individuals doing the testing are
11 as equivalent as possible. Otherwise the comparisons are
12 completely invalid.

13 Now, let me just give you a quick example of how
14 this has worked for E. coli 0157:H7. This is a comparison
15 of two tests from the literature.

16 All of the data that I'll show you this afternoon
17 will be based on paired fecal samples. Those will be
18 samples from an individual cow taken, split into two, and
19 tested by -- or handled independently. So they are paired
20 samples on an individual animal at a given time.

21 And what you find here is that this Method A gave
22 us four out 50 positives, for an 8 percent prevalence. And
23 four of those agreed with Method B. Method B, on the other

1 hand, gave us 23 out of 50 positives, for 46 percent
2 prevalence.

3 Now, that's a pretty straightforward example.
4 Clearly Method B is detecting more positives.

5 Now, we can't say that it's detecting all the
6 positives. We can't say for certain based on this data --
7 there's other data that does suggest this. But we can't say
8 based on this that some of these positives that Method B
9 detects that Method A misses are not false positives.

10 I can tell you based on other data that they're
11 not false positives, but from this simple analysis, you
12 can't say that.

13 So we're seeing here an almost 83 percent
14 reduction in apparent prevalence based strictly on culture
15 methodology. Now, that's a huge difference.

16 And you don't have to have been on the Titanic to
17 know that, if you don't see a big part of the iceberg,
18 you're going to be in big trouble.

19 Low sensitivity diagnostic tests, ones that
20 detect only one out of five positives, are really only
21 seeing a very small part of the overall problem.

22 Higher sensitivity tests will see more of the
23 problem, but we don't know that we're seeing the entire

1 problem.

2 Now, culture methods are part of the issue.
3 Culture methodologies are a part of a diagnostic test. But
4 diagnostic tests include more than just the culture
5 methodologies or other testing methodologies.

6 There are sampling issues associated with
7 diagnostic testing. And in the case of culture, there are
8 isolate characterization issues that go into determining
9 whether a test is accurate or not.

10 Now, the actual specificity and sensitivity of
11 any diagnostic test really needs to be evaluated on this
12 whole process, not just on that culture methodology or other
13 direct diagnostic test.

14 I'm going to give you a couple of examples of
15 this. Again, paired fecal samples from the same animals.
16 And in this case, we took a rectal swab from the animal --
17 this is a very common sampling methodology -- and
18 immediately afterwards went in with a grab sample of ten
19 grams of feces, so paired samples off of each animal.

20 And you can see here that, with a rectal swab, we
21 got about 10, 11 percent of those individual positives.
22 With ten grams of feces, we got 32 percent positive. Again,
23 you know, a three to one ratio of positives based simply on

1 sample size.

2 These were cultured identically. They were
3 evaluated by the same individuals in a blinded fashion. And
4 a very significant difference in apparent prevalence of E.
5 coli 0157 in these animals.

6 Sample handling is another issue. If you culture
7 E. coli 0157 fresh versus samples that are refrigerated
8 overnight, again we see from fresh species --

9 In this case identical sample sizes, ten grams in
10 this case, identical culture methodologies, you see a
11 difference of in this case almost a 12 percent prevalence
12 versus a 5 percent prevalence, and a 50 to 60 percent
13 difference in apparent prevalence.

14 Now, what does all this mean? Well -- and this
15 is a very simple analysis, and there are assumptions in here
16 that I'm sure certain people would take exception to, and I
17 don't want to be held to this as an absolute analysis, but I
18 think it illustrates the point.

19 If we look at the reduction due to sample size
20 and the reduction due to refrigeration and the reduction due
21 to culture method sensitivity and start out with an
22 assumption of a true prevalence, the actual number of
23 infected animals in the herd, of 35 percent, if you factor

1 in all of these potential errors in a multiplicative
2 fashion, you get an apparent prevalence of about 1 percent.

3 And I just did this the other day, this analysis.
4 We've had the data for quite some time. I had never put it
5 all together like this.

6 But in fact, this is about the difference in
7 apparent prevalence that we see in the literature between
8 some of the newer culture methodologies and some of the
9 historical data in the literature.

10 So what we see here is, you know, a 97-1/2
11 percent reduction in apparent prevalence relative to true
12 prevalence. That's a huge difference.

13 Well, does that make any difference? I mean, who
14 cares? Right?

15 Yes. The absolute number may be way off, but
16 maybe the trend is right, or maybe we're just seeing those
17 animals that are shedding the most E. coli, and so that's
18 probably okay. And those are the ones we're interested in,
19 anyway.

20 I've heard all of those arguments. And in some
21 cases, those may be valid.

22 But for example, someone this morning was talking
23 about sorting animals at slaughter and slaughtering the

1 clean ones first and slaughtering the ones that were
2 shedding a foodborne pathogen later on in the process.
3 That's a variation of this sort of test and cull, test and
4 treat, quarantine approach to disease control.

5 Well, if you're only accurate detecting one out
6 of ten truly infected animals, this isn't going to have any
7 effect on public health.

8 In the case of evaluation of control measures,
9 relative rates may be okay. I mean, whether it's 4 percent
10 or 40 percent, if it goes down by a half, maybe that's okay.

