UNITED STATES
DEPARTMENT OF AGRICULTURE

In the Matter of:)
)
NATIONAL ADVISORY COMMITTEE)
ON MEAT AND POULTRY)
INSPECTION MEETING)

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Tuesday,
May 16, 2000

Jefferson Room
Quality Hotel
Court House Plaza
1200 North Court House Road
Arlington, Virginia

The committee meeting in the above-entitled matter was convened, pursuant to Notice, at 8:30 a.m.

PARTICIPANTS:

THOMAS J. BILLY

CATHERINE WOTECKI

COLLETTE SCHULTZE KASTER

CAROL TUCKER FOREMAN

CAROLINE SMITH DEWAAL

ROSEMARY MUCKLOW

JAMES DENTON

MICHAEL GRASSO

KATHLEEN HANIGAN

BILL JAMES

CHERYL HALL

PARTICIPANTS: (Continued)

ALICE JOHNSON

DANIEL LAFONTAINE

CHRISTOPHER CHURCH

RONALD HICKS

DALE BOYLE

LEE JAN

DONNA RICHARDSON

JOANNE BOLTON

MAGDI ABADIR

MARGARET O'K. GLAVIN

DANIEL ENGELJOHN

NANCY DONLEY

CAREN WILCOX

DALE MORSE

GARY WEBER

ROGER BREEZE

JIM LINDSAY

JANE ROBBINS

ROBERT POST

PHILIP DERFLER

PATRICIA STOLFA

JUDITH RIGGINS

AMY RAINES

PARTICIPANTS: (Continued)

SUSAN RIBBONS

KIM RICE

P R O C E E D I N G S

(8:37 a.m.)

MR. BILLY: On behalf of the Department of Agriculture, I'd like to welcome the committee, the Advisory Committee on Meat and Poultry Inspection, as well as all the other attenders from the public to this session of the advisory committee meetings. Welcome to Washington. We arranged this weather for you. The only way we're going to get any work done. Since we often get blamed for the other kind of weather, I thought we would give you this.

This is, once again, a very important and timely meeting. The staff from the Food Safety and Inspection Service will be briefing the committee members and the rest of you on a number of important issues, and as always, we look forward to your recommendations and advice.

In addition, we have asked Dr. Floyd Horn to provide us a briefing on Agricultural Research Service research on food safety, and our understanding that either Floyd or one of his associate administrators will be here later today to provide that briefing to you.

I also at this time want to thank the committee

for its hard work. This committee, as in its current makeup, has met on two occasions and accomplished a great deal in terms of addressing a variety of issues. Included are the qualifications of personnel working under HACCP, extending inspection to all meat and poultry animal species, retail exemptions from inspection, the FSIS strategic plan, the in depth review of HACCP plans, the adoption of the food code, the regulatory reform area, and expanding the number of pathogens to be used in performance standards.

Some of these areas we will continue to focus our attention on, and on the agenda we have several new areas that we intend to address as well.

I believe we have a full agenda. We have tried to time things in a way that will provide an adequate period for discussion and comment certainly by the committee, and then also opportunity for input from the public.

With that brief introduction, it's my pleasure to introduce Dr. Cathy Wotecki. She is the under-secretary for food safety in the Department of Agriculture, and she is going to brief you on the President's Food Safety Council and its activities and achievements as well as focus briefly

on the international area, an area that is paying a great deal more attention to the area of food safety.

Dr. Wotecki.

MS. WOTECKI: Thank you very much, Mr. Billy, and good morning, everyone. I would like to add my words of welcome, and also extend to a welcome from the secretary of agriculture.

This is the first time that this committee has convened since the final implementation date where that whole HACCP implementation has occurred, and I think it's important to mark that. It occurred in January of this year. And this committee has played an important role in providing advice to the secretary and to the agency, as well as to my office, during the last three years of implementation of this very important new approach towards food safety.

And I thought it would be important, first of all, to mark that occasion, I think it should be noted, and also to extend my thanks to those of you who have served on the committee and provided advice to us over the last several years.

And I think another important role of this committee has been in providing advice to the secretary, to me and to Mr. Billy and the entire agency about future directions for HACCP. As Tom was reading down that list of areas in which the committee has made recommendations, there were quite a number of them that had to do with looking forward as to how this approach is going to evolve, and I think that that clearly is going to be an extremely important area in which we're going to be seeking this committee's advice not only during this meeting, but also in upcoming meetings.

Last time we met I provided you with an update on what the President's Food Safety Council had undertaken in the area of strategic planning and budgeting, and I thought today I would just give you a very brief update on where we stand on that strategic plan activity, and also, as Tom indicated, to talk about some of the work that we have been engaged in on the international level.

So, first of all, let's turn to the strategic plan. As I have told you in the past, and many of you have also participated in the public meetings, more than a half

dozen of them that have been held in the development of this strategic plan, it is a plan that's going to cover a five-year time horizon, and the goal of the plan is to improve the public health through food safety, and also, by better coordinating the activities at the federal, state and local level of government agencies.

The plan is actually going to serve a variety of different purposes. Clearly, it will set goals and objectives for the next five years, primarily focusing on the federal level but also emphasizing the working relationships between the federal and the state agencies.

It is also designed to identify areas in which to increase the efficiency of the work of these agencies, as well as areas in which they can better coordinate their activities, to identify where there are some gaps and shortcomings in the current approaches, and to provide action and to fill those gaps.

So it's going to identify priorities and with an eye towards making the best use of the limited resources that government has to apply to food safety.

We're coming very close to completing the plan.

Our intent is -- the task force that I have been chairing, co-chairing with Commissioner Jane Haney of the Food and Drug Administration, our task force will be providing a final draft plan to the President's council at the beginning of July, and the counsel, after it reviews it, will be then forwarding the plan to the President during the month of July.

The plan has three major sections to it. The first identifies a set of goals and action items to accomplish those goals, as you would expect a strategic plan to do, and that section is divided also into three parts with goals that address the role of science and risk assessment in food safety; the second area focusing on risk management; and the third on risk communication.

The second major section of the report deals with organizational structures at the federal level, and we will do a thorough analysis of a set of alternatives that are very closely based on the recommendations from the National Academy of Sciences report.

The third major section reviews legislation and identifies some areas in which some additional legal

authorities would be helpful at the federal level to fill in some of those gaps that exist.

Right now we are working on developing performance standards for the plan, so there will be some very objective performance standards that are included in the plan, and those performance indicators, some of them are going to be derived from the Healthy People 2010 report. Others are going to be derived from performance indicators that are part of agencies' Government and Performance and Results Acts strategic plans, which also call for very specific performance indicators.

Now, once the plan is delivered to the President, we will continue with seeking public comment on the plan. We have had a series of meetings with stakeholders. We also expect that the international community is going to have a great deal of interest in this report and its implications, so we will also be seeking venues for further discussions with the international community.

So at this point we're working very hard to just get the final editing done on the report, to get it into clearance so that the council, when it receives it, will be

able to do a rapid review of the report.

And as I indicated to you, the deadline that we are going to reach is to submit it to the President during the month of July.

I'd like to turn now to some international activities that have been occupying us for the last several months. One of them has been what has also been a major area of activity for FSIS over the past many years, and that's the work of the CODEX Elementarious Commission.

As all of you know, Mr. Billy was elected the chairman of the CODEX Elementarious Commission, and I think it's partly an indication of how important we believe that that work of that committee that we very actively supported Tom's candidacy for that position.

There have been, though, a number of concerns about some of the directions, particularly at the policy level that have been under discussion within the CODEX Committee on General Principles, and I had the opportunity this past month to be the head of the delegation from the United States that went to the meeting of the CODEX Committee on General Principles.

There was a paper that was under discussion on the agenda at the meeting on risk analysis, and it's a paper that has a dual purpose: to provide guidance to CODEX committees on risk analysis in their work, as well as to provide advice to countries on risk analysis in the way that they approach making their food safety decisions.

The European Union had attempted to introduce into this paper a concept that they call the precautionary principle. If you've been following this at all, you know that this is a concept derived from international law decisions that have largely been made in the environmental area.

The principle itself is not defined. Rather it's inferred from these international law decisions, and as we understand it and as the European Union has further elaborated it in a communication that they issued in February, it's called the Communication from the Commission on the Precautionary Principle. This concept would apply across safety decisions that are made in the environment and health, and include food safety.

Essentially what the precautionary principle as

it's elaborated in this document would do is that if it were widely adopted, it would permit risk managers to make what they call a political decision if there is an absence or a sparsity of information about lack of harm from a particular technology or a particular situation.

Risk managers then could invoke the precautionary principle and say since we don't know what all of the outcomes might be from the adoption of this technology or the adoption of this approach, we can refuse to permit it into our country or whatever the domain is over which the risk manager has this responsibility.

We have been very concerned about the application of this principle within the CODEX's framework of decisionmaking and our apprehension is actually shared by many other countries who are members of CODEX. In preparation for the CODEX Committee on General Principles meeting, we had prepared a response that essentially articulated a set of questions to -- actually addressed to the European Commission's paper that they had submitted on the precautionary principle, and we elaborated a set of positions which in a public meeting prior to going to the

CODEX Committee on General Principles we got comment from consumer community and also from the industry.

So the end result is that this paper that was under discussion during the CODEX General Principles meeting on risk analysis remained at the same level of discussion as it had been introduced at. There is an eight-step process for the approval of papers within CODEX, and this one remains at level three.

We were, as I said, very concerned, as were many other countries, that if this concept of a precautionary principle was introduced into this risk analysis paper, that it could be misused as a disguised barrier to trade. It's not that the United States is opposed to precaution. That is not at all the case. We believe that precaution is inherent in our own legal framework and in our regulatory framework.

What we're concerned about though is a political decision that could be used as a barrier to trade, and essentially the sanctioning of this approach with CODEX if this concept is included within this paper on risk analysis.

So as far as the outcome of the meeting on general

principles, we were quite pleased that we had achieved our objectives in the discussion of this issue within general principles. There was a very active and open discussion. There were many countries that supported some of the positions that we took during the discussion.

There was also a good deal of concern from developing countries about the introduction of the precautionary principle, and the end was that the paper, as I had indicated, stayed at the same step within this eight-step process. It remains at a very preliminary level at step three. There is a good deal of bracketed language which essentially means that that language is for further discussion this year. And we agreed during the meeting on a process to continue the discussion of how member countries in CODEX use precaution in their decisionmaking, and also how CODEX should approach the use of precaution in the elaboration of its standards and guidelines.

So as I said, I think we achieved what we set out to do, which was to have a good discussion of this, and also to continue those discussions over this coming year.

The second international activity that I wanted to

bring your attention to is something that perhaps has not received as much publicity as this discussion of precaution has. What I would like to bring you up to date on is some work that's been ongoing in preparation for the G-8 summit meeting that is going to be held in July this year in Japan.

At last year's meeting the President of France raised the question of whether there should be an international food safety organization established. And the G-8 presidents and prime ministers had a brief discussion of the question, and decided that they would refer it to the Organization for Economic Cooperation and Development, the OECD, which is located in Paris.

The U.S. is a member of the OECD as are 28 other countries. These are primarily the developed countries of the world -- Europe, U.S. Japan and others, and in referring the question to the OECD the G-8 asked for a set of reports that would guide their discussions when they meet this July.

The upshot was that the counsel of the OECD developed some terms of reference that ended up in the development of five separate papers for the G-8 consideration this summer.

One of those papers is a report from a conference that was held in Edinborough, Scotland a couple of months ago that focused on the safety evaluation of biotechnology. Out of that paper has come a recommendation from its chairman, Sir John Krebs, for an international forum to be established to hold meetings periodically, scientific meetings that would deal with issues of biotechnology and food safety.

Two other papers deal with very specific aspects of biotechnology as well. One of them is a brief review of the approaches that different countries have taken towards the safety evaluation of foods that are the products of biotechnology. The other one deals with the evaluations that have been done of the environmental impacts of biotechnology. Again, these are primarily plant products of biotechnology.

The final two papers are ones that describe national food safety systems of the OECD member countries, and international food safety organizations. This final paper describes the work of the CODEX Elementarious Commission as the international standard-setting body, but

also indicates that there are a number of other international organizations that do have specific roles that are played in food safety beyond the work of the CODEX.

So there are some things, for example, that the parent organizations of CODEX, FAO and WHO, undertake specific programmatic activities that deal with food safety that are described in this paper, as well as the work of other international organizations.

These five papers then are going to be summarized and submitted to the group that are preparing the agenda for the G-8 meeting, and we are also working within each of the eight member countries to develop our own country positions on this question of should there be an international food safety organization established.

An important point that we have made consistently throughout the discussions that have led to the development of these papers is that there is an international food safety organization. It is the CODEX Elementarious Commission. And if member countries have got some concerns about CODEX, then let's not set up anything in opposition to it or competition with it, let's fix CODEX and strengthen

CODEX to move forward.

So I thought it would be important for you to know that this activity has been ongoing very actively over the last six months to prepare for the G-8 meeting, and I will be happy to answer any questions that you might have on this as well as the President's Food Safety Council or other issues.

I, in preparation for the meeting today, looked over the agenda. I also had an opportunity to read through all of the papers that were sent to you in advance of the meeting. It is a very significant agenda that's under discussion with implications for the future of this agency and also for the future of the safety of meat, poultry and egg products.

So I also would like to get into that agenda as quickly as we can. It's going to be, I think, a very interesting and informative two days worth of discussions.

So again, welcome to all of you. It's good to see you all again, and I would be happy to answer questions.

MR. BILLY: Are there any questions from the committee? Hello?

MS. KASTER: Can you hear me? Is this on?

MS. WOTECKI: Yes.

MS. KASTER: This isn't exactly food safety related, but I was curious as to the flavor of the biotechnology discussions with the Europeans.

Did you get the feeling that they were working proactively in this area and were interested in alternative opinions to what we perceive a theirs?

MS. WOTECKI: Is your question more about the trade implications or about the safety --

MS. KASTER: Just whether or not they are open, open to both sides of the safety discussions. Our perception is usually that they are -- that they are not very open to that; that they have kind of made up their minds.

MS. WOTECKI: Well, it's been interesting for me because I have participated as the co-lead of the U.S. delegation in the development of the food safety papers. The two groups that -- or actually the three groups that prepared the papers that are dealing with biotechnology tended to be ones that were very technical and it was the

scientists and chief scientists and regulators from the participating countries that were participants in those discussions.

So the sense there was one of essentially that these are promising technologies. One of the outcomes of the meeting that was held in Edinborough was the conclusion that as far as the safety of foods that are the products of biotechnology, there were no indications of any safety problems which was a very positive outcome from that meeting.

So I think the composition of these groups was such that one would expect that there would have been a more objective review and approach towards it.

The Edinborough conference, though, did have representation from a broad set of organizations with sometimes less favorable views of biotechnology and still they had the outcome that I described; essentially a conclusion that there was not an issue of safety with the products that had yet been -- that had been brought on the market so far.

So that was in the area where there was a broader

participation in the meeting.

The issue, though, that you referred to I think is one of public acceptance, and certainly there remains an enormous amount of skepticism in the European public about biotechnology foods.

MR. BILLY: Carol?

MS. FOREMAN: It may not be much more than skepticism among the American public about the safety of biotech foods.

MS. WOTECKI: Yes.

MS. FOREMAN: Cathy, I think, will play such an important role in this. You, Karen and Tom, and I think it's terrific that not just our government has played this very productive role, but that the Department of Agriculture has taken the lead in terms of the food safety discussion in this regard. It hasn't always played exactly that role. I think it's very important and I appreciate it, as does my organization.

I continue to be a little concerned about the precautionary principle paper because you have the sense both sides are standing there saying, "I'm not going to go

where you want me to go."

It seems to me that it might be useful if we could have a -- and it may be that I've missed it -- some statement that says when you have an overwhelming preponderance, since we all know science is never final, when you reach an overwhelming preponderance, then precaution takes a secondary position. But to have some line in the sand, even though it might be a little fuzzy, that says we have reached a point at which all of 100 studies or 200 studies go one way and only one goes the other way, or there are none going to the other way, but some question still to be raised, then you might be prepared to move in a particular direction.

Where you have 10 percent of the studies that go the other way or 20 percent, I think you've got a very different question and one where even if scientists are comfortable going forward, you're going t have a hard time getting the amount of public confidence that's necessary.

Do you see any sense that there might be a willingness to lay out gradations of certainty or confidence levels?

MS. WOTECKI: I think that's a very interesting question, Carol. We have not started to talk about any kind of quantification. We have talked about preponderance of evidence, and among the things that I would expect over this coming year as we go through a much more detailed discussion of how CODEX should built precaution into its decisions, again in the context of this risk analysis paper that's under discussion. That may be one of the things that comes up during the discussion.

But we so far really haven't done anything in trying to quantify it, and I don't even know if that would be helpful in and of itself because sometimes it depends on what the nature of the problem is in the literature that would give you -- you know, much more weight to a minority opinion.

MS. FOREMAN: Yes. Well, I just find that, you know, precaution is one of those words that has -- is in the eye of the beholder. It's like that other "P" word, pornography.

MS. WOTECKI: Yes. Yes.

MS. FOREMAN: I know it when I see it.

MS. WOTECKI: Yes.

MS. FOREMAN: But it's -- if somebody could wrap some definitions around it that are understandable by the public, I think it would help.

MS. WOTECKI: Well, certainly the objective of what the discussions in CODEX's general principles are, are exactly that; trying to develop a better understanding, a better set of definitions, a better set of overall principles to be applied in risk analysis.

MR. BILLY: I would like to add to that in this sense, that I think that as discussions occur about caution or precaution and whether there is a principle or not, I think we don't tease apart how precaution is used by different entities.

There is an important distinction, for example, between the decisions that a national government need to make versus the decisions that a commission overseeing a common market like the EU needs to make to have discipline in the common market versus decisions that CODEX needs to make representing the interests of 165 countries.

And we tend to jumble all that together and talk

about it in a way that I think makes the discussion much more difficult and complex. As the chairman of CODEX, I am urging a series of workshops that, among other things, will allow us to tease all that apart and look at it separately.

I mean, the fact is that there is precaution inherent in HACCP, and that industry applies caution in its decisions. So depending on where you want to start, there is caution inherent in most things that are done in the food safety area, and it's case studies that look at that and get understanding about what exists now I think will be instructive in terms of what else might be needed at whatever level.

MS. FOREMAN: What's your time frame?

MR. BILLY: Within a year.

MS. WOTECKI: Yes, I think Tom also makes a very important point, and that is that with respect to how countries make their food safety decisions, that is dependent on the laws and the regulations and the traditions of operation that they have within their countries.

In the U.S., we've gone back and done as part of our background work for both the general principles meeting

as well as this OECD activity a very detailed paper that outlines how precaution is built into our foods safety legislation and regulations.

So in those countries that have that strong legal infrastructure -- strong legal structure, as well as the infrastructure, the use of precaution in the application of some additional principle may not be as important.

The question is then in other countries there may be a need for something like that. Throughout this whole discussion part of what we've been saying is it's perfectly fine for the European Commission to elaborate this and to have its discussion with its member states. They're, you know, working towards developing a stronger federation, a stronger, more unified approach towards their food safety regulation and food safety systems. So it's perfectly appropriate for them to be having these internal discussions.

MR. BILLY: Caroline?

MS. DEWAAL: Thank you.

I'm interested though in the application of not only the underlying statutes, but the application of some

more modern additions to the statutes, particularly within the USDA reorganization statute which requires every regulatory decision to go through at least two levels of cost benefit analysis and risk assessment; one at the department level and one over at OMB.

And I guess I'm troubled that it's taking the department so long to act on actual, not speculative public health risks or new product issues, but on existing hazards in the food supply. And I think the example is listeria where it's taking at least two years to develop kind of a regulatory response to that hazard.

So I guess I'm wondering whether in your analysis you have looked at some of the hurdles to precaution that may have been put in place in recent years to USDA and FDA application of the underlying statute.

MS. WOTECKI: Yes, we did. In fact, there is a section in the paper that deals with socioeconomic concerns and it does mention the fact that USDA does have this requirement. FDA and EPA do not.

By the same token though, I don't think that FSIS was hampered by economic assessment in responding to the

listeria outbreak. If you look at what the agency did by immediately requiring companies to review their HACCP plans, did not require any economic analysis, by issuing guidance on environmental testing, did not require an economic analysis. The agency moved very quickly to provide information to the public; did not require an economic analysis.

So, you know, from that perspective I thought that FSIS took very quick and appropriate actions that were not impeded by any additional requirements as far as new rulemaking went.

MS. DEWAAL: But none of those requirements are mandatory on the industry nor are they uniform.

MS. WOTECKI: Mm-hmm.

MS. DEWAAL: So what the agency -- and I understood from conversations with the administrator -- felt like they could not proceed in a regulatory manner to make mandatory uniform requirements on the industry without -- without being able to -- without having the data to meet the requirements of both your internal office, which applies only to FSIS, but also OMB's requirements, which do go both

to EPA and to FDA.

So I mean those requirements are actually slowing down rulemaking. They may not be slowing down the kind of voluntary efforts or the reassessment which, you know, we don't know yet what the impact of that reassessment was or how uniformly it was handled by the industry.

So I think that you need to look at some of the hurdles to precaution because we're not confident that precaution is being fully implemented, even if it is a statutory mandate, because of these delays.

For example, we had a discussion within this group, I think, at the last meeting on the impact of those particular requirements on emergency rulemaking authority at the department, and you -- it was my recollection that the answer was that even emergency rulemaking would have to go through all of these hurdles that the agency simply won't pursue.

MS. WOTECKI: Well, I understand the point that you're making. We've certainly got a discussion of listeria that's going to be on the agenda today, and certainly some of these points might also be appropriate at that point in

time.

I do think though that any move towards rulemaking would have required the collection of information beyond the economic analysis in order to move forward. So certainly I think we need to be cognizant and aware of the fact that this can be something that is difficult in order to collect the information and do those analyses, and it's one of the areas as well that we might want to seek opinion at some point from this committee about how to improve those risk assessments -- those cost benefit analysis.

MS. DEWAAL: But also the impacts on the precautionary principle because I am concerned that the U.S. may be representing that we have a precautionary principle which is in fact stronger than what is being practiced in this country.

So I just would ask you to really consider the impact of those, and if adjustments need to be made to those so the agency can respond to immediate public health threats, that that case is made to Congress and to others.

MS. WOTECKI: Good point.

MR. BILLY: Okay. Rosemary.

MS. MUCKLOW: One very brief question. I would just like to be clear what the U.S. position is.

Do we think as a nation that we need another food safety organization, or is CODEX it? Do we really want to try to wrap what you are doing with the GS-8 and so on into CODEX?

MS. WOTECKI: Well, at this point, Rosemary, we are certainly working to develop the U.S. position that's going to be taken into the meeting. I can tell you that among those of us who worked on the OECD activity, the development of these five papers, our conclusion has been that CODEX is the international standard setting body. We think that any issues and concerns that have come up in the working groups that we have been in within OECD about CODEX's slowness, as is mainly the problem that's pointed to, could be remedied by additional measures, and we would not want to see anything that would be set up that would compete against CODEX for resources.

So that's our conclusions. The U.S. position is in development.

MR. BILLY: Jim?

MR. DENTON: Quick comment about the precautionary principle that has been of concern for me since I first became aware of this midyear last year. I've been following that entire issue.

I think what you and Carol say is exactly right. Precaution is something that is threaded throughout our scientific process and regulatory process in the United States. It's our nature to approach things in that manner. We make every effort to ensure that every decision that we make is based on the most complete information that we can possibly have.

Now, my great concern about the precautionary principle is that it is a very well crafted attempt to require that we prove a negative, and in the scientific work that I live in that is not possible to do. We do everything we can to evaluate every potential hazard that we see from the application of any technology, but we can never prove a negative, and that's the thing that concerns me the most.

MS. WOTECKI: That's a good point.

MR. BILLY: Okay. Thank you very much. We will consider that again this subject area as potential area of

interest to the committee later in the agenda.

Let me now shift to the agenda and I will briefly run through it. If you will take out the agenda and look at it, this morning we're going to have several briefings in the same manner we have approached working with the committee in the past; that is, to provide updates on important areas of work within the agency, and obviously provide an opportunity for the committee to raise questions or make comments.

We then shift to a series of issues starting just before lunch, an industry petition on changes to the HACCP regulation; the issue of additional species being covered by mandatory inspection and a HACCP approach.

I mentioned earlier Floyd Horn or one of his associates will be briefing us on ARS food safety research. Then an update on the issues surrounding E-coli 0157:H7, as well as recent developments in the area of listeria monocytogonates.

With the cooperation of the committee then this evening, we have a series of evening subcommittee meetings to deal with the specific issues and hopefully to receive

from the subcommittees specific recommendations that we can then forward to the secretary.

If you turn to tomorrow then, we continue with report from the subcommittees and obviously discussion of the subcommittee recommendations by the full committee. That enables everyone, including those that weren't able to participate in the subcommittee meeting, to have their input and to shape any of the recommendations that go forward from the committee as a whole.

And then after lunch a couple more briefings and update regarding the National Microbiology Committee by Karen Hulebak; a briefing on policy issues related to campylobacter des juene. This is an area that the committee has dealt with previously and made a request of the micro committee, and we need to look at that and see what, if anything, the committee would like to do further in that area. And then a brief update in the area of meat and poultry inspection and food safety at retail.

We would like to wrap it up then with getting your thinking about remaining issues, and priorities in that regard. If there are particular issues based on the

discussions over the next day and a half that you think we need to spend more time on some of the current issues or new issues, you need to share those with us and we'll then use that as a basis for organizing subsequent meetings.

Included in that discussion from two to three tomorrow will be a report on noncompliance reports. Carol Foreman at the last meeting raised a concern about an analysis that was made of a certain number of plants that have received noncompliance reports. We developed a summary response and we also will be providing to you a little later a one-page translation of that report that I hope will make it clear what it means and how you should interpret the information that's there. And we will cover that report during that session from two to three tomorrow.

Obviously, both days provide opportunity for public comment. If anyone is interested in providing comment to the committee are encouraged to do so. You need to register and inform people at the registration desk of your interests and then we will call on you during the time that's provided.

Are there any comments or questions from the

committee regarding the agenda?

(No response.)

MR. BILLY: Okay. Then one last thing I'm going to cover is the committee renewal process. As I think all of you know we are now seeking nominations for membership on this committee, and we're seeking nominations from individuals that represent state government, industry, consumer organizations and academia. And nomination packages are due by June the 30th.

Now, as current members, all of you are eligible to serve up to three successive terms. So if any of you are interested in renewing your membership, what you need to do is just provide us a short letter or memo indicating your desire to be renewed on the committee, and we encourage you to give that serious consideration.

It is important to have, I believe, a significant amount of continuity on the committee if you're working on a series of issues to provide a thread of knowledge and understanding and get the best value in terms of your efforts working with the agency and the department. So I urge you to give it serious consideration.

And if you are aware of others that you believe might serve on the committee and play a useful role, contact them and let them know about this opportunity and encourage them to express their interest or support them through your own efforts.

Any questions about the committee renewal process?

(No response.)

MR. BILLY: Thanks.

All right, what I would like to do then is move to the first briefing item, which is a briefing on HACCP-based inspection models project, or HIMP. I'm not sure I like that acronym, but nonetheless that's what it is. And Mike Grasso who is our project manager will provide the briefing to you. You have a briefing paper in your materials that were provided and at this time I'd like Mike to come forward.

MR. GRASSO: Good morning. The briefing material is in tab No. 5. That's what I have been instructed to tell you.

The document that I provide on a monthly basis on the status support, I'd like to actually walk through that,

and if you have any questions feel free to stop me and I'll explain.

The first document, what we've done this past month, is actually taking a step backwards so that if somebody wants to read a two-pager, and that's what this two-pager is, it will tell you when this project started, kind of like where we have been and where we're going. So that's the HACCP-based inspection models project update.

The attachment No. 2 is the most recent key fact that we've provided at our last public meeting, and that gives you a general overview of the project.

Attachment No. 3, which was presented at the public meeting by Research Triangle Institute, was the report on the 16 broiler plants.

For your information, I need to maybe take you through what baseline is so that you have a better understanding, and then what the transition phase is and the models phase is.

On the broiler side, when we talk about baseline, we need to -- we need to have measured the accomplishment of the current inspection system, so we had 16 plants, 16

broiler plants that had volunteered. RTI was the contractor assigned to collect the data, and this report reflects the results of those 16 plants.

Number one, on the micro side for the generic E. coli samples and also for the salmonella samples, and on the organoleptic side are the results of the carcass by carcass verification inspection on 2,000 per plant.

I'm going to just quickly take you through the document, if I may.

MS. HANIGAN: Excuse me. Can I ask a -- my attachment 3 does not show that. My attachment 3 is a chart on turkeys, so I'm having difficulty -- that's what our attachment 3 looks like.

(Aside.)

MR. HANIGAN: Can you start from what we have in attachment 3?

VOICE: Attachment 3 is young turkey time line.

MR. GRASSO: Okay. Flip to the other one. Flip it. It's in the back.

MR. GRASSO: Do you have this? Yeah, it's attached to that. No?

ALL: No.

MS. HANIGAN: That's young turkey time lines that are attachment 3.

MR. GRASSO: Oh, okay.

MS. HANIGAN: If you look at tab 5 in your book, that's what we have.

MR. GRASSO: Okay, we'll get it to you right now.

MS. HANIGAN: Can you start from the top then?

(Pause.)

MS. MUCKLOW: Mr. Billy, might we go ahead with the other?

