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IN RE:

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AND POULTRY INSPECTION

SUB-COMMITTEE NUMBER 3

held on the 5th day of November, 2003

at 6:00 p.m.

Washington, DC

TRANSCRIPT OF PROCEEDINGS

MEMBERS OF THE BOARD:
DR. ALICE J. JOHNSON, CHAIRPERSON
DR. GLADYS BAYSE
MR. KEVIN ELFERING
MR. MICHAEL KOWALCYK
MR. MARK SCHAD
DR. DAVID GOLDMAN

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P R O C E E D I N G S

November 5, 2003

DR. JOHNSON: What I'd like to do, and you guys can stop me, is have like just a couple minutes where everybody introduces themselves, be sure we know who we're talking with. Questions of clarification, and if you check this, it's probably not exactly 120 minutes. But, you know, without a calculator. Five minutes of any type of clarification that we may have from Dr. Goldman or any of the folks in here, and then do a true brainstorming session. Just kind of throw out our initial ideas, go back and refine, 15 minutes for questions, and then total review for 15 minutes. If we do that, we're probably going to be in here until about 8:10. But, you know, I think we'll come out with a pretty good product. So I'm Alice Johnson. I'm with the National Turkey Federation. I'm working on my last term on the Committee. And Gladys?

DR. BAYSE: Gladys Bayse, Department of Chemistry, Spelman College. I just have begun my second term on the Committee.

MR. ELFERING: I'm Kevin Elfering, with the Minnesota Department of Agriculture, and I also work with the University of Minnesota in the Center for

Animal Health and Food Safety. I'm on my first term.

DR. GOLDMAN: Again, I'm David Goldman, with the Human Health Sciences Division in the Office of Public Health and Science in FSIS. Do you mind if I do a move a little bit out this way and I...

DR. JOHNSON: Sure, that will be great.

DR. GOLDMAN: ...go around the table?

DR. ALTERKRUSE: I'm Sean Altekruse. I'm in the Office of Program Planning and Development at FSIS. in...

DR. HOLT: I'm Kristin Holt. I'm with the Human Health Sciences Division, Office of Public Health and Science, FSIS. Dr. Goldman is my supervisor, so I have to behave. I serve and CDC is our agency's liaison through CDC's physically stationed...

DR. GOLDMAN: If I can interject, another reason that she's here, in addition to that very important duty, is she's also the Project Officer for FSIS on the FoodNet effort. So I mentioned earlier how important FoodNet was to the attribution issues. So she has that background as well.

MS. NAUGLE: I'm Alecia Marie Naugle, and I just joined FSIS as -- with Dr. Goldman's office as a Food Safety Fellow in Epidemiology. And although I'm

not a typist, I'm going to try to type up your report tonight.

MR. SCHAD: I'm Mark Schad with Schad Meats in Cincinnati, Ohio, and I'm on my first term on the Committee.

MR. KOWALCYK: I'm Michael Kowalcyk with Safe Tables Our Priority. I live outside of Madison, Wisconsin, and this is also my first term on the Committee.

DR. JOHNSON: And Michael started like at two o'clock this morning, trying to get here. And we have Jason over here, who is reporting everything. Jason, are we okay, you can hear us? The only thing I ask is that you say your name when we do some discussion. I think everybody's read our charges here and looked at some of the barriers. I would just ask, I don't know if anybody has any specific questions for anybody. I'd kind of like Kristin to do a little bit on the FoodNet just to give us a little bit of the whole history of why we have the FoodNet surveillance and where you think it might be going.

DR. HOLT: Okay, this is Kristin Holt. In about 1995 people started talking about an idea of the FoodNet project, so I believe the ball really got

rolling in 1995. And FSIS, I guess, was interested in such a project to work to perform active surveillance, a very, you know, important role of not just having passive surveillance where people send things in, but to really actively track human elements. And so FSIS stopped and thought that that might be a nice partnership for us in light of plans to implement HACCP and have food inspection regulations. And so funding was arranged and FSIS has been supporting FoodNet since 1996, when the program really went wide. And so there's a project there, basically, to use the active surveillance program to identify human illness and to look at the risk factors associated with those illnesses. And if at all possible, the third goal, to attribute the burden of illness by the commodity. And that's been the biggest challenge and, of course, that's where we are today. And also, within FoodNet, since this is a nice structured setup within the sites, there are special studies, such as case control studies that Dr. Goldman talked about earlier today, where they can interview people, try to look at risk factors among the people who are considered sporadic cases, meaning they're not associated with outbreaks. So we support that project. FDA CFSAN also supports the project and

CDC puts in the most funds.

DR. JOHNSON: Have they just started doing the sporadic case interviews?

DR. HOLT: No, they've been doing them for -- yeah, there have been many case control studies, though none formally published until, hopefully, the Clinic of Infectious Disease Journal supplement comes out early next year.

DR. ALTERKRUSE: Yeah, I would just add that, depending on how you count, there might be eight or nine case control studies that have been conducted. A couple more that are in various stages of analysis still. And probably, again, depending on how you characterize it, maybe at least six are going to be published in this supplement that Kristin referred to. Obviously, we have seen kind of previews of those case control studies, so there is some data that we're aware of already.

UNIDENTIFIED SPEAKER: And if I could add something...

DR. JOHNSON: Yes. Well, I -- I'm very comfortable with the crowd making comments. Does anybody else at the table have problems? As far as I'm concerned, you guys can pull a chair up here. Yeah, glad to share.

DR. ALTERKRUSE: This is Sean Altekruse. And so, for example, there was a timeframe when case control study was being conducted in the field for Campylobacter. And as a part of that, they looked at the Campylobacter isolates that were resistant to certain antimicrobials, and they looked at what the risk factors were for that. So it's not just one case control study that can be done per pathogen. Sub analyses can be restricted to certain serotypes of Salmonella or certain -- certain types of infections that might be of additional interest. So these -- these data sets, it's not just sort of one crack at the data. I suspect that we'll be learning more about risk factors from these for a long time to come. So there's...

MR. SCHAD: You need to help me out here. What do you mean by case controls?

DR. ALTERKRUSE: Well, a case control, what they do in FoodNet, this is something that's kind of unique to FoodNet. They are actually able to -- they -- this is every culture confirmed or laboratory confirmed infection in the catchment area gets reported to the FoodNet site. So there's very little loss of because a laboratory's not reporting. So there's sort of a

stimulated reporting system. And then, in addition, they are able to draw a matched set of controls. Who didn't get sick from the population that the catchment area includes, they'd be matched on, you know, gender, age, geographic location. That sort of -- those sort of characteristics. So that you can try to see, this is sort of the bread and butter of this type of epidemiology. What the exposures are of the cases that differ from the background exposure of people, other people, in the population who didn't become ill. That's where the idea of a risk factor sort of comes from, is that notion of that cases had a threefold risk of illness if they had such and such an exposure.

DR. JOHNSON: So right now, when we talk about a decrease in foodborne illness, we can't really say it's a decrease based on meat or poultry products because CDC reports all foodborne illness, be it cheeses, be it water borne. So that's one of the big problems, is how do we figure out what's meat and poultry as opposed to what's everything else.

DR. GOLDMAN: That's the core issue question.

DR. HOLT: And this is Kristin Holt. To add, the FoodNet sites, originally there were five, and not even all five encompassed full states. So the catchment

area, over time, has increased. There have been more states added. And in some states, where it was just parts of the states, is now like the entire state. So when you're talking about FoodNet, right now we're talking about about 14 percent of the U. S. population. And so when -- a lot of times people here, you know, FoodNet data, and then assume it's national data. Now there are some studies to look at the FoodNet site populations to see if they are comparable to U. S. populations, of the U. S. population to see if, you know, it's reasonable to go ahead and kind of extrapolate it to the whole country. So it's not -- so there is data that is the entire U. S. I think Dr. Goldman talked about some of that this morning. And then there's data that's specifically FoodNet sites. Right now there's ten sites.

MR. ELFERING: I might add -- this is Kevin Elfering. One of the things with the whole FoodNet process too is even those individual states might have better or less reportability. In Minnesota, we feel that we have a very good reportability. A lot of that is contributed to the Mayo Clinic being in Minnesota. Matter of fact, when we had the Salmonella outbreak with Schwan's ice cream a few years ago, probably implicated

several thousand people. Had it not been for some of the diligence with the human health practitioners submitting stool cultures for isolation, we probably would have never known about the Salmonella outbreak, even though, probably, 50,000 people became ill. So it's even more specific than just the states. Even some of the -- some of the individual states.

DR. JOHNSON: I have one question on USDA sampling. And we talked -- you talked a little bit about it this morning, but you were talking about pathogenicity of different species. Does the Agency do anything, particularly on raw products that we're testing for Salmonella and even Campylobacter? Do we -- is the Agency taking it out to look at *Salmonella Newport, Salmonella Kentucky*? Because CDC lists it, you know, and but what we have within the Agency is just Salmonella prevalence. Is the Agency considering anything on carrying it down further to look at?

DR. GOLDMAN: We do send the Salmonella isolates from the in house monitoring effort to NBSO. However, all of the isolates, or practically all the isolates are serotyped.

DR. JOHNSON: Okay.

DR. GOLDMAN: So if that was your question,

yes, we do. What I mentioned earlier was the question of subtyping the serotype. In fact, I misspoke. I said species and I meant serotype.

DR. JOHNSON: Yeah, you...

DR. GOLDMAN: But the -- you kind of, to take it to the next step would be to subtype some of those isolates, and those are not routinely done presently except when it -- when there's human illness involved and, particularly, in outbreak situations.

DR. JOHNSON: Now wait a minute, David. I don't understand. Say that again.

DR. GOLDMAN: All of the isolates from our routine monitoring that show Salmonella are sent to NBSO to be serotyped...

DR. JOHNSON: Okay.

DR. GOLDMAN: ...so that we get the Newport, Heidelberg, Kentucky, whatever.

DR. JOHNSON: Yeah.

DR. GOLDMAN: Very few of those are sent for further subtyping and particularly with PFGE...

DR. JOHNSON: Okay.

DR. GOLDMAN: ...except when involved in an outbreak, in which case they are. A good example would be a year and a half ago we had a *Salmonella Newport*

outbreak that was multi-drug resistant Newport, and that islet was subtyped, so it was matched to human illnesses, if I recall.

DR. ALTERKRUSE: You alluded to something else though, and that is that the strains that are found in -- in animals, it's what...

DR. JOHNSON: Well, that's...

DR. ALTERKRUSE: ...through slaughter are usually very different.

DR. JOHNSON: ...than what -- well, that's what...

DR. ALTERKRUSE: Oh, that's what you were...

DR. JOHNSON: Yeah. Well, what I'm trying to see is there -- if CDC is coming out with the serotypes, the *Salmonella Newport, Salmonella Kentucky*, and here's your top ten, you know...

MR. ALTERKRUSE: Right.

DR. JOHNSON: ...but USDA only reports Salmonella, but what you're telling me is you actually do the subtyping, or the serotype...

DR. GOLDMAN: Yes, we do.

DR. JOHNSON: ...but we never see a report on what that is.

DR. GOLDMAN: There was a...

MS. NAUGLE: Can I make a comment? There have been several reports in the peer review, Madam Chair, that look at serotype distribution of the Salmonella positive samples that have been obtained through HACCP testing.

DR. JOHNSON: Okay.

MS. NAUGLE: Those have been very, very basic descriptive statistics where they say, in this class of product, we got this many Salmonella -- and we got this many *Salmonella Heidelberg*, we got this many *Salmonella Kentucky*. So there have been a few of those in the peer-reviewed literature.

DR. ALTERKRUSE: Well, also...

DR. JOHNSON: Okay.

MS. NAUGLE: The journals, one of them was in The Journal of International Food Protection, I believe, and International Journal of Food Protection. One of them is actually in the process of being published right now. It's going through revision. It's not...

DR. JOHNSON: Where will it be published?

MS. NAUGLE: I'm not sure. I think there was talking either Journal of the American Veterinary Medical Association or Journal of the American Veterinary Research but those are AVMA.

DR. ALTEKRUSE: But the annual NVSL data are published in the proceedings of the U. S. Animal Health Association, so...

MS. NAUGLE: Oh, okay.

DR. ALTEKRUSE: Yeah. So down to the serotype level. So that's available.

DR. HOLT: This is Kristin Holt. CDC also publishes an annual Salmonella report, and in that are different sections of the report that will include human serotype data, and it will include non-human clinical serotypes, and that's basically mostly information from NVSL, National Veterinary Service Lab. This is part of APHIS. And then there's also a section, a table that covers the non-human, non-clinical, and all the serotypes that are found are in tabular form. And almost all of those are were the acid verification samples.

DR. GOLDMAN: But does that list -- does their list capture all them?

MS. NAUGLE: Top 20, I think.

DR. HOLT: Yeah, it has all the serotypes that they have listed. Yeah, it...

DR. JOHNSON: Okay, that's -- I didn't realize that that information had been published.

DR. GOLDMAN: Right, so that CDC has this annual report, which will -- it also gives you the sort of secular trends over time, but then a year-by-year thing. And I think what happens is that ten years ago disappears, you know, as you're -- yeah, as your window. Something like that. Right. So it's -- those are not peer reviewed, you know. That mind indexed reports. But they're out there, and they're government reports.

DR. JOHNSON: Okay. Because that would be interesting to do a comparison. Any other? Kevin, you've got -- I'm talking too much.

MR. ELFERING: Just -- no, that's fine. I sometimes talk way too much than I should. Some of the things that we're doing in the state is any samples that our meat inspection program are picking up under the -- doing the Salmonella performance standards, they're all being serotyped and they're also sent over to our Health Department for the doing the pulse field gel electrophoresis. We're doing...

DR. GOLDMAN: Well, what -- help me out on that, Ken? What's that?

MR. ELFERING: It really is more of almost a DNA test.

DR. GOLDMAN: Okay.