11 That assumes that these tests are going to behave the same
12 at various prevalences across the board. But that may be
13 all right.

14 However, when we're talking about things like
15 epidemiologic surveillance, and when we're talking about
16 control measures in the case where we start with 4 percent,
17 and maybe we get a 4 percent reduction, it looks like we've
18 eradicated the agent, and in fact there may still be an
19 awful lot present in the herd.

20 In the case of epidemiologic surveillance, the
21 absolute number of apparently infected animals may be
22 different, but we also may be misclassifying groups of
23 animals, slaughter lots, herds of animals. And I'd like to

1 just show you a quick example of that.

2 If we take an example of a herd of 250 animals,
3 again with a true prevalence, 35 percent of these animals
4 are truly infected with the agent.

5 If we look at the number of samples required to
6 accurately classify that herd as being infected or not
7 infected, with Method A we would have to test 195 of those
8 animals to have a 95 percent chance of accurately
9 classifying that herd as infected.

10 If we test 100 animals, we're probably not going
11 to accurately classify many herds.

12 With Test B, ten animals will accurately classify
13 that herd.

14 So the differences between these tests are more
15 than academic interest.

16 One of the things that we still hear is that
17 there are very few herds actually infected with E. coli
18 0157:H7. That's not true. We actually have trouble finding
19 a herd that's not infected.

20 And I think that a lot of it is based on these
21 sorts of sensitivity differences in diagnostic testing.

22 And a good example of this was provided to us by
23 Rod Moxley [phonetic] at University of Nebraska.

1 He had been using a test that a group up at the
2 University of Idaho had developed. It's a very laborious
3 test, but it should work reasonably well on paper.

4 But when you go out to field samples, we found
5 that it doesn't work very well. And Rodney found pretty
6 much the same thing.

7 In the summer of 1998, he tested almost 1,000
8 cattle in Nebraska feedlots; he found one positive.

9 Now, I would say, at the same time we were
10 testing in Nebraska feedlots, and we were finding about
11 somewhere in the 25 to 40 percent prevalence range.

12 He switched to the method that we were using the
13 next year. He tested a few more animals, but he found a lot
14 more positives.

15 Now, the difference between a .1 percent
16 prevalence and a 23 percent prevalence is fairly significant
17 in terms of estimating the magnitude of your disease control
18 problem.

19 Now, I've talked about sample handling, and I've
20 talked about culture. I'm not going to talk about the
21 characterization of those isolates. But you get the general
22 idea.

23 The same sorts of issues are in play in the

1 characterization step. The serotyping, the testing for the
2 presence of virulence genes and those sorts of things. If
3 those are not done correctly, you're going to misclassify a
4 lot of individual animals and misclassify a lot of herds.

5 And this is also true regardless of whether
6 you're talking about culture methodology, you're talking
7 about rapid tests of this is a very simple antibody based
8 test, whether you're talking about, someone mentioned gene
9 chips for diagnosis today, PCR, various other diagnostic
10 methodologies. These same issues apply.

11 If you're not handling the samples properly,
12 you're not taking an adequate sample, you're going to have
13 problems with sensitivity of your overall diagnostic test.

14 So in conclusion I just want to leave you with
15 two points.

16 The first is that -- and I am kind of hammering
17 this, but it is something that gets ignored often, and that
18 is that diagnostic tests include the entire process from
19 sampling to interpretation. And anywhere along the line you
20 can have mistakes that will result in misclassifications.

21 And insensitive tests will result in
22 misclassification both of individual animals and of groups
23 of animals. And that's quite important.

1 So since these diagnostic tests are used to make
2 decisions, either disease control, regulatory, or other
3 decisions that are going to affect the livelihood of
4 producers and affect public health, I would feel that these
5 tests really need to be rigorously evaluated, need to be
6 evaluated on samples from naturally infected animals.

7 And they need to be evaluated in a pair-wise
8 fashion and compared to tests that are in use in the
9 diagnostic community.

10 And with that, I'll take any questions.

11 (Applause.)

12 DR. GILLESPIE: Our next speaker is Dr. Steve
13 Lehotay. And Steven is lead scientist in the Food Safety
14 Research Unit at the Eastern Regional Research Center in the
15 USDA Agricultural Research Service in Wyndmoor,
16 Pennsylvania.

17 He's going to speak to us today about chemical
18 residue. Steven.

19 DR. LEHOTAY: This is my first Power Point
20 presentation, and I hope it goes smoothly. I prefer slides
21 for a number of reasons, but didn't have time to prepare
22 them. So this has the advantage of being something you can
23 prepare out in the audience when others are speaking.

1 I'm at the Agricultural Research Service, Eastern
2 Regional Research Center in Wyndmoor, Pennsylvania. I've
3 been lead scientist there since April.

4 Before that I had worked in pesticide residues in
5 Beltsville Agricultural Research Center for seven years.

6 This talk I'll try to go through in a reasonable
7 time frame considering the situation. And we'll see what I
8 skip on this.