MR. BILLY: I think what I would like to do, with the committee's indulgence, is to postpone this briefing until we can get the appropriate material into your hands so that it makes sense.

VOICE: Okay, we have it now.

MR. BILLY: Oh, good.

(Pause.)

MR. GRASSO: Okay. Are we on this yet?

MR. BILLY: Which is the second page of what was just provided to them?

MR. GRASSO: Right.

MR. BILLY: Okay. Go ahead.

MR. GRASSO: This was the document that was handed out at the last public meeting on the models project, and this was the presentation by Research Triangle Institute on the results of the baseline data collection of the 16 broiler plants. This report is broken up into two parts, the organoleptic side and the micro side. The micro side was the 300 generic E. coli and the 300 salmonella samples that were taken in each plant, and the organoleptic side was the 2,000 carcasses that were selected in each plant.

Taking you through the document, you will see what I just said is the overview. The next page is the actual names of the plants and the location in which RTI collected the data. The following page actually lets you know specifically how the organoleptic activities were done as far as the antemortem, the review process, examining 80 birds per day per shift over a five-week period of time until we had 2,000 carcasses, and also looking at the condemned birds, same amount, 2,000 carcasses.

There is the breakdown on the results on the

antemortem on the young chicken plants when the interview process took place. The next page gives an indication on looking at the pass birds before they went into the chiller by RTI, what percent were food safety diseases, what percent was the zero tolerance, and the 98.9 percent was OCP conditions.

The next page, page 6, actually starts to identify all of the conditions themselves and the description of the conditions that Research Triangle Institute veterinarians used to record the data on the organoleptic study, and that's on page 6 and 7.

On page 8 you start to see the percentages of defects within the carcasses for the individual defect, and that's on page 8 and 9.

On page 10 you see the results of the condemned samples, the percentages where no condition was found, whether it was a localized condition or a generalized condition within the condemned barrel.

Page 11 lays out specifically how we did the micro testing. In the plant we used a whole bird rinse at post-chill and we collected 50 samples a week over a six-week

period of time. We split the rinse for E. coli and for salmonella. RTI contracted with Silica Labs to run the analysis. All of the samples were sent there overnight delivery and all the results were sent to RTI.

Page 12 indicates results on the salmonella side and page 13 indicates the results on the E. coli side.

On the micro side the measurement of accomplishments were that the plant meet the current regulatory requirement.

Any questions on the RTI report?

MS. MUCKLOW: Mike, did Silicon also do the salmonella results?

MR. GRASSO: Yes. They did both.

MS. MUCKLOW: That's not in here, is it?

MR. GRASSO: Yes.

MS. MUCKLOW: I missed that. Oh, there they are.

MR. GRASSO: They actually had a real good system. Occasionally they actually did set up spikes outside of the plant that would go to Silica Lab as a quality control measure to make sure that Silica Lab was doing the proper job, and occasionally they also sent split samples to

another quality control lab to measure the performance of Silica Labs.

Now, right in your book now -- yes?

MS. FOREMAN: Could I just clarify? Baseline data represent what's happening in the plant before the HIMP project started?

MR. GRASSO: Correct.

MS. FOREMAN: That's the way it finally ended under HACCP but without any changes in the system as represented by the HACCP models project?

MR. GRASSO: Correct.

MS. FOREMAN: Okay.

MR. GRASSO: If you think in terms of the project, really actually think in terms of three parts. Baseline is the current system that's out there and the measurement of the accomplishments of that system. We used the baseline results, specifically on the organoleptic side, to establish the performance standards.

MS. FOREMAN: Baseline represents what's going on in all plants that are not part of the models project?

MR. GRASSO: Correct.

MS. FOREMAN: And what was happening there before the models started?

MR. GRASSO: Correct. And as I talk a little bit now, I'm going to talk about transition, okay. Transition is the change, when change occurs within the plant.

MS. FOREMAN: I just want to clarify a couple of other things before you go to that.

The ingesta is an OCP in all plants now?

MR. GRASSO: Correct.

MS. FOREMAN: And before HACCP?

MR. GRASSO: It's the same.

MS. FOREMAN: Thank you.

MR. GRASSO: The regulatory requirements now has that ingesta as an OCP.

MS. FOREMAN: Thank you.

Yes?

MS. DONLEY: On that note, can I -- Carol started my question. Can you explain when and why ingesta was changed from a food safety issue to an OCP, and the why and the when?

MR. GRASSO: Within the project, we didn't change

it. In poultry, that's the way it is.

MS. FOREMAN: How long has that been the case?

MR. JAMES: Forever. Forever is the short answer. Under the --

MS. FOREMAN: Since 19?

MR. JAMES: There was never a distinction made in the product standards between food safety and OCP for the old acceptable quality limits or AQL, nor for the more recent finished product standards.

For the purposes of this study, we did not attempt to make any change in the way that ingesta was handled. It's collected and for the purposes of this project it remains in OCP condition.

MS. FOREMAN: Oh, I just want to -- can I piece this out a little bit, please?

In a plant before HACCP went into effect, if an inspector saw ingesta on a bird, what happened?

MR. JAMES: Ingesta on a bird, if it occurred on the inside of the body cavity, that bird was reprocessed. If it occurred on the outside of the bird on intact skin surface, the bird was permitted to go down the line.

MS. FOREMAN: So inside, reprocessed; outside, no change, nothing happened?

MR. JAMES: That's correct.

MR. BILLY: Carol, I'm going to pick on you but it applies to all the committee members.

MS. FOREMAN: I'm sorry.

MR. BILLY: We need to move the microphone right in front of you so that the people --

MS. FOREMAN: I'm sorry.

MR. BILLY: -- in the back can earlier.

MS. FOREMAN: Earlier, earlier on I breathed hard, and I heard it.

(Laughter.)

MR. BILLY: You didn't want that misinterpreted.

(Laughter.)

MR. BILLY: Did you have another point you wanted to make?

MR. GRASSO: I should be the only one breathing heavy at this point.

(Laughter.)

MS. FOREMAN: But since we're into breathing

heavy, let's talk about air sacculitis.

(Laughter.)

MS. FOREMAN: OCP?

MR. GRASSO: OCP one.

MS. FOREMAN: Before HACCP was instituted, how was it treated?

MR. JAMES: Again, before HACCP was implemented, different diseases and conditions were all considered -- we didn't make a distinction between what was food safety and what was not. For purposes of this study, we have called air sacculitis an other consumer protection disease, and OCP, I'll just give a 30-second description of what that is.

If the disease or the condition does not cause illness in humans, the organism which is causing -- the disease in the bird does not cause disease in humans, then it is OCP and not food safety. Some diseases in these birds may be caused by an organism that would could disease in people but not through a foodborne route, and so the criteria for being food safety has to be that it will cause disease through a foodborne route.

MS. FOREMAN: Talk a little bit more about not

through a foodborne route. What do you mean?

MR. JAMES: If we were to be exposed to the organism perhaps in the same way that an animal was through exposure through an open wound, for instance, or get a blood stream infection through some route, or a respiratory illness, we might get the same diseases that the animals get from that same organism.

But what we limited food safety diseases and conditions to were those that were caused if they were ingested as part of the product.

MS. FOREMAN: So air sacculitis might be a health hazard to workers in a chicken plant?

MR. JAMES: There is a remote possibility for one or two of the different diseases or organisms that cause air sacculitis in birds, that's a possibility.

MS. FOREMAN: But no known case of anybody ever having become ill from eating meat from a chicken that had air sacculitis?

MR. JAMES: I can't go quite that far, no known case ever in any human being.

MS. FOREMAN: Okay.

MR. JAMES: But --

MS. FOREMAN: You're not aware of anything.

MR. BILLY: Just as a precaution.

(Laughter.)

MR. JAMES: I would say that using the HACCP principle rather than the precautionary principle is that we do not think it is reasonably likely to occur.

MS. FOREMAN: I just want to go back again for one minute, I'm sorry to take time, but I want to clear this up, historically in the meat inspection system in a poultry plant birds with air sacculitis were passed?

MR. JAMES: Once the air sacculitis condition was addressed, the birds had not proceeded on to an septicemic or toxicemia condition, the birds were passed.

MS. FOREMAN: And under HACCP birds with air sacculitis, if it hasn't proceeded into septicemia, are passed?

MR. JAMES: Yes.

MS. FOREMAN: And under the models project?

MR. JAMES: The same, same standards.

MS. FOREMAN: Same.

MS. HALL: Could I ask a question, please?

MR. BILLY: Cheryl and then Dan.

MS. HALL: Could you tell what organisms cause air sac. in humans in the plant that causes air sac. in poultry?

MR. JAMES: Well, actually, I didn't come prepared with my notes to discuss the different organisms, but most of the organisms that cause air sacculitis in poultry are probably not going to cause -- of course people don't have air sacs., but won't cause a respiratory condition in people. It's the E. colis, for instance, that are infective for birds and causing air sacculitis generally we do not believe will cause a respiratory disease in people.

Experience has shown through the decades where we have had people working on lines that our workers, our plant workers don't come down with respiratory diseases when exposed to heavy air sacculitis in flocks that come through, which is anecdotal evidence that these diseases and conditions are not readily transferrable to people under these occupational conditions.

I think also the literature will support, and I'd be happy to go into that in more depth probably outside of

this meeting, that those organisms that are causing air sacculitis in the birds are not -- not dangerous to humans or are not reasonably like to be dangerous to humans.

I will throw out this one caveat that we -- the same that we mentioned at the March 30th meeting -- we are ready, very ready to receive any new information that comes to light or any information that we may have passed over regarding any of these diseases and conditions which are currently classified as food safety, or OCP, which may cause us to change the category therein because science marches on and as more information is available to us that would indicate to us that we have some of these in the wrong place, we will be happy to reconsider those.

MS. FOREMAN: I'm sorry, one other, if I could just follow up. May I?

The young broilers, the incidence of disease is generally less than one percent?

MR. JAMES: Condemnations are less than one percent.

MS. FOREMAN: Condemnations for disease are less than one percent.

VOICE: Point five?

MR. JAMES: Point six, I think, was the last number we had.

MS. FOREMAN: Point six?

MR. JAMES: Point six percent.

MS. FOREMAN: Okay. I'm a little concerned about the word "condemnations" for disease. That might suggest that diseased birds were not being condemned and that the rate might be higher. Do I -- do I misunderstand?

MR. JAMES: Actually, what I intended to say was that we condemn birds for disease six-tenths of one percent those have come through. There are other birds which have some sort of disease or condition on them, which we then trim or handle in some manner as to make the carcass then able to be passed, which would raise that percentage of diseased birds higher, but they don't all deserve condemnation.

MS. FOREMAN: So it might be possible that you would have birds coming in to a plant, a flock that had -- that where 30 or 35 percent of the birds had air sacculitis?

MR. JAMES: That is a possibility, yes.

MS. FOREMAN: And those would be the birds condemned, that less than one percent that were condemned would be condemned because it had proceeded into septicemia or toxicemia?

MR. JAMES: Yes, and birds -- flocks that have that high a level of air sac. probably will have a much higher percentage than one percent condemned. That .6 percent figure is a national figure, and it is not randomly distributed. Birds with higher disease incidence have a higher proportion of the flock condemned.

MS. FOREMAN: Can somebody tell me what percentage of birds, young broilers have air sacculitis, just generally speaking?

MR. JAMES: I cannot give you that figure. What we keep track of on a national basis is condemnations and not disease incidents. So I think individual broiler companies would probably be in a much better than FSIS to give you those figures.

MS. FOREMAN: Would somebody tell me if there is an article in the literature somewhere where I can find that out, any of you in the chicken business?

Well, FSIS doesn't keep that. How about APHIS?

MR. JAMES: We will see what we can do to find some information for you.

MS. FOREMAN: Thank you.

MR. BILLY: Dan?

MS. HALL: Could I -- I'm sorry. Could I follow up on that?

MR. BILLY: Yes.

MS. HALL: Could I state that from the poultry industry's findings E. colis are a very specific on the type of problems they would cause even in chickens, so it's very doubtful that they would cause problems and respiratory problems in humans, so just for the record.

And also that air sac. birds are not just passed down the line. There are three different ways of working those birds. So it is not that if you find an air sac. bird on line that it becomes part of the food chain. There are three different ways that those are worked out rather than just condemned, but also condemned.

MS. FOREMAN: Oh, will you state what the three ways are?

MS. HALL: If it's very minor air sac., they are vacuumed and chlorinated water washed so that there is no trace that's considered a localized condition.

If there are more severe, they are -- if they have inner clavicular air sac, the upper part of the body is not allowed to be taken. This is -- now, these are healthy looking birds, no septic signs, no toxic signs on the carcass. If they are septic and toxic, they are condemned.

MS. FOREMAN: But is that plant quality control or is that regular authority?

MR. GRASSO: The second phase that she was talking about is a salvage operation.

MS. HALL: Mm-hmm, salvage operation.

MR. GRASSO: Whether they would be able to trim away the affected area.

MS. JOHNSON: I do think it's important to note that in all of these procedures that Cheryl identified USDA does go, and even the process that's on line, USDA still has another check of the bird before it goes out. So it is -- there are regulatory review of the meat and the cut and the whole works.

MS. HALL: How they are held and every part of it is regulated.

MR. BILLY: Okay, Dan?

MR. LAFONTAINE: I think I have been overtaken by events. No, I will be making two points.

Carol, you mentioned a couple times before and after HACCP in relationship to this discussion. And correct me if I'm wrong, but the antemortem and the postmortem part of the mission of FSIS was essentially untouched by the implementation of HACCP.

MR. GRASSO: Correct.

MR. LAFONTAINE: So what we are in now in this HACCP-based inspection models is aside or completely you may say essentially separate from implementation of HACCP. I just want to clarify and hopefully in your mind and others that there is two channels that FSIS is going down in this regulatory approach.

The other thing on air sac --

MS. FOREMAN: May I -- I thought I -- now I'm not sure I understand. I thought that it was clear that some things with regard, for example, to antemortem and

postmortem inspections were not changed by HACCP.

MR. LAFONTAINE: That's correct. I'm not --

MS. FOREMAN: Okay. All I wanted to know is that what's happening right now in these plants is not the models plans in some instances. Is that different from anything happening in all the other broiler plants in the United States right now or what -- or anything different than what was happening in them before HACCP was implemented? Is that not the case?

MR. LAFONTAINE: Let me restate it again, maybe I am not following you.

In the incremental implementation of HACCP in January '98, '99 and 2000, that requirement and the implementation thereof essentially left antemortem/postmortem untouched.

So in this HACCP-based models the baseline, as was stated earlier, does represent these 16 plants, but it also could be in principle expanded to represent the entire industry as they are operating now under traditional inspection.

MS. JOHNSON: Mr. Billy, can I ask Mike a question

about the baseline just real quick?

Now, it's my understanding with the broiler plants you have the 16 plants and you have the national standard established for the baseline. Plants that wish to come on the HIMP program now would come under without having the baseline because you've now established a national baseline. So it was your intend to follow up on Dr. LaFontaine. This baseline does represent the national for the broiler industry; is that right?

MR. GRASSO: That's our intention. We have taken the -- we call it the 75th percentile or the twelfth position to establish the performance standards to move forward with the rulemaking that would be for all broiler plants.

I think I would like to make a comment though on trying to get to your issue and I think for clarification is that as Dr. LaFontaine that with the initiation of HACCP it had nothing to do with the slaughter line itself, okay, but air sac. was measured and from the early eighties, and correct me if I'm wrong, via finished product standards, and there was a tolerance, I believe, of three birds in ten that

could have had air sac. identified. So that's a 30 percent tolerance under the finished products standards.

In the models project, there is a difference between the traditional plant that's out there today and a HIMP plant is the performance standards that they have to meet is no longer three in ten; it's 1.7 percent or two in 60, so there is a distinct difference between a HIMP plant and a traditional plant as it relates to the performance standards that that plant has to meet.

MS. FOREMAN: What's the performance standards in the HIMP plant that you cited?

MR. GRASSO: OCP-1 is 1.7, that's the twelfth position. Conversion to a whole carcass is two in 60.

MS. FOREMAN: Thank you.

MR. BILLY: Dan?

MR. LAFONTAINE: A couple other points I wanted to make.

On this air sacculitis, and this principle can be carried over to other infectious diseases, although currently it's under OCP, not a food safety like Dr. James explained, it still is aesthetically unacceptable to have

birds enter the marketplace, and I use the word "unwholesome," and that is part of the charter of FSIS is safe, wholesome animals and birds, meat and poultry.

So it is important to recognize that this is -- it is important to recognize this is regulatory issue, not just strictly quality control because the current laws we are operating under require wholesome birds and animals.

MR. BILLY: Nancy?

MS. DONLEY: I just have one quick question.

Air sacculitis, a bird that has air sacculitis is considered a healthy bird?

MR. JAMES: A bird with air sacculitis has a respiratory disease, and the affected tissue must be removed. Healthy tissue can then be passed for consumption.

MR. BILLY: Unless it's septicemia.

MR. JAMES: Right. As I said, healthy tissue can be passed. If the air sacculitis has caused a systemic change in the bird, the bird is condemned, but that is a principle that has been in place since OT-6, that affected portions of a carcass by a disease or condition can be trimmed away and if the rest of the carcass is healthy, the

rest of the carcass can be passed.

MS. DONLEY: I guess where it gets very confusing to, you know, the general public, if you will, is that these inspection models were always presented as being based on young, healthy and uniform animals -- I'm reading that right from here.

But then when you hear about these animals that are involved in these projects, they can have very high sickness rate, that's why I asked if air sacculitis is considered in an illness in an animal, that to me as the public doesn't sound like a healthy animal.

MR. BILLY: Dan. Dan.

MR. LAFONTAINE: Kind of a -- I'm trying to answer for FSIS, but I think I can give a -- young broilers in general, young swine, in today's marketplace are young and healthy across the board. And at least in air sacculitis with the poultry that I'm involved with, you will run into pockets where a particular house or farm had a respiratory problem, and you can get a very high percentage periodically. But across the board the percentage of birds that have come in with air sacculitis or any other disease

process is quite low.

So what I am saying is the young, health, uniform is an accurate statement, but there is, like any other situation, there is exceptions to that, and air sacculitis is one of those exceptions. So it is an honest statement on the part of FSIS to say young and healthy as a general statement.

MR. GRASSO: One comment I would like to make on that is that what we have noticed in the HIMP project so far, due to the fact that the performance standard, the 1.7 percent is extremely low, the awareness by the plants has gone up extremely high, so that they are taking a much better look at the growers, what they are receiving so that they get more healthy animals.

The other comment is that air sac. is usually has to do with seasonality, usually in the colder months.

MR. BILLY: Okay, I've got Alice, and then Caroline and then Cheryl.

MS. JOHNSON: When we talk about air sac. and USDA inspection and the whole works, I think one thing that we may not be aware of is that the point where the inspection

is being done back in the 1958-1959, I'm talking for turkeys and help me with the broilers as well, most everything was whole birds. And it was very important at what point you looked at these birds, you were looking at whole birds.

The industry has evolved both, I think, the entire poultry industry, and the majority of even our turkeys are cut up now, got through further processing and not the whole bird issue.

So I think the way that the air sac. viewed back in the fifties, you know, things are changing. It's still what Mike is talking about here is the baseline, is at one point in which the bird then goes on to several different other places, and there is USDA inspection throughout that process.

So, you know, if we truly look at what a new inspection system might want to offer, and I know this is the whole concept in a lot of the HACCP, is, you know, let the company do what's necessary, and take control of the process with FSIS verification, and that's where, I think, the agency is trying to go, and we have to remember that this is a different bird than it was when the original

regulations were put together, and there is the wholesomeness issue and going to the consumer, but it may be that there is a more appropriate place to make that determination now than there was back in the fifties because of the type of bird that was going to the consumer.

MR. BILLY: Okay. Caroline.

MS. DEWAAL: Thank you.

I did, Mike, having sat there through a whole day discussion on this, I want to tease out one issue that I'm not sure the other committee members are aware of.

On these OCP localized conditions, is that the same as the defect rate today?

So in other words, it's as one hair or more of any size. Is that what the defect rate is, or one feather?

MR. GRASSO: No. In traditional plants today, they use finished product standards which have tolerances involved. So just say like on a hair, to actually score a defect of finished product standards I believe you need 26 hairs to score it as a hair.

RTI, their role was not to use finished product standards, their role was to identify on the carcasses the

defects that were prevalent period.

MS. DEWAAL: And so the new performance standards --

MR. GRASSO: Yes.

MS. DEWAAL: -- that are being used in the HIMP plant, are those the old finished product standards or are those new standards --

MR. GRASSO: New standards.

MS. DEWAAL: -- based on what the actual performance is in the baseline?

MR. GRASSO: Correct.

MS. DEWAAL: Okay. And my final point here because I think this is a very important point in looking at the HACCP models, so the -- are any of the new performance standards that the HIMP plants are going to have to meet, are any of them worse than the old finished product standards, or less stringent?

MR. GRASSO: I believe we did a --

MS. DEWAAL: I mean, the 26 hairs.

MR. GRASSO: -- side by side and I believe -- I don't have the document in front of me, but I believe in

every category, except maybe one, the HIMP standards are tighter. And I just -- I think there is one.

MS. DEWAAL: And just to nail this down, like for hair, the old standard was 26 hairs.

MR. GRASSO: Right.

MS. DEWAAL: And under this system it's one hair. A carcass with one hair would violate this standard?

MR. GRASSO: Right. Like with feathers, I believe you needed five to score it as a feather?

MR. CHURCH: Right. There was a certain number of feathers of a certain size. I don't have that document in front of me and have been out of the plant too long. I can remember what precisely the numbers are. But as Mike said, we are now counting the defects that are there, and the tolerance was set on those.

It bothers me that I can't remember the one exception to that rule, but we'll get back with you on that.

MS. DEWAAL: Okay.

MR. GRASSO: I wasn't asked that.

MS. DEWAAL: It wasn't. Okay, I would be interested to know that. But just to -- again, so hair,

41.80 percent of the carcasses had one hair, but those weren't violating the finished product standards, they just had one hair?

MR. GRASSO: Correct.

MS. DEWAAL: Not 26. And so they are going to have --

MR. GRASSO: They are going to have 50 hairs.

MR. CHURCH: They had hair.

MR. GRASSO: They had a hair.

MS. DEWAAL: They had a hair.

MR. CHURCH: Yeah. One of the things that makes a comparison between finished product standards and the current standards is that we set it up slightly different. Instead of counting defects in 10 carcasses, we are now counting carcasses with defects. And so if a carcass has a defect, it's a defective carcass and it gets counted in that OCP category. It might be one of the five categories, it might be all five, depending on what the defects are.

So it makes a comparison just a little bit difficult to make, but I think an objective evaluation of the side by side that we handed out at the public meeting

will show you that these standards are not looser. They are in fact tighter that the finished product standards.

MS. DEWAAL: Thank you.

MR. GRASSO: I think if you just ask the HIMP plants if they think they are tighter because they are tighter.

MR. BILLY: Okay. Dan?

MR. LAFONTAINE: Mr. Bill and Dr. Wotecki, I'll make a comment that is slightly out of context but I do need to make it.

After the March 30th meeting, I got feedback that led me to believe some of my comments, my comments at that meeting may have been misinterpreted.

What I wanted to say briefly is that myself, and I was representing the American Veterinarian Medical Association at that meeting, strongly continues to support the concept of HACCP-based inspection model provided there is adequate government oversight and verification.

And as those were there know, I was quite vocal and my comments were strictly meant as constructive criticism and not hopefully misinterpreted as being against

the progress of this project.

So I wanted to take this public forum to say that, please. Thank you.

MR. BILLY: Thanks. Carol?

MS. FOREMAN: My question actually follows a little on that.

There are several members of the committee who have public health responsibilities. I would like to ask them, are there any of you who would be reluctant to have in your home or in the schools chickens that had been passed out of any of the HIMP plants? Is there any reason in your mind to believe that the products coming out of those plants, to the extent that you're aware, are less safe or less wholesome than product coming out of any other plant in the country?

MR. LAFONTAINE: No.

MS. FOREMAN: Anybody else want to take a leap at that? Is there anybody that thinks that there is a problem with the plants?

I understand that we don't have the data yet, which makes it a little hard to answer.

(No response.)

MS. FOREMAN: Thank you.

I'm sorry to take that on for so long but I think that the transcript of the meeting will reflect some information that will be useful.

MR. BILLY: Thank you very much.

It is the intent of the agency to continue to share information with the public as we move forward, and another public meeting is being planned that will provide to the public all of the results now with the -- under the model phase. And in this incremental fashion as more data become available, I think we'll have a more and more complete picture and be able to make the kind of comparisons that we worked on a little bit here this morning, and it will just become clearer and clearer to folks.

Even after that in the public process, we will go through notice and comment rulemaking if that's justified by the test results, and another opportunity for everyone in the public to actively participate in that process. So we've got a ways to go before we make a final decision about changing the existing regulations that dictate how we do

inspection on the slaughter line or in slaughter facilities.

So this is an ongoing process, but I think it is important that this committee, you know, understand and help us as we move forward and guiding this project and ensuring that what we are doing is understandable and makes sense to all of you and obviously the public as well.

Do you want to --

MR. GRASSO: Well, just --

MR. BILLY: Excuse me. Cheryl, I forgot.

MS. HALL: Thank you.

I have a couple of statements and then a couple of questions, Mr. Billy.

One is that air sacculitis, to revisit that, is not always caused by a bacterial infection. It can be caused by dust in the houses or other possibilities. It does cause the inflammation, the look of air sac., so there is not always a bacterial problem.

From this study that has been identified that 50 percent of the birds that are condemned should not be condemned. In this study, particularly, 33,000 birds were condemned and 50 percent was in error.

And I wonder if that is going to be addressed, and the number that was quoted for air sac. numbers, we could only assume that that number also has a 50 percent error rate in it, and therefore I wonder if these problems will also be addressed in plants that have not gone onto this new inspection program.

MR. JAMES: One comment I would make regarding that is I am certainly there were birds in the condemned barrel that don't belong there. The way that chart is constructed does show that 50 percent of the birds that are in there don't need to be in there.

From a practical consideration, I don't think we had a 50 percent error rate, however. As you know, in-plants oftentimes a plant due to the impracticalities of reprocessing a bird or salvaging a bird will sometimes throw birds in the barrel because it's easier.

And so there is -- there are birds in the barrels that don't need to be there. Fifty percent is probably just slightly higher percentage than error rate than actually occurs.

MS. HALL: Could I address that by the stockmen

and packers that you can't throw away a contract grower's birds in the condemned barrel if it's not condemned. So that has to be kept separate by the plants.

MR. JAMES: That is an issue that needs to be addressed, and that is a different issue.

MR. BILLY: You had another point?

MS. HALL: It's my understanding that the VMOs and ISEs are going to be less on the line and less looking at what's going on in inspection; is it correct, that's the proposal? I in other than HIMP plants, I mean.

MR. GRASSO: Oh. Other than HIMP.

MR. BILLY: That's going to be talked about a little bit in terms of the role of our veterinarians on another agenda item a little later.

I want to try to wrap this up.

MS. HALL: I do have -- I have one more since the issue of condemns have come up.

In one of these HIMP plants the rate of condemned heads went up very substantially after the appearance of a newspaper article about that plant.

Is there -- somebody want to talk to me about why

that happened?

MR. GRASSO: I'm not clear on the question. A broiler plant has increased --

MS. HALL: Yeah, this Gunthersville plant, I've got a list of dates and the percentage condemned, and it went up -- it was very high in the beginning, then it dropped down very substantially, and then after the February 4th newspaper article in the Cox newspapers, it went from running around three and four to 16, 25, 34, 52, 21 over the next week.

MR. JAMES: We can look into that. We haven't examined that data so we're not in a position to comment on that except to say in general terms, as we have already stated this morning, that condemnation rates for individual flocks will vary. If there is an association in time with that newspaper article, we're just not aware of it.

MS. HALL: Okay.

MR. GRASSO: But I would like to make a comment that. There is a couple of things that govern the activities in the plant.

Number one, the plant may not have a salvage

operation, so they choose not to correct the defect on the carcass. Therefore, the bird gets condemned. Or the plant has a salvage operation and because of the conditions of the flock coming in they choose to shut it off. Okay, and then they are not going to deal with the defect, so the carcass is condemned.

MS. HALL: And that would vary from day to day in the same plant?

MR. GRASSO: Correct.

MS. HALL: Okay. Thank you.

I do need to get some detail to a response on that.

MS. DEWAAL: Thank you, I will be very brief.

This is a very impressive data set, and it is a good place to start the analysis of the new inspection models. I do wish we had campylobacter data.

MR. GRASSO: The one thing I would like to mention regarding the whole conversation, regarding air sac., is that the steering committee was there at the last public meeting, listened to all of the comments on air sac.; specifically on the maximum limit which forces the plant

into potential rework at post-chill.

And for your information we are looking at the data as I speak, and we are reevaluating so that will prove to you that this is truly a public process and open public process.

MR. BILLY: Alice?

MS. JOHNSON: I just wanted to -- Mike, I know that some of the broiler plants are through the RTI transition sampling.

Can you comment on that or would you rather not until you have all of them through or things?

It's my understanding that the follow-up data looks good when compared to the older system. So there anything you can comment on the data that you've gotten that you have completed from some of the plants already?

MR. GRASSO: It's really early, but what I -- how much time do I have?

MR. BILLY: Zero.

MR. GRASSO: Zero.

MR. BILLY: But you can respond to that.

MR. GRASSO: No, no.