MR. ELFERING: It's not necessarily that specific because you may have microorganisms that are a lot more popular, you know, as far as humans. So -- but it will give an indication. For example, we'll get an outbreak, you know, with alfalfa sprouts with *E.coli* in Minnesota. That was also typed, using this but using the pulse field gel electrophoresis (PFGE). There was another outbreak in Colorado with the same PFGE pattern. Now we were able to determine, just because of that, just because it is so specific, that those probably came from the same lot of seeds, of alfalfa sprout seeds. So it almost is more of a fingerprinting, this PFGE. Our -- any Salmonellas that we're getting out of the diagnostic lab are also being serotyped and PFGE'd. Now there is a comment to that. What was that Dr. Holt brought the issue with using veterinary diagnostic labs, that those are sick animals. The only thing is the sick animals are with healthy animals. And I think some of the research that's been done with transport and -- especially in swine, is is that Salmonella is very easily transmitted from animal to animal. So I still think that that's valuable. We also have a large poultry industry in the state, so all the poultry samples...

DR. JOHNSON: Number one poultry producing state in the -- just thought I might note that.

MR. ELFERING: Yeah. Yes. We have a very, very active laboratory that just does samples with poultry. In all of those samples are being Salmonella positives are serotyped and also sent to the Health Department for a PFGE. So our Health Department has really been very active in trying to build a data base just on PFGE patterns, trying to associate those with human health cases, and also human specimens are PFGE'd. So all of that data is, right now, being collected, and is certainly something that I would suggest that USDA try to look at. If other states are doing something similar, that would be really valuable data. I think the -- the epidemiology that goes into our investigation with the Health Department does specify a certain commodity. And we really look at what commodity causes foodborne outbreak. Was it alfalfa sprouts, or was it eggs, or was it meat? So I think that's something that can -- that would be basic information.

MR. SCHAD: Again, the case in Colorado, did you -- how did you find out about Colorado? Did you happen to contact them, or was that...

MR. ELFERING: Through Pulse Net.

MR. SCHAD: Through Pulse Net, okay.

MR. ELFERING: I mean because the Health Department is viewing all of these things that are entered into Pulse Net and they see the same PFGE pattern.

DR. JOHNSON: Okay. So if we look at how that data linking -- I think Kevin's already got us moving along here. Thank you very much.

MR. ELFERING: Sorry.

DR. JOHNSON: That's good. How might data linking food products with foodborne illness cases be used to suggest changes in regulatory policy? One way to look at it is to look at state FSIS CVC. Do we want to say serotyping of organisms? Do we want to...

MR. ELFERING: Say serotyping and molecular typing.

DR. JOHNSON: Okay.

DR. ALTERKRUSE: Well, if I could make a comment. This is about what I -- what our -- the Office of Policies' perception of this is, it's that this -- it relates to something slightly different. This is talking about, you know, how we fingerprint, and in individual outbreak investigations, try to link up and that sort of thing. And these are very powerful tools

that states like Minnesota and Colorado and states -- a lot of states that are in FoodNet have. But I think what the policy people would like help with is if we're going to change our regulatory policy, we want to know how it will affect -- how we can obtain data show -- that will show the impact of that policy. So, for example, right now, with the ready-to-eat food, regulations *Listeria monocytogenes* that were just published, and the issue is can we show that the new policy may be having an impact on Listeria in the United States? And then another example would be if we were to relax requirements for nitrite -- nitrate, how might that affect Trichinella infections? You know, we -- so if we relax a policy because we think it's no longer relevant, because, you know, Trichinella is -- become less common, and it's not really associated with swine the way it used to be, with pork. Well, we want to be real sure that five years out we don't have an increase in Trichinella in the United States. On the other hand, we'd also like to be able to demonstrate that our regulatory policies to address things like Listeria seem to be having an effect. So that's where, I think, policy is looking at this in terms of attribution.

DR. GOLDMAN: This is David Goldman. I just

want to add a comment because I want to make sure that this doesn't throw the sub-committee off. Sean makes a very important point. And in fact, I share your view from what I've heard discussed in the Agency, that the Agency is quite interested in measuring the impact of changes, rather than the way this question is worded, it's, you know, how can data suggest to us changes. So his -- he's looking at it from kind of the other end of the chute. You know, we've made changes. What is the impact? And I think if this suggests kind of a 1A and 1B question, then maybe that's -- I mean...

DR. JOHNSON: That's...

DR. GOLDMAN: ...I'm throwing that out to the sub-committee because I think it is -- it is that important.

DR. JOHNSON: Yeah, I would agree that there is maybe two components to this thing.

MR. ELFERING: Okay.

DR. JOHNSON: One is the actual -- let's try to -- I still think that what Kevin is saying would apply for either question because you've got how are we going to link the data in order to make regulatory policy changes. We maybe need to look deeper into what are the serotypes of concern. You know, go beyond what

we're doing prevalent to Salmonella, you know.

MR. ELFERING: The same with what Dr. Goldman said today. The preference of *Salmonella Kentucky* in the isolates from raw product is related to human health cases. There's just no correlation.

DR. GOLDMAN: No apparent correlation.

DR. JOHNSON: Yeah, that's...

DR. ALTERKRUSE: And another example of that is the serotypes that you find in poultry don't correspond with the serotypes that we know are poultry associated serotypes in people like enteritis and Heidelberg to a certain extent. Somehow, certain serotypes seem to break through even though they're under represented in the animal isolates.

DR. JOHNSON: But...

DR. ALTERKRUSE: And I don't -- and nobody understands that. But that's kind of well established now.

DR. JOHNSON: Let me try to capture what our AA@ and AB@ questions are just so we can kind of -- does everybody agree?

DR. GOLDMAN: Yeah.

DR. JOHNSON: Sean, you're looking at, from the Agency's standpoint, how do we change policy?

DR. ALTERKRUSE: What we want to...

DR. JOHNSON: Is that...

DR. ALTERKRUSE: ...what we want to try to do is link our programs to public health data, both in terms of where we see a need for action and where we see...

DR. GOLDMAN: ...an action.

DR. ALTERKRUSE: ...an effect. Right. And particularly, maybe, the second. We'd like to try to demonstrate -- we'd like to be able to demonstrate that our programs are affecting public health.

DR. JOHNSON: And that's basically our two questions. Is that correct? Is there another -- link program to public health data, the effect it's having on current policy, and the need for action to develop new policy. That's our two questions. Everybody agree on the sub-committee?

MR. ELFERING: The only thing I'd caution is trying to evaluate some of this data in the case of *Salmonella enteritis*. There was a pretty high prevalence in *Salmonella enteritis* (SE), and all of a sudden we just saw a tremendous drop in SE outbreaks a few years ago. And everybody was thinking, you know, gee, we really -- we've really taken care of an issue

here. And we've done nothing because all of a sudden, now we've got another spike and we know. So I caution people, even FSIS right now, with coming out with information that we have a reduction in *E.coli*. That's one year.

DR. JOHNSON: Yeah.

MR. ELFERING: And you know, I just -- I'm always concerned about things like that, is how does that affect policy? Does one year of data, should that affect policy? And where do you start going out, you know, to five years of data? Should that affect policy? Those are the things I think we have to consider also.

DR. JOHNSON: Data trends, not individual -- I always had trouble the first thing we started talking pathogen reduction, and people were coming out after the first year, going, oh we reduced blah, blah, blah, blah, blah. And you just think, of my gosh, what happens next year?

MR. ELFERING: And what was that attributed to? Was that SSOPs or HACCP?

MR. KOWALCYK: Or just secular trends.

DR. JOHNSON: How far the industry -- yeah.

DR. GOLDMAN: Yeah.

DR. BAYSE: This is not a question, but how

constant and stable across the population of animals, I take it, are the antibiotics that are used by growers? I mean is -- I know the approval has to be there, but can that, possibly, be a compounded factor here? In a given group of poultry had a different set of antibiotics to another and resistance in -- I said it was not even a question.

MR. ELFERING: Well, I think it's really shown with the use of fluorquinolones in the poultry industry, especially in the broiler industry, that there probably has been an increase in antimicrobial resistance strains of Campylobacter.

DR. JOHNSON: Right.

MR. ELFERING: I think the turkey industry has actually been a lot more proactive in looking at use of vaccines rather than antibiotic use. You know, I don't think they've been as implicated as the broiler industry.

DR. JOHNSON: I think there's some data to say that even with poultry, with I guess it's the Denmark data that talked about, you know, resistance to those that are related to humans, doesn't seem to be impacted by the taking away of antibiotics in the poultry industry. You've got -- as far as constant and stable,

from my perspective, you know, any antibiotics that are used therapeutically are used without prescriptions and, you know, most of these companies have veterinarians. It's not an indiscriminate use by an individual grower.

DR. BAYSE: That's turkeys. Is that chickens as well?

DR. JOHNSON: I'm going to say there's a lot of that in chickens as well because chickens are a little more integrated than turkeys. And you've got, you know, you've got veterinarians with each one of these companies.

DR. ALTERKRUSE: They have a pretty limited formulary or repertoire of antibiotics that they can use.

DR. JOHNSON: There's only, you know, about four basics that are used from what the guys are telling me. Now there's generic variations of them that people use, but...

MR. ELFERING: But I think there's even in human health, there's an overuse of antibiotics. I don't think that we can look at animal production as being the sole contributor to antimicrobial resistance.

DR. BAYSE: Oh, sure.

MR. KOWALCYK: This is Michael Kowalcyk, getting back to the first part of the first question, where we link the Agency data with what public health data we have. I think Mr. Elfering's point about taking state data where states are collecting this data in more detail, getting not just the serotype level, but the molecular typing, I think addresses an issue that is talked about often, is the under reporting because of the ability to focus on outbreak data because that data seems to be collected more diligently. Whereas where you have sporadic cases, even if that data is collected at the PFGE level, you can, if you have that link match, I think that might make your data a richer source because it might give you a more accurate read on what's actually happening out in the general population because a lot of outbreaks might not -- might be missed because of resource issues around the country.

DR. JOHNSON: Under reporting of illnesses. Is that -- I mean the whole education of health providers. Mark, you're quiet.

MR. KOWALCYK: I guess I would also add, if the Agency is able to, in partnership with the CDC's, to get that information out to not just healthcare providers, but local health departments as well.

Personally, I suffered a family tragedy as a result of foodborne illness, and -- and I have worked with local health officials, and they are stretched for resources. So any help that they can get from the federal or state level, be it from FSIS or CDC, would probably, over time, enable you to gather a richer data set to do what you want to do.

MR. SCHAD: Do we know what all the states are doing and their capabilities? I mean -- no? Okay.

MR. ELFERING: I certainly don't. I don't even know what our own state's doing. You know, I think our health -- our Health Department is really is one of the most terrific health departments, I think, in the country. And they did -- they just -- they do things that I'm not even aware of all the time, and we're embarking right now on doing some work with antimicrobial resistance in organic poultry. And we're also doing some work right now on other *E.coli's* that are causing cases of HUS that are not 0157.

MR. SCHAD: Okay, what we're talking about here, I was just reviewing all available data. I mean would the first step be to see what the data is that's available out there? Like, you know, go to the states, and what are you doing? What data do you have?

DR. ALTERKRUSE: Well, Kristin, maybe you can comment on this, but essentially, FoodNet has identified states that have done the best job, and it's provided them with additional resources and to continue to do that work, and maybe even enhance it. So that gives us our most global picture. And we still know that, you know, that only one in ten people who develop diarrheal illness goes in and gets a culture. I'm making these numbers up, actually. And that of that fraction, only one in ten is. So of the ten, one in ten, who makes it to a physician, one in ten of those will have a culture taken. And then we knew that in some states those would never get reported to the state health departments. And then, in some instances, the state would never report it to CDC. So what we try to do is take the states that we know are doing the best job, and work with them to encourage them along. Meanwhile, encourage the other states to sort of, you know, bring -- bring along their standards as well. But to get the best picture we can from the best states. And that's the purpose of FoodNet. What -- what I think that -- well, what -- this -- we're talking a lot about, you know, about molecular subtyping and serotyping, that sort of thing. And how do you see that fitting in attribution? This

question of, you know, attributing, you know, the fraction of illness, or that sort of thing, to particular products?

DR. HOLT: Well, this is Kristin Holt. One of the projects that David talks about a little bit this morning was a Baysian modeling approach, which is what Denmark has done. And one of the attractions of that type of modeling is to look at all the available data, and you essentially can kind of throw it into the model. You do have to put, you know, parameters on it in terms of, you know, how much emphasis you want to put on one factor versus another. And so model, the Baysian modeling approach, we think is going to be a great project to give us some real attribution data for attribution by food commodity. So the idea of capturing all available data is of interest to the modelers. And I guess, you know, maybe there's some data sets that we hadn't thought about, and we need to maybe stop and say what really is out there. And that, actually, is one of their steps, to see what is all the data.

DR. ALTERKRUSE: In a Baysian model, I've noticed very -- a little bit only. But, apparently, you've got your information, like your existing data, and then you have experts that you go to. And you say,

so what percentage of, you know, illness, based on your experience of Salmonella is caused by, you know, by salads, or by poultry, or by meat. And those -- those two streams of data are combined. And you can do it now with computers thousands of times to get -- to increase your confidence in the information. But what is the prior? Is that -- is that this molecular subtyping data linking illnesses to -- what is the prior information?

DR. HOLT: This is Kristin Holt. Well, basically, all the data that you're going to use will go into the model, or you decide to use. And then you will put -- and, you know, part is putting the emphasis on one piece of data.

DR. JOHNSON: Would you weight that data? If you're developing a model, and you're getting all this data in, would you weight that, the areas in which you have or that you want to pull out your regulatory concerns?

MR. ELFERING: This is actually not a risk assessment model. It's a model that combines information that you have. But I don't know what the information is.

DR. JOHNSON: Well...

MR. ELFERING: Will you do all of it?

DR. JOHNSON: ...I thought risk assessment just is one of my little things I wanted...

MR. ELFERING: In Denmark, they use a lot of serology?

DR. JOHNSON: Yeah.

DR. GOLDMAN: And subtyping, yeah.

DR. JOHNSON: But with the model, would we say, if we get back to -- I feel like we're kind of answering both of these questions at once. I don't know how everybody else feels. But if we get back to how would we do regulatory policy, in talking about this model, would you rate the model based on the information you wanted to attain from the regulatory standpoint?

DR. GOLDMAN: No, you would...