9 One of these that I'll skip is this one. And I
10 just wanted to give two perspectives about chemical
11 residues.

12 I'm really surprised and glad that there has been
13 so much discussion about chemical residues. I expected that
14 microbiology would rule the day, as it has for the last
15 several years in these situations. Research funding has
16 been decreasing for chemical residue work. So it looks like
17 there is starting to become a comeback.

18 But there are two perspectives. Perhaps you've
19 had time to read it. And the other perspective perhaps you
20 could say that we should not use synthetic chemical
21 residues.

22 But the middle ground is what the current
23 situation is in regulatory agencies.

1 And we must keep the benefits in mind. If we can
2 recognize problems with chemical residues in food and the
3 environment -- which is often a lacking issue or point of
4 discussion or point of thought in regulatory environment --
5 is that if we have the means to measure, monitor, and
6 control residues, then we should do so, and within a
7 reasonable cost.

8 And that's what I hope my research does, is to
9 address this issue within a reasonable cost. So I hope to
10 develop methods that are low cost that can be used to solve
11 residue issues without bankrupting people or within the
12 limitations and resources.

13 So with that, there's several needs for chemical
14 residue methods research, method development. And that is
15 mainly for compliance, enforcement, monitoring.

16 Dr. Masters talked about this earlier in the
17 National Residue Program of FSIS. And that is one of our
18 main customers in the Agriculture Research Service, and we
19 try to meet their needs.

20 The international trade issues is a very
21 important issue for chemical residue methods, the trade
22 barriers that are created in relation to chemical residues.

23 Data for risk assessment, reregistration,

1 particularly for pesticides. Since the implementation of
2 the Food Quality Protection Act, the EPA is using the
3 results from methods that are used in states widely for
4 reregistration.

5 And these methods that are used by the EPA have
6 done a lot of good to save registration of many organic
7 phosphate pesticides.

8 Verification of organic food labeling, or
9 conversely, marketing of residue-free products. There are
10 programs that show that, if you can demonstrate that your
11 product is residue-free, it's just as good in the mind of
12 the public as organic food.

13 Antimicrobial resistance, which has been
14 discussed a widely in today's meetings.

15 Hormone and endocrine disrupting effects, which
16 has not really addressed at this meeting. But the risk
17 assessment of chemical residues is an entirely different
18 process than something that's an acute toxicity or acute
19 effect such as pathogens.

20 Chemical residues have unknown long-term effects.
21 And it's a much different problem. And you need data for
22 risk assessment. And that is the key component, is having
23 good solid data. Garbage in equals garbage out.

1 Protection from deliberate adulteration. This is
2 another way of saying terrorism. This has become an issue.

3 And chemical residue monitoring might be able to help
4 address those.

5 And monitoring in HACCP plans, you are more
6 familiar with this than I. And whether or not HACCP plans
7 need chemical residue monitoring is something that I'd be
8 very interested to know about. And I'm glad I'm here.

9 And if you would like to discuss such needs with
10 me, I would like to listen.

11 Current methods that are used by regulatory
12 agencies and industry and contract laboratories, academia,
13 around the world often are out of date. Many of them are
14 20, 30 years old and still being commonly used, using
15 technology that -- well, there's certainly better technology
16 now.

17 They're time consuming, often laborious,
18 inefficient, and single analyzing, many of the methods
19 developed by registrants, for example. They only are for
20 one pesticide or drug in one commodity, which is what they
21 were registered for. That is not useful for multi-residue
22 regulatory monitoring.

23 So the desire for new techniques, of course, you

1 want everything. You want your cake and eat it, too.
2 Rapid, automated, inexpensive, uncomplicated, waste-free,
3 sensitive, portable, rugged, and universally selective.

4 The chances of something that can meet all of
5 these needs is basically nil. So an old engineering maxim
6 is, Select any five or seven of these desired traits, and
7 you just have to live within the limitations.

8 The Agriculture Research Service is divided into
9 these areas. And in the past, when chemical residues, in
10 the early 1990s, was a big issue, there were six locations
11 with many scientists working on very different problems.

12 Then we went through a period, in the last six,
13 seven years, where residue issues were not part of the food
14 safety initiative. I personally applied for grants --
15 couldn't even apply for grants because chemical residues
16 were not part of food safety.

17 FSIS, for example, went through seven years where
18 they did not submit any residue requests for their research
19 program.

20 This year we had 33 requests, so we're grateful
21 for that. ARS had to send them back and narrow it down to
22 15, of which I think three or four were picked up by ARS
23 locations that are currently doing residue research. This

1 would be Fargo, Peoria, and Wyndmoor.

2 The Wyndmoor area, which I am the lead scientist
3 on the program using advanced techniques for veterinary drug
4 and pesticide detection method development.

5 In Fargo, North Dakota, Richard Larson is head of
6 the group working with dioxins, contaminants.

7 And Connecticut, for veterinary drugs, David
8 Smith is doing that one.

9 And Jerry King is exploring supercritical fluid
10 extraction in Peoria concerning veterinary drugs and
11 pesticides.

12 But in the meantime, while the ARS had been
13 consolidating and mainly focusing on expanding in the
14 direction of microbial pathogen research to address the
15 immediate needs, which certainly were worthwhile -- and I'm
16 not in any way saying that chemical residues rate as highly
17 as pathogens in terms of food safety, at least not in the
18 acute, short term.