It's too early, but what I wanted to get through to the committee is that we have the baseline phase, and we just had a good discussion of the baseline and what the accomplishment are.

So once a plant finishes baseline the next thing that has to happen is the change phase, and we call that the transition phase where the plant takes on some additional responsibilities and FSIS falls back into oversight and verification activities. We call that transition.

Now, on the broiler side we have 16 plants that have completed baseline. We have seven plants as I speak today that are in the transition phase or the change phase right now.

We have three plants what I call in the models data gathering phase. That's where RTI comes back into that plant and collects the same data from baseline, 2,000 carcasses, 300 and 300 on the micro for E. coli and salmonella.

So we are building a stockpile of 2,000 organoleptic samples in each plant. So if we can get like 10 plants, we will have in abundance of 20,000 samples to

evaluate whether the plants to meet the new performance standards on how they do.

We have two broiler plants that have completed the models data gathering phase, that's Goldkist and Townsend, and they are moving forward as a models plant today.

On the hog side, we have five plants that have completed baseline. We have one plant that's in transition right now, and two plants that have completed the models data gathering phase where RTI went back in and collected the data.

We are going to use the data from the five hog plants to establish the 75th percentile for the swine for performance standards. On the turkey side we have three plants that have completed baseline, we need to get two more plants for baseline data, and we would do the same thing for the hogs, like we do with the hogs. Five plants, look at the baseline data, establish performance standards, and then again go back into the plants and gather models data.

I think I will stop now while I'm ahead.

MS. FOREMAN: Thank you very much.

MR. BILLY: You are welcome.

It's 10:30. What I would like to do is to go to a break now, but I'm going to shorten it to 15 minutes. So I would very much like the committee to be back here at the table at 10:45.

(Whereupon, a recess was taken.)

MR. BILLY: Okay. If the committee members will take their seats, we'll get started.

I wanted to wrap up this discussion on the models project but there was -- one of our committee members, Alice Johnson, has been quite involved in this area of effort and wanted to share with the committee some of the initiatives that they have taken in their organization regarding preparing industry or plants for this kind of change in HACCP-based inspection.

Alice.

MS. JOHNSON: Mr. Billy said that I could do this but I had to do it quick, so no power point, no overheads, no video, doggone it.

Anyway, we've worked with a lot of the broiler companies and the National Chicken Council and put together a task force to look at how industry should consider

training. There are people that they are putting on line, and a lot of companies sent their individuals down to the basic poultry inspector training course in Texas, which they thought was very good. But as the inspectors, FSIS inspectors get ready to perform their function, they also have to go through a lot of administrative training, and so it was two weeks and a lot of it dealt with travel vouchers and T&As and looking at things that a lot of companies thought we needed more focus on just the pathology, the disposition.

The agency did come back and now offers a three-day training program that a lot of the companies have sent individuals to, which works out very well. But when you consider that a lot of these companies, one of the broiler companies that was a part of the joint NCC/NTF task force said they trained 60 people. And if you sent that many people down to Texas when this was happening, you probably wouldn't run birds for a couple of weeks.

But what happened was the task force got together and developed what they considered to be an appropriate training criteria, similar to what was done back when we

first stated with the HACCP training for industry. The training criteria was submitted to the International HACCP Alliance, which is a part of Texas A&M, and the criteria has been accepted and is a part of the training program that the alliance has their web page.

The intent is now that when people wish to be accredited, to have an accredited training program for the HIMP models, which if it becomes mandatory there will be a big need for the training courses. A lot of the industry put in hundreds of hours developing courses, and that's good for right now, but later on there will be more companies and there needs to be a center flow to keep the materials and to keep the training, the integrity of the program.

The criteria has been accredited by the alliance. Companies that wish to have their training program accredited can go through this accreditation review. They have to send in a copy of their materials. The alliance has an accreditation committee that reviews the materials and determines whether they meet the criteria that has been established, and we hope this will keep some uniformity in the way industry is doing things, and later on provide

resources with accredited trainers and the whole works.

And I appreciate the time.

MR. BILLY: Okay, thanks, Alice.

Any questions for Alice?

(No comment.)

MR. BILLY: I think that's great.

All right, we're going to move on. I think that was a very good discussion and elicited hopefully a better understanding of the models project and where we stand in the approach that we are talking.

Now, we're going to shift to the area of interstate shipment of state-inspected product. As the committee will recall, this an area of considerable effort by the committee that led to what I will characterize as consensus on a strategy or an approach to dealing with this issue, and based on that the administration produced a draft legislation that was forwarded to Congress, and is being given some consideration in Congress.

Chris Church is here to update us on where that stands and what some of the issues are. So Chris.

MR. CHURCH: Thank you. It was my pleasure last

meeting last November to tell the committee that the bill that they had been so helpful in shaping the concept for had actually been transmitted to Congress that day, so I think it was last November 2nd when we met here, and that was the day we sent the interstate shipment bill to the Hill.

And this morning I would just like to give a little chronology of what's taken place over the past six months and where we stand today, and hopefully get us back on track and turn it over to Ron shortly.

Most of you will have followed it pretty closely, but it was then two weeks after we sent it to the hill it was introduced by Senator Dashall and Senator Hatch as the new markets for state-inspected meat and poultry products.

Following that, in the spring back on April 6th, Senator Lugar held a hearing with the Senate Ag Committee on the bill. I know a number of you were there. USDA testified, Deputy Secretary Romenger for the department. I know Carol Tucker Foreman was there and various parties were represented, and a good hearing.

At that time Senator Lugar announced that it was his intention to get together all interested stakeholders

within the next couple of weeks to further explore all their views and then to move to markup. In fact, that did take place. Later that month there were two meetings where all the stakeholders did get together in the Senate Ag Committee, aired their views.

And at the present time it's my understanding that Senator Lugar does intend to mark up the bill in the near future.

On the House side the bill has not been introduced but I would say there actually is very great awareness of the bill and great interest, and they have been following the bill closely, and my sense is that the agricultural leadership in the House will monitor what happens in the Senate and then based on what comes out of the markup and what might -- they may move then or wait till action on the floor in the Senate, but I know they are monitoring it closely.

I know they came over to the stakeholder meetings that were held in the Senate to observe those, and I know from the calls we get in the office that small plants across America are writing their congressman because we get a lot

of calls at the office, how do I answer this letter.

In fact, I was up talking to the staff from a couple congressmen from Wisconsin last week, so there is a great deal of interest in moving the bill.

I have no prognosis for it. I think at this point people are jockeying. The bill as it is has held together, which I think is very important. One of the things we have discussed in the past is, you know, this was a concept that is sort of a delicate balance that had the consumer interest, it had the USDA interest, it had the state interest, and also had the trade interest all balanced, so the bill has held together so far, and USDA continues to support the bill as it is.

So it's kind of a stay tuned and maybe it will move to markup soon.

MR. BILLY: Okay. Comments or questions from the committee? Anyone?

(No response.)

MR. BILLY: Okay. All right, thank you very much.

The next item is another briefing that will focus on several administrative areas. One is the Workforce of

the Future, which includes our interests in establishing and filling consumer safety officer positions, what that's about. Another related initiative is a task force that we have had looking at the role of the veterinarian of the future, and then finally, we wanted to touch briefly on the areas of recruitment. We have had problems in the area of inspector shortages and we have mounted a significant effort to turn that situation around, and Ron will provide you more details in terms of what we have done and where we stand.

So it's my pleasure to introduce Ron Hicks, the deputy administrator for management in the Food Safety and Inspection Service. Ron?

MR. HICKS: Thanks, Tom. Good morning to you all.

I think the last time I was here I shared some information with you on what we hoped were going to be some successful efforts in the area of recruitment, and I think, as I speak a little bit more later on, you will hopefully agree that we have made some good in-roads and we have some good processes in place that are dealing with some issues, and we feel very good about where we are going in that regard.

Here with me at the table is Dale Boyle from NAFB, and Dale Boyle, Dr. Boyle worked with me heading up the task force of the workforce of the future, and asked if he would want to join me and to the extent that we wants to say some words about where we are with that task force and some of the things coming out of it.

I guess last May there were some issues that were presented to you on the workforce of the future and where we were headed in certain regards and certain areas, and my purpose here today really is just to update you on some things that have occurred over the past year.

Most of what we will talk about, I'll talk about, will be centered around a task force called The Workforce of the Future Steering Committee. It was a group that Tom assembled almost a year ago to help walk us through a lot of agency initiatives, so a lot of my comments will be based on some work that that group is doing.

The first update is on the CSO initiative, consumer safety officer. In '99, we advertised to fill approximately 30 positions in six metropolitan areas, and these are where the enhanced positions that we have gotten

feedback from you on that required more science and more education.

There were 100 internal folks who were qualified for those jobs or who applied for those jobs. Fifty were qualified. Unfortunately, we had to pull back those announcements due to some language that we've got in our appropriations bill for 2000 in which expressed some concerns or raised some concerns about CSOs and what they were going to be about and what the cost might be to the agency and so on.

So they asked us, Congress asked us to do a report that was submitted February 15th.

And by the way, the paper that I'm talking from is in tab 5 of your book, about half way through. And there is an attachment, an excerpt from that report that's attached to the document that I'm reading from.

We submitted a report to Congress that made our case, we feel, for why we think the consumer safety officers are a good thing, and we've been in touch with the Hill over the past few months, trying to answer any additional questions that they might have about consumer safety

officer.

We have yet to move forward with announcing and filling any jobs at this point in time. We are hoping to fill somewhere between 50 and 75, at least announce those this year and hopefully fill those as quickly as we can, but we're still waiting for the completion of our discussions with the Hill before we move forward with those.

We feel good about the report that we did put together, feel very comfortable with making our case. We've gotten good reactions so far from the House and Senate committees, and there are a few other folks who we have talked to, staffers that we feel are also understanding what we are trying to do with the consumer safety officer position, and we hope real soon to be able to get a positive nod so we can move forward.

But we didn't feel comfortable in light of the fact that we did receive such language in the appropriations bill, we didn't feel comfortable moving forward without having the proper amount of discussion on the Hill.

Some additional Workforce of the Future information that I want to share with you. The task force

is a task force that -- not like one that we've had in the past, the steering committee. Yvonne Davis heads it up and she has a staff of about three full-time people working with her. It's made up of representatives across the agency, NAFB, National Joint Council of Food Inspectors, ATSP, and others who don't have any affiliation with a particular group but who have different roles within the agency.

And the idea is to get a good cross-section of people who can contribute in a very meaningful way in terms of where the agency is headed and the different initiatives. Dale Boyle, who was part of VMO task force, as I indicated, is also part of the team. Every initiative in the agency that we have going on, that person, the lead person from that group is part of this Workforce of the Future Steering Committee.

Like I said, Tom assembled this committee last July, and the primary purpose is to make sure that with all these initiatives going on that there aren't conflicts or clashes in terms of the different directions that we are going with different initiatives, and to make sure that above all or as important as anything else we are

implementing initiatives in a way that is employee-sensitive while at the same time trying to accomplish what the agency is trying to accomplish.

So we feel really good about the fact that we have a group that's very dedicated, very hard working, has complete access to Tom and the other senior managers, and on a regular basis has been involved in meetings and is able to just ride herd over everything that's going on.

If you have ever had any involvement with agencies in the past where there are a lot of different initiatives going on at the same time, then you probably already realize and appreciate the benefit of having a group that's in place full time to just watch over and make sure that things make sense to and with each other.

I found interesting as the industry group was discussing and forming itself, it chose a quote from Melvin Toffler that says, "Our moral responsibility is not to stop the future but to shape it, to channel our destiny and humane directions and to ease the trauma of transition."

I wish I had thought of that, and suggested that to this group, but this is what they came up with and this

is how they see themselves, and they are not shy about -- this group is not shy about raising questions with anyone, the deputy administrators on down if they see an area of conflict where things just aren't working.

There is some challenges that this group is facing, that the agency is facing that I think it's worth just reading the paragraph in your handout where it says, "At the same time we are seeking to recruit inspectors and veterinarians for chronic shortage areas, introduce new occupation such as the CSO, retain season inspection employees, develop a career ladder that provides healthy opportunities for both long-term employees and external hires, develop a workforce succession plan and remodel our training and education program, all in the climate of limited resources."

Right there it just kind of points out where the agency's challenges are and what this Workforce of the Future Steering Committee has to handle. We feel really good about the fact that we have this group.

Some of the initiatives that this workforce is dealing with has workforce implications obviously is the

HIMP models project and the group is very closely involved in what's happening there in terms of looking at the jobs and where that project is going and making sure that the issues coming out of it are being watched and monitored.

One that you may not be aware of that the group is also dealing with is the Tech 2001, which is a training initiative. The agency has decided that it has a good training program, but it has a training and education program that may not be meeting the needs of all of its employees as much as it needs to and may not be getting the biggest bang for its buck.

So the task force is headed up by Peggy Nunnery, and once again it is a cross-section of people throughout the agency who are involved with it. And the idea is to look at our entire training program, maybe stop calling it a training program and call it an education program, and look at what we need to do differently in terms of what we are training our people in; what we are asking our folks to be more education and what our delivery is like; how we take advantage of distance learning; do we take enough advantage of distance learning; do we need satellite locations to

better accommodate and meet the needs of all of our employees because our dispersion is so great.

These are just some of the issues that the task force is tackling and taking on, and the Workforce of the Future Steering Committee is playing a key role and making sure that the proper answers, the proper questions are being dealt with there.

Another issue that the task force, Workforce of the Future Steering Committee is dealing with and it is obviously very near and dear to my heart is the area of recruitment.

We feel that we have had a good amount of success, as Tom indicated, since we last spoke. We have since November brought no approximately 290 inspectors and veterinarians. Just last pay period we brought on 29 full-time permanent inspectors and two VMOs. We have been doing a very good. Our top number so far has been 41, which is probably as many as we've hired in any one pay period, at least since I've been here and probably before then.

We feel that there is some combinations here that have caused us to improve, and we also appreciate all the

help and support that this group has offered us, and in some cases actually helped us with, so we appreciate that.

We have established a process by which every district manager can constantly keep track of what their numbers are in terms of on-board strength in these district. We have a process that allows them to anticipate attrition, and we have a process that allows them to identify key areas where recruitment needs are the most urgent.

On a regular basis those folks meet with my staffing people who are located primarily in Minneapolis, who service the field. I have approximately 12 to 15 specialists at any given time working with the 17 district managers in the field office, and their staffs on an ongoing basis, trying to keep track of where we are from the staffing standpoint and where our recruitment issues are and trying to stay on top of those. And we think that a lot of that has really caused some of the success that we have realized.

There is also bi-weekly reports that come in here to headquarters, and Mark Mina and I read them on a regular basis and then we share those with Tom and Maggie. So the

amount of interest and the amount of attention being paid to just what our recruitment needs are, our improvement efforts are has been tremendous, and I think we have benefitted as an agency as a result of it.

It's still hard work every day. These jobs, as in other job markets around the country, it's very hard to recruit and find people who want to be food inspectors and veterinarians. It's not the easiest thing for us to recruit for so we spent a lot of time and we've increased the number of test sites that we have from -- we've almost tripled the number of test sites.

We've made great use of temporary appointments, bringing people on board as the paperwork is being processed. We just recently got approval from OPM which is going to help us with our intermittants, to have them waive the two percent reduction in annuity that retirees would have to realize if they came back to work for us.

So now a person who is retired, and there is limitations place on how we can use these, but retirees that we know have a great amount of interest and coming back and doing some work for the agency from time to time for a year

or six months at a time are available and are very much interested. And now with that two percent penalty being waived, we have much more access to a large group of people who are trained and able to come in and help out on short notice and staffing shortage issues come in and help us out. We feel very fortunate and very pleased that OPM was able to grant that waiver and allow us to recruit from that source. We feel really about that.

So our efforts, we feel, in the recruitment area based on a process, based on the people that we have involved in it have created a great amount of success for us.

When I was making this talk last week, I said to the group that I was speaking with that while we have a goal to be at a certain point by the end of July, the best thing that we are doing is that we are institutionalizing a process, and institutionalizing a commitment to making sure that we do the optimal job in recruiting people and retaining people.

What is really happening is that as a result of the reorganization that took place a couple of years ago

some of the infrastructure that was in place in the field in the regional offices to deal with this recruitment and staffing was torn away, and we replaced it with another infrastructure, and now that infrastructure is starting to take hold, starting to work very well with the district managers and their resource people in the field, and it's starting to come together in a very meaningful way, so we feel really good with where we are, not just from meeting certain goals we have imposed upon ourselves for July, but also beyond that. We feel really good that we have a handle on what we need to do as far as recruitment.

Another initiative that we've been working on is the VMO of the future, goal of the VMO of the future. Dale Boyle and I have been working on this for about a year and a half, almost two years now, and we are about ready to issue a final report. We are going to be sending it to Tom in a week or so. We have some more feedback, if you will, to get from our task force members.

We had a wonderful task force to work with, both national and international, both internal and external to the agency. There were days when the vets were talking to

each other about very technical things where most of it just went right beyond me, and Dr. Boyle here was good enough to talk to me afterwards and educate me as to what was being discussed, so it was very informative and educational for me. They gave me a very good feel for what the veterinarians in the agency deal with and just what they bring to the table.

So that task force report is going to be going out as soon as we get the final nod from our task force members and Tom releases it, and Dale and I are working on an implementation plan to how we will implement some of the recommendations in here, but one of the things that it does talk about is trying to make optimal use of the skills and education of our VMOs.

So many of our vets right now are tied to the line. They are tied to the line dealing with supervisory or administrative type issues in terms of helping with staffing, dealing with union issues and problems and things of that nature, and feel that they don't get the opportunities to make as much use of their technical abilities and their education as they would like.

So there are some aspects of the report that talk about trying to find ways to make greater use of the vets' skills in that regard, which would mean taking them away from the line for some period of time. Now, what that period of time is is what we need to work through right now with everything that's going on in terms of looking at HIMP and looking at the role of CSO and looking at the role of compliance officers and things of that nature.

But what will hopefully come out of that is an expanded role for our veterinarians which will make optimal use of what they bring to the table, and will allow us to use them in different ways than just being so attached to in a plant on the line.

Dale, do you want to add to that?

MR. BOYLE: It's hard to even start without thinking about boring this group to death. I think some of you who have probably spent a day with us in February when we talked about the report. It really hasn't changed much. We're doing a little bit of nitpicking finishing up, but the general focus has been there. The primary response was quite favorable from practically everyone who talked to us.

For those who have to nitpick, they did give us a few things and we've tried to address those in a meaningful way.

I think I'll try to say this in two minutes or less. The report is in five parts, but number one is the role of the veterinarian as they exist in FSIS today is inefficient and needs to be fixed.

The veterinarian bring a lot of capabilities to the table but many of those capabilities are rusty, and so we also in the report said really you're going to have to give us the tools that we need. So one, use us; two, give us the tools; three, let's refine the way we are doing things, and we talked about some of the initiatives that the agency has underway, but we also went a little bit beyond and we are asking for some thing that have not been finalized. Some have been talked about for some time but haven't been done. But things like animal identification, expanded automation capabilities, expansion of partnering throughout, partnerships with industry, partnerships with trading partners, partnerships among ourselves, among the government itself. And finally, using the veterinarian in an expanded role throughout with the giving them more of a

role in the global food safety mission.

So that's kind of what it's about. A although this had a veterinary flavor, I think you could take this to any other discipline that FSIS possesses. Much of what we ask for are the same kinds of things that are needed by the inspection force, you could apply this to the consumer safety officer. We really need to concentrate on building an infrastructure that gives us an FSIS to be proud of.

And one of the things that I like to talk about is make FSIS an employer of choice. We can't say that right now, and we need to work toward that.

MR. HICKS: There on the bottom of page 3 of our handout just talks about the agency guiding principles for the Workforce of the Future, and just talks about what Tim Billy and what the other deputies views are on how we need to proceed, and I think that we had 11 principles that the Workforce of the Future Steering Committee developed and those four right there, those three at the bottom of the page and the one beginning of the next page kind of capture what those principles are and how we feel we need to proceed with our future workforce.

Just to finish off, the Workforce of the Future Steering Committee, you see there on page 4 some of the activities that it overall engages in and some of which I have mentioned already, identifies surface emergency issues or potential conflicts.

In our very first meeting we had an opportunity to do that when we made a decision, I think it was involving HIMP, and both NAFV and NJC were -- as being part of the group -- saw that in making the certain decision or change in a process that we were going to have some problems, and that it was different from what we had communicated to them in the past.

And so we had to get with Tom Billy during the week and meet with the key players and straighten now. Now, that may seem like a small thing, but in the past those are the sorts of events that would take us days, weeks, or event months to overcome given the nature of different relationships and just how difficult it is to reverse certain things once they go down a certain path.

So that piece of what this workforce does, workforce group does is extremely critical to us.

Facilities interaction between initiative leaders, Dale and I as a result of this group meet with other initiative leaders across the agency, and just to make sure that we headed down a path where we can co-exist with our initiatives.

Communicate with and support FSIS employees, this is an extremely vital role that this group plays. One of the things the agency is dealing with right now is some results from a National Partnership for Reinventing Government All Employees Survey, which just talked about the fact that a number of our employees just feel that we need to improve our communication and to be clearer in our communications. We need to be more frequent in our communication. We need to be also simpler in our communication in terms of keeping them informed as to what's going on.

So the work that this workforce group plays in that regard is extremely vital. The more we can engage our people and make them feel engaged the more successful we'll be in terms of what we are trying to do. So that's a very vital role that this group plays.

They have also put together a chronology which may be of interest to you all if you haven't seen it because it just starts out from when the rule was being drafted and brigs us up to date to now in terms of what all the events have been. And the tough part we're having is keeping the chronology to less than X number of pages. Of course, the longer you go the more things happen. But there are a lot of key critical events that are part of that chronology.

Our employees have found it very informative. Some of our managers have found it very helpful in terms of tracing what's happened. I imagine you guys may feel some interest in look at it as well if you haven't already seen this. So if folks are interested, we'll be happy to provide it to you.

And the last thing here on this page is like a flow chart, a functional flow chart. What the group is trying to do is create a flow chart for the agency in terms of what work that we do from slaughter through processing and try and lay out roles along this flow chart, much like you would on an assembly line, if you will, and make it more visual in terms of what happens at different points in the

chain and who is involved and where there may be overlap.

This is sort of an ambitious undertaking that the group is trying to accomplish, but we feel that if we can get this, it may be very, very helpful in terms of having folks just look visually to be able to see what we do and where the overlap may be.

Questions? Comments? Thoughts?

MR. BILLY: Katie?

MS. HANIGAN: One question I do have for you, you indicated that you had 50 qualified applicants for the consumer safety officers?

MR. HICKS: Mm-hmm.

MS. HANIGAN: Are you planning or is the agency planning on lowering the qualification standards because you indicated that they were wanting to fill 50 to 75 positions yet this year? So if we only have 50 qualified applications, where are the other 25 applicants, qualified applicants coming from?

MR. HICKS: Well, we don't intend to lower any standards in terms of what we are looking for. Those were announced in certain -- in six areas. So obviously,

hopefully, if we announce them in more areas, we would have more applicants.

And also just the second time around with more information to people in terms of what the jobs are all about. More familiarity with the job, we expect more people to apply just for that reason as well. But it was limited to those six areas, so normally that happens.

Just by way of comparison, not related to consumer safety officer at all, we have announced jobs in the labor relations field nationwide and gotten just a couple of applications. So you could go out tomorrow and announce that again, and get three or four times that many.

MS. HANIGAN: Okay.

MR. BILLY: Lee?

MR. JAN: Back in '95 or '96, when FSIS began reorganization and moved to the districts, there was talk about or a proposal to have a field epidemiology officer or epidemiology officers in each district. I think there are now eight or nine of the districts have epidemiology officers, and there is nothing mentioned in here for epidemiology officers.

Is that going to -- is that still part of the plan or is that going to go away or can you tell me about epidemiology officers?

MR. HICKS: It's not going to go away, and in fact I think in the beginning of this year while we were having budget discussions and making budget decision there was talk of having an epi officer in each district still. And we had to make a decision at that point that we couldn't do that just from a resource standpoint.

But it's very much alive. It's very much on the table and I am sure that we will revisit it as we start discussions at least for next time around and maybe sooner. So it's still on the boards to do that. The decision just will be made as to when.

MR. JAN: Okay, thank you.

MR. BILLY: Donna?

MS. RICHARDSON: Yes. You indicated that you were identifying locations where special recruitment activity was needed and then further down you talked about the fact that the efforts had been moderately successful, and two questions as to whether or not this success has shown up

where you have these critical shortages, and also when you say that you are in the process of hiring 265 new full-time inspectors and 105 new full-time veterinarians, what does that mean, we're in the process?

I mean, you have that many vacancies identified or you have actual applicants?

MR. HICKS: I have to admit the fact that that sentence was a little unclear to me. We've hired since last November close to 300, but we always have -- and we still have in the process, if you will, vacancy announcements that each district has submitted to us that we are hiring for. So we are continuing to recruit for vacancies across the country, and that's a fairly large number. I'm not sure if that 265 affects that or not.

MS. BOLTON: The 265 also reflects those where the decision has been made to select a certain person. You send a letter to them. You wait back to see if they -- if they have accepted, or the interview process has taken place, whatever stage, it could be in various stages. The reporting date has not yet been set, but it means that there is a candidate in mind, and that person is on his way

somewhere in the process.

MR. HICKS: This is Joanne Bolton, who works for us in HR, human resources, and she is also one of the permanent members of the Workforce of the Future Steering Committee, so she works pretty closely with the recruitment folks obviously because of her position, and so she is able to clarify what that 265 means better than me.

MS. RICHARDSON: With those identified bodies, are those identified bodies slated for some of these high critical areas that we are talking about?

MR. HICKS: Yeah. We have, especially in those critical areas, we have a staffing specialist or two working with the district manager and their resource management specialist in those areas on at least a weekly basis and sometimes, Ms. Richardson, on a daily basis, trying to deal with those critical areas. And sometimes -- sometimes we are able -- in some cases we have answered the need in those areas, but because they are critical areas where it's tough to hire areas, we're constantly needing to stay on top of it.

So in some areas, like in Kansas, we feel good one

week and then the following week we don't feel as good because the turnover is such that we need to stay on top of it on a regular basis. We feel the best about the fact that we have a process in place that helps us do that, and we have the resources dedicated to it to help us get there. So we are as positioned as we can possibly be in terms of being able to get at it, but sometimes each week brings a different scenario for, but we are able to identify, and that's part of this process that the district managers have before them, we are able to identify where the critical areas are on any given day and what the needs are.

MS. RICHARDSON: Okay, thank you.

MR. BILLY: Alice?

MS. JOHNSON: First a comment and then a couple of questions.

I think the agency needs to be commended particularly for the training committee that I know Peggy has been working with. Our tech and reg committee was in Omaha and they were a part of one of the focus groups. The questions were great. It was a really good interaction, and you're to be commended for reaching out to the various

groups to work through some of these issues.

MR. HICKS: Thanks.

MS. JOHNSON: I want to ask some questions about CSOs/CSIs. Currently, now you said that there were 100 that applied and 50 that were eligible.

Do we currently have consumer safety officers within the FSIS workforce?

MR. HICKS: Yeah.

MS. JOHNSON: And how many?

MS. BOLTON: Right now we have 17 who were former food technologist. They are in each district office. But other than those 17 who were reclassified from food technologists, we don't have any.

MS. JOHNSON: Okay, and there are none in plant right now?

MS. BOLTON: No.

MR. HICKS: Uh-huh.

MS. JOHNSON: What about consumer safety inspectors, do we have any inspectors that have been reclassified?

MS. BOLTON: Twenty-seven hundred food inspectors

have been reclassified to consumer safety inspectors.

MS. JOHNSON: Okay, and that's the on-line inspector?

MS. BOLTON: The off-line inspector and the ones in processing plants.

MS. JOHNSON: Okay. I'm going to switch here just for a minute. On the -- I'm looking at inspector shortages because we are really concerned, especially as we get into the summer months, and a lot of focus has been on the HACCP inspection models project and the freeing up some of the inspectors there here.

The agency also committed to do a work measurement within the HIMP plants. Have you started the work measurement for the oversight verification inspectors that are currently in the HIMP plant? Will that be a part of the rule or the proposed rule when it comes out in the next few months?

MS. BOLTON: Their work has already started. The visits have been made to some of the plants already, and so work is being done at this point to develop a system for determining the proper number of inspectors needed.

MS. JOHNSON: And one more question and then I'll be quiet here, for a little while at least.

Once you get an inspector in the system and a VMO into the system to get ready to go, I know you have an estimate for how long it takes by the time they accept till you get the paperwork till you get the training, to the point where they can be on the line.

Is it weeks? Is it months? How do you estimate how long it takes to get them on the line and ready to go? We have them in the system but when will they be able to man the line?

MS. BOLTON: The former process really was pretty elongated and took about 90 days. I'm sure that those steps have been cut. Again, Ron talked about temporary hires until the paperwork is processed and clearances are done and those types of thing until they can be scheduled to take the test.

So I'm not quite sure what the new time frame is.

MS. RICHARDSON: But it was 90 days just for the paperwork aspect of it and that didn't include the training and orientation?

MS. BOLTON: The 90 days included the process from announcing the position until the applications were rated, all the way through till the person being on board.

MS. RICHARDSON: Hired, but not trained.

MS. BOLTON: Right.

MS. RICHARDSON: Thank you.