DR. JOHNSON: I don't know a lot about Baysian modeling, so I'm not...

DR. GOLDMAN: What you do with that...

DR. JOHNSON: Alecia?

MS. NAUGLE: Yeah. What you do is you start with a prior hypothesis which is based on everything you know. So that could be available data. It could be expert opinion, whatever. So you start with what you think you know.

DR. GOLDMAN: Or it might be an example or, I

mean...

Ms. NAUGLE: Like a priori hypothesis might be I think the problems of Salmonella contamination in raw ground beef is, pick a number, 5 percent. Okay, so then what you do is you gather all the information, but you gather all the additional information that you can. Whether that's passive surveillance, whether it's information that...

DR. JOHNSON: State information.

MS. NAUGLE: ...comes from university studies, whatever. And you figure out a way to adjust your previous -- your previous thought about what the prevalence is in relation to this new information. And you put it in a modeling system and you run multiple iterations. You go over and over and over, and you can -- you can account for weighing, if you would like. You can account for which is the most important factor that drives the end result I get. And ultimately, what you want to do is you want to inform your initial hypothesis and change it to something more accurate in light of new information that is available.

DR. GOLDMAN: Yeah, so those phasing models that can be work in progress...

MS. NAUGLE: Yes, there always is a work in

progress.

DR. GOLDMAN: ...that is...

DR. ALTERKRUSE: That's what it is, and then you get a new input, and you go out and you collect more data. And then you -- you say, well now based on this, maybe I would have said it's a -- that it's -- instead of five percent, it's three percent because the new data suggests that it's 3 percent. And over time you'll get towards a better sense of what -- what the real number is. And it's not just smoke and mirrors. It's -- it's the idea that expert opinion, like people have been working in the field a long time actually have something to contribute.

DR. JOHNSON: Yeah.

DR. ALTERKRUSE: They can -- they can -- so that's...

DR. JOHNSON: Is that -- is that more of an answer to how do we get data that it's linked to this, or is that more on the regulatory policy? Would this modeling give you more refined what your presenting your initial theory on, 5 percent contamination level? This would actually give you -- the modeling would give you a better indication of linking to food or refinement of the food?

DR. ALTERKRUSE : Definitely, the first.

DR. JOHNSON: Okay. Now, I would think on this one that we'd want to put risk assessment because I think the Agency has started to use risk assessment in the interim final rule.

MR. SCHAD: I would agree with that, Alice.

DR. JOHNSON: Okay, but this one we would want to talk about the Baysian model theory. Is that -- does everybody agree with that, Michael?

MR. KOWALCYK: Yeah, I think so. Actually, I -- this is Mike Kowalcyk. I was thinking of some research that's going on, actually, with the Food Safety Research Consortium that's associated with Resources for the Future here in Washington. And they're doing something where they do work with food attribution, and they're relying on the meat study that was done out of CDC, I believe, and actually using FoodNet information from the State of Maryland. I was actually going to wait for a question, too, to bring that up, because, as a source, you have work going on in academia as well as in these think tanks, that they're doing something. And what they're trying to do, to me, is they're trying -- they do the iterations of these models to try to risk rank, certain pathogens, and they try to attribute that

to certain food products. So it seems like they're doing something similar to what FSIS looking to do with the Baysian model.

DR. ALTERKRUSE: So that's Resources for the Future?

MR. KOWALCYK: Yes.

DR. HOLT: Yes.

DR. ALTERKRUSE: And who are you talking about doing it? Is that the same group that we're talking about for the Baysian model or CDC?

DR. HOLT: The Baysian model project is a FoodNet project.

DR. ALTERKRUSE: Well, it's interesting they're both arriving at a Baysian approach because the Resources for the Future is also seeking expert opinion so, you know, both do -- to try to link the data to foods, it's interesting.

TAPE MONITOR: How do you spell Baysian?

DR. GOLDMAN: This is the last name that it's -- that the theory is named after, a guy named Bayse, and so it's B-a-y-s-i-a...

TAPE MONITOR: ...s-a-i-n?

DR. GOLDMAN: ...s-i-a-n.

TAPE MONITOR: Thank you.

DR. JOHNSON: All right. I think we're doing all the questions at once. So much for me trying to do 15-minute -- all right. It's a great idea, but...

DR. GOLDMAN: And what is the type of model that's being used, that will be in clinical infectious diseases, in the supplement?

DR. ALTERKRUSE: Now, the model that is being used for Gattry's [ph] work group is this Baysian model, and that will not -- their work is just beginning. So that will not be part of the CID supplement.

DR. GOLDMAN: So what is in the CID supplement?

DR. ALTERKRUSE: That was primarily the case control studies.

DR. GOLDMAN: So that's in addition to some other...

DR. JOHNSON: That would be...

DR. GOLDMAN: ...special studies and descriptive studies and...

DR. ALTERKRUSE: Attributable fractions?

DR. GOLDMAN: Some of them have -- some of them have population attributable fractions.

DR. ALTERKRUSE: So that's another type of stream of data that might be useful as the population

attributable fractions.

MR. ELFERING: Let's go one more time back to getting data, as there's a lot of research that's done where they are doing the -- the serotyping, but not necessarily the molecular typing. And I think that there's a possibility of being able to do that. In the case of, again, with FSIS, the data that they're getting with their Salmonella component standards, our Health Department would love to get every isolate that they ever get. Every positive that they ever get in the State of Minnesota to do the PFGE. So if you can get other states, other health departments, that would be -- if FSIS is willing to share those isolates, our state would want to do the PFGE on them.

DR. ALTERKRUSE: And they're posted on Food -- are they not posed on Food and Pulse Net?

DR. GOLDMAN: The ones that we subtype. I think what you're suggesting, if I understood, was for those that we are not routinely subtyping, is that right?

MR. ELFERING: But we would -- we would want the isolates to subtype them and do the molecular typing.

DR. JOHNSON: Aren't there some legal issues

with that because I know we have some of our industry folks that would like to get the isolates because they would send them off to do some subtyping and Agency won't -- we'd get a file, but that's about it. We can't actually get anything.

DR. HOLT: This is Kristin Holt. I think we're interested in fresh ideas. I don't want to speak to, you know, policy position because sometimes policy changes over time. So on a brainstorming note...

DR. ALTERKRUSE: It's been thrown out there.

[UNIDENTIFIED SPEAKER]: That's your group. That's the office, Health and Science that collects these, these strains, and do you see any problems sending all of it to NVSL for serotyping and putting it into Pulse Net?

DR. GOLDMAN: Only that it would be a resource issue and we do -- you know, there are several thousand positive Salmonellas every year. And right now, only a small number, as I said earlier, that might be associated with illness or when an illness is recognized, we go back and look at a particular isolate. So right now, I mean, among other things, resources would be an issue.

DR. ALTERKRUSE: So what is the -- the, like

the triage for deciding what gets serotyped?

DR. HOLT: This is Kristin Holt. Basically, everything gets serotyped. And as far as going to subtyping though, such as POGE analysis, right now we do not -- we do not run PFGE's on the Salmonella verification samples, the raw meat samples, raw poultry samples. What we do PFGE on right now is red meat products, which we're testing for Salmonella and *Listeria monocytogenes*. And then on the ground-beef products, we're testing for *E.coli* O157:H7, and we do all PFGE analysis on all of those. So there are -- there's a huge volume of the pathogen reduction Salmonella performance standard samples has some verification samples on the raw products that we do serotype, but we do not send those for PFGE analysis. Now there has been some discussion within the Agency on that subject, but no decision on it.

MR. ELFERING: What happens to those isolates? Do they get frozen back? Are they maintained?

DR. HOLT: At the outbreak lab they keep those. I think...

DR. JOHNSON: That's in the ready-to-eat though.

DR. HOLT: Yeah. Yeah. And then the *E.*

coli's in the ground-beef products. On the other ones, I think they keep them for a certain period of time, and then I think they're like, I believe, on the raw HACCP verification samples.

DR. ALTERKRUSE: Are they using ribo printing on the Listeria or...

DR. HOLT: No, I don't believe so.

DR. GOLDMAN: I don't think we're doing ribo typing on that. Yeah, I think it's all PFGE.

DR. HOLT: I don't know. They might be doing that, but I don't think they are...

DR. GOLDMAN: I'm not aware

DR. HOLT: ...at the outbreak lab.

DR. ALTERKRUSE: I just heard that ribo, they're using the ribo nuclear gases for Listeria as a little bit -- even more specific than using DNA.

DR. HOLT: This is Kristin Holt. There's two camps on that.

DR. ALTERKRUSE: Okay. Well, we don't need to get...

DR. JOHNSON: Yes.

DR. ALTERKRUSE: ...we don't need to get into that.

DR. JOHNSON: Let's get back. I think it's

excellent discussion, but let's be sure we have some answers to -- or some suggestions for these questions. And if I were like typing the report right now, I'd be worried that I didn't have it. And as facilitator, or whatever I'm called, I'm worried I don't have it. Okay. How might data linking food products to foodborne illness cases be used to suggest changes in regulatory policy? Okay, we talked about using -- we talked about looking at both the data and looking at the effect that's needed based on the data, as well as the effect that the policy has had based on data, and the need for action. We talked about using risk assessment. We put the Baysian model up here on how do we get the link. What else on how do we use the data to suggest changes in regulatory policy? And I think we've already started talking about what other kind of data we need. But let's focus strictly on what do we suggest changes in regulatory policy? How can they look at data? We talked a little bit about serotype and relationship to human illness, exploring that more. Mark, Michael, Gladys, Kevin ran out on us. Is that right? Am I characterizing what we've talked about so far? What else?

DR. ALTERKRUSE: Well, he was saying,

actually, that it runs into a -- you made a point. It runs into a resource issue. But if some of those serotypes that -- from just routine monitoring might be of interest in terms of PFGE patterns and that sort of thing.

DR. JOHNSON: Okay. We talked about...

DR. ALTERKRUSE: And that was Kevin's.

DR. JOHNSON: Okay. All right, I'm writing this statement just to get a reaction. Anything else? Mark, do you have anything else on this one? Suggested changes in regulatory policy.

MR. SCHAD: What's that word before policy? Is that AL@ something? Oh, AL@ mono policy, is that what that is? L-m...

DR. JOHNSON: Yeah, I was just writing down some of the thoughts.

MR. SCHAD: Okay. Okay. All right. Okay.

DR. JOHNSON: How do we -- how do we evaluate if the interim ready-to-eat rule works? And we talked about looking at data trends and not just individual years. Do we want to say review data trend?

MR. KOWALCYK: This is Michael Kowalcyk. Also beyond data trends, if Agency and -- I don't know if this data is readily available, but any statistical

testing to determine if the differences are statistically significant.

DR. GOLDMAN: I think that's a good point because I was thinking about that this morning when I heard these percentages dropped, you know, and I thought, well, you know, does that really mean anything?

DR. JOHNSON: And statistical significance?

MR. KOWALCYK: Yes.

DR. JOHNSON: Am I saying that right? Related to specific policies?

DR. ALTERKRUSE: Well, basically, specific policies if they see a decline in certain prevalence of pathogens. The Agency, if...

DR. JOHNSON: If it's...

DR. ALTERKRUSE: ...they're not already doing it, in my opinion, it should be done to see if they can show that there's -- determine if those changes are statistically significant. Where a good example is if you have a decline in E.coli, from the standpoint year to date there's .32 percent versus last year it was .78 percent. Depending on the incidents and the sample size and all that, how statistically significant is that drop To me, that's interesting.

DR. GOLDMAN: So that's a sample question?

DR. ALTERKRUSE: Yeah.

DR. GOLDMAN: That's a -- that's very helpful.

DR. ALTERKRUSE: So you're saying like based on the sample size and the confidence intervals and that sort of thing.

MR. ELFERING: I think you have to be able to apply science in extrapolating the data, and not be an agency that says that we're going to apply science-based inspection systems. You have to look at your own science and make sure that it's accurate. And one example is FSIS came out with a -- with a press release and said that they had a dramatic reduction in Salmonella, and CDC could have disagreed with them that it probably is not real factual. It ended up that FSIS wasn't including data of the Salmonella failures. And the Salmonella performance standards. They weren't including that in their data set that had showed this dramatic reduction. So I think they really have to be able to look at the data and be truthful with themselves.

DR. JOHNSON: Okay, Sean?

DR. ALTERKRUSE: Oh, but I think Michael's point included the idea that like the sample size and the confidence intervals around point estimates...

MR. KOWALCYK: Yeah, I...

DR. ALTERKRUSE: ...are important.

MR. KOWALCYK: For that significance of a point estimate? So is there...

DR. ALTERKRUSE: Yeah.

DR. JOHNSON: I'm wondering if this -- if this isn't all kind of inherent in the whole science principle. If we say -- if our overall statement here is apply science to extrapolating data using -- and we go statistical...

MR. KOWALCYK: Statistically sound methodology. Really, I think -- this is Mike Kowalcyk again. I think if you're going to use data to link food products to foodborne illnesses you're just looking at prevalence data...

DR. JOHNSON: Okay.

MR. KOWALCYK: ...that affects regulatory policy. There needs to be a sound methodology that, within the Agency, there is consensus among the experts that you have, and even if you wanted outside experts, National Academy of Science, or somebody credible like that, for making that policy decision, I think the Agency would probably have an easier time selling those policy changes to stakeholders, consumer groups,

industry.

MR. SCHAD: So, specifically, I'm just going to use the LM rule as an example. Could you not say, well, Plan is using alternative one? Was there a production -- statistical reduction or not? Alternative two, was it statistical reduction or not? Can you do that or not?

MR. ELFERING That's something that they'd have to even -- they'd even have to look at that if they're going to use that as -- you know, which -- which choice did the plant take as far as doing environmental sampling or product sampling. I don't know if you'd be able to do that in all this. I think you're almost going to have to stick with just the product.