19 But the Food and Drug Administration and others
20 are doing chemical residue research, of course. And I
21 wanted to mention that. Industry, academia, and states,
22 also.

23 So in our group at the Eastern Regional Research

1 Center, our goal is to develop better approaches using
2 advanced technologies and techniques for the rapid and
3 reliable analysis of chemical residues in food. And this
4 overall goal, the approach that's used will be lab-based and
5 also field-based.

6 So we're doing -- two scientists will be doing
7 veterinary drugs analysis using lab-based instrumentation.
8 And I'll be the pesticide residue chemist, and that's for
9 both fruits, vegetables, and animal products.

10 In developing methods and defining needs, it's
11 critical to assess these purposes, to define the purpose of
12 analysis.

13 And you have to have a balance with the need for
14 the data and the cost of the data and what it is worth. And
15 that is something that has to be very carefully defined
16 before you go into providing the necessary resources and
17 personnel.

18 I currently think there is a misbalance between
19 what the needs are and what requirements they require of
20 analytical methods.

21 There's a number of veterinary drugs and
22 pesticides. It's a very big problem, and it takes a lot of
23 effort and research to assess these problems.

1 We want multi-residue, multi-class techniques and
2 an efficient process that regulatory agencies and others can
3 use. We have a long way to go.

4 How do we assign our priorities? The selection
5 process that we follow -- and that is to get customer
6 feedback from the agencies and industry, a number of USDA
7 agencies, Food Safety Inspection Service as well as APHIS,
8 AMS, and the Grain Inspection, Packers and Stockyards
9 Administration, FGIS, as well as EPA and FDA, as well as
10 other international agencies and industry.

11 We take this feedback, and we look at what the
12 adequacy of current approaches are. And if there really
13 isn't -- if it ain't broke, don't fix it. So if something
14 is working well now and they have what they need, then we
15 won't perform research on that.

16 But we have to look at the technological
17 capabilities of overcoming the problems, and we have to look
18 within our laboratory resources and personnel to say whether
19 or not we can meet these needs.

20 And personally as an ARS scientist, we must
21 assess our own goals, and we try to make an impact as best
22 as possible. And I can assure you that all ARS scientists
23 have this in mind.

1 And goals are rapid methods, of course. If we
2 can increase the percentage of the food supply monitored,
3 then it will better ensure food safety. And that is an
4 overriding goal.

5 And there's a number of projects that we have
6 ongoing. And we've gotten feedback from FSIS, and all of
7 these have needs in terms of -- fluroquinolones in
8 particular have antibiotic resistance concerns.
9 Thioureastats are banned substances, growth-promoting
10 substances. EU is particularly concerned about these in
11 trade practices.

12 Beta agonists is another one of the growth
13 promotants. Anaracopamine has certainly made the news
14 recently that we're including in our mass spectrometry
15 studies. And we have several projects concerning
16 pesticides.

17 Here's an example of the florescence method that
18 we're using for fluroquinolones in chicken. And you can see
19 that from five to 50 parts per billion can be detected in
20 real chicken liver using a microdialysis approach.

21 This is an on-line automated system, little
22 cleanup, and the use of nonhazardous solvents. This is a
23 real sample we incurred.

1 But in the coming years what we're focusing on is
2 mass spectrometry. It took several years for me to get an
3 LCMS instrument that we'll be using for our studies to do
4 multi-residue, multi-class analysis, which is something that
5 has been sorely lacking in the laboratory. It is both
6 confirmatory and quantitative, and it can be done
7 simultaneously.

8 It's able to distinguish trace levels in a
9 complex matrix, which saves on cleanup, which is a major
10 labor saver.

11 And as time goes on, like computers, such
12 techniques as mass spectrometry is increasing in quality
13 while costs are going down. So benefits exceed the costs.

14 Here's an example of something that it took me
15 about two weeks, when we started applying mass spectrometry,
16 to do, that John Pensoveny [phonetic] in our group had been
17 working on for some time using a nitrogen phosphorous
18 detector. You know, we did a derivatization in -- the
19 details don't matter.

20 But here is an example of confirmation of .1
21 parts per million of four thioureas, growth promotants,
22 at 100 nanograms per gram spiked in meat.

23 And over here we have unambiguous confirmation

1 using MSMS techniques. And this meets EU standards for
2 banned substances, which requires four points of
3 identification, and MSMS does that.

4 And I'd just like to point out that the baseline
5 is flat. And if you had seen this using the traditional
6 approach, the nitrogen phosphorous detector, the whole thing
7 would just be graphs, and you would see four peaks that you
8 could not know really what they are.

9 So I'm very keen on this approach and looking
10 forward to doing more work using these techniques.

11 And here's another example of what can be
12 possible with low-pressure gas-chromatography mass
13 spectrometry.

14 The traditional method for these 20 pesticides
15 would take, at the minimum, 20 minutes.

16 This peak out here, which you might not be able
17 to see too well, is Delta-metharine, which is a very late
18 eluding [phonetic] pesticide.