MR. HICKS: We get them more in the matter of weeks now. Sometimes, depending on when the person is able to report or when a certain district is ready to receive them, where there is not a shortage issue kind of determines what the amount of time is. But it is weeks now as opposed to months.

At some point we can give you all some -- because we are going to analyze and assess our progress in a very detailed way -- we can give you some estimates as to what the average times have been to bring people on board. We would be happy to share that with you because we want to know ourselves just how much we have improved or how much we haven't improved.

But we think what we will see is that we obviously have improved in terms of how long it takes to bring people

on board and we will be looking at those kind of figures and numbers to see how much more improvement we can do and what things we need to do. So we will be happy to share those with you.

MS. JOHNSON: Thank you.

MR. BILLY: Magdi?

MR. ABADIR: Yes. We should gain about these 50 consumer safety officers and right now what you have is --

MR. BILLY: Would you move the microphone right in front of you? Thanks.

MR. ABADIR: Of those 50 that are qualified are originally inspectors that are on line with experience now or I mean, the data that you have right now on those 50 that you talked about, are those people working on the line at this stage or been not working on the line?

The other issue I want to raise too is backup, for example, for small plants and very small plants. When you see an inspector, someone backing up instead of having four or five plants to look, you have an inspector in one day that he's looking at 12 or 16 plants. That means he's spending a few minutes there, and without knowing those

plants, never been in this area, becomes very difficult for a real good job or a quality of it when someone doesn't know anything about the facility.

MR. HICKS: Okay. As far as the 50 that I mentioned to you, those jobs were pulled back. We announced those jobs early on. We did not proceed with filling those jobs because Congress has some issues with the consumer safety officer concept. So we felt we needed to deal with that, and we're still in the process of dealing with that. So those people who qualify for those jobs never did really move forward.

The CSOs that we have on board are the ones that Joanne mentioned, that we have one in each of the districts.

MS. BOLTON: But those that apply for the jobs were not people in line jobs. They were processing inspectors and some VMOs did apply for those jobs as well.

MR. BILLY: Okay. Rosemary?

MS. MACKLOW: I would like to make a brief statement and ask a question.

It's not well understood by the community the real importance under the existing law that you must have in a

slaughter plant an inspector on site before operations can begin, because antemortem inspection continues to be a critical issue. And thus the staffing requirements that you are handling and the concerns that the industry has are critical to making sure that the industry can operate.

In my lifetime in this industry, I have known quite a few occasions where because of some error the veterinarian didn't arrive in time for antemortem inspection. An animal got killed. It got condemned because antemortem is part of the process, absolutely critical. And therefore we are very interested in ensuring that there are sufficient people to conduct the business of the agency.

It's particularly tricky because most slaughter plants are in rural areas and if he has a problem at home or, you know, there is a myriad of reasons why people don't get to work some day and accidents happen. But when an accident happens on antemortem inspection, they don't operate. Or if they do, the animals are condemned.

Like others around the table, Ron, I think things have got a lot better. I'd like to ask a question on the attrition rate, which is the other end of the equation of

why do you lose inspectors? Why do they leave? What do they go to do if they leave the agency? Is it mostly retirement, honorable retirement, or do they leave for better jobs? What kind of exit interview information do you have for losing inspectors at the other end of the equation?

MS. BOLTON: We have an exit interview system in place but at this point the form has not been approved by OMB, so it cannot be issued to anyone after they leave. So we sometimes don't find out about a person leaving until afterwards by the time it gets from the plant to the person, to headquarters, that the person has left.

But of those that we have gotten from inspectors, there is a myriad of reasons, but the majority of them are retiring. The average age for our inspector workforce is about 48. We have inspectors who love their jobs and most of them do tend to stay in those jobs. But the reasons they leave are better working conditions. They do feel isolated at some points.

One, I know, left to go into the ministry. There are just various reasons. But the majority of the ones that leave it has been because of retirement.

MS. MUCKLOW: How many numbers have you got leaving versus numbers coming in?

MS. BOLTON: Because of the aging workforce federal government-wide, all the baby boomers are the ones that are now leaving, and that's been the problem with the staffing shortages is as soon as we feel we have gotten up to the number that we need we have other people who are leaving, and I think in the last year the retirement rate in December was a little higher than it was in previous years.

MR. HICKS: Normally December and January are our toughest months, and at points, different points during the summer. But this year our attrition continued into February and March and a little in April. I do think that we lost people just because we have a mature workforce and folks just decide that it's time to leave.

But just from talking to folks, and we do make a lot of visits to the field, and they communicate with us, people just -- like Joanne says -- have a lot of reasons. The work is less desirable. Some people who are here don't change, it's very difficult for a lot of folks, and they are not quite certain either how they fit into it or whether

they want to fit into the change that's going on.

So it's just a lot of reasons that people are leaving, a lot of different businesses and places right now is trying to find better jobs, trying to find more money, trying to find better situations. That's a part of it, and that's the part of it that we have to deal with. Tom and I have had more than conversation about being an employer of choice.

Saying that is one thing and making it happen is a challenge. But as we tackle that challenge, I think it will also affect our retention and our recruitment because people will say, "I wouldn't mind working for that place."

So it's a number of reasons but that's an issue as well as retirement.

MR. BILLY: Cheryl and then Nancy.

MS. HALL: Thank you.

I think it's an excellent idea to try to free the veterinarians from the administrative paperwork and the scheduling and all that. But I have a question about how we're going to proceed with the line inspectors.

If you free the veterinarians from the line, who

is going to oversee the calls on pathology and who is going to do correlation, that sort of thing because the only person that the agency has in a plant to do that would be the veterinarians?

MR. HICKS: Yeah.

MR. BOYLE: There was no will of the committee to exonerate from the technical oversight. Where we see a real opportunity is in the young healthy animal slaughter and similar to a HIMP mode in that you have either an oversight responsibility, whether it's plant personnel or inspection personnel that are performing the removal of pathology. You're going to have a responsibility to make sure that's going well.

If you have a truly effective HACCP system and you aren't doing young healthy animal slaughter, then this is a fairly easy thing to do.

If you have a truly effective HACCP system, and there are problem animals that are being introduced, we will know that ahead of time. It won't be a surprise. Industry will inform the entire inspection team that this is going to occur, and we're going to schedule or line speed, and we're

going to schedule our activities appropriately.

So when that occurs you can -- you can, again, refocus the veterinarians back into those things. However, I don't think it's necessary nor did the committee to take time and attendance of inspectors, and that's been a big part of what we do. I don't think it's necessary for us to, when the union is unhappy about something, to be the main mediator of whatever that issue might be at this particular time.

It's not particularly important for us to be overseeing that line at all times when that line is going very well, and there may be days and even months in certain operations where that can occur.

Having responsibility throughout the entire plant is far more reasonable. In other words, you know what's going on on line because you visit that on a regular basis. You more or less have a quality system yourself, a quality system for vets, if you will.

Well, we know where we're going to be, and we are going to set it up on an irregular basis to oversee the entire plant. We're going to be interacting with whatever

microbiological controls are in place. And I think I'm getting on a soap box so I will step back off. I can see myself going.

MS. HALL: I have one other question.

We have a lot of safeguards in place for the pathology to be called correctly, but we don't have anything and you are removing the one thing that does say whether inspector by inspector they are making the calls correctly. In other words, they are not overculling such as the 50 percent of birds in the barrel. And while this study wasn't done on the baseline to say how many birds additionally are called for air sac. or other conditions that should not be called for that, that does happen, I can say that and I'm sure everybody that goes in the plant has seen that.

What do you have in place for that, to address that problem? When you have an employee -- I mean, we have inspectors that rotate from red meat plants to poultry plants, and there is a whole different way of looking at the carcasses. So what do we have in place to address that problem?

MR. BOYLE: I don't think you have anything really

in place right now other than the veterinarian in the plant, as you said before. And I see no reason for that role to go away.

MR. BILLY: Yeah, maybe I can help a little bit. I don't think there is any intent to extract our veterinarians from playing those kinds of roles, but there are certain functions that many of them play now that we believe could be carried out by inspectors and free up some of the time of veterinarians to do other things.

We will be starting a public process to look at that and there will be plenty of opportunity for this committee and everyone else to provide input. But it will be done in a way to strike an appropriate balance. And to the extent that inspectors aren't filling in on the line, if that's needed, then we have a responsibility to have another source of inspection capacity to do that, to play that role. So that's a part of what we need to sort out as we look at implementing the recommendations in the report.

MS. GLAVIN: One of the things that many of our vets complain about is that in this time of short staffing they are spending three-quarters to all of their time giving

breaks to inspectors. So in effect, we have a highly trained veterinarian working as a food inspector, and, you know, so that's the kind of thing that this task force is trying to come to grips with.

MR. BILLY: Nancy?

MS. DONLEY: I'd like to make a comment and also ask a question.

On this consumer safety inspector role where I want to voice a concern that it says here that roles are going to be filled by converting processing and on-line food inspectors in HACCP plants. And I think that the amount of inspection done in processing plants now is at far too low a level currently, and I am very concerned that to even lower that further we could be putting additional -- creating additional problems.

What Magdi had said earlier about the fact that, you know, in some of these processing plants you will have an inspector who is covering, you know, 10 or 12 different plants. They are in the plant for five to 10 minutes. It's just not enough time to really, you know, be doing a thorough job. So I'm very concerned with that particular

plan.

And second, I have a question is on the first page under the main points. Ron, it says -- maybe you can clarify this, tell me what it means. "We have no plans to reduce current employment levels, but we do seek to limit workforce growth in a rational manner."

I don't think I understand what that means.

MR. HICKS: What that means is that we are not looking -- I mean, we are looking to hold onto the resources that we have, that we need the resources that we have. But we need to make sure that we are making the best use of those resources that we possibly can.

MS. DONLEY: The resources in terms of personnel?

MR. HICKS: Mm-hmm. Right.

MS. DONLEY: So these new positions are going to be additional personnel or you are converting individuals?

MR. HICKS: If we can get additional personnel, we will get them. But we plan to use our existing personnel. It won't be additional one, but we want to make sure that we don't have fewer personnel either, and we hope to convert our current personnel resources into some of these

positions.

MS. BOLTON: I guess, to add to that, we wanted to keep the same number of staff years that we have now. And as attrition occurs we want to fill those positions either through the conversion of the current workforce to those positions, or by hiring in others, but we want the staff years to remain the same instead of being decreased.

MR. BILLY: Maybe I can help clarify that point and the earlier on you raised.

A way of reading that is to read it as a notification that the agency is making to all interested parties that we believe we need to maintain the size workforce we know have; that we have other roles that people can play beyond those that they have traditionally played in addressing food safety issues.

So for those that might be thinking about targeting the size of our workforce and trying to impact it, we are just saying for everyone to hear, hopefully, that we need the people, the resources we have, but we're -- our workforce of the future strategy is about redefining roles, and in that process creating opportunities for our people

to, through more training and education, get higher paying jobs, safer jobs, more effective jobs in terms of food safety.

MS. DONLEY: And that's the rub because -- I'm sorry.

MR. BILLY: Let me finish.

And then the concern you raised about the conversion, don't read conversion as those people leaving. They would stay in place, but if they qualify or if they are taking additional class work to meet the qualification requirements for consumer safety officer, we can redefine that job from what it now is to a consumer safety officer, and the person will receive more pay. There will be more rewards and they will be in a position, we believe, of doing a more effective job in a HACCP environment.

So it's not taking people away; it's upgrading the skills consistent with our approach to inspection, and then rewarding people that are -- you know, through further college classes and on-the-job training and so forth, qualify to meet the requirements of a consumer safety officer.

MS. DONLEY: And I really applaud what the agency is trying to do in getting -- in upgrading and getting additional skills and levels of education. I think it's very important.

But as those skill levels go up, pay levels go up, and if your budget remains the same the numbers have to -- the numbers of individuals have to go down.

I mean, I just -- and I think you don't need, as far as monetary resources, you can't expect to remain the same. You have got to go up.

MR. BILLY: Yeah, and that's consistent with the budget strategy we have been pursuing, and would intend to continue to pursue.

MR. BILLY: Carol?

MS. FOREMAN: I had to step out for just a minute. Did you have a discussion of this year's -- the 2001 budget, which suggested that as a result of the implementation of the HACCP models projects and changes in processing inspection, you would need fewer inspectors?

And it is my understanding that in the Senate Appropriations Committee report it says that they expect you

will have these processing changes in place by next March and that you will sustain certain personnel reductions as a result of those changes being made.

Now, this goes absolutely contrary to all of this. Does the department know that we need all these positions? Does OMB know that we need all these positions? It's sure that the Senate Agriculture Appropriations Committee doesn't know we need all these positions.

There will be a tussle with my organization if there are any attempts to reduce the total workforce for the Food Safety and Inspection Service. We need those inspectors. We agree that we need them doing some different things. But as Nancy pointed out, the level of processing inspection in some plants is far below what's needed. And unless you go through notice and comment rulemaking to alter the process -- the manner in which processing inspection is doing, we will oppose it vigorously, and we will make a big fuss about it.

It's contrary to everything else the department is trying to do.

MR. BILLY: Cathy?

MS. WOTECKI: Yes, let me first of all make a few observations and then address directly the issue that Carol has raised.

I have been quite struck by the nature of this discussion and I think Rosemary's comment early on was right on target. I have been struck because the problems that FSIS is facing with maintaining the size of its workforce, upgrading the skills of that workforce, retaining those people is also the problem that's being faced by almost every other federal agency.

There was a very good article in the Washington Post last week that, Tom, we might make available to this committee because it kind of points out that this is a problem that's facing the federal government across the board. We have already pointed out that the FSIS -- the age structure of the workforce is such that we've got, and we should expect also over the next 10 years to have a major proportion of our workforce retiring.

At the same time we're struggling to attract people into job that are in this current economy rather low paying jobs, and we are competing against growth in a number

of other sectors. So FSIS is having these problems. Many other federal agencies are having the same problems.

So I think it's good to kind of put that in context. It just isn't a problem for FSIS, it's an across-the-board problem. It's perhaps the more acute because of the reason that Rosemary brought up. The agency does have a legal responsibility to have the proper qualified people in-plant so that they can operate. So there is this additional requirement on the agency that if there are no those appropriately qualified people in-plant, the plant can't operate, and that is creating across the country some problems in some particular areas where it's been extremely difficult to recruit and to retain people in those particular areas of the country.

So I think it might be worthwhile if we could get a copy of that article and provide it to you. For those of you that don't live in this area, it's kind of illuminating because it does point out that this isn't just a problem for this agency, although we do have some particular concerns as well.

With respect to, Carol, your comment, constructing

the 2001 budget was very challenging to put it mildly. The agency has been over the past several years designing the inspection models project, putting it into place, keeping this committee and the interested community at large involved through a series of public meetings about that project. The implications of the project have also been spoken about in a number of public meetings.

So that project and its implications were taken into account in constructing the 2001 budget.

In addition to that, the changes in --

MS. FOREMAN: I'm sorry. Did you say were or were not?

MS. WOTECKI: Were taken into account. Beginning, you know, two years ahead of time to construct a budget you have to make some assumptions, and the agency did make some assumptions based on the progress to date of the inspection models project, particularly in the poultry plants.

So looking forward the implications of that were among many underlying assumptions that were used in the construction of that budget.

We made it very clear though in the testimony that

we gave on the House side -- this year we did not have the opportunity to testify before the Senate Appropriations Committee but we did submit written testimony, and in both cases the written testimony and the oral testimony that we provided we did indicate that we would not be move forward until we had thoroughly evaluated the full implementation of the models project.

So I think that any language that the Senate has written in is not taking into account that, and we will certainly be working with them for that further clarification.

Now, the reductions that you're talking about were associated with overtime pay for processing plant inspection and did not reflect actual people. It is a difficult concept in the budget, but the FTEs that were accounted for actually were reflecting overtime pay and not a real reduction in the number of people.

So we've tried in the testimony to make that clear. We have tried as well whenever we've had an opportunity to talk in public or with groups to make it clear, but it is certainly in the area that obviously we're

going to have to do some additional talking and explanation, and so that people can understand that.

MS. FOREMAN: Let me -- look, I first became associated with the meat and poultry inspection in the mid 1970s, two years after OMB had contracted for its first effort to excuse reducing the number of inspectors, the Booze Allen Hamilton report.

Every -- virtually every year since then the Office of Management and Budget has been looking for ways to reduce inspectors. From time to time, they have succeeded for short periods of time. Industry and consumers all get together and say this isn't acceptable. For years you all have been sending budget proposals up to the Hill to fund inspection with user fees, and again we all get together and we oppose those.

When the poultry industry began to expand very substantially the department started, because of the carcass by carcass inspection requirement, to pull inspectors out of processing and they have never been replaced, and it is very alarming for me to read anything that suggests that there are savings to be made in processing.

I would like to see the department and the administration be saying that to the extent that position savings are made as a result of the HIMP projects, they will be utilized to make up for some of the shortages that we have in processing inspection.

And although your testimony on the House side was very reassuring with regard to the process that you'll go through in terms of the HACCP models and personnel, I was not very reassured by the statements about processing inspection, and still haven't seen anything that says that you're not going to go in and reduce further, as your budget suggests you will do, the level of processing inspection. It says in the budget that you will not be visiting plants on a daily basis in processing -- I'm sorry, on a shift basis, and that's not sufficiently clear.

We'd like -- obviously I think that a risk-based processing inspection system is the way to go. That means in some plants, like plants that grind hamburger and are now visited on a patrol basis, you might have inspectors there all the time.

There is nothing in the budget documents that say

a word about that. I don't think it's in your appropriations testimony, and I think it's fairly clear from the Senate Ag Appropriations Committee report that they don't understand where you want to go, and I don't believe that the people who hold the purse strings at OMB understand and what's worse, I don't think they are sympathetic. I think they see 7,500 slots and they have already started calculating, oh, yes, with all these changes we can get down to 5,000, and then other government agencies will be able to have more employees.

The bean counters really have more capacity to undue all the progress that's been made in updating inspection than anything else that I can think of.

MR. BILLY: Rosemary and then Lee will have the final word.

MS. MUCKLOW: I'd like to see if I could allay Nancy's fears and to some extent Carol's fears about processing inspection, and maybe give the committee a bigger picture on that as I tried to do slaughter inspection.

People who process, not slaughter, are required to provide the government with their schedule of operations.

They are not permitted to start their operations before the scheduled starting time or to end them after the scheduled starting time without notice to the government. This is vastly different from every other food product that is processed in the United States.

This gives the government the flexibility to visit that plant on a patrol basis at any time. The government also under the reorganization that FSIS has done has two levels of people that may choose to go visit that plant. One are the regular foot patrol inspection; the other are the increased level of compliance staff.

So if there is a concern or an issue, they have two levels of people that can be deployed, in addition to a circuit supervisor who may casually drop by.

The processing plant may see an inspector once a day. That inspector may spend 20 minutes there, he may spend two hours. He has a flexible schedule to go into a processing plant and look at very specific issues. This is part of HACCP. The transition is beginning to take place. Some do it better than others. Some plants do it better than others. But this flexibility does exist.

I would just like to assure that each plant is assessed by the agency in terms of how much inspection it needs. That process started in 1986 with the passage of the Processed Meat Inspection, the performance-based inspection system. That flexibility, that assignment of tasks has been an evolution that has occurred over time.

The processing inspectors are higher grade inspectors. They are people with more qualifications that can walk into a plant. They have more knowledge, more understanding of what that operation is, and they can accomplish their tasks and conduct their inspection activities and look at records more rapidly than an inspector who is standing on line in the slaughter plant. It's just a whole different process, and it's why with a smarter working force you can cover a lot of space as distinct to stationary inspectors who stand on a line looking at slaughter operations.

The one last point I would make is that one of my favorite books that you publish is the Annual Report of the Secretary to Congress. And you only have to look at the map in that book and see the map of the United States, and each

state is marked with how many inspected establishments and how many inspectors there are. That picture tells a thousand words.

It tells you where the large numbers of inspectors are standing in those stationary positions on lines. Those people are not necessarily interchangeable with processing. They will need more qualifications, upgrading, further education to take the processing inspector; really running two systems, and they simply are not interchangeable.

But I would certainly like to assure that processing inspection is conducted every day in every plant in the United States. There may be some rural plant that will get an inspector every other day, but in most plants you are getting inspectors every day, spending a meaningful amount of time on a random basis. They can go at six in the morning or two in the afternoon. The company doesn't have that schedule of their assignment.

MR. BILLY: Lee?

MR. JAN: I won't need to take a whole lot of time because Rosemary is thinking, I think, on the same line that I am. But I wanted to make a comment to make it clear that

this committee is not unanimous in supporting maintaining or increasing the number of inspectors.

I think we need to have a number of inspectors necessary to do the job, but we have a system now that we have all embraced, the HACCP system, and we need to rely on that system that, that system that says the responsibility for food safety is the plant's responsibility, and inspection's responsibility is to assure that the industry has taken that responsibility to heart and carrying it out. And you don't, in my opinion, have to have an inspector holding the hand of an industry to carry that responsibility out.

The inspectors need to be in a plant often enough to verify records and verify that things are being done properly, but we don't have enough inspectors, and I as a taxpayer don't have enough money to give government to keep putting in an inspector to do the job of an industry when an inspector can do that, not necessarily every day, even though right now that's the goal is every day, but under HACCP, HACCP is applied every day. HACCP system works every day. HACCP system worked when the inspector is not there.

So if there is a time that an inspector is short, rather than having someone in the wings waiting to cover for him, have an opportunity for HACCP to work and an inspector may miss a plant a day or two, but the system continues and the records are there to verify that it worked and it continued to work.

So, but I think that's basically where Rosemary was going and I just wanted to make that point.

MR. BILLY: Okay, I want to call this discussion to a close. A lot of good discussion and different points of view. We're a little behind, but then what's new. It's 12;15, so I would like to resume at 1:15, and we will pick up on the agenda with the industry's petition.

(Whereupon, at 12:14 p.m., the meeting in the above-entitled matter was recessed, to resume at 1:15 p.m., this same day, Tuesday, May 16, 2000.)

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A F T E R N O O N S E S S I O N

(1:24 p.m.)

MR. BILLY: We're missing several committee members. Unfortunately, the restaurant upstairs was a

little inconsistent delivering its food, including the Chairman. So there are about four or five folks that were just finishing and should be down momentarily. I'll talk a little bit about the agenda in anticipation of those folks coming.

What I thought we could do is the ARS presentation is going to be by Roger Breeze instead of Floyd Horn. Roger is one of the associate administrators, and he was here earlier. He had to run and get something, but he said he'd be right back, and I'd like to try to keep him on the time slot that he's scheduled for. So what I was think of doing is dealing with the industry petition immediately, and then we will play it by ear in terms of how far we can get into the additional species. Maybe we could deal with both of those before Roger speaks at 1:45.

So with that, let me introduce Dan Engeljohn who will be addressing an industry petition that proposes a series of changes to the existing HACCP and pathogen reduction regulations.

Dan?

MR. ENGELJOHN: Thank you, Mr. Billy, and good

afternoon everyone.

Each of you should have a copy of the petition itself as well as the issue paper that addresses our current thinking in tab number six. In addition, we did make sure that each of you got a copy of the Federal Register reprint that came out yesterday which published in its entirety the petition that was submitted to us by the industry. So you should have both those documents.

The notice that published in the Federal Register is virtually word for word as to what is in the petition. There is just a bit more information in the notice simply because it provides a little more framework as to why we are issuing the notice through the Federal Register.

I do want to say that this is a unique opportunity for us here at the agency to present a petition to this committee in particular. To my knowledge, we have never put a petition in front of a committee before nor have we published one in the Federal Register and asked for comment.

So as part of the efforts within the agency to be transparent in what we are doing and to be informed about the decisions that we're making, we've gone the extra step,

I believe, to elicit public comment and the expert advise from a committee such as this to help us in formulating how we move forward with a regulatory change.

I do want to just say a little bit about the petition process because it's not in this particular paper, and for those of you on the committee not familiar with rulemaking it may give you a little insight as to the process.

The department has regulations. Actually there is one sentence within the regulation that says that the federal agencies must accept petitions from the outside on how a regulation can either be improved, deleted or a new one added. And so the process that we have right now is we received a petition from a group of industry organizations, eight of them as a matter of fact. We signed on to the petition letter, and are asking for some changes to the exiting regulation.

And so part of that process normally would be that the agency would take that petition, submit a letter back to the petitioner saying that we received it, and then we would go about looking at the options provided in the petition,

looking at the pros and cons and then making a decision as to whether or not it fits within our statutory authority. If it does, and we choose to address all the issues in the petition, we can grant it in its entirety, which then puts it into the process of going to the public notice and comment process of regular rulemaking.

If there are things within the petition that don't fit within the statutory authorities that we have, then we respond back to the petitioner by denying the petition and telling them that we don't have the authority to do what's being asked and therefore don't pursue it further.

In this particular case, we've not yet made a determination as to the merits of the petition, as to whether or not what was being asked for in fact are within our statutory authority or whether or not there are things within the petition that can be handled through an instruction to our employees as to how they interpret the regulation.

So this is the beginning process. Again, I repeat, this is the first time that I am aware of that we have actually put a petition in the Federal Register and

asked for public comment. That comment period closes July 14th, so there is still ample time for anyone in the public or from this committee to submit a comment.

We will consider the information derived from this committee, in essence, as comment to the notice and we'll take that into consideration as we move forward.

Just to let you know what we have and what you have in tab number six in terms of our current thinking, we are providing you the entire petition. We are making clear that the HACCP regulations went into effect for all meat and poultry establishments as of January of this past year. And so with regards to meat and poultry, all of our establishments are operating under HACCP.

This committee was selected as the one which would at least be presented the petition in that we're asking for input because we see this as an implementation of an exiting policy as opposed to a science-based reasoning, and therefore we put it to this committee as opposed to the National Advisory Committee for Microbiological Criteria for Foods.

We summarized briefly what the petition asked for,

which in general it's asking for interpreting the HACCP advisory committee's paper, the NACMF paper that came out in 1998, when it actually published, that we've interpreted that paper too narrowly, and so the petition is asking to make it more broad.

It's asking for a number of definition and interpretation changes. It's asking to change the scope in terms of when a product is produced or shipped and it deals with just inadequate plans in general in terms of them being too strictly interpreted.

With regard to what the agency has done and will be doing, we did respond back to the petitioners in January with a letter saying that we have received it and we have put it into our tracking system that we have internally with regards to the petition the agency is dealing with.

We published yesterday in the Federal Register a notice which contains in its entirety the petition. Again, that comment period closes on July 14th, and we will accept comments from anyone as to the merits or as to any issue related to the petition itself.

I do want to point out that the agency has begun

looking at the implementation of HACCP since now all of our federal establishments are operating within that system. We are now going through the process of looking at the HACCP plans that were actually put in place to see if in fact they contained the types of information that we would expect to be there. This would be a more thorough and complete review than what we have done in terms of putting forward the basic requirements for implementation of HACCP. That's underway.

We have put together a survey which will ask our own inspection employees questions about some things contained within the HACCP plans, primarily those things related to what's in the hazard analysis as well as the critical control points and critical limits.

In addition, we'll be asking questions about compliance with the E. coli requirements that are in the existing regulation, so it's to elicit some information to help inform us about what actually is in the HACCP plans within the federal establishments.

We have not yet begun looking at any directives or notices that would be appropriate as a consequence of this petition. Again, we wanted to start the process of getting

feedback from this committee as well as the public before we made determinations as to what can be handled through a directive to our employees, which are instructions, versus those things which in fact would require a regulatory change.

I think the last time that I was here in November I went through the regulatory process to tell you a little bit about what happens when we make a change to the regulations. The HACCP regulations when they were first implemented or first issued were in fact significant regulations that had to undergo departmental and OMB review.

It's been our experience that changes to the HACCP regulations, the technical amendments as an example that we have issued, have also had to undergo departmental review and OMB review, and so we would not expect any changes as a consequence of this petition to be dealt with differently, and consequently that puts additional burdens on the agency in terms of putting forward what changes may be necessary.

I do want to also point out that as we're looking at this petition we are also keeping in mind the fact that we have egg responsibility for process eggs and we are

looking into shell eggs as well and intend to move forward with sanitation SOP and HACCP-type regulations for the egg industry.

So any changes that we would make to the meat and poultry HACCP regulations would likely also be reflected in the egg regulations. We don't expect there would be much difference there.

Again, in terms of what we intend to do at this point would be for this committee to take this issue this evening and specifically deal with the questions that we have identified, the six questions. I'll briefly just walk you through those.

The first question is: The industry petition relies mainly on the NACMF document and does not provide any data, for example, to support its request. What we are asking this committee is are you aware of any information that would support taking any of the actions requested in the petition.

The second question is: Would amending Section 417.2(a), which is our HACCP regulations dealing with the hazard analysis, in the manner suggested in the petition

result in regulations that provide the level of public health protection required by the Federal Meat Inspection Act and the Process and Products Inspection Act?

Again, we work within the statutory authority that we have. We can't go beyond that, and we can make an interpretation as to how we are going to implement the statues as are written, but we have to work within the framework of those two statutes.

The third question is: Should FSIS consider regulatory modifications that would acknowledge the prerequisite program's concept of a micro committee's paper?

And I would point out for those of you that might not be familiar, when we issued the HACCP regulations we did in fact identify the sanitation SOPs as prerequisite -- as a prerequisite program. So we actually put that language in the final rule preamble.

The fourth question is: Do FDA regulations, such as the good manufacturing practice regulations found at 21 CFR, Part 110, offer an approach that FSIS should consider? How would such an approach fit within the HACCP concept and how would FSIS implement such an approach?