MR. SCHAD: So, really, you all are touching on some really interesting stuff, and what you're saying, he said something that -- a couple things that I think are really important, Michael. You talked about sample design, and you suggested that it might be worthwhile for the Agency to consider consulting with outside experts on sample design. And you mentioned something that sort of related these, you know, AB@ sets, AC@ sets. Right now, I think we have a lot of information, but it's all mixed together, and there isn't

sort of a -- it's very difficult in some instances. And you talked about the same thing, you know, among groups with -- who did one type, you know, AA@ or AB@ or AC@ approach. You know, it takes -- you have to have enough sample size in those groups before you can have a meaningful result, and it has to be captured in that way so that there needs to be flags by the groups that went with AA@ or -- and -- or AB@ and AC.@ So I'm not sure whether, right now, the Agency's data is collected in a way that allows those sorts of things to be done afterwards. And it might be helpful to have an outside consultant help with that.

DR. JOHNSON: Okay, so the subjects I have are the two subjects I have are apply science to extrapolate data using statistically sound methodology. There should be consensus among experts on the sample design and methodology used. Does that capture it?

DR. BAYSE: Do we need to -- sorry, Gladys Bayse.

DR. JOHNSON: That's okay.

DR. BAYSE: Do we need to define experts, whether they're inside or outside the Agency?

DR. JOHNSON: Yeah, that's...

DR. BAYSE: Okay. Well, I'm concerned about

what Kevin said. If all the -- if the choice to use data or not use it is made in the Agency, and that's presented to the outside experts.

MR. KOWALCYK: This is Michael Kowalcyk again. I think, in a sense, as I think within the Agency, because they're the ones, ultimately, doing it. But I think with an impartial third party expert, probably academia, National Academy of Science, or somebody like that, that isn't a direct stakeholder.

DR. JOHNSON: How about peer review by...

MR. ELFERING: I was just going to say, almost peer review, you know.

DR. ALTERKRUSE: I'd almost rather see it perspectively. You know, a review of how -- how data are collected, and a recommendation on how future...

MS. NAUGLE: That was -- I can't even read the last line, please.

DR. JOHNSON: Peer reviewed by a third party.

MS. NAUGLE: Okay.

DR. ALTERKRUSE: Rather than review after the fact.

MR. KOWALCYK: Oh, it would be...

DR. ALTERKRUSE: Review and the proposal.

DR. JOHNSON: The sampling...

DR. ALTERKRUSE: Really consultation before the fact.

DR. JOHNSON: ...the sampling, and I think this brings up a good point. And somebody, Mark or Michael, said it. Maybe in the methodology and the sample design is not appropriate, and maybe we gather data and it says something different about the way we should construct the sample, either the way we take it, how we're doing it. Does that make sense? I mean we may learn from the data that we have that we need to be doing it differently. We need to be doing collection differently. But do we want to put -- okay, when we talk about extrapolating data, we're already to the point we have the design and the methodology figured out. So we probably ought to add another sentence about reviewing sample design. Anybody want to give me wording?

MR. ELFERING: I think -- I think that would -- I guess we could probably incorporate that in with the determination of whether or not the design's statistically valid. I think that gets to Sean's point that the Agency, I understand this, wouldn't want to invest time and money into something and then, after the fact, have GAO or NAS come back and say, well that was

done inappropriately.

DR. JOHNSON: But we already have a bunch of data that, my personal opinion is, the Agency isn't doing a good job in reviewing. I mean I think we're getting there. We're doing a little bit better. But there's already a lot of stuff that they've got that we could probably be working through. Now, in the future, we need to -- data gathering? Make your comment about -- because you had some good wording. Sean, I'd focus on are there two different concepts here.

DR. ALTERKRUSE: Yeah, I think there's two parts. There's really the analysis and the results. And then there's the design of the actual task.

MR. SCHAD: But design or development of statistically sound sampling design?

DR. JOHNSON: I'm just going to put SS. I'll put ST, statistically sound sampling methodology.

DR. HOLT: This is Kristin Holt. Maybe Dave and I could take a minute and talk about kind of the two main data sets that the Agency has. We do baseline studies, which probably give you closer to a true prevalence or frequency of the pathogens on the products, because the prevalence studies or the baseline studies will go for a full year. So you take into

account seasonal variations on some of these pathogens, like E. coli goes up in the summer, and goes back down. Also, there is a collection of volume, product volume, so you end up with kind of knowing, you know, how much product was sampled and what you found, and numerator, denominator type data. And baselines are not done that frequently. There were a whole series of them done prior to the implementation of the pathogen reduction HACCP regulation. And we've repeated just a few, few others that aren't finished and public yet. And then we, basically, have a very large set of data which goes to the HACCP verification samples. Very, very robust sampling promo, but it's designed actually for verification purposes. So it's not designed kind of as a -- you know, to be, you know, random statistically designed sampling program. It has a specific purpose. And so that is not necessarily, you know, out there taking care of seasonal influences. I think one of the reasons FSIS focused on the AA@ set data, because that actually is the set that is sort of closer to like a random collection. And then the AB@ sets are more biased because you're going into a plant and, you know, carrying on further. So the AA@ set is closer, probably, to baseline, which is just, you know, you went

out there and you've got everybody. So, David, I don't know if you have something to add.

DR. GOLDMAN: No, I was just about to add those points, and also to remind you that I think in the presentation today, I pointed out in the last page of Dr. Murano's vision statement, she talks about a commitment to ongoing baselines. So it's important that ongoing is important too, because you've already identified trends as being important. If you do a baseline once every five years, you're left to kind of impute what you think is happening in those interval -- or intervening years, whereas if we truly get to doing ongoing baselines, then we have the ability to monitor trends. And as Kristin just pointed out, they will be more reflective of what we think is the actual distribution of a certain pathogen and a certain product class nationwide. I mean it will, hopefully, it will be more representative than the monitoring verification data that we get now, which was not designed nor intended to be national representative data.

DR. HOLT: And this is Kristin. I think the HACCP verification data, though, is not something that we can just throw out and say, hey, it won't work, because, as Alecia was describing, you can take data for

the Baysian model and kind of, you know, decide how it works and how it fits. So the data there that we have from the HACCP verification, and it was very robust. There was a very large number of samples that were pulled. So that kind of increases your confidence in results.

DR. JOHNSON: Okay, sub-committee warning on this. We have two components now. Analysis and design. The design is development of statistically sound sampling methodology, reviewed by outside experts. And maybe we should put going -- ongoing -- ongoing process. does that make sense? Because I think, as Dave mentioned, this is something that's going to be continuous. It's not like the original baseline that -- where we did it and then there was a -- in 1995, and then we had the -- so we should continually review if our methodology is appropriate. And then as far as the analysis, apply science to extrapolating data and using statistically sound methodology consensus among the FSIS experts on the sample design methodology used. Peer review by third-party experts.

MR. ELFERING: I think that's great. I just want to -- maybe this isn't the right time to add something like this, but I think we also have to look at

what really is contributed to foodborne illness. For example, you've got plants that are doing generic *E.coli* testing. Is that data being collected or captured in any way in relationship to foodborne illness? And is -- if that's not, is that something that is even of value any more? Do the Salmonella performance standards of raw product, are they covering the same thing that these generic *E.coli* testing is doing? Because, to me, really, generic *E. coli* is pretty meaningless as it relates to foodborne illness. So, I mean, if you're looking at how the Agency should be going with the data that they collect, I mean with the data that they collect, and if you're looking at attribution, maybe they should be stopping some sampling too.

DR. JOHNSON: I think that's what Sean was making the point, that this doesn't just add to. There may be data to support, you know, do we really need our nitrite/nitrates any more? Is data showing that this is no longer a problem? And I think that's a good point, is -- is are we getting what we need too. And I think that goes to how do -- can we get data that is linked to food, right?

MR. ELFERING: Right.

DR. JOHNSON: All right, so give me a

statement of what you just said. Mark's got -- Mark's got something. Michael, you've been writing. Did you come up with great wording?

MR. ELFERING: What you're talking about doesn't only relate to microbial sampling. There's a -- there may be inspectional procedures that aren't necessarily giving us information that's going to inform us on -- on food. Maybe some of it is just work we've been doing because it's the way we've done things.

DR. ALTERKRUSE: Checking heat records for thermic control. You know, is that something that really is beneficial any more?

MR. SCHAD: So we're talking about doing an ongoing review of what, regulation, micro sampling, inspection procedures?

DR. JOHNSON: Well, I think that this is a really good point. The Agency has made a make shift in their Public Health Regulatory Agency. Has there been any review of regulations and policies to make this consistent, or more consistent, with the public health aspect? You know, a lot of the regulations that they -- and policies were established based on the 1957 and Poultry Statute 59 and Poultry Statute 1906. Has there been a review? Do we still need to focus on some of the

issues that we're focusing on if, in fact, we're moving to public health?

MR. SCHAD: So some of the pre-HACCP procedures that might be fastidual and not really relate to public health that could free up resources for more public health oriented work.

MR. ELFERING: Policies and procedures.

DR. JOHNSON: I want to keep the word regulation because there's a lot of old regulations that, in a lot of cases, the inspectors realize they shouldn't be worried about it. So regulations...

MR. ELFERING: There's still some inspectors out there that...

DR. JOHNSON: ...policies...

MR. ELFERING: ...are still enforcing regulations that have been repealed.

DR. JOHNSON: And procedures.

DR. ALTERKRUSE: So wasn't your sort of that this is leaning towards, that we have resources?

MR. SCHAD: Um-hum. Definitely. Both for the industry and for -- the thing is is the industry, and I -- I look at the small industry, you know? I don't look at the large companies because they're -- the testing that they're doing is going to easily be passed on to

the consumer. But the small industry is now looking at doing additional testing for Listeria. And they have been doing testing for generic *E.coli*. Well, if -- it's going to be -- they're going to be much more likely to want to put their emphasis on Listeria, if that's a real concern. Is generic *E. coli* a concern? And should they have to spend an additional $500 a year, which may be minimal to a large company, but to a small company, it's not. They're going to be more likely to say, I want to focus on the Listeria sampling, but maybe they'll do additional sampling.

DR. JOHNSON: And you free up the larger company to be doing more of the sampling than...

MR. KOWALCYK: I think you really brought up an excellent point here, Kevin, just because I'm a small plant, and that's some of the frustrations I have sometime. Why am I spending all my time worrying about these organisms that I know are not a public health issue? I want to -- I'm concerned about Listeria in a ready-to-eat product.

DR. JOHNSON: I think this kind of gets at question three, what other type of data should be considered in development of regulatory policies? And all these say development, but it may not be

development. It may be removal. And I think that, you know, FSIS currently collects -- we focus on micro data, but they currently collect a lot of information over a lot of the economic kind of policies that have been in place forever that aren't related to public health. Would we agree that this statement probably belongs over here?

MR. KOWALCYK: Um-hum. Yeah, I would agree with that. This is Michael Kowalcyk. I would agree with that. I think that was on track, thinking about question two, as far as getting data linked to food. I think that's an excellent point, that the regulations should be looked at to make sure that we're using our inspection force as efficiently as possible. In number two, one thing that came to mind was the use of case control studies, where they look at foodborne illnesses. And then they look for what makes that population different from the controlled population, and see if you can pick up certain foods that -- I mean we know ground beef and *E.coli* 0157:H7, but there are certainly other types of foods that might be outside of the regulatory authority of USDA, but their relationship with the foodborne illness. Maybe that would help drive some of the regulatory policies. We're focusing more on

Listeria from a small plant more so than generic E.coli for example.

DR. JOHNSON: And Michael, I'm not sure I captured. You were talking case control studies and population differences in the types of products.

MR. KOWALCYK: If like...

DR. JOHNSON: That we may be outside...

MR. KOWALCYK: ...yeah, if I understand case control studies correctly, I think you have these reported illnesses and you have control sample that looks like them demographically, and then you look for differences and what potential exposure there was. So I think that aggregated case control studies and the findings might find certain foods are leading to certain types of illnesses over and over and over again. That's just how I was thinking about that question. How do we link directly to food?

DR. JOHNSON: Continuing review of case control studies?

MR. KOWALCYK: Yeah.

DR. JOHNSON: If we look at some of the barriers that they gave us in our original paper, they talked about incomplete investigation of foodborne illness, and now in reading somewhere, and it may have

been one of these articles, they talked about they couldn't get out fast enough with their questionnaires. And one of the problems was resources. So I don't know how we address that, but I think that it's kind of very basic, but if we could get to the folks quicker. It relates to reportability as well as getting the resources to get out there. And I think one of the issues was they didn't have a standardized form, which now -- questionnaire, which evidently we've got in place now. But I don't know. Is there something that we need to suggest as far as resources? Do we need to suggest that CDC have more funding, or that there be more -- you know, I don't know. But if one of the problems is they don't have the resources to get out and interview the folks that have had problems, then, you know, we're -- we're behind the curve. The quicker we could get to them, the better. I don't remember what I had for lunch, much less what happened three weeks ago.

DR. GOLDMAN: This is David Goldman. I think that it's important to identify it as an issue. I don't know if it's one for which FSIS, in particular, has a lot of influence in changing. But, I mean, this -- you know, it's certainly been the scope of the sub-committee to point out, as I did in the presentation, to point out

some of the issues and barriers, even if they might extend beyond our bounds.

DR. JOHNSON: Okay, so, Kevin, we get back to increasing reportability, right? Because that could always be an issue. And keep talking. I'll think of a good word. And how much do -- do your FE officers get involved in doing some of the...

DR. GOLDMAN: This is David. And they don't get involved on the front end. That's not really their role to do. Investigation of either individual cases or outbreaks typically starts at the local level, meaning local public health authorities, sub jurisdictions, and then if it exceeds their ability to respond, the state might be called, and beyond that, CC might be called. Our officers get involved at some point down the road in the investigation, once there is either a strong indication or a confirmation that the illnesses have been linked to one of our regulated products. And we often hear about it before that is confirmed, when there's just a suspicion, or when there -- it's among the considerations. But I don't -- I'm afraid, I don't think our eight or ten, you know, will be ten, perhaps soon, will be able to really help make a dent in that particular public health workforce problem.

MR. ALATEKRUSE: I have a question. Your point is that there's a need to enhance the public health infrastructure though. And that's beyond FSIS. That's state, local, and maybe CDC's ability.

DR. GOLDMAN: I mean CDC does provide funding through a variety of arrangements for training of the public health workforce. And that is part of their mission, certainly.