19 And here we have dichlorovos [phonetic], which is
20 the earliest eluding compound, and in between we have a
21 range of all pesticides. And this is a six-minute analysis
22 with very good sensitivity and sample capacity.

23 Another approach that I'm very hopeful for is

1 direct sample introduction for gas-chromatography mass
2 spectrometry, tandem mass spectrometry. And the procedure
3 is simply four steps or five steps.

4 You weigh the sample, and you add some salt if
5 it's moist. You add some acetonitrile and blend it. You
6 centrifuge it if you're in the laboratory. If you're not in
7 the laboratory, you might be able to separate it by another
8 means. Then you add some anhydrous magnesium sulfate to dry
9 it, and you just inject it.

10 No cleanup, no sample preparation, no filtration.

11 It's sensitive, confirmatory, and quantitative. And
12 furthermore, it's a very rugged approach because the
13 nonvolatile residue sample components that would contaminate
14 your system stay in a little microvial.

15 It still has some concerns that you can't have
16 your cake and eat it, too. It's not portable, it's manually
17 run at this moment. And it can be automated. But it's also
18 only for targeted analyzing.

19 Here's a picture of what it entails. You take
20 your sample extract, you put it in this little microvial,
21 put the little microvial into the probe, and you put your
22 probe into your MS. It's a five-minute sample preparation
23 procedure, really, and a ten- to 15-minute analysis for, we

1 can do maybe 40 pesticides.

2 So one of the other problems is, if we build it,
3 will they come? Acceptance criteria, it's a very difficult
4 problem to transfer technology, and that's the end result of
5 our work. It must be transferred.

6 I mentioned supercritical fluid extraction. ARS
7 scientists, there are three of us who spent seven years on
8 supercritical fluid extraction because we thought it was the
9 next coming technology that would revolutionize how sample
10 preparation has been done.

11 Well, in my case I spent seven years on this
12 project, and just this last year AOAC method has been
13 approved -- well, more or less -- it's going to be approved.
14 The statistics were validated.

15 But of course, in that meantime, supercritical
16 fluid extraction technology died for a number of reasons.
17 Good reliable instrumentation was one of them.

18 But each of these has to be met. Capital is also
19 very important.

20 The removal of arbitrary barriers. And I just
21 want to point out that of course there are arbitrary
22 barriers, and we must recognize how -- what is the purpose
23 of such an obstacle that is placed in technology transfer?

1 So that's something I would like to talk about at some point
2 in the future with customers, and I have in the past.

3 And this shows in any new technology there is
4 implementation costs involved. And in theory you will have
5 a savings out at some distance time. And it takes some time
6 to get there. But the status quo is generally rising.

7 So with that, I hope that the work that we're
8 doing at the Eastern Regional Research Center and other
9 places in ARS will have these impacts:

10 Higher lab efficiency; lower costs; increased
11 monitoring rate, which will better ensure food safety;
12 provide statistically valid and accurate results; overcome
13 trade barriers that have been problematic; and improve
14 understanding of endocrine destruction and microbial
15 resistance; and of course, greater consumer confidence.

16 So with that, thank you.

17 (Applause.)

18 DR. GILLESPIE: Our next speaker is Dr. Monty
19 Kerley. And his talk today is on the management of water
20 and manure. Dr. Monty.

21 DR. KERLEY: I'm going to take a page out of Al
22 Pope's book. And when I get back, I'm going to tell my
23 chairman, I had the paper everyone couldn't wait to hear

1 today.

2 (General laughter.)

3 DR. KERLEY: I won't tell him that it was the
4 last paper of the day. I also will take license that if I
5 skip a few slides, I'll assume nobody will protest about
6 that, either.

7 The only thing, in connection to the waste,
8 manure management and water will be, the approach we've
9 taken in our research and laboratory is, if we take the
10 pathogen, whether it's animal related or human related, out
11 of the equation, it's going to be hard for the manure to
12 have that or for it to recontaminate the water.

13 Now, the whole approach we've taken there is, we
14 want to do things that's going to improve intestinal health
15 of the animal.

16 And the way I define intestinal health currently
17 is, we're going to take the bad bacteria out of the
18 equation, and we're also going to promote proper function,
19 if you will, of the mucosal and cirrhosal layer of the
20 intestine. So that's how I define intestinal health.

21 Now, I think in the future what we're going to
22 see is a movement into how the bacteria signal the gut,
23 peptides that may be important in the gut, and then, how

1 that second largest endocrine gland in the body -- i.e., the
2 intestinal tract -- communicates with the body systemically.

3 So, the approach to our work: We start with the
4 substrate. What's important about this is we can, to a
5 large degree, affect the population of bacteria that are
6 present in the colon and throughout the intestine of an
7 animal by the substrate that we give those bacteria to
8 ferment.

9 Whatever substrate is present the bacterial
10 species can set up a unique advantage or niche to ferment
11 that over other species, that bug is going to become a
12 dominant player in the gut.

13 So that's how we make an indigenous bacterial
14 species, or these good guys that are present in the gut,
15 come about and, related to what Norman talked about, some
16 competitive exclusion at work.