The fifth question is: What will be the effects of making FSIS and FDA HACCP regulatory requirements dissimilar?

And on that point I would point out that in the preamble to the final rule we did identify that we tried as best we could to follow the intent and the language contained within the FDA regulation for seafood, on the fish and fishery products. We also took into account the requirements that other countries have, such as Canada, Australia and New Zealand with regard to HACCP.

And that relates to the sixth question which is: Should the changes suggested in the industry petition be considered in light of the views expressed on HACCP by Codex and other countries?

So those are the six questions that we identified that we would like specific input from the committee. I intend to be available to answer any questions that you might have related to the statutes that we work within as well as any issues you may have as to what in fact may be handled through a directive in the manner that the regulations already provide for, and it may just be that we

need to issue instructions to our own employees, and then possibly identify issues which would in fact require regulatory change.

So with that I will end it there and entertain any questions that you may have.

MR. BILLY: Any questions? Rosemary?

MS. MUCKLOW: Dan, I'm not sure if I heard you exactly right. Did you make an either/or decision on which committee to submit this to and you decided on this one, and you are not submitting it to the micro, or are you submitting it to them also?

MR. ENGELJOHN: I would say that when we received the petition, having read it, we immediately decided that this is an issue related to the implementation of HACCP since we have a regulatory framework already in place, and it doesn't go to the detail in terms of the science base beyond the HACCP regulations. And so our decision was that this is an implementation issue and it should come to this committee.

To my knowledge, we don't intend to go to the other advisory committee.

MR. BILLY: But obviously they would be free to comment on it individually or collectively.

MS. MUCKLOW: I think I would like to strongly suggest that they also be formally asked to give some advice on this subject because HACCP was their baby, and we're now growing the baby up a little bit and applying it in slightly different ways, and I think their advice would be very useful on this.

MR. BILLY: I don't want to preempt any discussion now but I would suggest, Rosemary, that that be something that the subcommittee consider in terms of recommendations.

MS. MUCKLOW: Okay, I don't think I'm on that subcommittee.

MR. BILLY: Well, okay. Alice?

MS. JOHNSON: Well, I think I am on that subcommittee, but I would like to support Rosemary in that the micro committee, their development process, the first question asked for data are examples, and it looks like we could review what the micro committee did and get some of their input, and see if they had the data and examples that you're looking for to help support.

MR. BILLY: Okay.

MS. JOHNSON: But we'll talk about it tonight.

MR. BILLY: Okay. Lee?

MR. JAN: I just have one question on -- well, you've mentioned beginning surveying selected establishments to assess the content of the HACCP plans.

Are you using that tool that was presented at the last meeting that we had?

MR. BILLY: Yes.

MR. LEE: Okay. And then the selected establishments are random selected, are they preselected on some criteria?

MR. ENGELJOHN: I would clarify that this particular issue related to beginning surveying, there are a number of issues the agency is doing. One is the in depth verification, which you've heard about the last time. This actually is a separate initiative in which we have started the process of making some evaluations, some very small based surveys of randomly selected establishments regarding specific issue.

As an example, for those of you who attended the

listeria meeting yesterday, we presented the outcome of a survey that we did on 30 establishments with regard to how they handle the listeria reassessment.

This would be a similar type survey where we -- we do not have OMB approval to go to the public or to the establishments themselves to ask the questions that we are looking for. We therefore have to ask this of our own employees. We don't need OMB approval to do that. And so this will be an initial effort to help us identify maybe some of the things we need to specifically tackle first in terms of making an assessment of what is actually being done in the HACCP plans. So it is in fact a different tool than what you were presented last November.

MR. BILLY: Okay. Caroline and then Katie?

MS. DEWAAL: Thank you.

When you say in your questions what is -- what will be the effect of making FSIS and FDA HACCP regulatory requirements dissimilar, can you elaborate on that a little bit? How would this petition do that?

If you could just give us a little bit of background on that, I would appreciate it.

MR. ENGELJOHN: What I can say about that particular issue is, again, we have not made decisions about the merit of the petition. So in terms of what effect this petition would have, that is different than what is in the FDA regulation for seafood. I'm not able to say that at this time.

That issue is getting to the very specific concept that we would expect we would have to go back to OMB with any of the rulemaking related to this particular amendment and changes to the HACCP regulation. OMB oversees all the federal agencies in terms of their rulemaking activity and is very interested in ensuring that there is consistency and uniformity across the federal government in terms of regulatory activities.

With regard to food safety, we all have an interest in trying to have a system that is uniform and consistent. And so changes -- when we put together our regulation, we in fact took into account what was in the FDA regulation, which did in fact go into effect before our poultry regulations went into effect.

And so if we have a change in terms of concept or

how we would approach HACCP, we also have to go the extra burden of identifying why it's necessary to be different in terms of a regulatory format than what FDA has in their seafood regulation.

MS. DEWAAL: There are other notable differences with FDA because you have got microbial testing is a key component of your regulatory structure and you have the whole pathogen reduction concept which they don't -- their HACCP rule is more like window dressing.

But I'm interested particularly is the definition of hazard analysis that would mark that difference.

MR. ENGELJOHN: I would say that that is one issue that in fact could make maybe a substantive difference between the two regulations. Again, we have not yet made -- we did not provide you with our assessment of what this petition does. Again, we are not in the position to do that at this point.

MS. DEWAAL: But again, that definitional issue really goes to -- I mean, hazard analysis is such a core concept to HACCP that it strikes me that this petition is going to a really key issue in the HACCP regulations, and

I'm just -- I am struck that if that concept were to change it would have other ramifications as well.

Thank you.

MR. BILLY: Katie?

MS. HANIGAN: I will be chairing this subcommittee tonight and I am requesting permission to hand out five different documents at this time to our entire committee here. One I've been very vocal about, not receiving information ahead of a discussion.

And kind of following up on what Caroline is talking about, we have put together a comparison of FSIS micro committee, Codex and FDA, the definition of hazard, and I'd like everybody on this committee to have a copy of it.

Also there are a series of definitions that are laid out in the pathogen reduction HACCP rule, everywhere from control measure to CCP and we will be using these documents too, so I'm requesting that they be passed to the entire committee at this time.

Have an article here that we're going to reference tonight. It is the role of prerequisite programs;

informative article; would like everyone on the committee to have a copy of that.

MS. DONLEY: Excuse me, Katie.

Who is "we" that you refer to that has done all this stuff?

MS. HANIGAN: There is a series of industry groups that got together with the original petition, so they were good enough to assemble this information in preparation for the meeting tonight, when I saw what part I was going to be chairing.

MS. DONLEY: Okay, so it's the signers sign on to the petition?

MS. HANIGAN: And an example being as Farmland is a member of the AMI, so clearly we are strong supporters of this petition, and I had asked when I saw the agenda for tonight's meeting that I have additional information that I could refer to, so that the committee could come back with a more solid recommendation.

Teaching example of HACCP and also a model that we will be referring to tonight, and I know I have been very vocal about not having information in the hands of committee

members to look at ahead of time, so I just would like everybody have a copy of it.

MS. DEWAAL: Could I ask that we adjourn now so that we can review all of Katie's material before the subcommittee meeting this evening?

MA. HANIGAN: And I did just get the information this morning, but I do respect your comment on that. Yes.

MR. BILLY: We need to -- our requirements of the Advisory Committee Act require us to make available all information to the public, so we need to be able to share this information.

It sounds like what we should do is to treat this as information that's provided by the petitioners through you, Katie.

MS. HANIGAN: Okay.

MR. BILLY: And it should be looked on in that regard. It's not something obviously that the agency has had a chance to see or evaluate or validate or anything of the sort. So it needs to be clear to all of the committee members and to the public that this is the trail that's being provided from the petitioners through a member of the

advisory committee for consideration as you have your discussions this evening.

MS. WILCOX: This has not been reviewed by general counsel at USDA or FDA or anybody else that would know whether this is comprehensive in terms of side by side. So everybody should be very clear about that.

MS. HANIGAN: And clearly, I didn't mean to create a problem there, but whatever disclaimers you folks need to put on it, it is fine. I think it should be available to the public, the information.

MS. JOHNSON: And I think a lot of the information will help with some of the discussion on question one, and I think the group that put this together was looking at is there supporting document and what we should be considering for part of the discussion.

MR. BILLY: Are there other -- yeah, Dale?

MR. MORSE: Well, it's nice to have more information. But I guess the question are we at a disadvantage of only getting one side of the story of information, and I don't know if there is other information that we should have to review. So it makes -- I mean, we

make a decision when we are reviewing just one side of --

MR. BILLY: Well, one thing that the committee could consider, the subcommittee and then the full committee, is to consider the information that's available but based on the fact that there is a public comment period and we will be collecting all kinds of information, we could organize all those public comments and make that available to the committee for further deliberation at the next meeting. So we can share with the full committee and the public all the additional information we get in a manner that will enable you to look at all aspects and sides of the issues that are represented by the petition.

MS. HANIGAN: Can I just comment on Dale --

MR. BILLY: Sure.

MS. HANIGAN: The other reason for my request on additional information was when I looked at the agenda and saw what I would be chairing tonight, and clearly six questions were laid out for discussion for tonight, and even when I looked at question number one there was no way we were going to have any answer unless we brought some additional resources to the committee meeting.

I mean, it was very evident when the agenda came over to each one of us that we had six questions here we were going to be expected to go through.

You may be right, Dale. There probably could be other information, but I was doing the best to get answers or additional information so we could attack each one of these six questions.

MR. BILLY: Gary?

MR. WEBER: Just a comment in this regard. Our organization did not sign onto this, but what concerns me as a committee member here as I hear a lot of statements and concerns about this information, I'm a little bit -- I'm not on the committee but I'm a little bit offended that people find this threatening, and this shouldn't be. Everyone who is on this committee has the technical capability, the intellectual capacity to look at this and make some decisions tonight or at least raise some other questions.

This is in the Federal Register. Every person sitting behind us and every person who gets that can put in comments. I don't think anybody needs to be threatened that anybody is going to force anything through anyone's not

whole here today.

So I want to be on record saying I'm concerned about the concern about this, that anybody is going to be intimidated by this process, and I want to applaud your efforts for providing information and people can make that decision whether this is appropriate independent of what OGC or anybody else thinks about it. This committee ought to feel comfortable having that information, and I am glad that you've provided it, and I want to be on record saying I think people should be offended by the fact or the idea that we are not able to interpret that and judge it accordingly.

MR. BILLY: Caroline?

MS. DEWAAL: Thank you, and I was going to make this remark before Gary just said that, but I'm definitely going to make it now.

One thing that strikes me in this list of six questions is there is an assumption of knowledge about the regulatory structure of a sister agency, the Food and Drug Administration. And it comes out in two different questions.

FAD seafood regulation is similar to USDA's, but I

don't know how many people have read it or really studied it. I have, but I don't know how many members of this committee, I don't know, Gary, if you're an expert in FDA seafood regulation.

In addition, the FDA regulations on good manufacturing practices is something which is unique to that agency. And if people are not regulated by FDA or if people don't have that background knowledge, then in fact these questions are assuming knowledge which may not be within the ability of this committee.

I would be happy to look at the materials that Kathleen has put together, Katie has put together, and I am excited she did that. But I agree with Dale and I agree with your statements that maybe we just need to slow it down and consider this issue as a multi-meeting issue so that we can really analyze the material that you have given us and make sure we have all relevant information. I know I would feel more comfortable because I didn't bring all my FDA regulations with me for tonight's discussion.

Thanks.

MR. BILLY: Yeah, I could add to that, and for

example, I could envision that one of the recommendations you might want to consider is that you ask the agency to do a side by side by side comparison that looks at FDA's regulations, FSIS's, CODEX recommendations, and any others that are relevant in the context of this petition and what it's trying to achieve, and make that information available. I think that would be constructive and would, you know, inform people where they could provide comment if not in the initial comment period if in fact we move forward subsequently, and certainly help this committee with its work.

Are there other comments? Questions?

(No response.)

MR. BILLY: Okay. And again, you're going to be present this evening?

MR. ENGELJOHN: Yes.

MR. BILLY: Okay, good.

Okay, what I'd like to do, Roger has just arrived. Roger, are you ready?

MR. BREEZE: Yes.

MR. BILLY: Okay. Okay. We're going to make a

slight adjustment in the agenda here. Dr. Roger Breeze is here on behalf of Floyd Horn and is prepared to provide us an oversight of ARS food safety research, emphasizing in particular the work that's being done on E. coli 0157:H7.

So Roger, the floor is yours.

MR. BREEZE: Well, that was actually very nice timing because for the first time in my life I came here with the slides on a power points presentation on compact disk. As I was coming here on the subway I thought what a wonderful thing. You don't have to carry those overheads and everything with you anymore.

And of course, I neglected to call ahead and make sure there was a power point projector, but thanks to the wonders of American capitalism there is a Kinko's within walking distance.

(Laughter.)

MR. BREEZE: So your delay came in very handy because, you know, it was very nice timing.

Well, it's a pleasure to be here today and talk to you on behalf of Dr. Horn about food safety research in ARS. As many of you will realize, I hope you -- can you see

this? Do we need to dim some of the lights?

As many of you will realize already, the food safety, the research investments in ARS has been rising quite rapidly over the last few years. In 1986, we were just over 20 million, and now we are -- the total investment this coming year is over 80, almost 90 million dollars a year, and especially in the last few years. With the present administration, there has been a dramatic increase.

For those of you who are not very familiar with ARS research programs, you can find them on the web. They are all described in some detail there. We have gathered our research over the past year into a series of national research programs, of which food safety is one.

We actually have 23 of these programs. But you know the way in government how we name things, it's actually program 108.

As an ex-director of Plum Island, I know I'm going to be intensively questioned about what are all these missing programs here.

So the program components, just to sum up where they are on microbial pathogens, mycotoxins, chemical

residues and poisonous plants. Again, the details, it's on the web. It's MPS.ARS.USDA.GOV. If you get that far, you will be able to find these programs without any problem.

Now, we also have, in addition to this research within ARS, we have anti-microbial research program under NOUNS, which is an interagency endeavor involving ARS, FSIS, the Center for Veterinary Medicine, and the FDA and the Centers for Disease Control.

Our food safety pre-harvest program concentrates on issues of sampling, isolation, identification, quantification of microorganisms, the ecology and assessment of risk factors of pathogens, sights and mechanisms of colonization, virulent attributes of pathogens and their role in the host/pathogen relationship, intervention strategies to reduce colonization of pathogens in animal hosts and shedding from those hosts, efforts to decrease pathogens in the slaughter houses, and of course the spill-over effects of manure handling and utilization of microbials.

Let me talk a little about the pathogen reduction part of the program. The focus here, of course, is on the

usual suspects of salmonella, campylobacter, listeria profingents, and the epidemiology and biology of these organisms.

We are looking, of course, at the ecology of pathogens on foods and within the processing environments like new materials and bio-films. We are developing methods for regulatory and research use, and intervention strategies to aid in the application and development of HACCP programs.

We want to be able to measure the effects of intervention strategies in terms of microorganisms on whole food, and we need to provide data, of course, to provide scientific risk assessments and predicted models of microbial load.

In the case of E. coli 0157:H7 in particular, we currently have 30 recent projects, totaling almost $9 million a year. Seventeen of these are related to meats, nine to manure and manure handling, four fresh fruits and vegetables, and the President's budget proposal would add significantly to this in the coming year, and from what I have seen of the Harrison Senate markups so far the Congress may actually increase the investment over the request of the

President, and of course we also have five cooperative projects with the members of the National Food Safety Alliance.

Let's talk about some of the recent results with research on E. coli 0157:H7. At the Meat Animal Research Center in Nebraska, we have recently found significantly higher levels of 0157:H7 in cattle coming to slaughter than have been previously reported.

There is a large reduction noticed in carcass prevalence of this microorganism from previserations of post-process. And this is just the procedures, how effective in the processing plant.

We have not been able to find any detectible effects from pen cleaning in lowering E. coli virulence but both test and control groups in this study showed lowered pathogen numbers with time on the study.

The studies on -- our studies on the effect of giving feed just prior to slaughter are not conclusive. We need to do some more studies in this area to understand all the variables of this effect.

We have a feci method which will differentiate E.

coli 0157:H7 and other shiga-toxin-producing E. coli. We have some experimental E. coli models which are very useful in determining virulence attributes of this microorganism, and describing the effects of shiga-toxin-produced disease in cows. And we have also developed hand-held fecal detector.

Now, the conclusion of our research is we have greatly increased our knowledge of the biology of the pathogen and its environmental and host interactions. But, and it's a big but, which applies to ARS and to everybody else researching in this area, neither ARS nor any of the researchers have found out how to prevent 0157:H7 infections in shedding in any animal.

Now, our research is moving into some new areas of emphasis in the near future. We are going to concentrate on the characterizing bacterial/host relationships and prevention strategies. I'm going to talk about these in a little more in the next few slides. Development of intervention strategies. We will talk about fecal detector to scanning of entire sides of beef. We're talking about more rapid and more sensitive assays and the utilization of

chloride in inhibiting E. coli and salmonella burdens in cattle.

MS. MUCKLOW: Mr. Billy, could we -- could I just ask, is it going to be possible for us to have a copy of Dr. Breeze's slides because then we don't have to write madly?

MR. BREEZE: I will make sure you have a copy. I would be happy to give you this disk.

(Laughter.)

MR. BREEZE: I will be happy to --

MR. BILLY: The answer is yes.

MS. MUCKLOW: How about the shinko slides?

MR. BREEZE: You can even have the bill if you --

(Laughter.)

MR. BREEZE: So yes, it's a great mistake to be scribbling away. We can move on with technology.

Let's talk about bacterial/host relationships. We're looking at the basic biology of infection with microorganism in animals. The specific host/pathogen interactions which are going to define the sites and the mechanisms of bacterial adherence, colonization and pathogenicity.

We are looking, particularly with the E. coli mutant, these factors of adherence and colonization in order to identify the genes, bacterial genes that are required for their growth and colonization. And we're focusing on identifying the source of initial infection in animals, including the infection of cows by the dams.

In terms of intervention strategies, we're looking at short-term interventions, which we mentioned just a few moments ago about feeding hay or grain just prior to slaughter, and other management of other controls which may help to reduce its burden.

We are trying to determine is intimin vaccination will prevent or reduce E. coli infection, colonization and shedding. Intimin is a protein on the surface of E. coli, which is an attachment, and we have some evidence that vaccination of cows against this particular protein will prevent these bacteria attaching.

We are trying to characterize the effects of a specific bacteriocin on E. coli in affected animals, and we're continuing to pursue the competitive exclusion cultures of probiotics for short-term use, especially just

prior to transportation for slaughter.

It takes longer to print these than it does to tell you what's on them.

At the National Animal Disease Center, we have been working on a fecal detector which we're hoping to extend so they can scan the entire sides of beef. This is in cooperation with Iowa State University and a private company. These devices are based on patented technology from ARS and Iowa State. And we think they could be used by slaughter facilities in the HACCP programs to reduce fecal contamination and to meet FSIS tolerance requirements.

This is a device which works by detecting a breakdown of product of particle presence in very, very small amounts of feces, and it's very sensitive, and we're trying to scale this up from a hand-held device to a larger machine which can scan the whole carcass.

Faster, more sensitive assays, I suppose, is a grill that we are always going to pursue. If you do things very fast the next thing, you know, people want to do them even faster. So we are probably never going to stop the search for quicker, simpler, more sensitive assays.

At NADC, again, we have a PCR-based assay which we are trying to target E. coli and other shiga-toxin-producing organisms. And of course we are trying to modify the frequently used TACMAN assay by monitoring of expression of selected E. coli genes in people.

One interesting area is the use of chlorate as a method to kill bacterial pathogens in animals. This depends on the properties of certain bacteria, like salmonella and 0157:H7, which have a metabolic process which enables them to reduce chlorate to chloride, and the bacteria are killed in the process of production of this chloride. This would hit salmonella or E. coli, but would have minimal to no effects on other gut bacteria which don't cause disease or human illness because they don't have this biochemical property.

Now, we know that the low concentrations of chloride which will be produced are not toxic to cattle. But of course, you know, like anything else, using this in the field would require FDA approval.

Let's talk about some of our post-harvest goals with E. coli. We want to improve slaughter and dressing

practices and controls to minimize contamination, improve our food processing methods, develop predictive models for growth on meats, and more rapid detection methods.

At the Meat Animal Research Center post-harvest research projects are going to focus on virulents and genotypic characteristics of different E. coli isolates from various sources. The technology is moving very quickly now in this area and it's possible to quickly and simply understand genetic changes going on in the bacterial, and genetic expression of specific genes in the animal's host as a result of infectional colonization.

We're going to use these techniques to look at the mechanisms of binding an attachment of E. coli to carcasses and the molecular mechanisms of bacterial tolerance to acid washing. And the gene expression arrays and detectors which are coming into use now are going to allow us to look much more closely at virulence and the effect of anti-microbials.

At the Eastern Regional Research Center in Philadelphia we have mathematical models to determine the effects of many food formulation variables on thermal and irradiation inactivation with a goal of improving multiple

barriers to reduce or eliminate contamination.

We are providing thermal and irradiation data for regulatory agencies, and we are concentrating on more sensitive and more rapid detection methods.

In particular, I should mention a multiplex PRC assay, which means it does many different assays at the same time, which simplifies detection of 0157:H7. It identifies the H0 group and the type of toxin genes possessed by the bacteria.

The sensitivity of this assay is less than or equal to one colony-forming unit per gram of food or bovine feces, and results can be obtained in less than 24 hours.

Similar detection levels are obtained with gram samples which underwent enrichment culturing immediately after inoculation, and samples that are frozen and refrigerated prior to enrichment.

This multiplex PCR facilitates detection of 0157:H7 and can reduce the time required for confirmation of isolates by up to three or four days.

At the Beltsville Agricultural Research Center we are looking at temperature indicating devices for consumer

use and methods to predict the potential pathogen contamination of cooked gram meats.

Again, at the Eastern Regional Research Center in Philadelphia, they are studying anti-microbial activities of various plant essential oils against E. coli 0157:H7. Of the oils which have been tested so far, red thyme and seborrhea essential oils were the most effective in inhibiting growth of 0157:H7. Application of these oils to food may result in an inactivation of the organism, and this is currently under investigation.

We have nine projects underway with the National Alliance for Food Safety. Five of these fund E. coli 0157:H7 research. The topics of these are listed here: mechanism of colonization, presence and distribution of the organism in feed lots, feedborne dissemination, epidemiological association, and the prevalence of the organism in dama cattle.

In FY-2001, the initiatives which we are proposing deal with methods that deal with antibody resistance, studies of gut ecology, competitive exclusion cultures, and immune responses. We are looking at transportation, dama

cattle issues, and pre-slaughter feed, aerosols in the processing environment, new technologies that are necessary for processing for various ethnic or religious groups, and biosensor technology for pathogens in application of various products.

For 2002, we will be proposing to continue the emphasis on antibody resistance, to look at pathogens in milk prior to pasteurization, chemical and antibiotic residues in animal manure, and fumonisms and aflatoxin in corn.

Our post-harvest research initiatives in 2002 will focus on pathogen transmission in bioaerosols, protozoa effects on organism virulence, emergence of pathogens, potentiation of virulence, responses to stresses in the host, risk assessment data, surrogates for use in carcass decontamination studies, decontamination strategies for small processors. We will continue with the hand-held pathogen detection devices because there is a lot of new technology that could be very practical in this area. And we are pursuing imaging technologies to determine surface contamination.

So that's a lightening pass through of all the things that we have got going on. I will try to answer some questions if I can, and if I can't, Jim Lindsay, who is hiding at the back, should be able to.

So thank you.

MR. BILLY: Roger, maybe you can come over to the microphones here at the table.

MR. BREEZE: Okay.

MR. BILLY: And your colleague could join you.

MR. BREEZE: Yeah, Jim, do you want to come down? This is Jim Lindsay. He's in the back.

Come on. No excuses.

MR. BILLY: Roger, why don't you --

MR. BREEZE: You want me up here?

MR. BILLY: Yes, right over here, yeah. Join us here at the table.

MR. BREEZE: Okay.

MR. BILLY: Okay, questions? Nancy?

MS. DONLEY: I was just wondering if you could tell us of your -- your kind of breakdown percentages of your pre-harvest versus post-harvest budget of how much you

allocate pre-harvest versus post-harvest.

MR. BREEZE: I'm glad Jim Lindsay is here to answer that.

MR. LINDSAY: It's about 60/40 pre-harvest - post-harvest.

MS. DONLEY: And is that what you are going to be done going forward as well --

MR. LINDSAY: Yes, it's approximately the same.

MS. DONLEY: -- in 0157?

MR. LINDSAY: Yes, it's consistently around about 60 percent.

MS. DONLEY: Sixty percent pre-harvest?

MR. LINDSAY: Correct.

MR. BILLY: Caroline?

MS. DEWAAL: What difference has the budget initiative, the President's food safety initiative made to your work on food safety research?

And going back a few years, I remember actually when Casar Motecky was over managing some of the -- or managing ARS, and we went through this whole strategic planning process that I participated in for at least one

day, but what I recall about it was that I believe -- it seems that the emphasis of the food safety research at that point was more on plant pests and mycotoxins and other hazards but they really weren't on the microbiologic hazards which you talked about today.

So that was a number of years ago now, but I'd like to know what -- what's changed.

And my second question is: What's your full food safety budget today and what is the total budget on research generally?

MR. BREEZE: If money alone can solve research problems, we would have a lot of solutions. And I don't believe just money alone would do that. But obviously money is very, very important if you are trying to have a comprehensive sustained program of effort over a period of time.

So the money was tremendously important, but I don't think it would have made the difference it has without able leadership, not just in USDA, across the agencies, but actually in the industry and in other groups that have been involved in trying to set an agenda, whether it's some

clearer goals about what we want to do, to build some teams and actually to move this progress along. And it's not just in research. If research doesn't know what regulatory agencies want and on what other consumers of the research need, it can be a blind alley.

But I think the dialogue that's taken place, not just in this particular research program in ARS, but in creating all of these national research programs. Dialogue with customers and stakeholders and the public and other groups has been very, very important.

But I think there has been a team effort and I think the President led this with these initiatives and it was pushed through by the secretary and other people, the public, consumer groups, and the industry and our action in the regulatory agencies.

And Jim, what about that -- the budget figures?

MR. LINDSAY: The dollars. The research budget is 834 million total for ARS, and the food safety is 83 million. It's actually 9.9 percent exactly of the total budget.

MS. DEWAAL: And that food safety money breaks

down into all those categories you gave us earlier?

MR. BREEZE: Correct. I can give you a full breakdown. If I had known, I would have brought it for you. It's easy enough to do.

MS. DEWAAL: Could you just give us --

MR. BREEZE: Sure.

MS. DEWAAL: -- breakdown on microbiological hazards versus the other thing that was on that -- on that list?

MR. BREEZE: I think micro hazard is about 50 -- between 58 and 59 million of the 83 million is on microbial hazards.

MS. DEWAAL: Fifty-eight to?

MR. BREEZE: I think it's 58 to 59, but I can get you the exact data. That's not a problem.

MS. DEWAAL: That strikes me, and Cathy, tell me if I'm wrong, but that does represent a big increase over what we were talking about a couple of years ago?

MS. WOTECKI: Yeah, four years ago when we did those estimates I think the total food safety at that point was about 56 million. We may have done a slightly different

analysis for the preparation of this chart. But in the strategic planning it was a total of just under 60 million was in food safety.

MS. DEWAAL: So, and that would compare to the 83 million figure?

MS. WOTECKI: That they had as the most recent, yes.

MR. LINDSAY: Yes.

MR. BILLY: Are you finished, Caroline?

MS. DEWAAL: Yes. Thank you.

MR. BILLY: Rosemary?

MS. MUCKLOW: Dr. Breeze, you are every bit as good as you name. You really breezed through that thing about as fast as anybody I've seen go. I'm glad we are going to have it to take home because there was a lot of wonderful stuff there, and thank you very much.

While I was still scribbling, I heard you say that you want to be able to measure the effect of interventions. Talk to us a little bit about how you have some ideas about measuring the effectiveness of interventions.

It is always the dilemma in the business that I'm

in, which is beef slaughtering and processing, or a trade association representing those who do, because we never want to take that ugly organism into our plants. In fact, we won't. I don't think Mr. Billy would let us. And testing these things in the laboratory is always very different from finding it in the real world.

Do you have some new ideas about how we can effectively test the effectiveness of the interventions that we are using?

MR. BREEZE: I'm going to steal and ask Jim Lindsay first to respond to that.

MR. LINDSAY: Jane, did you want Jane?

MR. BREEZE: I'm sorry. Jane Robbins is here.

MR. LINDSAY: I think the important --

MR. BILLY: Silent ranger at my elbow.

MR. LINDSAY: I think the important thing here is to consider it as a two part. It also has to be considered as both pre-harvest and post-harvest.

MS. MUCKLOW: Well, I'm talking post.

MR. LINDSAY: You're talking post-harvest.

MS. MUCKLOW: Yes.

MR. LINDSAY: And what type of intervention strategies are you referring to? Are you talking about during the processing itself using acid washes, using steam washes?

MS. MUCKLOW: Well, I'm open to all sorts of new ideas. At the moment, you know, we are using previsuration washing.

MR. LINDSAY: Mm-hmm.

MS. MUCKLOW: Hot water pasteurization.

MR. LINDSAY: Right.

MS. MUCKLOW: Steam pasteurization.