MR. ELFERING: But the typical outbreak never gets identified. I mean the typical outbreak that gets identified, no food -- or, you know, no source of infection is ever realized. It's the rare outbreak where there's some information.

DR. JOHNSON: You actually -- yeah. And why is that?

DR. GOLDMAN: Because -- well, the reason they don't get identified is because sometimes -- there used to be this classic situation of the church picnic, and people would get sick, and they'd say, oh you got sick, so they understand there's a church picnic, and then you could look at it and say, well, it must have been the macaroni salad. But now, you know, a lot of things are like Schwan's ice cream, where it's distributed across the nation, and there's -- if it wasn't for, you know,

Minnesota identifying that, it might have gone months without ever being recognized.

DR. JOHNSON: So it's increasing reportability, education of consumers.

MR. ELFERING: There's so few claims that you have that proverbial smoking gun, and we've got a bunch of *Salmonella Heidelberg* cases right now in Minnesota, all associated to consumption of eggs. Well, I find it pretty unlikely that it was eggs. It probably was a ill worker who we did find out who tested positive. But still, almost every person who became ill consumed eggs. But if you look at the concerns with transovarian Salmonella, Heidelberg isn't one of them. And how are you going to have a huge outbreak, or sporadic outbreaks, associated with one Salmonella type? So it isn't easy to -- plus, like you, how many people know what they had for lunch today?

DR. JOHNSON: So what do we do to facilitate getting data that's linked to food that we can depend on?

DR. ALTERKRUSE: Well, it's not an enormous amount of money in the context of in the big picture that's available for -- for state, local, federal, you know, foodborne disease surveillance. I think that this

gets to, you know, supporting the notion of, you know, improving the infrastructure for identifying these things, really. I don't know beyond that.

DR. JOHNSON: Gladys?

DR. BAYSE: I'm just thinking about, and I know David spoke about it today, but maybe -- you said education. And I thought, why did you say that? Then I realized, okay, is food assessable by a GP? I mean can you report how...

DR. JOHNSON: Isn't that how the local health department?

DR. BAYSE: Yeah.

DR. GOLDMAN: Well, actually, FoodNet depends only on lab -- lab-confirmed cases, so the food...

DR. JOHNSON: Yeah.

DR. GOLDMAN: ...the active surveillance component is that they have a team of people who call labs on a periodic basis, on a regular basis, every week or every month, depending on the size of the lab and the volume. So I don't...

DR. JOHNSON: Okay, so...

DR. GOLDMAN: ...as far as I know, there's not a mechanism within the FoodNet model for practitioners to report, which is unlike the usual surveillance

system, which depends both on practitioner reporting and lab reporting.

DR. BAYSE: But if he sent the sample to the lab...

DR. GOLDMAN: Oh, yes. Yes.

DR. BAYSE: Oh, okay. Okay.

DR. GOLDMAN: Yeah, I mean, if there was a sample taken, and a culture confirmed, a pathogen, then, yes, that report would be captured, which is really one of the strengths of FoodNet, is that it captures nearly all lab-confirmed cases, if not all.

DR. BAYSE: Well, then I guess we've got the added issue of that lab tests cost money, the way insurance, health insurance, is these days. It's probably unlikely. Okay. That's really a question. That's not a contribution.

DR. HOLT: This is Kristin Holt. I guess, probably, in this country, probably any country in the world, we'll probably never have precise numbers on how many people get sick because I think Sean was talking about not everybody goes to the doctor. They go, they don't all get cultured, and they get sent. And still a sample gets to the lab, the lab may not test it for the right thing. So we'll probably never have exact

numbers. And so what we work with is, you know, what we have reported, and try to use that data. And I guess, in terms of outbreak, just kind of throw out maybe a question to the sub-committee. Is there not outbreak data available that may not be perfect because of all these infrastructure, you know, concerns, and, you know, problems with getting the true numbers, but is there not data out there that would give us the best we could get, and maybe use that?

MR. ELFERING: It would be for additional surveillance. You know, if you're having some, like in our case, some *Salmonella Heidelbergs*. Well, how can that -- but it still gets the curiosity of everybody else out there if we're going to have any other *Salmonella Heidelbergs*. So it's still good data. I mean even though we have not linked it to -- 100 percent to a particular commodity. It still is good data to be able to have. And if you -- if three weeks down the road you start having some sporadic cases again.

DR. HOLT: Well, this is Kristin. And then a science may come in down the road that Heidelberg is transovarian.

DR. ALTERKRUSE: Transovarian. That occurred to me.

DR. HOLT: Transovarian. So...

MR. ELFERING: Well, there's even some speculation that -- yeah, there's speculation that there are other Salmonellas that are transovarian.

DR. ALTERKRUSE: I think if you look at CDC's, well, getting back to what you're -- you were saying a second ago, by the way, is there data out there that would already inform us? You know, CDC has their outbreak surveillance database, and it sometimes is informative. I think you'd be surprised how many *Salmonella Heidelberg* outbreaks have been associated with eggs, for example. But -- and that's -- your question relates to this because I don't -- from a policy standpoint, I don't think we're asking these questions in terms of what research could be done, and you know, where could we spend more money, because that's not the issue here. It's with existing streams of data, how can we link that to foods, you know, or how could it be improved, the data that we are collecting.

DR. HOLT: This is Kristin Holt. In a meeting David and I attended last Friday, Carolyn Smith Dewaal, CSPI, talked about the data that they keep and make available, and they actually do sort the outbreak data by food commodity. So, you know, that's something that's

out there, and CDC is working on a project that's, you know, not available. You know, the results of their assessment isn't available. But there is a lot of outbreak data. And when they list what the food vehicle is, it could be a suspect vehicle where, you know, they think it's eggs because like everybody's eating eggs. Or it could be truly an implicated food vehicle because, you know, it's like Schwan's ice cream. Eventually, they found it in the ice cream. It took a while to find it in the ice cream. I'm assuming there was really PFGE or something that really just said this is -- you know, this sums it up here. The people bought the ice cream, they ate the ice cream, they got sick. We got this out of, you know, their clinical sample, and we got the food that they said they ate, and then we got it in that sample. So the outbreak data is rich. There is, though, some gaps, like Sean was saying. In not all cases do they have what made people sick, whether it was *E.coli* or Salmonella, or, of course Norwalk virus is really the human -- to human pathogen, and a lot of labs do not test for Norwalk virus, so there's a very, you know, large amount of foodborne illness in this country that's, you know, it's a human pathogen, going from human to human, maybe via a food item that takes it to the

next person. So there's a lot of data there. There are pieces. There are outbreaks where they found what, you know, made people sick is *E.coli* 0157:H7, but they never figured out even a suspect vehicle. They couldn't even wager a guess because just the data didn't tell, the food histories didn't lend to that.

DR. JOHNSON: Okay, sub-committee, we've only got about 30 minutes left. How do or can we get data that is linked to food? We've talked about continuing review of case studies, education for increasing reportability, decreasing time span of interview of patients, looking at outbreak history, the CDC surveillance. We've talked about the Baysian modeling of risk ranking considering, you know, information put out by think tanks, academic, consumer groups, we'll have to add, and re -- well, okay. I think we've already done that. Does that capture everything? Is there anything else that the sub-committee feels we need to put in there?

DR. ALTERKRUSE: You know, I've got a thought. It's related to this serotyping PFGE relationship to human illness. If we have isolates that, from the HACCP inspections or, you know, the ones that we're not doing more work with, that belong to some of the top, you

know, 20 human serotypes, could we put those into Post Net? I think it would be a small number. Rather than putting your Kentucky's in there, which it seems like that's -- you know, that's kind of questionable because that's background noise. But if we have, you know -- Heidelbergs and Montevideos and Agonas and Enteritis...

MR. ELFERING: I think that's something that's, as far as I know, is being considered.

DR. ALTERKRUSE: Well, I think that...

MR. ELFERING: Has been suggested and is being considered because you might get matches to the human isolates, and that might inform the food link.

DR. JOHNSON: And I think that's what Kevin was trying to say that we maybe didn't capture.

DR. ALTERKRUSE: So but focused on it so that enriched sample of the serotypes that are important from a human health standpoint.

DR. JOHNSON: I should be writing here so we shouldn't see it. Okay, let's go real quick and we'll talk about that in a minute. Okay, what other types of data could be considered for development of regulatory policy? Data FSIS currently collects. We talked a little bit about the whole regulatory. They have a lot of regulatory data that should be reviewed. Right. We

can make this statement. Review of regulations, policies and procedures to be consistent with public health mission. Free up resources for public health. This data not only includes micro sampling, but includes inspection data from PBIS. Is that -- look, I'm getting bigger here, Alecia.

DR. GOLDMAN: And Alice, if I could just expand on that last point, something you raised earlier. I think a re-examination of our existing data is something that we are engaged in. I mean we're not to the point of having analyzed and ready to publish something, but I think it acknowledges that what Kristin mentioned earlier, that this is a big data set. There are thousands of data points in this data set. And things like the geographical distribution of pathogens, seasonality, has not been thoroughly examined in the past. And I think there is some more data that could be pulled out. And in addition, I'll speak for Alecia, one of the projects she's proposed to do is to employ a technique that I don't even fully understand, which would help us -- help us treat this data or recast this data as more representative or more random. So, in other words, take the data we have, even though it wasn't collected in a random way, or meant to be random,

but to use an analytic technique that would -- called resampling, that would allow us to make a better determination as to its representativeness. So I think, I mean, that's rather detailed, but I think there's several things that we can do and intend to do with the existing data.

DR. JOHNSON: Okay, would you say re-examine that existing data, determine different uses of data and different ways to analyze the data?

DR. ALTERKRUSE: Sort of approaches to analyzing the data.

DR. JOHNSON: Different uses and approaches.

MR. KOWALCYK: By the way, in terms of that re-examining existing data, I don't -- that's a slightly different issue. That re-examining existing data up there...

DR. JOHNSON: Uh-huh.

MR. KOWALCYK: ...to make sure that it is analyzable, and I would point people towards PBIS as an example but, you know, we collect lots and lots of data. But to what end? And that sort of ties in with this looking at regulations, policies and procedures to make sure that they're consistent with public health policy. You know, if we're going to do this work, it should

have some useful purpose.

MR. ELFERING: So the PBIS is -- that is not useful?

MR. KOWALCYK: I'm not sure. I'm not sure. I think it needs to be looked at.

DR. JOHNSON: Back in the old days...

MR. ELFERING: I think there's a lot of things in PBIS that are not useful at all, but...

DR. JOHNSON: Back in the old days, which I guess now has been about 15 years, I'm showing my age. I could have retired if I stayed with the government. But PBIS was -- and, Kristin, do you remember, when we were teaching this, it was what, 30 percent public, our food safety, and 70 percent other consumer protection? And then the Agency's done a lot to try to change that mix, and I think it's definitely weighted more on the public health side. But it's kind of there hasn't been a total overhaul. It's been kind of an adding to the existing type.

MR. ELFERING: Well, so some of the public health beings like HACCP, but it's do -- it asks questions like do they have the right records? And I'm not sure that that's, you know, for a...

MR. SCHAD: That still has a lot of command

and control to it.

DR. JOHNSON: Yeah, does this capture -- re-examine existing data to determine usefulness for public health? Or to measure public health? Or to -- Michael?

MR. KOWALCYK: Yeah, I think usefulness is a better term, better word to use.

DR. JOHNSON: Mark?

MR. SCHAD: I got a word someplace on the tip of my tongue. I can't get it out, what it is. But usefulness is fine.

DR. JOHNSON: Okay. Are we able to print?

MS. NAUGLE: We have things that we can use.

DR. GOLDMAN: I think she meant was the computer talking to the printer right now.

DR. JOHNSON: Yeah. Okay, so they're talking. That's good. They got over their little problem. All right, anything else? Can you print that?

MS. NAUGLE: I sure can. I'll print out a copy for everybody. What I did is I kind of jotted down things, and I tried to like star things that looked like they were working toward a phrase or sentence.

DR. JOHNSON: Okay. I think we've put out -- we've got some sentences, some complete thoughts, I think. If we see it on paper, we may decide they're

not.

MS. NAUGLE: And what I did, I wrote these out to a page per question. I'm just not -- so there are going to be a lot of pages, but I'll get them.

DR. JOHNSON: We can probably print out two. We can probably share.

MS. NAUGLE: Oh, it prints fast now that's it's talking.

DR. JOHNSON: Oh, good.

MS. NAUGLE: And again, I'm not a typist, so...

DR. GOLDMAN: You all covered a lot of ground.

DR. JOHNSON: Yeah, it's...

DR. ALTERKRUSE: Had a couple hours to think about it.

MS. NAUGLE: Thank you, Sean. I don't know how many I've printed now.

DR. JOHNSON: Well, one...

MR. KOWALCYK: Think that's enough?

DR. JOHNSON: Yeah, you're good. All right. Michael, do you want to start the discussion on one?

MR. KOWALCYK: Okay. One, how might data linking food products to foodborne illness cases be used to suggest changes in regulatory policy? We split into

two parts. How do we link FIS -- FSIS programs with health data, the effect on current policy, and then the need for action? The points we came out with were review available data trends and statistical significance, produce competent intervals around point estimates related to specific policies. Apply statistically sound methodology to science when extrapolating data, consultation with outside experts on sampling design methodology used, significant use to adjust policies, prevalence data, data sampling designed statistically sound, I guess.

DR. JOHNSON: Let's go over that part. I don't know that we need -- do we need prevalence data? I think that was just a thought we were brainstorming on. Do we need that in there?

MR. ELFERING: No, I don't think so, Alice.

DR. JOHNSON: Michael?

MR. KOWALCYK: I don't know whether that would go under AA,@ as looking at current policy, and then having that prevalence data information in there.

DR. JOHNSON: Would that just be a part of reviewing available data?

MR. KOWALCYK: Yeah.

DR. JOHNSON: Okay. I'll try to make it...

MR. KOWALCYK: Yeah.

DR. JOHNSON: ...where I can talk about it, and just -- I don't know.