17 What do they do? Two things. First and
18 foremost, they make short-chain fatty acids whenever they
19 ferment the fiber. They do this by simply fermenting the
20 carbohydrates to acidic, propionic, and butyric acid.

21 And if you remember some of the biology of the
22 gut, butyric acid is the one we're most concerned about,
23 because that's the preferred fuel for a colonocyte in the

1 gut. So we can make a healthy intestine with that.

2 The other thing the short-chain fatty acids have
3 been attributed to do is to control growth of various
4 pathogenic bacteria in the gut. So besides keeping the gut
5 healthy, we also have some suppressive effect on the bugs we
6 don't want to grow, some advantage, then, to the bugs we do
7 want to grow.

8 The indigenous bacterial species in the gut are
9 also known to produce antimicrobials or bacteria that
10 prevent growth of pathogenic bacteria. If you know about
11 niacin and how it's used in human industry, in large part
12 that's how it works.

13 So both of those things come into play, and we
14 have a positive effect on disease prevention.

15 I also want to show some work that we have done
16 and that's been done by ARS lab that we can also have an
17 effect on foodborne pathogens, as well.

18 Mucosal proliferation differentiation, the thing
19 I want to say here is, the nice thing -- or at least my
20 current take on what fiber does when it's fermented in the
21 gut, we have these short-chain fatty acids produced. What
22 they do is cause not only proliferation of the intestinal
23 tract, but also differentiation as well.

1 The importance there is that's the difference
2 between cancer and normal gut.

3 As we have differentiation at the same time as we
4 have proliferation of the gut, we've seen increased
5 digestibility. Our model we've worked with has been the
6 young pig. We see increased digestibility when we have this
7 more normal functioning intestine. And all that hopefully
8 comes together as improved performance.

9 The way that we have approached this is, yes, we
10 want to get rid of the foodborne pathogens, we want to get
11 rid of odor, some of those sorts of things. But how does
12 the producer get paid back for that? And if we can tie in
13 some performance advantages, then that makes an economic
14 incentive for the producer to do that, and we have the good
15 benefits that come along with it.

16 Okay. The other point I want to make about the
17 short-chain fatty acids. The concentration and ratio of the
18 short-chain fatty acids are dependent on the type of fiber
19 we put into the gut. The reason for that is the type of
20 fiber selects the type of bacteria we're going to have
21 present or dominant in that intestinal tract.

22 So if I want more butyric acid, I need a
23 substrate that's going to give me as much butyric acid as I

1 can get out of that fermentation.

2 Fermentability of the fiber will also affect the
3 point in the gut where the short-chain fatty acids are
4 produced; i.e., if I have a very fermentable fiber, then I
5 can see short-chain fatty acids produced in the terminal --
6 the small intestine, the cecum, and the proximal colon.

7 If I have a moderate fermentation, I can move
8 that back further into the colon of the animal. So I can
9 control that in large part by the type of fiber that I put
10 in the diet.

11 We've used short-chain fructooligosaccharide in
12 the work we've done, and the reason for this is it's rapidly
13 fermented. The second thing it does is, it's uniquely
14 fermented by Bifidobacteria.

15 We wanted to get a Bifidobacteria population
16 established in the gut, because they, like Lactobacillus,
17 have been shown to be inhibitory to growth of several
18 pathogens that can affect both the animal and also have some
19 human foodborne concerns.

20 The short-chain FOS we've used has a glucose of
21 2, 3, or 4 fructose units bound to it. And what's important
22 about that is the Bifidobacteria is unique, and if they have
23 a fructocidase enzyme, it allows these fructose units to be

1 cleaved off of these short chains.

2 The chains are short enough that they're soluble,
3 and it's relatively easy for the bacteria, then, to pull
4 these oligosaccharides intracellularly, where they can
5 hydrolyze them and then ferment them to short-chain fatty
6 acids.

7 Okay. Some of the specifics on what the short-
8 chain fatty acids do on intestinal health: pathogen growth
9 and mucosal development I've already mentioned; they
10 increase intestinal blood flow.

11 Actually, if you look at colonic anastomoses that
12 are done now in hospitals, what they'll actually put those
13 people on oftentimes rather than bowel rest is some liquid
14 type diet that has a fermentable substrate -- i.e., FOS --
15 in it. The reason is the fermentation promotes more rapid
16 healing of the colonic tissue.

17 Stimulate secretory responses. If we have the
18 right type of bug that's attached to the intestine, my
19 interpretation of some of the work is that those bacteria
20 will ferment some of the mucin that's produced and actually
21 sets up the right type of secretory mucin response by the
22 intestinal cell; i.e., intestinal health.

23 Enhances absorption, probably of most concern in

1 young animals and companion animals, certainly in preventing
2 scouring.

3 The presence of short-chain fatty acids in the
4 small intestine will result in increased peristalsis of the
5 small intestine; i.e., there is a recognition there that
6 overgrowth of bacteria is beginning. The gut wants to shove
7 that out of there, because it doesn't want fermentation
8 there in the small intestine.