MR. LINDSAY: Right.

MS. MUCKLOW: Lactic acid or other --

MR. LINDSAY: Right. Organoleptic things, right.

MS. MUCKLOW: Organoleptic things and so on. And we're looking at, of course, the new one which is still in trial stage that was presented at the February 29th meeting, which was lactoferin, which certainly looks very interesting.

But again, we don't have any way in the real plant to be able to test. We can do it in the lab.

MR. LINDSAY: Right.

MS. MUCKLOW: We can't do it in the real world. And I just thought maybe you guys are so damn good maybe you've got a good idea about how we've got some better ways to test the effectiveness. I want to pump your brain a little bit.

MR. LINDSAY: It's a bit numb from the flue but I'll try and do it.

I mean, other than doing, you know, swab testing of carcasses the difficulty is, you know, how do you specifically identify or how do you identify a specific pathogen if you're talking about a beef carcass. You can't. There is no mechanism to do that.

What we have been able to do is to genetically modify known pathogens or pathogens that are knowingly found on carcasses and put fluorescent markers on -- you know, incorporate them into the genome, and then, you know, we can attach them. We can spray them on a carcass that goes through a processing, and then monitor the reduction in the levels of these genetically marked strains.

There was some interesting work that was done by

Greg Surugossa(ph) when he worked at Clay Center using a fluorescent marked strain of E. coli to show that by doing various types of interventions that you could significantly reduce the number of pathogens in certain areas.

Now, the problem is that each of these pathogens bind at different levels, depending on the fat, depending on the facia or the types of proteins found on the surfaces of carcasses.

So what intervention strategy may be useful in one area of the carcass may not be as efficient in another. So by understanding the physiology of attachment and detachment of these organisms then we can develop intervention strategies.

It's not quite as easy as just spraying a carcass with hot water and saying yes that works. It's not like that.

MS. MUCKLOW: Well, that, of course, is the principle behind what the industry has moved to in the last ten years, which is the multiple hurdle approach.

MR. LINDSAY: Correct.

MS. MUCKLOW: So if they don't get it with this,

they get it with that.

MR. LINDSAY: Correct.

MS. MUCKLOW: So you know, that is -- and I'm glad that you acknowledge right up front that these interventions have been remarkably successful.

My keen interest is that you want to focus, or that's what Dr. Breeze told us early on, on measuring those interventions. And I think it would be unusually helpful if indeed you can help us come up with some methodology, and maybe the gene marker is one way of doing that. I don't remember that research but I'm not the scientist. Maybe we need to go back and look at Dr. Surugossa's work and see if it has some further applications in some of the new kinds of hurdles that both you and private industry is looking at.

MR. LINDSAY: One of the assumptions in doing this is where are the organisms actually coming from, and the assumption is it's probably coming from feces that have contaminated the surface of the carcass.

So if you believe that pathogens are associated with feces, we have two new projects whereby we can monitor the presence of feces both on beef and on poultry carcasses,

and we have some new initiatives regarding that, and it's relatively -- this can all be done on line. This is done -- computerized whereby we can actually locate areas of fecal contamination. And by seeing this using these on-line detectors, these can be spot washed to eliminate the presence of the feces and probably eliminate the presence of the pathogens at the same time.

MS. MUCKLOW: Another piece of the hurdle approach that the industry is moving to, but again it's a huge transition step, is the separation of the various rooms in which different parts of the process occurred. The high don, the high doff, the guts out, you know, the three segmented floors. And it's really nice to see in the plants that are being designed today, and even some older ones that are being redesigned, that this separation is beginning to occur, and that reduces those microorganisms that learn to fly in the process from getting attached.

MR. LINDSAY: That's correct.

MS. MUCKLOW: It's another piece of the hurdle.

MR. LINDSAY: Correct, and that's why one of the initiatives in the future is to look at bioaerosols in the

presence of pathogens, and bioaerosols within the processing plant. There is some work that came out of Canada showing that when the hide is taken off a carcass, this is cause for transmission of pathogens through the air between those --

MS. MUCKLOW: Yes.

MR. LINDSAY: -- as you say, those three areas. So we want to look at that and show, or look and see whether or not we can reduce the presence of dust and therefore the presence of pathogens within the rest of the plant. That's true.

MR. BREEZE: Just to answer, I think, your question in general. If you were looking to develop an intervention strategy, first of all, you do it on a very small scale in the laboratory. You know, is it effective, is it safe, is it likely to be practical, is it, you know, economic, feasible, those kinds of things.

Then the scale-up after that, we have some pilot plants in Athens, Georgia. For example, we have a little poultry processing plant within the research facility which has all of the machinery on a much smaller scale.

MS. MUCKLOW: Mm-hmm.

MR. BREEZE: So you can simulate well there, you know, the effects of, you know, plucking and scalding and those kinds of things, and work at that type of scale actually with viral pathogens if you choose to do that.

MS. MUCKLOW: Mm-hmm.

MR. BREEZE: But of course when it comes out to taking this technology into the real world, into a commercial plant, you are not in the position of doing deliberate infections. Either you will be looking with a surrogate or you are actually measuring real interventions --

MS. MUCKLOW: Yes.

MR. BREEZE: -- as they occur, and that's part of the difficulty of extrapolating these things, but it's a condition that we work with and we have those kinds of facilities at Athens and Mohaken and other places.

MR. LINDSAY: I should mention that there is some very innovative work that has been done by Dr. Yak Chin at our Beltsville facility, and I think in the past six weeks we had a meeting with FSIS regarding actual -- the scale-up of his pilot, his pilot computerized on-line detector,

whether or not this could actually get to the next level. And he's produced a video where the detector was actually used in one of the Tarsan's plant, and I could make that available to the committee. This is not a problem. And the meeting was with Bill James, and he was very impressed by the accuracy of this machine. I think this will significantly reduce the presence of potential contamination on these carcasses.

MS. MUCKLOW: Each new intervention that we have we, you know, have welcomed it and heralded it and thought it was absolutely it, but still this stuff gets through the system very, very rarely but rarely enough to give us cause for concern.

And so your new methods, and particularly the methods of measuring interventions, will be fascinating and you can go home with my card and send me any of that stuff you have. I'd love to see it.

Thank you very much.

MR. LINDSAY: Sure.

MR. BILLY: Katie?

MS. HANIGAN: Yes, my question focuses on the

fecal detector that you referenced in your presentation. I'm gathering from what you're saying it's computerized. I just wondered how much detail you can give us on it, as to when it will be available, if you have any idea of what the cost is. I mean, what details can you tell us now about it?

MS. ROBBINS: We have a creta with a company in Florida that is scaling up the process. Our scientists at the National Animal Disease Center did the basic work on it, showed what it would detect. But they really didn't get too much further than saying it would work in a little circle like this, and we have to scale it up so that it will look at a whole side of beef at a time, or that would be one avenue.

The other would be the hand-held wand that could go up and down on the side of a carcass.

But the laboratory out there does not have the engineers and things that could really scale it up and make it practical, and we are working with a creta partner. I do not have a schedule.

MS. HANIGAN: And no idea of the cost of that? Because obviously it sounds like absolutely a great -- a

great thing to have available. I just wondered --

MR. LINDSAY: The one for the poultry, we're for a creta partner at the present time. That will probably come in at about a quarter of a million, and this is portable, can be used anywhere in the plant.

Currently, it detects pathophysiological abnormalities. This has been the primary focus of Yak Chin's work. The group at the Russell Center, the new unit, they will hopefully have the fecal detector, I think, by the end of next year. This work is being done in cooperation with the Institute for Technology Development at the Stanis Space Center. So we are looking to combine the two detectors. Have one at the beginning of the processing line and one towards the end, probably after the final wash. And again, it will probably come in at about a quarter of a million dollars.

MR. BREEZE: Now, can you just describe what the unit is? I don't everyone to go away thinking about a hand-held wand.

MR. LINDSAY: No, no, it's not a hand-held wand. It's a self-contained portablized unit that is refrigerated.

And again it would be easier if I just send you a copy of the video which has all the details of it, including all the schematics and currently we are in the process of trying to find a creta partner, and I would think within the next month or so. We have had some interests from a Dutch company as to -- they would like to be involved in this. They are a processing company.

MR. BREEZE: You raised a very important issue though, so let me just talk about technology transfer because in ARS we are not in the business of doing research, passing it off into the ether and hoping somehow it settles down, you know, in terms of a product that people can use.

Scientists obviously are in the business of doing research in their own laboratories. But within ARS we have a technology transfer arm, which is specifically directed to take the research results, and get them out there into the field where people can use them. And the mechanism which is used for this is a cooperative research and development agreement of which ARS is the leading edges in the federal government in terms of the number of these agreements we have with private enterprise. But it requires a certain

amount of nurturing to get these products out there.

And in the case of the devices we were just talking about now, a company that's attracted by a piece of research like this will be trying to build a business plan, and they want to know, well, before we can tell you how much it will cost, how many of them will we sell, how many plants will use them.

Well, if there are no technologies out there that are comparable, it's very difficult, you know, to come up with these numbers, and that's where it's sometimes a painful process to bring these devices along.

A lot of the devices that are out there now are coming from the military. Well, the military is a different kind of customer with a different kind of wallet than the people around this table.

So this is something that we are very aware of and we do our best to work with these companies to make these technologies available.

MS. HANIGAN: Thank you.

MS. ROBBINS: Another intervention that wasn't mentioned yet is the steam pasteurizer, and that's been

developed at the Eastern Regional Research Center. I think Mr. Billy has seen that one.

MR. BILLY: Yes.

MS. ROBBINS: That's for birds. It's nothing -- yes, you have seen it.

MR. BILLY: It's amazing.

MR. LINDSAY: And the steam pasteurizer, the unit has been modified so it's portabilized, and there are a series of different cavities to not only do poultry. It can be used for fish. We also have an initiative that it can be used for steam pasteurizing hot dogs, and all of those projects are currently being initiated by Mike Kazymple at the Eastern Center, and I can try and get you all the information, or I will get you all the information regarding the latest in that.

MS. HANIGAN: And what is your best guess of cost on that portable unit there?

MR. LINDSAY: Now, that's a different set of circumstances. I would think that's looking at, at least a half a million dollars.

MR. BREEZE: I don't want people to go away with

the idea of 250,000 to half a million, that this is the unit that we are thinking. This isn't part of what I set out to talk about today, but those of you around the table, I'll pass this around in each direction. This is actually a new technology which I haven't referred to today. It's a method of detecting pathogens by a PCR primer directly embedded in an electronic circuit.

And this is a device which is very, very cheap to produce, and we are a long way from having something practical with this in terms of food safety. We are looking at it with different pathogens right now. But this is something that will be less than a dollar. It will be a bacteriological, a definitive identification for less than a dollar. So we are looking at disposable, cheap things. We are very, very well aware of the pressures that you face, but sometimes you do need to spend a quarter of a million for certain things, but that's not all that we're looking at.

MS. MUCKLOW: This is some sort of chip that fits into something?

MR. BREEZE: It fits into a little container and

that's where you put the sample, and then it reads out in that directly without any --

MS. MUCKLOW: Without plating or --

MR. BREEZE: Correct.

MS. MUCKLOW: -- growing up or any of those kinds of things.

MR. BREEZE: Correct.

MR. BILLY: Okay, I've got three more and then we will wrap this up. Cheryl, then Nancy, and then Collette.

MS. HALL: Thank you.

We appreciate the work that you do there. It's really helpful for the industry. But I have a question about releasing information when a project is finished, something that is not going to require a patent or passing technology to another firm.

What is the policy on releasing information on projects? Are you waiting for specific publications for those to appear in or formal presentations because some of those things would be useful if we had that in our hands earlier?

MR. BREEZE: Yeah, and usually we are encouraging

the scientists to write those results up and get them published as quickly as possible.

MR. LINDSAY: There is an annual food safety report done, and it's available on our web site, and has been available for the last three years. We also have hard copies of it.

MS. HALL: The reason I asked this question is we are aware in the industry of a lot of different projects that you do at times, and we need that information, those answers as quickly as possible. Yet your scientists are reluctant to release them until their publications appear even though the project is finished.

Is that a policy of the --

MR. BREEZE: Well, it's really part of the scientific method. You know, scientists have results and they do experiments, but part of the scientific method is you send those results forward to a journal. The journals will review them. You have to persuade other scientists that there is some measure of credibility there and the experiment was well designed. Then those are published for everybody to see and critique and to try and replicate the

results, and that whole cycle is tremendously important in finding out whether scientific ideas are valid or not no matter how strong the results are put forward. Cold fusion would be a very, very good example of that.

So we are not trying to, you know, keep things concealed. We urge our scientists to publish, to get them out there where everyone could see and the data is competitively critiqued.

But if there is some specific issues, we would have to follow up on those. But there is a policy of pushing the things out through this scientific process.

MS. HALL: Thank you.

MR. BILLY: Nancy?

MS. DONLEY: Yeah. Well, I'll tell you by dinner time tonight, it's going to be totally gone.

I think here we want to figure out how workable it is to make these wands and these imaging things is it sounds like it's exciting for industry that they have the tool, but I think also it sounds like a wonderful inspection tool. So what we really need to do is get government behind this, and get the government contract or something like that, and then

put it in as an inspection tool. And I think that's wonderful. Even post-harvest technologies, it's a very necessary thing.

In an ideal world, I would like to see these pathogens prevented from even getting past the slaughter house door.

What do you think in the case in your research in 0157 specifically holds the most promise at the pre-harvest level to eradicate or at least prevent these pathogens from getting in the slaughter, ideally irradiate because, you know, we are focusing here on meat and poultry, which is our agenda, but you did mention manure previously in one of your slides, and 0157 contaminated manure has also caused foodborne illness in other food products as well?

So what do you see the pre-harvest that holds the most promise?

MR. BREEZE: I'm going to let these two guys answer as well as me because I personally agree with you that elimination of the problem altogether would be the goal. And if we're talking about eliminating it, you're talking about preventing these bacteria colonizing the host

in the first place, and that is probably an achievable goal scientifically.

I can't tell you when, but you have to start walking along that road to get towards that goal if you have got any hope of ever reaching that.

I think some of the technologies we are talking about, about competitive exclusion, very productive technologies which have shown their value elsewhere and I think we can look forward to disease or colonization-resistant animals in the future.

But let me ask Jim and Jane to comment.

MS. ROBBINS: I think it's going to be very hard to eliminate the organism because there are so many in nature for 0157. The best we can do is to decrease the exposure of our animals to it. We are not going to be able to eliminate it.

But be that it's there, I think the first thing that where we might see some breakthroughs in feeding prior to slaughter. As Roger stated in his slide, we have a lot of different results now. There is nothing we can say that's going to do it now, but I think that is an avenue

that if it's probed further we hopefully will find some combinations of feeds that will decrease the shedding. It's not going to eliminate it, but I think they could decrease it.

MR. BREEZE: There are only a couple of organisms that we have really succeeded in defeating in the world. Smallpox is one. Polio is soon going to be another. And that was really the result of research and then intervention strategies that focused on specific attributes of those organisms. So it can be done, and the way to get there is to focus very specifically on these niches and where these things are coming from, and to close them off one by one. It's not an unobtainable dream.

MS. DONLEY: Are you doing any research on -- I know a couple of years ago it was talked about -- on vaccines, animal vaccines? Anything being done on that?

MS. ROBBINS: Yes, we do have the project at the National Animal Disease Center which is focusing on the effect of intimin now.

You may have heard from NIH how successful they have been in the initial stages of a vaccine for humans.

But let me remind you that our task is a whole lot more difficult than theirs because we have to prevent shedding. We are not just keeping an animal from being clinically sick, which is probably a goal with humans at least, but we have to prevent shedding, and we're working on it hard but it's not going to be easy to produce an effective vaccine, and effective on our terms.

MR. BILLY: Collette?

MS. KASTER: I have a quick question and a comment after that. My question is does the organism colonize in lymph nodes or has it been primarily found in the gut?

In other words, do you find it in lymph nodes? Do you isolate it from lymph nodes or only from ingesta or fecal?

MR. BREEZE: No, it's sepis colonize.

MS. KASTER: That's fortunate, good.

Unlike salmonella which would -- would you battle it that way?

MS. ROBBINS: Right.

MS. KASTER: Okay, and then my comments followed by what Nancy said, she hit the nail on the head as far as

the technology transfer. If you have ever tried to stand on a line and actually look for fecal or ingesta contamination, whether you are an FSIS inspector or an industry inspector looking for this. This is a chore. I am telling you what to -- and it doesn't matter so much lines, we're just talking about a lot of surface area. So this would be a remarkable tool.

I mean, I'm like Katie, how fast can you get it to us, and I'm not really even that interested in what it costs because the ramifications of that kind of technology are so important to us.

MR. BILLY: Dale, final word.

MR. MORSE: Final word. I think the presentation and the discussion on this technology is really exciting and fascinating and holds a lot of promise. Just a cautionary note. There are difficulties in implementing this technology, potential for false positive, false negatives.

So I am glad to see that the breadth of your research agenda includes a whole spectrum of things. One, because they also focus on the prevention areas of reducing the levels of microorganisms because this technology is sort

of a fall back, and I'm not sure that the technology will be able to reduce that cheap, that quickly and implemented, you know, industry wide scale, so I think it's good to go forward with the technology, but realize that it may not solve all the problems.

And so I'm glad to see you have a total breadth from farm to table in terms of either research and trying to reduce the levels of pathogens in case this methodology turns out to be too expensive or not easily implemented. And so just to compliment you on maintaining the other programs and not focusing on one area, but it is exciting.

MR. BILLY: Thanks.

Okay, Roger and Jane and Jim, thank you very much. It was an excellent presentation and I'm going to make a suggestion now to the committee in your presence, which is that I think that we should consider arranging some sort of ongoing interaction with ARS and this committee that perhaps in the future we could delve into one or two projects in a little more detail or different strategies to inform this group and obviously potentially be very supportive of what you are trying to do in your research.

So thank you very much.

MR. BREEZE: Thank you.

MR. BILLY: And thank Floyd as well.

MS. DEWAAL: We want a field trip. We want a field trip.

(Laughter.)

MR. BILLY: The next presentation is going to be on additional species. It's a subject that the committee has already addressed. There is some new information and we want to share. I'm going to try to keep this very short. It is on the agenda for this evening and the information is under tab 8.

Robert? Robert Post.

MR. POST: Thank you, Mr. Billy.

Now I have the task of shortening my half hour to one-third. I will talk every third word or something.

MR. BILLY: Good.

MR. POST: Well, I was planning to update you on the activities in this project area. As we had planned, I would -- at the conclusion of the last advisory committee meeting in November, and at the last meeting I presented a

draft of an October 1999 concept paper which recommended that additional species, such as ratites, planobison, buffalo and squab, should be added to those currently under mandatory inspection in order to be consistent with the USDA vision that -- of a public health risk-based seamless federal and state inspection system.

In the October 1999 draft paper is Attachment 1 in tab 7 where all the materials we are talking about are in your notebooks.

If you recall at the last meeting the committee listed several recommendations. We now find those in the current issue paper. The recommendations included requesting more detail in the paper to address the available public health data and microbiological testing, to further consider economic concerns, and to address the issues of non-amenable products in interstate and international commerce.

The committee also asked the agency to address and resolve the specific issue of the use of nitrites in non-amenable and exotic species. And as a final point the committee endorsed the application of the criteria outlined

in the concept paper for determining which species of animals and their products that are intended for human consumption should be subject to mandatory inspection.

So what you have -- what you have presented to you now is a work in progress with various parts being expanded and refined. The intent, as was concluded at the last meeting, is to have the draft concept paper completed in November 2000 for presentation at the next advisory committee meeting.

There were a variety of activities that have occurred on this project since the last meeting, and I thought I would cover those.

A working group on exotic species amenability was formed subsequent to the last committee meeting. That includes representatives from various program areas in the agency, as well as representatives from the FDA.

The working group participants are charged with collecting information based on their program area expertise and forming draft text for completing the October 1999 draft concept paper.

The concept paper discussed the process and

relevant legal authorities to expand the list of species under mandatory inspection in sufficient detail, so I won't go into that here. Rather, I will note that in addition to monitoring the developments on the interstate shipment bill, which was covered earlier today, we have monitored legislation introduced in Congress on amending the FMIA and PPIA to include additional species under mandatory inspection. And there are three bills in the House on rabbits, pigeons and ratites, and one companion bill in the Senate on ratites.

All four pieces of legislation are pending in their respective committees on agriculture, and we will continue to track any progress on these bills and their impact, if any, on this project.

With regard to public health implications and microbiological testing, there is no question that non-amenable and exotic species can be a vector for agents of public health concern. Our goal has to been to gather data on microbiological, physical and chemical hazards reported to be associated with non-amenable and exotic species.

And an in depth review of the literature has been

conducted and copies of the literature reports were provided to you as well as a bibliography that is Attachment 3 in your packet.

These public health reports deal with a variety of non-amenable species and animal diseases, some of which are transmissible to humans, some of which are mainly flock and herd concerns, and others that reflect toxicological concerns.

The table, which is Attachment 2 in your packet, entitled Table of Diseases Known to Exotic Species, lists the literature cites and the causative agents, transmission vehicles, and recommended prevention reported in the literature. And I might note that the title of the table really should be Table of Hazards Known to Exotic Species because not everything reported is a disease.

From the literature, I could preliminarily say that it appears that with few exception non-amenable species are carriers of the same types of zoonotic diseases that are found in amenable species.

With regard to transmissible microorganisms that pose concerns at the slaughter house, the data show that

salmonella, E. coli, camplylobacter and listeria are found in many exotic and non-amenable species. Also, the literature reports indicate that cherkina has been found in several exotic species.

The literature reports appear to show that non-amenable and exotic species pose essentially the same hazards as amenable species with regard to microorganisms of public health concern. But the literature reports provide one perspective on a potential public health hazards with regard to exotic species. They report incidences of diseases in non-amenable species. However, they do not reflect in all cases the prevalence or level of microorganisms of public health concern.

Therefore, we are currently attempting to compile data on the prevalence of microorganisms of public health concern in exotic species, and so far we have found prevalence data from only three published reports: undressed ostrich carcasses, fresh and processed rabbit carcasses, and ratites. Two of the three reports are from foreign sources and that may not reflect the domestic situation.

And this is an important point. There are many published baseline reports of microorganisms and amenable species, but very few seem to exist for non-amenable species, and therefore we continue to request that members of the advisory committee, perhaps those in state inspection programs, help us obtain this data.

We are also attempting to compile data on the mean level of microorganisms of public health concern and exotic species, and so far we found data from eight published studies from foreign sources, on reindeer, ostrich, rabbit and deer. Again, we could benefit from data that some members of the advisory committee may be able to obtain. Without these types of data an assessment of the microbiological risks associated with exotic species and their products cannot be effectively accomplished.

With regard to economics and costs and benefits, the draft concept paper described the need to examine the costs and benefits of adding to the list of species under mandatory inspection and the ramifications on state and federal agencies, the industry and consumers.

In Attachment 4 of the issue paper in tab 7, we

included tables on the types and numbers of non-amenable species slaughtered in federal establishments under voluntary inspection in 1998, and a comparison with the types and number of non-amenable species slaughtered under state inspection in a 12-month period in 1998 to 1999.

I will add that with the help of Dr. LaFontaine we also presented tables of the types and number of non-amenable species under mandatory state inspection and voluntary state inspection in 1998.

And these production data are cited as being useful in determining exposure to potential pathogens or agents of zoonotic disease which may be associated with particular species. They are also useful in developing the economic assessment of extending the coverage of USDA mandatory inspection to additional species.

Numbers and types of exotic and non-amenable species slaughtered under voluntary federal inspection and in state inspection programs are not enough to deal with the estimates of the costs of mandatory inspection for additional species.

Therefore, we have performed a survey that is now

being completed of non-amenable species slaughter inspection in federal plants, in other words, those under voluntary inspection, and of non-amenable species slaughter inspection in states in the cooperative state inspection program.

The data requested were for two fiscal years, 1998 and 1999, and the data includes the number and type of each species slaughtered and inspected, the hourly rate of cost of a federal inspection, and the total cost of inspection.

When the survey is completed later this month, the data will show the estimated annual total cost of slaughter inspection of non-amenable species in federal plants and the estimated total cost of inspections of non-amenable species in state plants.

And we have noted in the issue paper that we are continuing to gather and develop other types of data that are needed on the costs of mandatory inspection for additional species, and I think we have listed them in the issue paper so I won't repeat them here.

With regard to nitrite use in non-amenable and exotic species, a specific request of the advisory committee last number was to address the issue of the use of nitrite

and nitrate in non-amenable and exotic species, and a rather tall order of resolving the issue.

We have had many significant discussions on this issue with FDA representatives, and if you recall at the last advisory committee meeting, we discussed the legal authorities and implementing regulations regarding the safe use of nitrites and nitrates in meat and poultry. I'll try to recap the discussion as well as give you the latest views on this issue.

The Federal Food, Drug and Cosmetic Act, under which FDA operates, gives FDA authority over food and food ingredients. The food additives amendments of 1958 to the FFDCA require FDA approval of food additives prior to their use in food. Under the food additives amendments of 1958, FDA is required to reach an affirmative finding of safety under intended conditions of use for any substance to be used in food, and there are a few exceptions to this requirement as well as a restriction on FDA's ability to approve substances.

The exceptions are: approval is not required for substances whose use is generally recognized as safe by

qualified experts; approval is not required for uses of substances which had been approved prior to October 1958 by FDA under the FFDCA or by USDA under the Federal Meat Inspection Act or the Poultry Products Inspection Act, and this is known as a prior sanction. Additional approval is not required for pesticides approved by EPA and obviously that's not relevant here.

In terms of a restriction, FDA cannot approve any use of a substance if that substance has been shown to induce cancer when ingested or by other appropriate means.

USDA approved the use of nitrites in meat and poultry prior to October 1958 under the FMIA and the PPIA. However, USDA did not have the authority under the FMAA or PPIA to approve uses in species that are not -- that were not subject to those statues; in other words, non-amenable and exotic species. Thus, the prior sanctions do not apply to species that were no subject to those statutes prior to October 1958.

And FDA has approved a few additional uses in certain fish products but no new approvals have been issued since 1970.

Over the last 30 years safety concerns have been raised concerning the use of nitrites. At one time FDA had proposed to review uses of all nonessential uses of nitrite salts but later withdrew the proposal.

The National Academy of Sciences was commissioned to evaluate the safety issues, and while these concerns were initially raised regarding the reaction of residual nitrite to form nitrocomenes, a class of chemical that is generally capable of inducing cancer, studies in the 1970s and 1980s raised concerns that nitrite salts themselves are capable of inducing cancer.

Because of these concerns raised by animal feeding studies, the government commissioned new studies under the National Toxicology Program, which is part of the National Institutes of Health, to address such issues. In the meantime, FDA has taken the position that current evidence is not sufficient to prove that nitrites provide an unreasonable risk but that uncertainties remain which prevent the agency from reaching the affirmative finding of safety needed for new approval.

The results of the National Toxicology Program

studies should have a major impact on what decisions will be made in the future. Just last week we learned that the National Toxicology Program has planned a public meeting to review their draft technical report on the toxicology and carcinogenious studies of sodium nitrite in rats and mice, and this meeting was announced in the Federal Register on October -- on April 19th, and will take place on May 18th t Research Triangle Park in North Carolina. And I understand that copies of this Federal Register notice have been made available.

The National Toxicology Program report and other related information can also be found on the National Toxicology Program/NIH web site, and that's provided in the Federal Register notice.

According to FDA representatives, the National Toxicology Program review of nitrite will influence any options for approving new uses of nitrites, so it's premature to consider options that FDA discussed with us previous to this NTP report.

We have to consider that the resolution of the issue of nitrite use in non-amenable species is unlikely in

the foreseeable future while the results of the NTP studies are considered. We can certainly revisit the options when FDA has reassessed their position in light of this new information.

In closing, I'd like to emphasize that this is a work in progress. We continue to gather economic information and hazard data that I described.

I would also like to note the questions we raised in the issue paper on current thinking, so that we can address them later on today, this evening. And specifically, we are seeking input on whether the committee believes the concept paper and the data needs described sufficiently address the data that are necessary to refine estimates of risks and benefits, and to support legislative and/or rulemaking processes. If not, we are asking what other the data points are needed, and do members of the committee have data that addressed the data needs.

As I mentioned earlier, one area of data needs relates to baseline micro data on exotic species.

Another question is whether the committee wishes to raise substantive new issues relevant to the extension of

mandatory inspection to exotic species.

And with that, I will conclude my remarks. Thank you.

MR. BILLY: Rosemary?

MS. MUCKLOW: Robert, you've given us a lot of information. Thank you.

Have you received or do you contemplate having any data on what consumers' expectations are?

You know, more and more we are seeing the non-amenable species product sitting alongside those that are federally inspected in the retail counters in stores and certainly on restaurant menus. And it would seem to me that consumers have every reason to expect that these things that they eat in the center of the plate products are inspected just as meat and poultry is.

Do you have any kind of information as to consumer perceptions or expectation?

MR. POST: At this point I'm not aware of any data that exists. I know we have heard similar concerns, but that's an interesting area and certainly one that we will continue to explore in terms of available literature or

reports. And certainly if there are any other individuals here who have that kind of data, we would be interested in it.

MS. MUCKLOW: Some of the people that produce these kinds of products may indeed have that kind of information. And I know that there are a variety of organizations, the ostrich and others, and I think under some state programs these products were inspected, just not inspected under the federal program.