DR. BAYSE: I'm not clear with the statements under the AA,@ AB.@ Are those meant to refer to both AA@ and AB?@

MR. KOWALCYK: Yeah, that's what I'm trying to -- I mean...

DR. BAYSE: I'm trying interpret it.

DR. JOHNSON: Okay, so the effect on current policy, review available data trends and determine statistical significance with appropriate competent intervals around points established relating to the specific policy. That's definitely an AA,@ right? And there should be statistically sound methodology -- science...

MR. ELFERING: You may want to just reword that a little bit.

DR. JOHNSON: Yeah.

MR. ELFERING: Just apply sound scientific methodology when extrapolating scientific data?

DR. JOHNSON: Right. Apply -- rewrite it, Kevin.

MR. ELFERING: Apply sound scientific

methodology.

DR. JOHNSON: Sound scientific methodology.

MR. ELFERING: When extrapolating scientific data. Well, maybe we get too scientific in there. How about just sound...

DR. JOHNSON: How about methodology...

MR. ELFERING: ...methodology when extrapolating scientific data?

DR. JOHNSON: Okay.

MS. NAUGLE: And that is under AA@ or AB?@

DR. JOHNSON: Well, technically...

MR. ELFERING: I would say that...

DR. JOHNSON: ...it would be under both.

MR. ELFERING: Yeah, it really would.

MS. NAUGLE: See, that was the problem that I had. I didn't know where some of these...

DR. BAYSE: Maybe it does all belong the way it is...

MR. ELFERING: Um-hum.

DR. BAYSE: ...under both AA@ and AB.@

MR. KOWALCYK: I'm wondering if we need to get rid of AA@ and AB@ altogether and just have it all under the question.

MR. ELFERING: Well, yeah and maybe just say

there's no way that you can look at it just...

MR. KOWALCYK: Yeah.

MR. ELFERING: ...once. Maybe this almost a two-prong approach. You have to have both of these.

DR. JOHNSON: We can say we considered this question based on the effect on current policy and the need for future policy, and we consider the methods outlined applicable to both.

DR. BAYSE: Right. Not separable though.

DR. JOHNSON: How's that? Yeah.

DR. BAYSE: Okay.

MR. KOWALCYK: And I don't know, I guess for efficiency of our report back to the full committee, Kevin's sentence with applying sound methodology, would we want to put bulletin points for the -- because, really, the consultation with outside experts, sampling, the test design needs to be statistically sound. Those are kind of -- I'm thinking kind of like bullet points that would be examples underneath that.

DR. JOHNSON: I like that. Yeah.

MR. KOWALCYK: And those things that...

DR. JOHNSON: Yeah.

MR. KOWALCYK: That significance used to adjust policy, maybe we ought to do something with that

because I'm not even sure of what that means, or what we were trying to say there.

DR. BAYSE: It's probably significance of the data, but we've already said that.

DR. JOHNSON: Yeah, I think we have, haven't we?

MR. ELFERING: We're talking about statistical significance? Is that what you're talking about there or...

MR. KOWALCYK: Yeah.

MR. ELFERING: Okay.

MR. KOWALCKY: I think we're talking all methodology and that if we were going to make a -- if FSIS is going to make a policy recommendation based on sound studies, it would be -- it would rely upon statistically significant results.

MR. ELFERING: Okay. Policy should be adjusted based on statistical significance?

DR. JOHNSON: Should we -- is that in here in the first review, available data trends and statistical significance?

DR. BAYSE: Or do we need to separate them?

MR. ELFERING: Yeah, that's over -- I guess over the existing stuff we're looking at. The

prevalence data and changes of what's pathogens. That's one part of it. But then there's the second part is, I guess, kind of the taking action part, being proactive, that those actions should be based on statistical significant findings.

DR. JOHNSON: Okay, let's put that actions -- future -- let's put future policies. Future policies based on statistically significant...

MR. ELFERING: Results.

DR. JOHNSON: Okay.

DR. BAYSE: And that's one of our bullets. I'm sorry. I was...

DR. JOHNSON: I'd also like to put in the use of risk assessment because I think that we need to -- to consider regulatory policy. And then the design and the analysis all go under the review data trends, right? And I think it's probably more appropriate to say, design and development of statistically sound sampling methodology reviewed by outside experts. Ongoing needs to be in there somewhere, but not -- probably not...

DR. ALTERKRUSE: That was the ongoing baseline, I guess where that word got introduced.

DR. JOHNSON: Yeah, we're trying to -- yeah, we were trying to capture that, but...

MS. NAUGLE: Maybe continuous.

DR. JOHNSON: On a continuous basis? Design and development of statistically sound sampling methodology.

MR. ELFERING: Unless you're going to put it at the beginning of the importance of continuing the baseline studies.

MR. KOWALCYK: That's what I was thinking.

MR. ELFERING: And using that data.

DR. JOHNSON: The importance of continuing baseline studies using a design and development -- using sampling methodologies, using sound scientific methodology reviewed by outside experts.

MR. ELFERING: Something that we recognize the importance of that, to the continuing -- continued baseline studies, or that they have to be reviewed appropriately...

DR. JOHNSON: Well, and I...

MR. ELFERING: ...in a sense.

DR. JOHNSON: ...think that the NACMCF came up and NAS both, are -- with some recommendations on the sampling and the need to be sure that you look at seasonality and I think some of the recommendations from the outside groups are already been put in place.

That's what I'm assuming with the new baseline.

MS. NAUGLE: So, excuse me. Where did you want that last sentence, the importance of continuing baseline studies using scientifically sound sampling methodologies reviewed by outside experts? Where did you want that to go?

DR. JOHNSON: Oh, somewhere on there.

MS. NAUGLE: Oh, it's somewhere on there.

MR. SCHAD: Read what you have.

MS. NAUGLE: Everything for number one?

DR. JOHNSON: Yeah.

MR. SCHAD: Yeah.

DR. JOHNSON: Really. How might data linking food products to foodborne illness cases be used to suggest changes in regulatory policy?

MS. NAUGLE: We considered this question based on both current policy and the need for future policy and methods applicable to both. Point 1: Review available data trend and determine statistical significance (competence intervals around point estimate) related to specific policies. Indented: Design. Design and development of statistically sound sampling methodology reviewed by outside experts. Analysis: Point 1: Apply science to extrapolating data.

This is redundant. Apply science to extrapolating data using scientifically sound methodology. Consensus amount FSIS experts on the sample design and methodology used and peer reviewed by third-party experts. Next point: Future policies based on statistically significant results and use of risk assessment. Next point: The importance of continuing baseline studies using scientifically sound sampling methodologies reviewed by outside experts. Do you want me to print out that first page?

DR. JOHNSON: Yes. Thank you.

MR. SCHAD: Okay, under analysis, the first bullet point, why don't we just say, extrapolate data using scientific sound methodology, and get rid of the first three words?

DR. JOHNSON: Yeah. Good. Consensus among FSIS experts on sample design and methodology. Let's put peer review process.

MS. NAUGLE: And where was that? I'm sorry, I didn't hear that.

DR. JOHNSON: It's instituted -- well, read what you've got and then we'll do -- we'll make some more changes. Make that two sentences. Consensus among FSIS experts on the sample design and methodology. Peer

review process instituted.

DR. BAYSE: Let me call on our different bullet.

DR. JOHNSON: I don't know. Help me. And that may not be good. But we need to -- I think we need to separate it out a little more.

DR. BAYSE: It seems really redundant. We've said outside so many times, and...

DR. JOHNSON: Yes.

DR. BAYSE: ...statistically significant. Maybe when we see it all on a page. Can't we...

DR. JOHNSON: Yes.

DR. BAYSE: ...just...

MR. ELFERING: I mean why don't you do this scientifically by asking one of the outside?

DR. JOHNSON: Yeah.

MR. ELFERING: Yeah, you're exactly right. We're getting a little bit...

DR. BAYSE: And we came out, what, Alice, a year ago? Was it a year ago?

DR. JOHNSON: Yes.

DR. BAYSE: It actually was controversial over the choice of the outside expert, so I guess we don't want to go there this time.

DR. GOLDMAN: I think the outside expert is especially relevant to sample -- to design because we benefit from it. Not to keep us honest or anything, but there are people within the agency with an understanding of it, and I think that it might be helpful to go over all process to have -- to have an expert look at what we're doing and give us some feedback.

DR. ALTERKRUSE: That's a good point. I think maybe the second bullet under analysis.

DR. BAYSE: An outside -- beating to death a...

DR. GOLDMAN: Right.

DR. JOHNSON: Okay.

DR. ALTERKRUSE: That's the second bullet under design...

DR. JOHNSON: Okay.

DR. ALTERKRUSE: ...because design mean -- the first bullet we have, design, develop a sound sampling methodology, take out the reviewed by outside experts, and then the second bullet would be consensus. You know, gain consensus among FSIS experts. That way everybody within the agency that's doing analysis, they're in agreement that, okay, that's the right thing to do. So gain consensus among FSIS experts on the

sample design and methodology, and then maybe a mention.

DR. JOHNSON: Maybe we put just a general statement up top that talks about FSIS should institute or should continue to use out -- third or outside experts to review because, in an essence, they are already doing that with NACMCF and...

MR. ELFERING: In a sense...

DR. JOHNSON: ...the Academy of Sciences.

MR. ELFERING: ...in a sense, you're saying in the design that you want -- what we want them to do is we want them to design a statistically sound methodology, have it reviewed by outside experts, and then after that design is developed, when they analyze the data, that they have to be -- there has to be consensus within their own expertise. So we don't even have to have that at the very end. Just consensus among the FSIS experts on the sample, design and methodology, period.

DR. JOHNSON: Okay. Everybody agree with that? Do we want to keep in design reviewed by outside experts or do we want to just put a basic statement at the front that FSIS should continue so that the overall process is concluded in an expert review or...

MR. KOWALCYK: And then, Alice, when you said

up front, what do -- where do you mean?

DR. JOHNSON: Well, instead of putting it for each bullet point like we were doing, and maybe what Kevin just suggested takes care of that. Instead of having it each bullet, put an overall sentence. The Agency has kind of already started this with the information that you -- they supplied NACMCF with, all sorts of data, from what I understand, on the ground beef, you know, and talked about how they looked at it, what they did, and then the committee came back and made recommendations. Same thing happened with the Research Council. The guys went in, and they looked at the data, and they talked about what happened, and they came up with recommendations. So some of that's already in place. You did the same thing with the HNNT Project. You pulled in outside people and said, what do you think. So maybe instead of putting it for each bullet, we have just to...

MR. ELFERING: Yeah.

DR. BAYSE: Yeah, a continuing.

DR. JOHNSON: Okay, so, Mark, what's the good work? Give me some good words here. Are you okay with that, Kevin, if we put a...

MR. ELFERING: I'm just writing some stuff up.

I just put utilization of outside experts is imperative to achieve concise, impartial...

DR. JOHNSON: I'm grasping your pretty wording. Did we get that? Did we get that?

MS. NAUGLE: Utilization of outside experts is essential...

DR. JOHNSON: Imperative.

MR. ELFERING: Imperative.

MS. NAUGLE: ...imperative -- is imperative...

MR. ELFERING: ...to achieve concise, impartial review?

DR. BAYSE: Concise, impartial -- concise? Would it be concise?

MR. ELFERING: Analysis of data?

DR. ALTERKRUSE: What about unbiased design?

MR. ELFERING: Yeah, unbiased, yeah.

MR. KOWALCYK: Unbiased.

MR. ELFERING: Um-hum.

MR. KOWALCYK: Unbiased recommendations?

DR. JOHNSON: How we doing over there? Did you get it?

MS. NAUGLE: I'm not sure.

DR. JOHNSON: You're doing great. Thank you. You're doing great.

MR. KOWALCYK: Unbiased design analysis.

MR. ELFERING: Um-hum.

MS. NAUGLE: Unbiased design and...

MR. ELFERING: Design and...

DR. JOHNSON: And so that takes out, if we put that -- we considered this question based on both current policy and the need for future policy and methods applicable to both. And then do we want to say a pretty statement now?

DR. ALTERKRUSE: About being imperative?

DR. JOHNSON: Yes, about we want to be imperative here that, di, di, di, do.

MR. ELFERING: Are essential.

DR. JOHNSON: Imperative.

MR. ELFERING: I'm easy.

DR. JOHNSON: Imperative. Okay, so that means we take out each time we have reviewed by outside experts.

MR. ELFERING: Okay.

DR. JOHNSON: And then we can talk about the committee recommends a review of available data trends, recommended design and development, talk about extrapolating data, consensus.

MS. NAUGLE: How about take out the peer

review by third-party experts?

DR. JOHNSON: Yeah. And under design, take out, reviewed by outside experts. And future policies based on statistically significant results and the use of risk assessment. And we can say the committee said the support of the agency, and emphasize the importance of continuing baseline studies using scientifically sound sampling methodology. And then everything else goes. Page 2. And how do/can we get data that is linked to food? Continue a review of case-control studies to identify population differences, increasing reportability, decreasing time span of interview of patients, enhance public health infrastructure, education of consumers, health providers, whoever, reviewing outbreak history. Looking at CDC surveillance data, Baysian modeling, looking at work being done on risk ranking from academia, think tanks.

MS. NAUGLE: I'm not sure what that next line was, actually.

DR. JOHNSON: Well, I think we included that in decreasing time span of interview of patients, and then we talked about...

MS. NAUGLE: I have no idea where that next statement came from. You wrote down serotypes.

DR. JOHNSON: Well, see, I was writing it little so you wouldn't see it. Serotypes of...

MS. NAUGLE: Well, you've strained my eyes.

DR. JOHNSON: ...we were talking looking at serotypes from the HACCP, the isolates that we have now. We have serotypes. That's already been done. And I think Kevin suggested maybe doing some subtyping and doing...

DR. BAYSE: Serotypes AP@ and APE@ in relationship to human illness. That's what you...

DR. JOHNSON: Yeah.

DR. ALTERKRUSE: Is that sort of putting the serotypes that are -- that rank high among human isolates in PulseNet, something like that, or that was -- it was sort of a considered, you know.