9 The large intestine or the colon, just the
10 opposite happens, the slowing of peristaltic activity,
11 allowing absorption of these short-chain fatty acids the
12 animal will use for energy.

13 Okay. We looked at several different
14 oligosaccharides that were purported to have bifidogenic
15 properties of the oligosaccharides; i.e., promote growth of
16 the Bifidobacteria.

17 On top of the bench, in culture, we looked at
18 two. One is a short-chain FOS that we were interested in
19 studying. The second, the red-line, which shows wild
20 growth, or exponential growth, occurring later on, was a
21 xylooligosaccharide.

22 And we had interest in those two and how they
23 might promote growth. And we used the mouse as a model in

1 this work.

2 We fed four diets, nutritionally complete diets,
3 but we had either no fiber in the diet, the control diet; we
4 had the short-chain FOS that we've used; gum arabic, which
5 is kind of a standard fiber, a positive fiber control, if
6 you will; and then, the xylooligosaccharide.

7 What I've got in the three columns is the
8 Bifidobacteria population at 10^8 and then the total
9 anaerobic flora that was present in the gut. And then I
10 expressed the percent of the total anaerobic flora as
11 Bifidobacteria.

12 Now, the thing that I think is important about
13 this work is that it shows, depending upon the fiber type --
14 and maybe what happens in the test tube isn't exactly what's
15 going to happen in the gut of the animal. The FOS was the
16 only fiber in the work that we've done where we've seen an
17 increase in Bifidobacteria populations in the gut.

18 Why is this important? There was some work that
19 was done. We looked at two populations of Bifidobacteria,
20 10^8 and 10^7 . And then they set up some mucosal cells in a
21 continuous culture, and they looked at invasion, then, by
22 either pathogenic E. coli or salmonella.

23 And what they found was that the higher

1 concentration of Bifidobacteria got a little over 90 percent
2 prevention of invasion by E. coli in the cells and around 40
3 percent for salmonella.

4 So what happens here is the Bifidobacteria are
5 providing some protection against invasion by these
6 pathogens to mucosal cells.

7 Well, knowing that information existed, we were
8 interested in seeing if we could set an animal model to
9 study that.

10 We took pigs that were about eight days of age,
11 put them on a complete milk replacer -- and so day one would
12 be eight days of age in the pig's life -- fed that for seven
13 days. And at seven days, then, we gave them oral gavage of
14 pathogenic E. coli, and at ten days, we took fecal samples
15 on those pigs and also looked for clinical signs of disease.

16 What we found, by day one, they were similar
17 populations of the Bifidobacteria and total E. coli -- this
18 isn't just pathogenic -- total E. coli.

19 On day 10, the pigs that did not have FOS in the
20 diet, seven of the eight showed clinical signs of disease.
21 And if you look at the pigs compared to those that were fed
22 the FOS in the diet, there was a tenfold higher
23 concentration of Bifidobacteria and about a tenfold lower

1 population of E. coli when FOS was present.

2 We showed essentially the same type of results in
3 a hamster model, studying Clostridium difficile, protection
4 against C. difficile infection whenever the hamsters were
5 fed a diet that had FOS. If you look at the proximal colon
6 and the distal colon data on this slide, we measured --
7 crypt depth and proliferation is the only two I showed.

8 We were interested in these neonatal pigs, same-
9 age pigs, what happened to some of the intestinal morphology
10 if we fed the diet with or without FOS, and again, these
11 were milk replacer diets.

12 What we found was that, in both cases when FOS
13 was in the diet, at the proximal and distal colon, there was
14 an increased crypt depth, increased proliferation zone. I
15 think this falls right in line with the work that's been
16 done looking at other fiber, the effects of other fiber
17 sources on intestinal morphology.

18 The indices we have are, we have a healthier
19 intestine -- i.e., a thicker mucosa -- and, we would think,
20 perhaps a more active or greater digestive capability.

21 The other thing I thought was interesting is some
22 work we did. We looked at small intestine morphology. So
23 if you look, villus height was increased in pigs that had

1 FOS in the diet.

2 And this goes along with other work that's been
3 done with fiber, showing there is a systemic effect
4 throughout the gut whenever fiber is included in the diet
5 and fiber fermentation occurs.

6 Now, we've also seen an increase in nitrogen
7 balance, which makes sense, because we see an increase in
8 growth of the pig whenever it's fed FOS.

9 I thought an interesting concept was what happens
10 to nitrogen digestion. In this experiment, we fed either 0,
11 3/4, 1-1/2 grams of FOS per day or 1-1/2 grams of FOS then
12 recommended a level of carbodox [phonetic]. We looked at
13 digestibility retention of nitrogen.

14 What we found in this work was a significant
15 increase in nitrogen digestibility, and the only way we have
16 at present to explain that is we had an intestinal tract
17 that had greater functional capabilities in this age pig to
18 digest the protein that was presented with it.

19 Now, it's interesting. A lot of the bacteria,
20 the salmonella, clostridium, a lot of the bacterial species
21 that cause disease or foodborne pathogens also have the
22 capability to take the aromatic amino acids and to ferment
23 those to skatole, indole, paracresol, those type of

1 compounds.