So, you know, I think all of this builds towards the equity end to support that these products should be treated in a manner similar to meat and poultry because consumers really think that's what is happening anyway. I'd be surprised to find out that it wasn't.

MR. BILLY: Dan?

MR. LAFONTAINE: As the chairman of the subcommittee that will deal with this issue tonight and tomorrow, looking back to the last meeting I don't want to preempt, but the flow of -- this is a reasonable step forward was a general consensus. What we got bogged down in was the nitrite issue because it's a Catch-22, especially

for the red meat people, and this is kind of a day late and a dollar short, but is there any possibility -- is there a person in FDA that could possibly join us tomorrow that can help us deal with this issue of where it's headed? Or is that too tall a task to ask at the eleventh hour?

MR. BILLY: My impression from what Bob said was that a lot is going to turn on this meeting scheduled for the 18th. And what we might want to do is make sure that we're -- we monitor that meeting and the outcome of that because it will influence FDA's attitude about change in the status of these species and an awful lot of other food products where nitrites arguably could play a useful role.

So I don't know if you agree with that or not or.

MR. LAFONTAINE: I do agree with that. I think they have said that the potential impact of the results of the NPT report show will have an impact on any decisions at this point with regard to new approvals.

MR. BILLY: I am also aware that the -- I think the American Meat Institute and perhaps other industry organizations have assembled a great deal of information that will be considered as part of that process on the 18th.

I don't know the details, but that's my understanding. So there is input that, as I understand it, that is being provided about the use of these compounds obviously, and their importance. So I don't know anymore than that.

If we had someone from FDA come, I think what you are going to hear is a repeat of what Bob said about, you know, they are going to wait and see what this advisory committee recommends. I don't know if that satisfies you or not.

MR. LAFONTAINE: Like I said, I realize it's a tall order at the eleventh hour, and like you said, this meeting on Thursday, I guess, so timing is not very good.

MR. BILLY: Yeah. Katie?

MS. HANIGAN: I just have one quick comment, and Bob, I think you did an excellent job of getting together the information. I know you were part of our group last time as a representative from the agency.

I just thought it was odd that this morning Kathy talked to us about a precautionary policy and we talked about the benefits and et cetera, that they could weigh on the side of politics, if you will, on that precautionary,

and it sure seems a shame that that's what it appears the FDA has done with this nitrite policy here, and I just thought that was an interesting thing that you mentioned this morning.

MR. BILLY: Caroline?

MS. DEWAAL: Did the agency get any new money or request any new money in its budget on the amenable/non-amenable species issue? In other words, to increase your inspection and expand it to these species?

MR. BILLY: I'm not aware of getting any money.

MR. DEWAAL: Did you request it?

MR. BILLY: I think perhaps at an early stage in the formulation of the agency's budget there were funds proposed in that area, but it fell out fairly early on in competition with other needs. So I don't remember. I'd have to go back and look at the records to find out specifically, but it was acknowledged as a need but it didn't survive very long in the budget process.

MS. DEWAAL: Okay, and I just -- I'm glad to hear that because I think we do need to balance this against other food safety issues, particularly when it comes to the

budget on the FDA side where we have eggs, seafood and fruits and vegetables and other things which are contributing significantly to foodborne illnesses, yet have a very minimal regulatory program. So I would hope that this issue doesn't take precedence over things that are causing actual harm.

MR. BILLY: Okay. Any other comments?

MR. POST: All right, thank you.

MR. BILLY: Thanks a lot. And you will be available tonight --

MR. POST: Yes.

MR. BILLY: -- to work with the subcommittee, right.

All right, here is my plan. It's a quarter after three. I think we need a break about 15 minutes. I held you a little extra. And then we're going to try to get through the two issues that remain, E. coli and listeria in half hour to 40 minutes each. I'm going to allow our lapsing a little into the public comment period in part because at this point in time we only have one person that's registered to speak, and we've provided 45 minutes as you

can see. So we will monitor that, but I think it's important that we have an adequate time for discussion of those two important issue areas, and we will manage time accordingly.

So let's take a break for 15 minutes.

(Whereupon, a recess was taken.)

MR. BILLY: Alright, we're going to get started, and we've got two very important issues remaining on the regular agenda, plus the public comment period.

The next issue is the recent developments in terms of E. coli 0157:H7, and this discussion will be led by Phil Derfler, the deputy administrator for policy, program development and evaluation within the Food Safety Inspection Service.

Phil?

MR. DERFLER: Thank you. Thank you, Mr. Billy.

MR. BILLY: Move the mike real close so people will hear you.

MR. DERFLER: Okay. With me is Patricia Stolfa, who is an assistant deputy administrator within the Office of Policy and Program Development and Evaluation.

I'm going to do two things pretty much. I'm going to do a little bit of a summary about how we got to be where we are today, which maybe everybody is familiar with, but I'll run back over the history. And then I will briefly summarize the action plan that the agency foresees with respect to E. coli 0157:H7 which is set forth in the paper that you all should have received.

FSIS has approached E. coli 0157:H7 like its approach -- oh, it's in tab 8 in your books -- like its approach for listeria that you are going to hear about next, has really been a process. The process started in 1994, when FSIS determined that raw ground beef products are adulterated if they contain -- they are found to contain E. coli 0157:H7.

But the process really started to gain momentum in 1999. In January of 1999, FSIS clarified its policy and made clear that any non-intact beef product would be considered to be adulterated if found to contain E. coli 0157:H7.

After clarifying its policy, however, the agency put most aspects of it in an abeyance while certain other

matters proceeded, and the developments have come fairly quickly on its heel.

In March of 1993, we held a public meeting on E. coli 0157:H7 and at that meeting a coalition of industry groups said that they would conduct a study on the prevalence of E. coli 0157:H7 on hides of cattle coming into slaughter plants and then at various points in the slaughter process.

MR. BILLY: Phil, I think you said '93.

MR. DERFLER: I did?

MR. BILLY: You meant '99.

MR. DERFLER: '99. Whenever.

(Laughter.)

MR. DERFLER: I'd be a lot younger if it was '93.

(Laughter.)

MR. DERFLER: I'm sorry.

MR. BILLY: All right.

MR. DERFLER: '99. ARS, as you heard before, has also recently conducted some similar studies.

The agency's risk assessment has proceeded apace and it's nearing completion now. In addition, the agency

has begun to use a new, much more sensitive method for detecting the pathogen, and as a result, since January of 2000 -- 2000, the agency has had 11 positives for E. coli 0157:H7 in its surveillance system. That's 11 out of the 63 positives that there have been since the agency started looking for the pathogen in 1994.

FSIS has reviewed -- rather, FSIS reviewed all of these developments and reported on them in a white paper that I delivered to this committee last November.

In February, we held a second public meeting and at that meeting some very significant information was presented. Data presented showed that the prevalence of E. coli 0157:H7 in livestock and on carcasses moving through the slaughter plant is higher than previously thought, although the prevalence appears to be highly seasonal.

For example, monthly prevalence in fecal samples showed a significant variation from 4.8 percent to 36.8 percent, with the highest levels in the spring and late summer. Evidence was presented at the meeting that the interventions in the slaughter process are effective in reducing the presence of the organism, although not

necessarily capable of totally eliminating it. That was alluded to in the presentation you heard before from ARS.

Data on illnesses associated with E. coli 0157:H7 indicate that the overall burden has not been reduced. CDC estimates that ground beef accounts for 55 percent of the E. coli 0157:H7 outbreaks, and FSIS has estimated that 18 percent of illnesses caused by E. coli 0157:H7 are associated with ground beef.

Data were presented by scientists from Kansas State University at the public meeting, and they claim that this data showed that cooking non-intact pin beef products to a surface temperature of 145 degrees eliminated the risk from E. coli 0157:H7. And at the public meeting consumers made very clear that they remain extremely concerned about this pathogen.

FSIS has carefully considered the information presented at its public meetings, as well as the comments that it received on its January 1999 notice. And based on this consideration, the agency has developed its current thinking which is set out in the paper that you received at tab 8, and I'd like to just review that with you now.

First of all, the agency considers to believe or continues to hold that raw ground beef or other non-intact products will be considered to be adulterated if found to contain E. coli 0157:H7. FSIS is open to excluding certain non-intact products from this policy if scientific evidence is presented that cooking using normal practices results in a product that does not present a food safety hazard. We intend to consult with the National Advisory Committee on microbiological criteria for foods at their August meeting about the type of data that would be necessary to make such a showing. But at this time we are not prepared to exclude the pin beef from this policy based on the Kansas State University data.

We note that the conference on food protection in April considered a request based on the Kansas State University data to revise the food code to allow pin steaks to be cooked like intact steaks. And the Council on Food Protection delegates rejected this suggestion.

Second, FSIS intends to publish a Federal Register notice announcing that E. coli 0157:H7 may be a hazard reasonably likely to occur in beef production. The notice

announcing this determination would be similar to the one that the agency published last year on listeria monocytogenes and would lay out the basis for the agency's view.

Third, in response to the notice, we would expect that all establishments engaged in beef production and processing would reassess their HACCP -- their hazard analysis in their HACCP plans. They would be expected to validate that any changes that they make to their HACCP plans as a result of the reassessment will work to improve the safety of their product.

Fourth, FSIS intends to redesign its testing program for E. coli 0157:H7 so that it will become a HACCP verification activity. Thus, instead of focusing -- in addition, instead of focusing on grinding operations, the agency would test product that cleared final pre-shipment review from plants at any stage of the beef production chain.

Fifth, FSIS intends to revise its directive to reflect the revised testing program. The agency is considering providing for reduced sampling at plants that

have controls for 0157 in their HACCP plans that provide access to test results and corrective actions if they find the problem to inspection personnel and whose records evidence that the HACCP system is working to prevent adulterated product from entering interstate commerce -- from entering commerce.

Sixth, FSIS also intends to develop guidance materials on controlling or reducing E. coli 0157:H7 in the slaughter plant, to update its guidance to grinders, and to develop materials for producers. We hope to be able to do all this over the next four months.

And finally, there is the question that we would appreciate the comments of the advisory committee on, which is whether the committee's views on the agency's current thinking that I just laid out on measure to control E. coli 0157:H7 in a HACCP environment, and what additional measures should FSIS take to address E. coli 0157:H7.

Thank you.

MR. BILLY: Lee?

MR. JAN: I just want to ask one question or a clarification.

Did I understand you to say in your comments that the cooking non-intact beef to 145 external temperature made it safe or?

MR. DERFLER: That was the claim that --

MR. JAN: That was a claim.

MR. DERFLER: -- the Kansas State people presented, yes.

MR. JAN: So it's a claim. Did they have any scientific --

MR. DERFLER: They presented scientific data, and we are interested in hearing the comments of the microbiological advisory committee on how to approach this issue. We are not looking to close the issue now. All we are saying is based on what we have and what we know we are not prepared to make an exception for this product.

MR. JAN: So you need more of that evidence from what Kansas State did?

MR. DERFLER: Well, unless the advisory committee tells us -- describes a set of evidence that actually describes what Kansas State has provided, but you know without trying to prejudge the issue, yeah.

MR. JAN: Okay.

MR. BILLY: Gary?

MR. WEBER: We have conducted a number of research projects in this area to determine the scope of the risk here because when this was first brought to our attention we were concerned about it as well and wanted to know what we were dealing with.

The first thing we did was try to look at some of the epidemiologic data relative to foodborne illness and outbreaks, and in that context couldn't find evidence that these types of products were linked to illness, and that was one piece of evidence.

We then went on to do a retail survey of products and tested for salmonella, 0157:H7, campylobacter, total plate count and all sorts of other things, and that was back last summer. We didn't find any 0157:H7 on any of these products, both neither external nor internal. These are needle tenderized, blade tenderized, et cetera.

And some of these products weren't the most -- I mean, some of them had fairly high spoilage organism plate counts, so it's not as if they were sterile by any stretch.

So we didn't find the prevalence there.

Then the next issue, of course, was this study on cooking that shows that with steaks of fairly uniform thickness that the cooking, coupled with the time it takes to cook that steak, was very effective in reducing it.

So in looking at this from the scientific perspective, we have, and it comes back to this proving a negative issue. You have got three sets of data apparently which indicate that there isn't a major problem here: one epidemiologic case studies of health, outbreaks, et cetera; one you've got retail surveys with the prevalence of organism; and three, you've got the cooking data, all of which indicates that we shouldn't have a problem.

Now, if you just looked at the cooking data and the prevalence data, you'd say, well, I'd be surprised if I saw in the public health side a problem given this reality.

We are going to continue on in this project. We are working with some of the manufacturers of equipment because there are issues that I think ahead of this curve. One needs to consider cross-contamination, needles going into another cut or whatever and other problems that may

occur there.

But as we see it, it comes back to this issue that Dr. Denton mention of proving a negative. We see a lot of negatives here that we're picking up. And so I can certainly make that information available and certainly the micro committee, if they can provide us some advice on some experimental design to sort of further verify what our initial observations are, that would be great. But at this time, again, we don't see the evidence that there is a problem at this point. Now, we are taking it seriously and looking further.

MR. BILLY: I would suggest that the information you just referred to be made available to the micro committee at its August meeting.

MR. WEBER: Okay.

MR. BILLY: Because this item is specifically on the agenda.

MR. WEBER: Okay.

MR. BILLY: And let that be part of what they consider in reacting to the questions that we are posing to them.

MR. WEBER: We also have some data I just wanted to mention briefly on some combo testing, but I don't want to dominate the discussion. Maybe if you want to talk more about intact, I can come back to these studies that we just completed and just share some of the overviews of what we are finding there.

MR. BILLY: Okay. Nancy?

MS. DONLEY: I have a couple questions and it's basically on the action plan.

MR. DERFLER: Mm-hmm.

MS. DONLEY: Is there -- you had said that FSIS would expect all establishments.

Is there going to be anything stronger than that that will -- or is that the exact terminology? Are you going to require plants to --

MR. DERFLER: We didn't require for listeria. We don't expect to require it here. What we want to do is put out our view. We want people to start acting under the regulations, the HACCP regulations, as quickly as possible to address this problem.

MS. DONLEY: But under -- because under this new

umbrella, if you will, of it being recognized as a hazard reasonably likely to occur, wouldn't you, FSIS, expect to see it addressed in a HACCP plan in some way, shape or form, and identified as a hazard?

MR. DERFLER: WE would certainly hope so, yeah. And I think -- you know, any plants that didn't have that, as I said as part of our testing plan, would be subject -- we would target our testing in that plant. And if it did show up, then I think then it would be difficult for the plant to say that it was not a hazard reasonably likely to occur.

MS. DONLEY: But could any inspector now in a beef plant take a look at the plant's HACCP plan and say you have not identified 0157 has a hazard reasonably likely to occur, and you haven't identified any steps along the process -- well, let's -- just the first part of it.

MR. DERFLER: Yeah.

MS. DONLEY: If they haven't identified it as hazard reasonably likely to occur, what would the agency's next step be?

MR. DERFLER: Well, we would expect them to at

least have discussed it in their hazard analysis and decided why it wasn't a hazard reasonably likely to occur in their plant. And then, as I said, as we develop our testing program, our testing program is going to target the plants in which it's not -- it has not been identified as a hazard reasonably likely to occur.

MS. DONLEY: But to know how to identify those plants you are going to have to look at HACCP plans, right?

MR. DERFLER: Absolutely.

MS. DONLEY: Okay, so you will be looking at all plants?

MR. DERFLER: Yes.

MS. DONLEY: Beef plants' HACCP plans?

MR. DERFLER: We are going to --

MS. DONLEY: Okay. Fine.

MR. DERFLER: Yes.

MS. DONLEY: Okay.

MR. DERFLER: We a re going to send out directives to our inspectors to --

MS. DONLEY: Okay.

MR. DERFLER: -- look to see what steps, if any,

the plants took as part of their reassessment, yes.

MS. DONLEY: Okay.

MR. DERFLER: At least that's our plan.

MS. DONLEY: Okay. And then the second question I had is in redesigning FSIS's -- using this as a HACCP verification activity, are you planning to increase the numbers of samples that you conduct now in your random samples, or maybe or is it just a continuous random sampling program, or are you going to actually be conducting in all beef plants 0157 testing programs as a verification step?

MR. DERFLER: I mean, the number of tests that we're actually able to do depends on our resources. I don't think there is any plans to increase the number. What we hope to do is be able to target them more effectively, so I think the answer to your question is sort of no, but I think we intend to use our resources more effectively.

MS. DONLEY: Okay. And then can I ask one more follow-up question? That is, in these -- with the provided for reduced sampling in plants that have -- included controls, are -- is it -- is that product, so let's say it's in a slaughter plant, and that product gets shipped to a

different processing plant, that exemption, if you will, doesn't carry through to that processing plant necessarily, does it?

MR. DERFLER: Well, it depends on what what's going to be in the other plant.

MS. DONLEY: In a system plan?

MR. DERFLER: Yeah, HACCP plan

MS. DONLEY: Where I'm coming from is that -- if my understanding of what the industry had put -- had initially proposed was that anything that -- for instance, if there was carcass testing being done, that that exemption, if you would, carried all the way through retail, so that's kind of where my question is coming from.

MR. DERFLER: It would depend on the circumstances and the content of the plan, the steps that the other plants had in place.

MS. DONLEY: Throughout each --

MR. DERFLER: Right.

MS. DONLEY: -- individual establishment --

MR. DERFLER: Right.

MS. DONLEY: -- is -- okay.

MR. DERFLER: You know, if the plant, you know, used only product from plants that certified that their product was negative or they had been tested for 0157 and not been found, that would be one thing.

If they were mixing product from various --

MS. DONLEY: Right.

MR. DERFLER: But also you started that question be reduced simply. I'm not prepared to accept that characterization.

MS. DONLEY: Oh, except it's right there in point four.

MR. DERFLER: What?

MS. DONLEY: It's right there in point four. I'm sorry. I'm just using your words.

MS. STOLFA: It's reduced, it's not an exemption.

MS. DONLEY: Correct.

MR. DERFLER: Oh, reduced sampling in the -- okay, I'm sorry. I thought you meant for the agency.

MR. BILLY: Finished, Nancy?

MS. DONLEY: I am. Thank you.

MR. BILLY: Caroline?

MS. DEWAAL: Katie wanted to go next.

MR. BILLY: Okay, Katie?

MS. HANIGAN: My question follows Nancy's, and that's exactly what I was going to ask.

Currently if I am making ground beef, I can get a letter from my supplier that is slaughtering these animals talking about the intervention system at their facility as well as their testing program.

So once this Federal Register notice comes out, I am getting fictitiously this trim in. I have no CCP in my facility that's going to control this because it arrives with the trim that I got from the slaughter.

Are you saying that initial letter and testing program at the slaughter plant is not going to be acceptable? What -- because I'm looking at --

MR. DERFLER: You've confused me.

MS. HANIGAN: Okay, I'm looking at the HACCP model and the CCP and the Federal Register notice saying that 0157:H7 may be a hazard --

MR. DERFLER: Right.

MS. HANIGAN: -- reasonably like to occur. But if

it arrives at my facility in the trim, what CCP do you see me putting in to control this?

MR. DERFLER: You might want to have some controls at receiving.

MS. HANIGAN: Like what?

MS. STOLFA: You might want to have refrigeration.

MS. HANIGAN: Sorry?

The refrigeration is not going to control it. It would already be there. And at receiving when it comes in, the --

MS. STOLFA: The risk assessment.

MS. HANIGAN: -- CCP should be set up so that I look and I monitor and I say go/no go.

MS. STOLFA: The risk assessment tells us that the organism is there in the material you are receiving at extremely low levels, but it is much more prevalent than what we had believed previously. And so in addition to whatever kind of receiving controls you might want to have, refrigeration seems to us to be an important thing to do so that the broad prevalence which comes to us from the risk assessment, you know, we don't have the stuff growing out.

MS. HANIGAN: And I don't want to get us way into a deep conversation, but the agency has already issued directive to the industry clearly saying using receiving temperatures as a sole CCP was not acceptable. So now we're backing up here saying receiving temperatures.

MS. STOLFA: No, I don't know what directive that is.

MS. HANIGAN: Clearly that came out of a number of the district offices, and I hear Terry saying "That's right."

MS. STOLFA: I think after we issue the Federal Register notice and we provide the basis for your belief that the organism may be a hazard reasonably likely to occur in all stages of beef production, and you consider the basis for that, then people may arrive at different conclusions as to what their HACCP plans ought to look like.

MS. HANIGAN: See, and my concern is for everybody in the room we get talking again about product temperatures, receiving temperatures, room temperatures and pretty soon we're into these prerequisite programs that we've been talking about, and those -- that is not going to control and

it's not going to eliminate E. coli 0157:H7 in a grinding plant, temperature isn't.

MS. STOLFA: Well, we're into -- one of the things that an accept CCP can do is to make sure that the organism is reduced to the lowest possible level. As we say, we know that -- you know, we believe from the risk assessment that its prevalence is much greater that previously anticipated, although that prevalence is at extremely low levels.

And so we are very interested in controls which prevent those low levels from growing into levels that will be of concern.

MS. HANIGAN: So then now we do know the infectious dose and all that on the organism?

MS. STOLFA: No, we don't know that. We anticipate that it's quite low.

MS. HANIGAN: Okay. So I still go back to the Federal Register notice is going to come out may be a hazard reasonably likely to occur, I am not slaughtering these animals. I am bringing the trim in. Your suggestion, refrigeration. But since we don't know the infectious dose here, I'm not sure how that CCP is going to work, and I

think it's just white wash. Perfectly honest with you, I think it's white wash to do that.

And that why when Nancy started in on the questioning about the letter, the testing program of the slaughter, I'm wondering where that is going to end up because a number of people buying trim in require whoever slaughtered those animals have a testing program going on on those carcasses, and have it validated, and send us letters with each lot.

Is that not going to be acceptable anymore?

MS. STOLFA: The testing program will be targeted first to establishments that have not included in their HACCP plans a CCP addressing 0157:H7.

MS. HANIGAN: And Pat, I clearly understand what you are saying but I'm not sure if I'm being understood.

Even if I do a hazard analysis and say, okay, it's reasonably likely to occur, I have no way of controlling it in my facility if I am grinding.

MS. STOLFA: Well, I guess we probably wouldn't necessarily agree with that view.

MS. HANIGAN: So you are recommending temperature?

MS. STOLFA: As a thing that can be done.

MR. BILLY: I think we need to move on, and this could be discussed more this evening and later.

Caroline?

MS. DEWAAL: Thank you, Tom.

I'll note that this policy clarification has been hanging around for about 18 months now, and it's good that the agency is finally moving forward with it, so I want to congratulate you on taking the step.

And the industry has been on notice for a long time that the agency was contemplating this, so I think what Katie is just talking about is one of the difficulties about translating a HACCP as a process -- as a processing system into the production of raw meat, and the definition, as I recall it, controls is that they reduce or eliminate the hazard. It doesn't always have to eliminate the hazard, although in this case, Katie, I agree with you. We want to eliminate this hazard as much as possible.

Just on one note with what Gary mentioned. We do have outbreak data indicating that roast beef and some other cuts of meat have been implicated in outbreaks, and that's

available at CSPI's web site in our report called "Outbreak Alert," and that report is being updated now, so that the most recent version will be out in August.

Phil, I have a question for you, and that is, the industry did a really excellent job, I thought, at showing the feasibility of carcass sampling for 0157:H7. They ran a series of tests in their own plants, and demonstrated that carcass testing for this terrible hazard is quite doable, and they came in and shared the results with us at a meeting several months ago.

CSPI asked, and a number of other consumer organizations as well, that carcass sampling be mandated for the industry. It's an additional protection. It's something that's highly doable. And I want to know what happened to that proposal because I don't see it here as one of your recommendations.

MR. DERFLER: I think the answer is if you believe in HACCP, you believe in the type of HACCP verification testing that we're looking at. I mean, we're not saying that industry shouldn't test carcass. Industry can put in any control system that they want. That's the point of

HACCP.

But from our effort, our point of view, how we're going to focus our resources, we're going to focus on verification testing to ensure that our program is working as well as it can.

MS. DEWAAL: But wouldn't it make sense -- I agree that you should be focused on verification testing, and I think I share Nancy's concern about the directive 10.01.l. There seems to be a trade off where the industry, you know, gets a -- you know, get out of jail free card because we're not going to check your products anymore just for agreeing to do testing.

Now, why isn't testing utilized both by the industry and the government? Why don't we have two layers of protection? Why are you just giving us one, either industry or government?

MR. DERFLER: Well, let me -- this is an action plan. It's a thought paper. We are happy to get any input that we have.

I guess I should say though just from a personal standpoint, and it doesn't necessarily reflect the views of

the agency, but at the public meeting that we had was Mr. Gill from Canada spoke, who talked about, you know, the fact that you really can't test your way into effectiveness of a program like this; that you really need to have a HACCP system in place and HACCP system working.

Naive as I am, and I will freely admit that, that was significant.

MS. DEWAAL: I beg your pardon. I agree with that. We're not talking about either/or here and we never have been. And I know that people who went through the numerous meetings we held on the original HACCP rule understand that we're not saying micro testing instead of HACCP. We're saying that both industry and government should be using testing as a verification tool.

And Mr. Gill represented, or Dr. Gill represented the old thinking, the old philosophy that it's an either/or system. Maybe that's new to you that it's not an either/or system. We can have both. But the government needs to be giving us two layers of protection here. It's doable. The industry is already doing it. We saw that in the listeria presentations yesterday. And I want -- I need to understand

from the agency, and I'll be asking this question again when we talk about listeria, why not? Why can't you give us two layers of protection?

MR. BILLY: Dale? No?

Alice?

MS. JOHNSON: I'm going to go back and piggyback a little bit on what Katie said. And Phil, you just made the comment "if you believe in HACCP." I think you just said at one of the very first parts of your presentation if a company has their hazard analysis that they have the problem under control, they don't consider it reasonably likely to occur, they have their supporting documentation, they will still be targeted is what you said; is that correct?

MR. DERFLER: I said that we would target our testing at them, yes. That doesn't mean that they are going to be tested, you know, every day. It does mean that, given the limited resources that we have for testing, that would be a higher priority than a plant that has a HACCP plan that is giving us access to the records, and their records are showing that their HACCP system is working. It would be a waste of our effort to test in that situation.

MS. JOHNSON: But there won't be the credibility given in the hazard analysis?

MR. DERFLER: No, we're not going to -- we're not going to make them change their HACCP plan or hazard analysis or add it as a CCP. But you know, to the extent that we have an ability to do some testing, that's what we will do.

MS. JOHNSON: But they will be tested if they don't have the CCP?

MR. DERFLER: People may be tested if they do have the CCP. It would just be in our --

MS. JOHNSON: But they will be targeted?

MR. DERFLER: Well, that's our plan right now, yes.

MR. BILLY: Rosemary?

MS. MUCKLOW: Phil, there are a lot of questions about this policy that are going to surface. The first one, I'd like to go back to the discussion earlier about the needle product, or as you call it, pin product.

There was extensive data submitted by distinguished microbiologists who studied this product, and

yet you have indicated this is insufficient to allow you to accept that data; that you want something more. We heard around the table today that there may be some additional information.

Do you have any information of illnesses that have been attributed or H7 that has been found in this product? Do you have that kind of data?

MR. DERFLER: Well, other than the information that Caroline alluded to, I'm not aware of any.

MS. MUCKLOW: I don't know what Caroline's data is. I haven't heard about that before.

MR. DERFLER: I know that CSPI has published a list of outbreaks, and on that list of outbreaks there is one that was a roast beef product, I'm sure of that.

MS. JOHNSON: Was it a needle product?

MR. DERFLER: I don't know. I just am --

MS. MUCKLOW: Okay.

MR. DERFLER: I'm not trying to argue one way or the other.

MS. MUCKLOW: Well, you know, Carol likes government. She's never much liked industry data, but she

does like government data. Like you, I have some respect for your information and data. And to date some reputable scientists have submitted data that showed that that product will not have H7 if it -- even if it has been needled and cooked properly. And I don't quite understand why that particular product is lumped in here when the data goes the other way. That's just one little comment on that.

And if you have data to show us otherwise, then I would certainly ask you to make it available to us.

MR. DERFLER: Right. I don't know that I'm saying that it's not sufficient. What I am saying is for the reasons that we laid out in January 1999 notice we would want to have as much confidence as possible about this product. That's why we intend to go to the advisory committee. It's not to say we need more, it's not there. We would like a group of experts to look at it and to give us guidance. We think that's the prudent way to proceed at this time.

MS. MUCKLOW: Okay. So you're taking the non-intact product to the micro advisory committee?

MR. DERFLER: Right. Yes.

MS. MUCKLOW: Okay. I think that that is a useful place to take that request to because I think this is a science issue, and while we have some scientists here, most of us are political scientists, not real scientists, and you will probably get a better scientific response from the micro committee.

The second question I have is that somewhere in here it says, and I think you said in your comments that the risk assessment is being prepared.

Is it possible that we could be provided with a draft copy because obviously you guys know more than we do at this point?

I mean, we need to get all the cards on the table on this one.

MR. DERFLER: Right. I would say we highlighted features of the risk assessment in the public meeting that we had in February. The risk assessment, I believe, is going to be published in August, and so it will be available quite soon.

MS. MUCKLOW: Is there a preliminary draft of it that we could begin to work from because I -- you know, most

people who are scientists, and it's going to -- again, I'm the wrong kind of scientist to understand this, but the real scientist is going to want to look at what you have got.

MR. DERFLER: And it will be made publicly available. My understanding is that they are still doing final cleanup, final running through, and it's going to take until August.