DR. JOHNSON: Well, I don't know that we even want to say what you do with them because there's maybe a difference in looking at the raw data. I -- what we're getting off raw products as opposed to, you know, ready-to-eat products, and we probably need to figure that out. But I think that maybe the committee just needs to say we need to be looking at this to see, and your point, yeah, there seems to be a change somewhere down the line, and what we're finding in poultry. Do we

need to be looking at sampling differently, somewhere?

DR. GOLDMAN: One of the things that's not in here that was on your list was population attributable.

DR. JOHNSON: Attribution factors. You had mentioned that. And CDC is doing that type of work.

DR. GOLDMAN: It's part of their...

DR. JOHNSON: It's in the journal?

DR. GOLDMAN: ...the work that comes out of the case control studies, so it's kind of a piece of information that is contained in the case control studies.

MR. ELFERING: But is -- those attributable fractions, that was one of the main things that -- that was one of the main things FSIS wanted out of their sponsorship of FoodNet or their support.

DR. JOHNSON: Yeah, that was the whole purpose, right, when, I mean...

MS. NAUGLE: Yeah, and...

DR. GOLDMAN: It was one of the three purposes, yes.

MS. NAUGLE: Again, printing out the first page again. I'm sorry.

DR. JOHNSON: All right. How do/can we get data that is linked to food? Continue review of case-

control studies to identify population differences. All right, we know -- do we want to specifically talk about the case-control studies that are going to be published, and talk about a thorough review and...

DR. GOLDMAN: Of those subjects?

DR. JOHNSON: Yeah.

MR. ELFERING: I'm not really sure what this means. That first part.

DR. JOHNSON: What's...

MR. ELFERING: The first item.

DR. GOLDMAN: Continue review of case-control studies to identify population differences.

MR. ELFERING: Just as they occur, right? Sort of like breaking news.

DR. JOHNSON: Yeah, Michael, that was...

MR. KOWALCYK: Yeah, I guess the first part, continuing review of case-control studies. I don't know if to identify population differences is what I was thinking of when I brought that up. Is to...

DR. JOHNSON: Maybe risk factors?

MR. KOWALCYK: I guess, yeah, maybe to investigate risk -- identify risk factors.

DR. JOHNSON: So FSIS should continuously review case-control studies as they're made available?

Can we pick up some pretty words there?

MR. SCHAD: It's imperative.

DR. JOHNSON: Okay. And Michael, what was -- made available to identify risk factors?

MR. KOWALCYK: Yeah.

DR. JOHNSON: Okay.

MR. SCHAD: Is this sporadic or outbreak associated cases or both?

DR. GOLDMAN: These are sporadic.

MR. SCHAD: That's what I thought.

DR. GOLDMAN: Yeah. I mean FoodNet very specifically excludes outbreak cases because when they call a lab, they're going to get both, but they -- and I don't even know how they do it, but they are able to discriminate outbreak cases from -- do you how, practically, they did that?

DR. JOHNSON: Well, for the...

DR. GOLDMAN: Or I guess when they start to...

DR. JOHNSON: ...MMW...

DR. GOLDMAN: ...interview them?

DR. JOHNSON: When for the MMWR, that includes sporadic and outbreak cases.

DR. GOLDMAN: Right, but for the case controls.

DR. JOHNSON: And going to -- in fact, that's one of the attribution working group's projects, or sub-projects, is trying to separate that, and it's not as easy at some sites as it is at others.

DR. ALTEKRUSE: In an outbreak, a lot of times like for sporadic illnesses, they'll -- they'll accept a first case, and then they'll exclude...

DR. ELFERING: All the others.

DR. ALTEKRUSE: ...subsequents.

DR. YOUNG: Okay, so FSIS should -- FSIS should continuously review sporadic outbreak case-control studies as they are made available to identify risk factors.

DR. ALTERKRUSE: Maybe you just want to say all case control studies, rather than just sporadic. Just all case control. And then maybe even put outbreak and sporadic.

DR. JOHNSON: Okay in parentheses.

DR. ALTERKRUSE: Parentheses, yeah.

DR. JOHNSON: Outbreak as well as sporadic. All right. Now, the attribution project, is that the same thing as the case control that's going to be published in infectious? No. Okay. So what do we call what the CDC case-control studies that are going to be

published? What are -- help me understand. You said there were somewhere between six to eight and the first six were going to be published.

DR. GOLDMAN: They're -- they're individual case-control studies of sporadic illnesses that have occurred in the FoodNet sites. And they are different ones because they are based -- they are related to different pathogens. And in some cases, as Sean mentioned earlier, they are even more narrowly focused in that. For example, there's one about risk factors for drug-resistant Campylobacter, I think -- resistant Campylobacter infections. So -- but that's why there are those discreet numbers of case-control studies because they're pathogen focused. So there's some -- there's one on *E.coli* 0157, there's one or two -- I think two on Campylobacter, possibly. There's one on *Salmonella Enteritis*. Right, there's a separate one on *Salmonella Heidelberg*. There's some that are under way on Listeria and infant cases of Salmonellosis and Campylobacter.

DR. JOHNSON: Okay.

DR. GOLDMAN: And there's a case-control study on *S. Newport* that's under way. I mean there is a long list of them.

DR. JOHNSON: What, FSIS should take this information and do something with it, right? What do we recommend that they do?

DR. ALTERKRUSE: So if it implicates products that they regulate, that should inform, you know, their regulatory thinking, I guess. Is that what you're trying...

DR. JOHNSON: Well, I'm trying to -- how do/ can we get data that is linked to food? So we talked about, you know, identifying risk factors associated with case-control studies. All right. Now, we're talking about the project that CDC's working on. And CDC's going to publish this. So what is it that we would ask FSIS to do with this information once it's published?

MR. ELFERING: Evaluate the CDC attribution published report to...

DR. JOHNSON: Is it attribution or case control?

MR. KOWALCYK: Those are case-control studies.

MR. ELFERING: Case control.

DR. JOHNSON: Now I'm confused with the attribution thing.

DR. GOLDMAN: They're one tool used to get at

attribution, so attribution is kind of the big issue, and these are tools that we're talking about.

MR. ELFERING: So...

DR. GOLDMAN: Case-control studies are one, analysis of outbreaks are another, the Baysian modeling are another. These are all different tools used to try to describe the attribution issue.

DR. BAYSE: And then there were, I guess, recognition that other people were doing attribution projects, such as food safety research as well, or guess that is where the think tanks come from.

DR. JOHNSON: Maybe we should just talk about FSIS should review current work from other groups, and then I can just list academia...

MR. ELFERING: Yeah.

DR. JOHNSON: ...think tanks, consumer, you know, CDC.

MR. ELFERING: You know, because it could be a local health department...

DR. JOHNSON: Yes.

MR. ELFERING: ...that comes up with an issue, and we should be considering those, too.

DR. JOHNSON: So we should, technically, put attribution projects should -- okay, FSIS needs to move

forward with attribution projects, to include concepts such as Baysian modeling, thorough review of the CDC case-control studies. That's how we can tie all this together so it's not just bullet points. Gladys, do you agree with it?

DR. BAYSE: Yes, ma'am. Yeah.

DR. JOHNSON: Everybody?

DR. ALTERKRUSE: Is anyone doing population attributable fraction models? The thing about them is they're really clean. They say we estimate, based on these data, that 30 percent of Campylobacter is caused by drinking surface water, you know, that hasn't been treated. So is anyone doing that sort of work, you know, or...

DR. HOLT: You mean outside of FoodNet?

DR. ALTERKRUSE: No, inside of FoodNet.

DR. GOLDMAN: Some of these studies that we're talking about...

MR. ELFERING: We'll have that.

DR. GOLDMAN: ...do have those.

DR. ALTERKRUSE: I see.

DR. GOLDMAN: I don't think all of them do because not all of them apply the specific methodology to get -- to derive that number, but some of them do.

MR. ELFERING: Usually, you go after, if there's something that has sort of a -- a bang. You don't just -- you don't -- you wouldn't do it for everything. Only the ones that, you know, look like...

DR. GOLDMAN: They get active. Yeah.

MR. ELFERING: Right.

DR. JOHNSON: All right. If we -- if we restructure this page to look like what we've just talked about, the first one is FSIS should continuously review all case-control studies as they are made available to identify risk factors, outbreaks, as well as sporadic. FSIS should continue or move forward with the attribution project. This would include outbreak history, reviewing outbreak history, CDC surveillance status included in that, look at Baysian modeling, consider risk rankings and other -- and review all work being done by other groups, such as academic institutes, think tanks, industry, consumer. Does that -- does that flow like we want it to? She's typing faster and faster back there.

MS. NAUGLE: I don't have much progress made. My typing's getting a lot better though.

DR. JOHNSON: All right. Let's go on to three while she finishes that up.

MS. NAUGLE: Sure.

DR. BAYSE And we -- did we decide to leave out the increasing reportability, decreasing time span of -- have we taken out some of those other items then too? I don't -- I don't have a problem with it, but I just didn't know if we...

MR. ELFINGER: Yeah, I think we have, haven't we?

DR. JOHNSON: I don't know. I'm asking Michael.

MR. KOWALCYK: I don't know if that's underneath the realm of what FSIS can do other than...

DR. BAYSE: It would be good, but it may not be.

DR. JOHNSON: Well, and maybe we want to put a separate section on this page that says, while this may be beyond the scope of FSIS, efforts should be made to enhance, you know -- where possible, efforts should be made to enhance public -- would that be okay? I mean we're recognizing this.

MR. KOWALCYK: I think that would be good.

DR. BAYSE: Okay.

DR. JOHNSON: That this might be out of the scope, but the committee discussed enhancing public

health infrastructure, you know, increasing reportability and, you know, decreasing time span of interview. And just so we know we've talked about it. Now, we also need to talk about the -- did we get this -- this idea in here? Where is it? Serotyping information from the top human illnesses and doing -- providing some subtyping information?

MR. ELFERING: Serotyping and molecular typing, PFGE typing?

DR. JOHNSON: Yeah. Yeah, typing the serotypes, the key top disseminating for human illness, and then looking at some subtyping information. We're not going to say, put it on FoodNet or do whatever, but is there -- should FSIS should look to see if there's any value in there. Our little typist looks at me and kind of has a funny -- funny face. I don't know what to do for her.

MS. NAUGLE: Yeah. Okay, so tell me about the last thing that you said again, please, with the serotyping, the serotypes and subtyping.

DR. JOHNSON: All right. Serotyping. Reviewing foodborne -- top foodborne illness serotypes...

DR. ALTERKRUSE: For humans.

DR. JOHNSON: For humans.

DR. GOLDMAN: It's the -- let's see...

DR. JOHNSON: And relating that to information from FSIS sampling and maybe taking those isolates and looking at subtyping, molecular subtyping.

DR. GOLDMAN: And this specifically refers to Salmonella. And that's understood.

DR. HOLT: And subtyping might include -- typing or Salmonella.

DR. JOHNSON: Okay. So we'll just put subtyping. Is that right?

MR. ELFERING: It's a little outdated, but...

DR. GOLDMAN: PFGE's. Yeah.

DR. JOHNSON: Yeah.

DR. ALTERKRUSE: Could you -- what about -- you said serotypes, but then maybe additional subtyping? I mean that's sort of redundant, but...

DR. GOLDMAN: Well, actually, subtyping allows them more specific identification of -- it's a further identification of the pathogen.

MR. ELFERING: Right. Further subtyping. Something like that. Just I think my concern is that the people reading serotype, subtype, it just might sort of get lost. But if you said, take the most prevalent

human serotypes and conduct further subtyping, then, you know, it...

DR. GOLDMAN: Yeah, I think that...

MR. ELFERING: ...is just that serotype, subtype, I think I'm afraid that someone will just be...

DR. JOHNSON: Yeah, if I say it fast, I'll -- you know.

MR. ELFERING: Okay.

DR. JOHNSON: I'll just keep going on with it. Yeah.

MR. KOWALCYK: Are you afraid to ask me the question?

DR. JOHNSON: Yeah. Yeah. No, I have to start and think because we start serotype, subtype.

MR. KOWALCKY: And you -- I think that's a good point you made. Sean.

DR. ALTERKRUSE: Well, and you mentioned -- thank you -- the -- typing. You know, you could put like, for example, typing, A-F-G and...

MR. SCHAD: A-F-G.

DR. JOHNSON: Well, let's just put -- yeah, let's just put subtyping, parens, ribo, PFGE...

MR. SCHAD: That's...

DR. JOHNSON: That way there's...

MR. SCHAD: ...more descriptive.

DR. JOHNSON: Yeah. All right, let's look at three real quick. What other types of data should be considered in developing a regulatory policy (data FSIS currently collects in plants)? And we're suggesting that FSIS review regulations, policies and procedures to make them more consistent with the public health mission. This might include reviewing PBIS data, a re-examination of existing data to determine the usefulness of -- for public health. That was our PBIS thought. And look at different uses and approaches to analyzing data.

DR. GOLDMAN: Does -- on that last point, do you mean new and different approaches to analyzing existing data or any?

DR. JOHNSON: I think it would be both. We talked a little bit about are there other ways we should be looking at the data we currently have.

DR. GOLDMAN: Right. That's what I thought it meant.

MR. SCHAD: Well, if you use the word investigate instead of determine.

DR. JOHNSON: Okay. Okay. And it looks like, though, that if we -- if we're looking at data we

already have, and we want to -- and it's useful to consider it in a different light than current data, we'd -- current data we're gathering, we would want to apply the same principle, right? Investigate different uses and approaches to analyzing data, and then we'll put parens (both current and future.) Do you think one little click is going to stop that? Oh, we've got to go now. The tape's up. Time to go.

MS. NAUGLE: Okay, so my computer just froze up.

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[Interruption to fix equipment]

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MS. NAUGLE: Okay, I'm back on track.

DR. JOHNSON: Okay, so what do you have for number three?

MS. NAUGLE: Okay, I have review of regulations, policies and -- exactly what you have printed out.

DR. JOHNSON: Okay. All right. So let's help with the wording on number three, and then we will...

DR. GOLDMAN: How about review of regulations, policies and procedures to ensure consistency with their public health mission?

DR. ALTERKRUSE: What about relevance to?

DR. JOHNSON: So better say to assure consistency, we're going to say relevant to?