2 We had four diets, a factorial arrangement of
3 either the short-chain fatty acid or antibiotic, again using
4 carbodox in this work, and then took fecal samples --
5 doesn't include the urine -- but took fecal samples and
6 submitted those to Mike Williams at North Carolina in the
7 Animal and Poultry Waste Management Center and had a human
8 panel evaluation of those.

9 Why they use pleasantness to describe fecal smell
10 is beyond me, but it's not my area of research.

11 The point that's important about that is the
12 combination of the FOS and the antibiotic gave a
13 pleasantness score of 5.1. 5.0 or lower is a ranking that's
14 nonobjectionable to humans.

15 So the point is, even on the odor front, and
16 taking a microbial link here, we can do much, I think, to
17 have some control on odor in animals.

18 I show this slide because a combination of the
19 FOS and the antibiotic gave us essentially tenfold
20 reductions -- and that should be paracresol, not just
21 cresol -- but gave us essentially tenfold reductions in
22 fecal excretion of these metabolites.

23 What I take away as important here and the

1 possible link is food quality. Skatole is one of the big
2 problems in terms of how humans associate boar taint to pork
3 meat. And my understanding from some of the swine people is
4 that can transfer even to gilts as well.

5 So I have a curiosity here. If we go in, we
6 reduce skatole production in the intestinal tract, the colon
7 primarily, can we then also reduce that concentration in the
8 meat and have some effect on food quality?

9 Early weaned pig growth. This is performance
10 data. We looked at several different levels of FOS and then
11 the combination of FOS and antibiotic.

12 Two things that are important. If you look at
13 the body weight -- and this is weaning pigs at about 17 days
14 of age -- and body weights, then, at around I think four
15 weeks beyond that, what's important is level.

16 I think we can, if we go in with a prebiotic
17 approach to the gut, we can do too much of a good thing. So
18 there's an optimum, at least for the FOS that we've studied.

19 The second thing that I would point out that I
20 think is interesting, if you look at the .4 plus AB, that's
21 FOS plus the carbodox, in the experiments, where we've seen
22 a positive response to antibiotic, we tend to see, or we
23 have seen a positive to the fructooligosaccharide.

1 There's experiments were we don't see a response
2 to antibiotic, and in those we tend not to see a response to
3 the fructooligosaccharide as well.

4 The interesting part is, we essentially have
5 always seen an additive response to both antibiotic and the
6 short-chain fatty -- fructooligosaccharide. The point is,
7 we're having an effect on the bugs, but it probably occurs
8 through two different scenarios.

9 Final work I want to -- being a beef person
10 giving largely a swine study -- Jim Droulliard [phonetic]
11 would know that I have to finish on a beef slide just to
12 feel good about myself.

13 Some work that Jim Russell's lab did at Ithaca,
14 ARS scientists. And what Jim showed, if you look at the
15 acid-resistant E. coli concentration, that whenever the
16 cattle were fed hay, there was a substantial decrease in
17 acid-resistant E. coli, the guys that we really want to get
18 rid of from a foodborne pathogen standpoint.

19 If you look at that work, the whole effect there
20 is primarily -- and I think Jim's interpretation as well --
21 is primarily the consequence that we're increasing pH, and
22 we don't set that bug up, then, to have acid-resistant
23 capabilities.

1 So in conclusion, the first approach that I would
2 really lobby for from the standpoint of trying to have some
3 control or reduce foodborne pathogens as well as animal
4 pathogens is start with the diet.

5 What can we do in that diet to manipulate the gut
6 and the environment of that gut?

7 Secondly is the indigenous microflora population
8 of the digestive system can be manipulated to greatly reduce
9 if not alleviate foodborne pathogen loads in food.

10 And then, the reduction in foodborne pathogens
11 may also have beneficial effects well beyond our current
12 yardstick of just trying to reduce their numbers or
13 alleviate their numbers in the food products; namely, it can
14 be beneficial to animal performance to the producers who are
15 producing those animals and be a driving force for including
16 those in the diet.

17 That's it.

18 (Applause.)

19 DR. GILLESPIE: I'd like to have you join me in
20 thanking all our presenters.

21 (Applause.)

22 DR. RAGAN: Thank you very, Dr. Gillespie. I
23 would just call your attention to the reception in the same

1 area that we had lunch at 6:30, and to say that tomorrow is
2 breakout group day, but we will all gather here at eight
3 o'clock. And we will have information on where to go and
4 who is in charge.

5 Thank you very much, and have a good evening.

6 (Whereupon, the meeting was adjourned at
7 5:45 p.m., to reconvene September 7, 2000, at 8:00 a.m.)

8 //
9 //
10 //
11 //
12 //
13 //

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

REPORTER'S CERTIFICATE

IN RE: National Conference on
Animal Production Food Safety
DATE: September 6, 2000
LOCATION: St. Louis, Missouri

I hereby certify that the proceedings and evidence
are contained fully and accurately on the tapes and notes
reported by me at the hearing in the above case before the
U.S. Department of Agriculture.

Date: 9/27/2000

Phyliss Lund
Official Reporter
Heritage Reporting Corporation
1220 L Street, N.W.
Washington, D.C. 20005