MS. MUCKLOW: And who is doing this?

MR. DERFLER: The Office of Public Health and Science within FSIS.

MR. BILLY: It's an interagency team. CDS and --

MS. DEWAAL: Rosemary, it was -- they did present it to the National Advisory Committee for micro within what, the last six months?

MR. DERFLER: It was last fall.

MS. DEWAAL: Yeah. So they have looked at it several times while it's being written.

MS. MUCKLOW: Is that correct, Mr. Billy, that it was presented to the micro committee?

MR. BILLY: Yeah. The design of it and the approach, and then the final report will be presented in

August.

MS. MUCKLOW: Okay. So the final report was not presented to the micro committee last August?

MR. BILLY: Not yet. That's right.

MS. MUCKLOW: Rather the design and --

MR. BILLY: Yes.

MS. MUCKLOW: Okay, and that was probably publicly available and scientists have that, I assume.

MR. DERFLER: I think on our web page, you know, part of the risk assessment that was presented in February is available in our risk assessment -- on our web page now.

MS. FOREMAN: Is it possible still to get copies of that so we could have them available tonight for the committee meeting?

MR. BILLY: The material that was presented at the public meeting.

MR. DERFLER: Yeah.

MS. FOREMAN: I didn't bring that with me. If we could have it for the subcommittee meeting.

MR. BILLY: Okay, we will see what we can do.

Yes?

MS. MUCKLOW: I think that would be useful.

As I --

MR. DERFLER: We'll try and get it.

MS. MUCKLOW: Okay. I listened carefully to Katie and then to Alice, and again I'm trying to get a handle on something that is occurring in a raw product that is cooked before it is consumed.

And what you are doing is you're in effect saying this is a hazard reasonably likely to occur and therefore we want you to have a CCP. And a CCP then you have to design something to either prevent, eliminate, or reduce to an acceptable level.

And Pat has told us that it is the agency's belief, based on what they have read in their risk assessment, that it is out there in very, very low levels.

The question becomes do you believe or what is the acceptable level for H7 on a beef carcass or in ground beef because those are the two places that we're going to have to deal with it? What is that acceptable level because we need some help on that?

MR. DERFLER: Yeah, when it's detectable.

MS. MUCKLOW: So we can have it there but we can't detect it? And as soon as we can detect it -- so we're back to proving of a negative, and the tests today are better than they were two years ago. I mean, refrigeration isn't going to get rid of it. You know, Katie is absolutely right. And refrigeration in this industry is pretty good. The interventions in this industry are pretty good.

Do you have any information on the outbreak data that you have where you have tracked that product back to a company which slaughtered the meat that the ground beef was made from and been able to show whether or not they had interventions working? Have you been able to do that at the tracing?

MR. DERFLER: I don't know. I mean, I just don't know.

MS. MUCKLOW: Well, when you've got 11 -- I think you said you had 11 --

MR. DERFLER: Yeah.

MS. MUCKLOW: -- this year out of a total of 64, and those are all pretty recent. I mean, it's not an easy task, and I'll grant you --

MR. DERFLER: Right.

MS. MUCKLOW: But if you indeed -- there is this huge impact, shouldn't we be or shouldn't you be trying to track those 11 to see what the source of the problem was? Isn't that a place that we need to go and investigate and see if interventions are or are not working back at the source at the plants because that's where we are going to have the best control?

There is no control --

MR. DERFLER: Right.

MS. MUCKLOW: -- in a grinding plant. Refrigeration isn't going to do it.

MR. DERFLER: I mean, we're certainly looking for control first, I mean, at the grinding plant, and I think Pat said that before, that's certainly where we are -- we are changing our testing. We are going to not only be looking at the grinding plant anymore. We are going to be looked at the slaughter plant and we hope that there will be the interventions in the slaughter plant, and that the slaughter plant become the key to this.

MS. MUCKLOW: Well, are you looking back for those

11 positives this year to see if you can track them back and see how effective the interventions were or were not at the source plant?

MR. DERFLER: I just -- I just don't have any personal knowledge of that. I'm sorry.

MR. BILLY: We will review what was done. We don't know the answer.

MS. MUCKLOW: I'm finished for the moment.

MR. BILLY: Lee?

MR. JAN: I just don't need to say much. I think Katie and Rosemary covered it. Refrigeration is not an acceptable control for an organism that there is no tolerance for, so I think that -- that was my point.

MR. BILLY: Gary?

MR. WEBER: First of all, Caroline, I'll take a look at that data because seriously we have looked and talked to CDC and they were not -- didn't feel that there was an issue here, but we will certainly look at that.

Back to the HACCP discussions where -- as a preference to my comments -- we talked a lot about micro testing. We've talked a lot about testing for pathogens,

and at that point in time I think everybody felt that E.coli generic plate counts, what have you, as an indicator of fecal contamination is a process indicator. It's something that was routinely measurable and could be used to verify and validate HACCP. We have been down this road, folks, before where we tried to chase after these things.

Everyone sort of reluctantly went ahead and said okay, let's try to do salmonella. It is a little bit more repeatable in measuring.

But when we listened to the risk assessment, which we have not been able to get a copy of the data, there is a lot of things made absolutely no sense. It's very difficult looking at other models to have one which when you look at trying to verify the estimates, that you can't do it.

One being the prevalence in combos, which we have been doing a lot of research on, to come back to this issue of 89 percent having a level.

So with the help of actually Mark Mina and others we received 10 combos that had been determined to be positive from packing plants, and we took those combos apart. We broke them into five layers. Each of those five

layers we took nine samples. That's 450 samples. Now remember these are combos that were felt to be positive for 0157:H7.

We then took five samples of purge from those thinking if we could find an indicator that might give us some higher probability of finding it that was easy, that gave us another 50 samples.

So we have 500 samples that we ran through the most stringent testing we could. And again, I will get you copies of this and give these to the micro committee. Out of those 500 samples we found three positives. We found three positive for 0157:H7 out of 500 samples. That's a rate from the 500 of .6 percent.

Now, these are combos that were viewed positive, so that's why testing of this is so difficult. And you could test in another part of this, another layer and say it isn't there, and then what would you do?

So we know that. That's why this testing for this organism doesn't give you very much.

Now, if you take a look at -- we ended up with two combos out of 10 that were positive. Now, again, this is 10

that should have been positive. We took the whole thing apart, so that's a prevalence of 20 percent basically, 20 percent of those that people thought were positive showed up here.

Well, then the question is what level did you find? Well, the lowest level was -- by the most probable number -- was .015 colony-forming units per gram. The highest level they found was 4.6 colony-forming units per gram.

So not only are we not finding it in positive combos, but the levels we are finding and the sensitivity of this technology is very sophisticated.

So the point is if you're going to make this change or you are going to say this hazard reasonably likely to occur even in combos where somebody said it was, and these are good companies, good labs that have indicated this, you can imagine what you are facing in trying to generate this kind of program around these kind of numbers.

And I think you really have to go back, and we can do more work. I think we need to invest and taking some of these combos apart, finding it out, because I think what you

are going to find is you are chasing a tail, and it's a huge investment. I don't know that you are going to get out of it what you want.

I think we have made huge advances using other technologies. But this idea, and we're going to give this to the risk assessment people because nothing fits in those numbers; not the .33 percent positive you're picking up with the general testing, which I would argue is targeted. That isn't coming up with 89 percent. We are running 20 percent of already positive combos, so that doesn't match. We actually running .6 percent of the 500 samples of these combos.

So we will contribute this data to the process. I've got a couple more things to review in it. But there is a lot going on here and we're going to do more study on it.

I think you really need the micro committee to look at this and really design a science-based approach to getting this done or you're going to waste government resources, you're going to -- that takes money away from making a substantive, real contribution to public health.

We have been through these arguments for six

years, and now I see us coming back all the way around to where we were in 1994 about what do you test for and, you know, we want to do the right thing, but all the data we have says you're just chasing a rabbit here and I don't think it's going to get you where you want to go.

We need to do something. I'm not saying we don't. But we need data like this that helps us understand the challenge, and it hasn't changed. It's getting harder actually because the companies are doing such a good job of eliminating it.

MS. HANIGAN: Gary, I have two questions for you.

MR. WEBER: Yes.

MS. HANIGAN: Four hundred and fifty samples, each one 25 grams?

MR. WEBER: Yes.

MS. HANIGAN: And what's the total weight in a combo?

MR. WEBER: I don't know how big these were.

(Simultaneous conversation.)

MS. HANIGAN: So 450 samples taken out of a 2,000 pound combo?

MR. WEBER: Yeah, I think they -- I think they may have taken a homogenate though, you know, blended it or something. I can find out more exactly what the methodology was. That's my understanding of it.

MR. BILLY: Nancy?

MS. DONLEY: What you just said that within the stuff, within a combo you mix it all up. So I think what you're showing is that the initial, the original determinations that these were positive combos is indeed a fact.

MR. WEBER: It isn't true. It was only two out of the 10 that were positive.

MS. DONLEY: But you know what, we have all said, and let me remind Rosemary of this too, and it's actually what Dr. Denton also said this morning. Just because you don't find it doesn't necessarily mean it's not there, and I'm going to say the same thing in your testing regime here, and it's the same thing for this needling program that we're talking about too.

MR. WEBER: Actually you've got to have data, you've got to have something to measure, and if you measure

in a 000, would you believe zero?

MS. DONLEY: We're finding --

MR. WEBER: No, I guess not.

MS. DONLEY: We're finding it more now, we're finding it more now than we ever have before. And I think as we continue to develop more sensitive tests, as we continue to evolve, we're going to continue to find it more, and I think anytime we have something and we can divert this dangerous product off the market or divert it into a cooked product, I think we are definitely protecting the public health and safety, and I want to go record saying I think this program needs to be strengthened and not dismantled in any way, shape or form.

Also, I want to talk -- Rosemary brought up a very interesting point about tracing it back from contaminated ground product, back to a slaughter plant, and something that STOP has always maintained is that a way to effectively manage at the processing level is to reduce your pooling of raw products so that you can identify which of your suppliers is giving you the better, cleaner product.

So that is something that we have always

advocated, that grinders do limit the amount of pooling that they do of trims and products.

MR. BILLY: I'm going to wrap this up here shortly, so Jim, then Caroline, and then the chairman of the subcommittee.

MR. DENTON: Apparently I'm not quick enough on the draw because some of the points that I have to talk about have already been talked about just a little bit. But I do want to make at least two things clear, particularly as I speak to Phil here.

Number one is that we do not want to in any way be considered adversarial. We would like to be considered a partner --

MR. DERFLER: Right, that's true.

MR. DENTON: -- with regard to the agency and what the committee is charged with doing.

Listening to what Katie has said about HACCP leads me to my second point. I probably believe as strongly in HACCP has a food safety system as anybody sitting at the table. We have been engaged in education of our industry since 1994, with regard to HACCP principles.

I have difficulty understanding and accepting that a temperature monitoring on receiving incoming raw product constitutes a CCP in the situation that Katie described. If we monitor the temperature and everything is as it should be, we have not done anything that would reduce, eliminate or control that particular pathogen. It has to be addressed at an earlier step in the supplier who provides that particular product.

I think we all are going for the same objective. I just can't quite in my knowledge of what HACCP is and how we control this particular organism --

MR. DERFLER: Right.

MR. DENTON: -- can see that we are doing any good in that approach.

MR. DERFLER: Can I just sort of -- I mean, I take your comment and I hope that we are partners. I just wanted to say there was one intervention that I didn't mention in part because I wanted -- I thought it was important that people, you know, talk about it, and it's one of the newer developments that we have.

I mean, we have approved their use of a radiation

with this -- to get ground beef -- of beef to take care of this pathogen in part. That may not be the answer. It is there. It's another alternative. And I just wanted to put that back on the table.

MR. BILLY: Caroline?

MS. DEWAAL: Thank you.

I just want to make two points because I think they are very important to remember as the subcommittee goes into tonight's meeting.

First of all, the Kansas State study, one of the things that it showed to me that I thought was very important, and by the way, there have just been numerous meetings on this particular policy since last year. So if people had attended those meetings, they will be going into tonight's meeting with a lot of information. If they haven't been, they will begat.

But in the Kansas State data it did show that the product -- the E. coli 0157:H7 could be transferred from the exterior of the meat to the interior during the needling process. And then their data also looked at cooking and whether that was sufficient to eliminate it. But the key

was that the needling did in fact introduce 0157:H7 into the interior of the meat. So I think that's a very important point to remember as you go into tonight's meeting.

Secondly, the industry data on carcass sampling that was discussed at the meeting a couple weeks ago, or months ago now, I guess, I think that would be very beneficial if we could get a copy of that data for tonight's meeting. And the reason is that --

MR. DERFLER: They never submitted it to the agency, to my knowledge.

MS. DEWAAL: Do we have any of the slides from their presentation?

MS. STOLFA: Probably in the transcript we would have that.

MS. DEWAAL: Okay, because I think -- you know, Gary has come in with some unpublished data that, you know, they have run a couple of -- you know, they have run 500 samples on -- you know, he's coming with some data. Well, the industry presented a whole bunch of data at the meeting, and what it showed was -- and it was actually pretty exciting. They tested, and I'm remembering this and maybe

someone in the audience will during the public comment period actually give a better presentation, but they tested it at a number of points. They tested carcasses for E. coli 0157:H7, and what they were showing is that their current systems were in fact reducing 0157:H7 on those carcasses.

Well, what that says to me is carcass sampling can be used as a HACCP verification tool because if you found it, I mean, in a working HACCP system, you would have 0157:H7 on the carcasses before the processes has worked, and at the end of the line you should have zeroes. But if you had a positive, it would clearly show you that the system was not working.

The goal of micro testing in some cases is to get lots of zeroes because you are verifying that the system is working. And I do believe that that data would be -- seeing that it's already been presented to the agency in a public forum in an agency meeting would be very beneficial to the discussion tonight. That is the best data available on carcass sampling as a HACCP verification tool.

So I hope the agency might be able to get that for us.

MR. BILLY: Carol, you have the last word.

MS. FOREMAN: At least until we get together this evening.

Table 2 in the -- under this tab 8 shows where E.coli cases have gone from 1987 to 1999, and there has been by and large a continuing decline in the number of cases; is that right? Is that what Table 2 shows?

MR. DERFLER: Right.

MS. FOREMAN: So I think by and large something that both the industry and the government have been doing has been working to benefit the public, and I think that testing is an important role in that.

Could I draw something on the board for just a minute? There is a continuing problem that I have about what is HACCP.

No one has ever said that my handwriting is great, but it would seem to me that part of the disagreement that we keep having here is about -- of HACCP. It seems to me that HACCP with company X, and that's what the company does to meet its standards using a HACCP system. It's a verification to meet whatever the company requires to put

its trademark on a particular product.

And then there is HACCP today for a different kind of trademark, the USDA seal of approval.

If you are doing HACCP verification for your own trademark, that's where you set your standard. But if you are doing HACCP to get this trademark, the USDA seal of approval, then there has to be something in that verification that says this needs a public health goal and it's good enough to assure public confidence.

It seems to me that the indications of -- they might not be the same. They may not be the same. They should be, but they may not be because you have some people who are selling not under their own trademark. You have some people who clearly just don't care, and you have some who are just incompetent.

This is the thing that says you have to be competent and you have to have a standard that's good enough to get this seal on. And I think that for public confidence you not only have to have HACCP and all of the identification and control and reports, but you have to have in addition to that the testing of end product in order to

assure public confidence.

Now, we keep having it suggested to us that we take this, that and the other back to the micro committee. The micro committee has an assignment to deal with scientific data. I think we are the ones who are assigned the responsibility for determining what it is that is appropriate in order to assure public health and public confidence in particular, and it goes along with the USDA seal, and that's why I think it's appropriate for us to be discussing this, and that's just lead in to where we go tonight.

MR. DERFLER: Thank you.

MR. BILLY: Okay, we're going to wrap this up?

MS. MUCKLOW: Can I just have one last word?

(Laughter.)

MS. MUCKLOW: I would just like to redeem the reputation of Colin Gill. He is a most distinguished international microbiologist. He has written an excellent paper that was the conclusions of the best microbiologists in this country who met at the International Livestock Congress in Houston in February. Be glad to provide that

paper by e-mail to anybody. It's on sampling and testing. He is not outdated. He is on the cusp of the future. He's not setting with the sunset.

MR. BILLY: Thank you.

All right, the next and final issue to be presented for consideration by the committee and then the subcommittee this evening is listeria development, and this presentation will be by Judy Riggins. This is a follow-up to a day-long meeting we had yesterday on this same subject area, and I know many of you participated in that.

Judy, would you please set the stage for the discussion this evening and you will find the materials under tab 9.

MS. RIGGINS: I would like to focus your attention to tab 9. We provided you with an executive summary which summarizes all of the information that I'm going to talk to you about today. You also received this morning a much larger package which is our white paper on listeria, which basically tells the history, where we have been, where we are now, and where we are going, so with that I'll begin.

Last year the agency increased its focus or

strengthened its focus on listeria monocytogenes in response to an increase in the number of recalls that we experienced, attributable to listeria monocytogenes in ready to eat meat and poultry products. And we held a public meeting. We also developed an action plan.

One of the centerpieces of that action plan was a reassessment notice that was published in the Federal Register in February of 1999, which basically said to the public we consider listeria to be a hazard reasonably likely to occur. And based on that determination we instructed companies to reassess their HACCP plans to determine what appropriate actions might be taken to reduce an eliminate the occurrence of listeria in ready to eat meat and poultry products.

If you look on page 6 of the large package, there is a complete description of all of the actions that we completed in response to that action plan last year. Yesterday at our meeting we went through an entire litany of those. In the interest of time this afternoon, I will just move on, but I just wanted you to note that the list of accomplishments is on page 6 and it goes on for several

pages.

On May 6th, President Clinton gave us at USDA and HHS a memorandum which basically was a directive that instructed us to -- instructed us to achieve the administration's goal of reducing listeriosis by 50 percent by 2005 instead of by 2010, the original goal in the Healthy People 2010, was to eliminate it by or to reduce it by half, by 2010. So we are not ratcheting up our purpose and our aggressive actions to reduce from .5 to .25 per 100 cases per year.

MR. BILLY: One hundred thousand.

MS. RIGGINS: I'm sorry. What did I say? I'm sorry. One hundred thousand cases per year. We know that listeria has a very high fatality rate. Although people don't become ill from it as often as they do from other pathogens, when they do become ill that there is a higher risk of dying from it. We know that those who are at risk are the very young, the very old, and those who are immune compromised, and pregnant mothers can pass it from themselves to their children while they are pregnant; in other words, in the womb.

So we know that it is a serious illness that we must address. And the President in his directive basically said to Secretary Glickman and to Secretary Shalala that he want us to, as I said, reduce the number of cases by 50 percent, and to Secretary Glickman he gave a more specific goal of reporting back within 120 days on an aggressive set of steps that we would take to significantly reduce illness from meat and poultry, ready to eat meat and poultry products.

He directed us to propose regulations for comment that would include any appropriate microbiological testing and other industry measures to prevent cross-contamination in the processing environment, to ensure that processing of ready to eat meat and poultry products meet appropriate standards and to ensure that such products are safe throughout their shelf life.

And so with that we have -- with that directive we have developed a much more aggressive action plan which you will find in tab 9, and I will walk you through that right now.

We are proposing to do a very comprehensive

rulemaking which will basically be -- the framework will be a performance standard for meat and poultry, ready to eat meat and poultry products which will include provisions for listeria that are specifically targeted at listeria elimination in processed meat and poultry products.

We plan to require or propose to require that companies conduct listeria species testing in their environments as verification of their standards sanitation operating procedures.

We also will propose that FSIS will conduct listeria monocytogenes testing of the finished ready to eat meat and poultry products as verification of the effectiveness of HACCP plans.

We will also develop industry guidance in conjunction with the rulemaking which will provide information on appropriate interventions for the elimination of listeria in ready to eat meat and poultry products.

We have also started to conduct in depth reviews and in those in depth reviews we will make sure that we review all documentation relative to listeria testing and any other interventions that companies might include in

their HACCP plans or in their SSOPs to address listeria.

We are awaiting the publication of the interagency risk assessment, which we expect to come out some time in July, which will identify for us the most risky foods. We know that from our 1993 and 1999 data that meat and poultry products, more specifically hot dogs and luncheon meat, are among the riskiest foods for listeria.

We also plan to modify specifications for ready to eat products for USDA commodity programs, so we are working with AMS and with FNS to develop guidelines for the contracts that would be let for those products, for the purchases of those products.

We also plan to investigate instructional labeling on those products to provide information that those who use those products in the commodity programs will have in preparing those foods for school children and for elderly and others who are in the feeding programs.

We are also working on an interagency and actually constituents working group that will develop public messages with regard to listeria. Some of the members here are also on that working group. We expect to develop those messages

some time during this summer.

And we will also use the information that we gain from the risk assessment and other information from CDC to develop consumer messages and to improve and clarify the information that we currently have for consumer education.

And we also plan to do research. That's a longer term, a longer term plan is to work with ARS to conduct a three-month study which will look at the prevalence of listeria in ready to eat hot dogs over their shelf life to see what grow up is, to see what information we can gain that will help us in determining what interventions might be useful, might be effective in eliminating listeria monocytogenes in ready to eat products.

So the questions that we would like you to focus on this evening are: The agency would appreciate feedback from the committee on possible additional measures for control of listeria monocytogenes, including those described in the updated action plan, as well as additional measures that the committee envisions.

Secondly, we would like you to give us feedback on the specific types of research that the committee believes

would be appropriate to understand the organism and its mechanisms in order to enable intervention to prevent or reduce the likelihood of foodborne illness.

And thirdly, we would like your feedback on data needs and specific sources of data needed to support rulemaking and education, to prevent or reduce the likelihood of foodborne illness.

And with that I'll take any questions you might have.

MR. BILLY: Katie?

MS. HANIGAN: Judy, one of the action points laid out here is the in depth verification review, and I see it talks about a revised draft.

MS. RIGGINS: Mm-hmm.

MS. HANIGAN: I think we first saw that information in November of last year. So I am wondering where we to date, we, the agency? How many of these in depth verifications have been done since the last time this committee met?

MS. RIGGINS: I don't have the exact number. We have conducted about half a dozen and they were for "for

cause" this year. We have focused our resources on those cases where we felt we needed to have more information about what was going on in the plant. In cases where companies failed their salmonella sets, for instances, we have conducted in depth reviews, and in some other more serious enforcement cases. So we have focused our resources this year thus far on "for cause" in depth reviews.

Next year we plan to institute random in depth reviews so that we are not only doing reviews for cause but are also randomly reviewing both small and large and very small companies to ensure that we have a better understanding of the hazard analyses and their HACCP plans and the decisions that they made with regard to food safety basically in their plants. So we do intend to initiate a random testing or a random review next year.

MS. HANIGAN: And does that all hinge on an earlier presentation we had where they talked about the consumer safety officers positions not being filled? I mean does that --

MS. RIGGINS: We have not yet -- no. We have not yet reached the point of filling a significant number of

consumer safety officers. We are planning to use HACCP experts from the tech center, HACCP experts from headquarters, microbiologists from headquarters, food technologists from headquarters, along with HACCP coordinators in the district offices. And they will conduct the reviews in conjunction with the IIC and the circuit supervisors. And we will have a complement of skill sets for each review.

We are not at a point where we have CSOs in place. Over time we hope to achieve that, but we don't have that right now.

MR. BILLY: Rosemary?

MS. MUCKLOW: Katie mentioned in depth reviews and Judy addressed it.

It is my recollection that at the November meeting we made some recommendations from the committee about the in depth reviews. And when I looked at the update on the recommendations, I didn't see any mention of that on the recommendations.

I particularly remember that we talked about doing it more like a third party audit company does things, and

having an exit interview before departing. And I happen to know of a recent in depth review where there was no meaningful exit interview, and so I would appreciate it if we could go back and catch that recommendation from the last meeting and get it into the system.

MS. RIGGINS: I'm not sure what happened in the case that you just described, but our procedure does all for an entrance and an exit interview, and then we would also put in writing any findings that rise to the level of concern so that the company has a full understanding of what we found. So that is in our current procedures, so I don't know what happened in that particular case, but that's our intention.

MS. MUCKLOW: But there was nothing about that recommendation in the updates that we were provided as a committee here today, and I know that we made recommendations. I think you were part of our discussion on that last November.

MS. RIGGINS: Yes. You mean that in this we didn't describe what we incorporated and what we did not? Is that what you mean?

MS MUCKLOW: Yeah.

MS. RIGGINS: Okay.

MS. MUCKLOW: Well, we didn't include the recommendations we made as a committee and I just -- it touched my brain when I heard about this recent review where there had not been that kind of a closing discussion.

MS. RIGGINS: Okay.

MR. BILLY: Caroline?

MS. DEWAAL: Thanks, Tom.

Yesterday industry -- the industry groups also presented some very exciting data and I know Dane Bernard and Denny Stotz is back in the -- are back in the audience, and perhaps they will come up and talk about it during the public comment period.

But what I got out of that information is that clearly the state-of-the-art testing regime for the industry right now involves both environmental testing and end product testing, and the numbers were quite high, and Dane will correct me if I'm wrong, but it was something like 100 percent of the large plants were doing industry testing, environmental testing, and something like 88 percent were

also doing end product testing. So it was very compelling evidence that these systems are in use and that they really do represent the state of the art.

My question to the agency is if that represents the best possible approach for the industry to evaluate its own process, why aren't we using the similar system to verify the HACCP system, and for the -- and for the industry as well, to verify their own HACCP system?

So why aren't we mandating that the industries -- that the companies use these state-of-the-art systems that the industry has already put forward and that the government also used verification techniques which are very similar?

So I hope that the agency is going to fully address why they are not mandating end product testing as part of this proposed rule in response to the President's request, and why they are not using techniques to really enforce, better enforce the performance standard we have today for listeria monocytogenes on ready to eat products, which is zero tolerance.

So I really hope that the agency is going to give us that information.

MR. BILLY: Any other comments?

(No response.)

MR. BILLY: Okay, thank you, Judy.

Okay, that completes the presentations and issues discussion. Now we are going to move to the public comment period. Two people have identified their interests in making presentations. The first I would like to call to the microphone is Dr. Amy Raines, who is with the American Ostrich Association, who wishes to speak on the inspection for non-amenable species.

It's on. Go ahead. Go ahead.

MS. RAINES: As an ostrich producer and president of the American Ostrich Association, it's been a little frustrating by the lack of urgency that this particular committee's progress on the issue of mandatory inspection for non-amenable species. I guess that means that nobody has died yet from eating ostrich meat.

But like all good ratite producers, we haven't put all our eggs in one basket, and have other items underway to achieve mandatory inspection.

Our request is to urge the secretary of

agriculture to support mandatory inspection for non-amenable species by whatever means it can be achieved, and suggest that this progress move forward with data available with a possible bill and use ratites as a model for updating the ongoing food safety inspection program.

It seems apparent that there are many other species now being produced for food that do and will have the same inspection requirements, and the sooner the process for future additions of non-amenable species can be perfected the better these food industries and their consumer markets will be served.

Thank you.

MR. BILLY: Okay, thank you very much.

And then the last person requesting to speak is Susan Rivvole? I can't read the writing. Sorry. R-I-V-V something.

MS. RIBBONS: It's Susan Ribbons.

MR. BILLY: Ribbons?

MS. RIBBONS: Yes.

MR. BILLY: Okay.

MS. RIBBONS: And I really just wanted to kind of

open dialogue or make a further suggestion on some of the comments that were made regarding the 0157 and the agency looking for a possible CCP in that point.

And as a grinder, if we have prerequisite programs at receiving, and I think we thoroughly discussed the refrigeration is not an adequate control, I think it goes one step further; that if we did look at that and address that as a CCP, it's certainly easy to control refrigeration. We expend a lot of energy in those areas.

But then if sampling is performed and a positive should occur, we infer that that means that the HACCP plan has failed, and that is a large concern to people that are further processor. So I would just like to make that point.

MR. BILLY: Great. Thank you.

MS. JOHNSON: Mr. Billy, there was on the 0157:H7 there was a lot of discussion about the AMI program, and I know Carolyn mentioned it several times. I just wondered if there is anybody -- Kim, do you want to -- are we getting copies for the subcommittee and was there anything else?

MS. DEWAAL: Yeah, I've got somebody making copies of the presentation and the executive summary of the

research that's been available since the 29th of February on the American Meat Institute Foundation web site.

But to clarify your question, Caroline, there were three sites that were tested. It was hides, prior to intervention and post-intervention.

MS. DEWAAL: Thank you.

MR. BILLY: Are you having them brought over to the committee or is that the --

MS. RICE: I asked that they be here by 5:30.

MR. BILLY: Great. Okay, and we'll make them available to the public as well.

Any last minute thoughts from anyone? I know you are all tired. I am.

VOICE: Can we leave our stuff in the room?

MR. BILLY: Can they leave their stuff in the room?

No, I'm sorry, because they are a part of our physical fitness.

The committee meetings will start at seven. If any of the committee members can't remember which subcommittee they are part of, please check with Mike or one

of the other staff people. It's also under tab 3 in your book.

This is real important. This is where the real work of the committee gets done, so I really appreciate your commitment by working through the evening and look forward to getting your recommendations in the morning.

Thank you all very much.

(Whereupon, at 5:02 p.m., the meeting in the above-entitled matter was recessed, to resume at 8:30 a.m, on Wednesday, May 17, 2000.)

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Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 1 through 258, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by John DelPino, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

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