DR. ALTERKRUSE: No, relevance to...

MS. NAUGLE: To ensure consistency and relevance.

DR. JOHNSON: Okay.

DR. ALTERKRUSE: Um-hum.

MS. NAUGLE: For their public health mission. Does that sound right, or should it be...

DR. ALTERKRUSE: Could be there or with FSIS...

MS. NAUGLE: Right.

DR. ALTERKRUSE: ...public health.

DR. BAYSE: Right. We need to be clear about, not just a generic, but...

DR. ALTERKRUSE: Now this bullet on free up resources for public health focus, that's more of a -- that's not really a separate thing. That's kind of like...

DR. JOHNSON: Yeah, that's...

MR. KOWALCYK: A benefit of doing...

DR. ALTERKRUSE: Yeah, benefit. Right. Yeah.

DR. JOHNSON: Yeah. I don't know whether we

need that in there, or if I just -- we just need to talk and say that. But now we do need our next sentence to talk about a re-examination of the existing data. Are we saying the same thing when we say a review as the re-examination of existing data and determine the usefulness for public health? Is that saying the same thing that we just said?

DR. ALTERKRUSE: I think -- yeah, go ahead Kevin.

MR. ELFERING: The only thing is is I think that it should be emphasized either in the presentation or in -- and probably in the presentation, is is that we've got to go backwards here too. And there's some things that maybe can be repealed with this review process. So you could expand on that first bullet with that, the step that's in that free up resources, like -- I think that's what you were saying, Mark, was -- so, for example...

MR. SCHAD: Some bullet or whatever.

DR. JOHNSON: Yeah.

MR. SCHAD: That's where I took it out. Yeah.

MR. ELFERING: So it could be something like this process should both eliminate unnecessary activities...

DR. JOHNSON: And determine the need...

MR. ELFERING: ...and free up resources for public health focus.

DR. JOHNSON: That's good. Did you get that?

MS. NAUGLE: Yep. It's not spelled right though.

DR. JOHNSON: All right. That's okay. All right. And then we can say, this would include inspection data from the PBIS system as well as micro and chemical analysis as currently being done.

DR. ALTERKRUSE: Do you really want to say that? PBIS, I think, is a good example. I agree.

DR. JOHNSON: Do we really want -- we don't want...

DR. ALTERKRUSE: No, I'm just kidding.

DR. JOHNSON: What are we talking about?

DR. ALTERKRUSE: No, it's like -- I'm sorry. He really -- I agree with yours. You know, PBIS needs a -- it needs to be looked at.

DR. JOHNSON: But I think we need to consider chemical as well as micro because your point, we keep focusing on the micro sampling, but we have a lot of -- okay. Might I suggest, and you guys can tell me no, that we print this out one more time, and we'll take a

quick look at it, and then we'll kind of sleep on it tonight, and then tomorrow morning we could all huddle real quick over the coffee and muffins at the table and just be sure everybody still feels good about what we've done?

MR. SCHAB: I think that's a good idea. Fresh look in the morning.

DR. BAYSE: Right. Come at eight?

DR. JOHNSON: Yeah.

DR. BAYSE: Does that suit?

MR. ELFERING: I think that's good. Yeah.

MS. NAUGLE: Can I ask a question? Will this be printed out en masse to distribute it...

DR. JOHNSON: Yeah. After we hand it in tomorrow, they will -- well, they're going to want to make copies tonight though, but we can always change it during the presentation.

DR. GOLDMAN: Now I thought I might be out of place here. I thought I understood Robert to say that the -- the report would be projected on the screen, and then the full committee would have an opportunity to edit it, and someone could actually edit.

DR. JOHNSON: Yeah.

DR. GOLDMAN: It's on a screen, so I don't know

if you need to print it ahead of -- I mean I don't know.

DR. JOHNSON: Well, usually, they ask for us to give it to them, and then they print it out and they make copies for the committee. Not for everybody.

DR. GOLDMAN: Oh, okay.

DR. JOHNSON: And then the committee reviews it, and we make changes up there, and everybody looks at it and goes like that.

DR. GOLDMAN: Okay.

DR. JOHNSON: But we can always...

MS. NAUGLE: Here's the -- here's the first page.

DR. JOHNSON: Thank you for doing that. I know that's hard.

MS. NAUGLE: Spelling. My spelling's bad anyway. Toward the end here, it's questionable, really questionable. So that's it.

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[Pause for printing and distributing copies]

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DR. JOHNSON: Saundra will take one, I think, and that's the one they'll work off of tomorrow. But I kind of think we need to look at the first...

MS. NAUGLE: Okay.

DR. JOHNSON: ...sentence one more time. We considered the question based on both current policy and the need for future policy and methods applicable to both. Is that okay, or do we have too many boths in there?

MR. SCHAD: Do you need the and methods applicable to both?

DR. GOLDMAN: And my question also would be are you going to verbally expand on this, because...

DR. JOHNSON: Yes.

DR. GOLDMAN: ...I think, you know, if -- it begs a little expansion...

DR. JOHSON: Yes.

DR. GOLDMAN: ...at least orally, if not in writing.

DR. JOHNSON: Yeah, we get -- we generally go through the whole committee discussion, which is already marked, and keeping everything, and then the committee, of course, chimes in at each point. Right.

DR. BAYSE: Sub-committee.

DR. JOHNSON: Right, my fellow sub-committee people.

MR. ELFERING: We don't leave you hanging out on a limb.

DR. JOHNSON: Alice goes and Kevin, what?

MR. ELFERING: What did you say last night?

DR. JOHNSON: And Kevin, you were talking about what now?

MR. KOWALCYK: About using the word imperative.

DR. JOHNSON: Yeah, what were we imperative?

MS. NAUGLE: So do you want and methods applicable to both taken out?

DR. JOHNSON: Well, we have it in there, both current policy and the need for future.

MR. SCHAD: I don't think it's many boths in there. I don't know if that's grammatically correct or not.

DR. JOHNSON: Yeah. It just...

MR. SCHAD: That's fine.

DR. BAYSE: Back on the issue, Alice. Isn't that their associate better? Oh, I'm sorry. I am tired. Sorry. Never mind.

DR. JOHNSON: We're now to the point of taking the question.

DR. GOLDMAN: I think it is associate.

DR. JOHNSON: Okay, this is better associates.

DR. BAYSE: No, read it again.

MR. ELFERING: No, you're right.

DR. JOHNSON: Oh, well okay.

MR. ELFERING: Associate. Associate.

DR. JOHNSON: All right. Thank you. And double points. Double points.

MR. ELFERING: No, that is very good. We weren't even looking there.

DR. JOHNSON: I'm going to start with we changed the question.

MS. NAUGLE: And methods applicable to both is taken out.

MR. KOWALCYK: And I think it's fine either way. I don't see a problem with it either way.

DR. JOHNSON: Okay.

MS. NAUGLE: Okay, so it's out right now. I'm sorry. Let me ask a question here. Okay, number one that's on the document here that we just printed out. It looks like it reads the same as what was the issue, the issue on the issue paper. Maybe I missed the conversation. I thought the question was different.

DR. ALTERKRUSE: And they were -- time out. This -- the overriding issue question.

MS. NAUGLE: Oh, okay.

DR. ALTERKRUSE: I think.

DR. JOHNSON: Yes. Okay, so we talk about utilization of outside experts is imperative to achieve unbiased sampling design and data analysis. FSIS should review available data trends and determine statistical significance specific policies. This would include design and development of statistically sound sampling methodology, and this is done through gaining consensus among FSIS experts. Data analysis should be extrapolated using applied science. Extrapolate data applying science to extrapolating data.

MS. NAUGLE: Oh, my.

DR. ALTERKRUSE: I think we just want to say extrapolate data using scientifically sound methodology.

MR. KOWALCYK: So take analysis out of there.

MS. NAUGLE: Yeah, I think that's probably -- I'm stuck on that.

MR. KOWALCYK: Then we want to take the consensus bullet out...

DR. JOHNSON: Yeah.

MR. KOWALCYK: ...also because we have that.

MR. ELFERING: Okay. Yeah. Um-hum.

MR. KOWALCYK: We have that, then design.

DR. JOHNSON: Okay. So under analysis we have extrapolate data using scientifically sound methodology.

DR. BAYSE: Then we need a base future policy rather than...

DR. JOHNSON: Yeah, base future policy and take out the base there, on statistically significant results, and the use of risk assessment. So the committee supports...

DR. BAYSE: Or support the agency in...

DR. JOHNSON: Support the agency...

DR. BAYSE: ...in continuing...

DR. JOHNSON: That's okay. He's done good to...

DR. BAYSE: Oh, we've done it again.

DR. JOHNSON: Yeah, we want those experts in here.

DR. BAYSE: The three AS's@ and the outside experts.

DR. JOHNSON: Using scientifically sound sampling methodology.

MS. NAUGLE: I have it now.

DR. JOHNSON: Our sub-committee is the -- scientifically sound sampling group. That's our logo. And outside experts.

MS. NAUGLE: Now, is it okay to leave this bullet in place or are -- what about tomorrow?

DR. JOHNSON: Gladys, do you want...

DR. BAYSE: Are we still on one?

DR. JOHNSON: Yeah, we're still on one.

DR. BAYSE: Do we want to leave it as bullet points?

DR. JOHNSON: We maybe should say, after the utilization, after being imperative, we maybe want to say FSIS should, and then put...

MS. NAUGLE: Okay.

DR. JOHNSON: Would that -- FSIS should review available data. I'm looking at what we did in two. I guess we -- whatever we do, we need to be consistent between...

MS. NAUGLE: Yeah.

DR. JOHNSON: ...point two and three.

DR. BAYSE: Can do FSIS should, but then when we get to two we're going to have to pull it out.

DR. JOHNSON: Yeah.

DR. BAYSE: Yeah, okay.

DR. JOHNSON: All right. FSIS should, and then review...

DR. BAYSE: And then bullet because...

DR. JOHNSON: Yeah.

DR. BAYSE: ...the rest of it...

DR. JOHNSON: And then when we get down to future policies, we put base future policies.

MS. NAUGLE: Right.

DR. JOHNSON: Okay. Take out the other base, and then support the agency. Okay.

MS. NAUGLE: All right.

DR. JOHNSON: And though on the second, we take out all the FSIS should, and just put it once and then bullet. FSIS Should. And then our -- while this may be beyond the scope of FSIS, we need to pull that out, right?

DR. ALTERKRUSE: You're taking that out?

DR. JOHNSON: No, we're pulling it down because that should be FSIS should.

DR. BAYSE: It could maybe be a separate...

DR. JOHNSON: Yeah, it should be a separate bullet. Separate sentence, yeah. And should the review Salmonella serotypes most frequently associated with, that should be FSIS should, right? FSIS should...

DR. BAYSE: Right.

DR. JOHNSON: ...and then take out with regard to, and just put review Salmonella serotypes most frequently associated with and related to those obtained through FSIS HACCP regulatory sampling. Further subtype

of selected isolates should be considered. And then a separate little sentence that says, while this may be beyond the scope of FSIS, and we'll do that.

DR. BAYSE: And then we mean that to refer to all of the bullets when we say that.

DR. ALTERKRUSE: You know, you could take out this may, while beyond the scope of FSIS.

DR. JOHNSON: Okay. Put beyond. Okay. And then on question three...

DR. ALTERKRUSE: And that ends with the word should.

MS. NAUGLE: Oh, yeah, you're right.

DR. ALTERKRUSE: Something like that.

MS. NAUGLE: Thank you.

DR. JOHNSON: Okay, well...

MS. NAUGLE: Is reportability, is that a word? I mean it's come up on my spell check, and there's no alternative spelling for it.

MR. ELFERING: No, that's fine. What about -- it is.

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[Discussion about word]

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DR. GOLDMAN: I mean it's sometimes referred

to as increased disease reporting, i-n-g.

DR. JOHNSON: Well, maybe that's better.

DR. GOLDMAN: I mean I think it's -- I think it's the same concept, isn't it?

MR. ELFERING: I like reporting, myself.

MR. KOWALCYK: It's better.

DR. JOHNSON: So use reporting. Okay.

MS. NAUGLE: Erase disease reporting?

DR. JOHNSON: Yeah. On three, FSIS should conduct reviews, should, new bullet, conduct reviews of regulations. And it should be re-examine instead of re-examination. Did you keep in there different -- investigate different uses and approaches to analyzing data, both current and future data gathered? Did we take that out?

MS. NAUGLE: Now, that may have been lost in my little...

DR. JOHNSON: In the little incident. Do we want to keep it in? Do we want to put it in? Determine -- investigate different uses and approaches to analyzing data. This would apply to both current data and future data gathered.

DR. BAYSE: And then freeing up the resources. Piece of that we used.

DR. JOHNSON: We had -- we put that in with review. This process should both eliminate unnecessary activity and free up FSIS -- is that?

DR. BAYSE: Yeah, that's fine.

MS. NAUGLE: Okay, so I'm sorry. Could you repeat? Investigate different approaches to utilize and analyze...

DR. JOHNSON: Investigate different uses and approaches to analyzing data. This would apply to both current and future data gathered. Oh, oh, pulling up nametags. We're done, I think.

MR. ELFERING: I think we just need to look at it with a fresh view in the morning, definitely.

UNIDENTIFIED SPEAKER: Alecia, does Baysian have a capital AB?@

MS. NAUGLE: Well...

DR. GOLDMAN: I think it does because it's named after...

MS. NAUGLE: ...I'm not sure. Probably. I've seen it both ways, but it's probably more correct to capitalize it. What page is that on

DR. GOLDMAN: Two.

DR. JOHNSON: Excuse me. Could we ball the questions, like one, two and three?

MS. NAUGLE: Yeah, I thought I did that.

DR. JOHNSON: That may have gotten lost in the...

MS. NAUGLE: I'm sorry. I need you to repeat that last. Investigate different uses and...

DR. ALTERKRUSE: Approaches.

DR. GOLDMAN: To analyze data.

MS. NAUGLE: Okay. Sorry about that.

DR. JOHNSON: That's okay. Thank you very much. Jason, thank you. Alecia, thank you very much.

CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

IN RE: NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION

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