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C O N T E N T S

P R O C E E D I N G S

DR. BENEDICT: Why don't we get started, even though our sound person will be here soon.

To begin with, my name is Steve Benedict. I'm in the Department of Microbiology and Molecular Biosciences at the University of Kansas, and I am not Ed Brandt, whom I'm temporarily replacing.

For those of you who have known me before, let me offer my apologies for the fact that you thought you weren't ever going to see me again, but sadly, here I am. Ed offers his apologies for not being able to be with us. He's cheerfully doing other things that he couldn't get out of. So just to let you know who I am, I was on this committee for however many years one is on the committee, and I just cycled off, and I've come back just for this day and for tomorrow.

What I would like for us to do is do this sort of the way Ed does it, and when he gets back you'll see that he does it much better, and he's really the Chair of the committee and he has tenure for as long as he wants to do this. If he's the Chair, I guess that makes me the stool. That's why I offered my apologies at the beginning.

What we're here to do, for those who are just joining the committee, is to discuss issues that the FDA finds extremely relevant and that they would like to have

help and advice on. And so what we'll do is hear presentations that will follow pretty closely what's in your briefing books. At the end of those we'll ask you for questions, for questions of clarification, for discussion, and then at the end of the session you'll be asked to respond individually to some specific questions that the FDA has posed to you and that we will read to you in just a moment.

The way it has been done in the past is that when time comes for questions, if you'll raise your hand and just be acknowledged by one of us here, we'll keep a running list of who wishes to ask questions or speak and then in turn we'll recognize you to speak, which will make it a lot more orderly than a free-for-all discussion. This is the way Ed does it, and so we'll continue it in that fashion.

Secondly, the proceedings are being recorded, and we are continually reminded, people have been doing their Master's degrees on what we have to say. And so please, when the time comes to speak, get thyself to a microphone and speak into the microphone, and I will state your name before. But if I mispronounce it, state it more clearly so that they will know who it is that they're listening to as they transcribe what you have to say.

A favor that I'd like to ask, since I don't know very many of you, if you could make sure that your name

cards are sort of aimed in our direction, I'd be very grateful, and I apologize for that.

So what we will do first is I will introduce Dr. Bob Buchanan, sitting to my right, who is serving along with Kathy DeRoever as the Executive Secretary at the moment, since Lynn Larsen has moved to another position. We will then go around the room and introduce ourselves. It would be good, since many of us are new to the committee, to be a little more expansive about yourself than your name. Tell us where you're from and sort of what your area of expertise is. That would be nice.

And then when that is done, we'll have some administrative matters to deal with, and then we'll go right into this. And so, Dr. Buchanan.

DR. BUCHANAN: And I'll start this off correctly. Bob Buchanan, Food and Drug Administration. I wanted to take a couple minutes to explain who I am and why I'm here, and then just to introduce myself. For many of you here at the table, I already know you. And for the rest, I'm looking forward to meeting you and working with you on the committee.

I am the senior science advisor for the Center for Food Safety and Applied Nutrition, and with the establishment of that position last March, the activities of scientific advisory committees were transferred over to my

office as part of the duties of the new position.

I want to up front thank you, and I want to express Joseph Levitt's thanks for your willingness to serve on this committee. One of the things that our Commissioner, Dr. Haney, has strongly emphasized is how important the science base is to FDA, and we consider our advisory committees a very important component of our science base. And we're looking forward to your participation and your advice on a series of scientific matters that are going to be facing you in your tenure as committee members.

So with that, I'm not going to take any more time, Steve. I'm going to send you over. I do want to indicate to you that if there is anything that we need to help you with, please do not hesitate, and Cathy will explain a little bit more about that in a minute.

DR. BENEDICT: So why don't we continue around the table and each of us introduce ourselves? Cathy, would you like to?

MS. DeROEVER: Good morning. I'm Cathy DeRoever. I work with the Office of Science. My staff, Linda Hayden, and Sylvia Washington who is outside, I think that you've all been in contact with them at some point.

We're here to make this go as smoothly as we can for you, and since we got off to such a crackerjack start, we had said we'd hoped to make an impression, and we did.

It's not the impression we wanted to make, but we will certainly--the only way to go is up.

If there's anything we can do to help you, please let us know, if you have any questions. We'll be giving you expense vouchers and those sorts of things so you'll have them, and we'll be talking to you individually on how to get those things in to us. And as I said, the only way to go is up, but it's nice to have you here today. Thank you.

DR. MONTVILLE: I'm Tom Montville. I'm Professor of Food Microbiology and Chairman of the Department of Food Science at Rutgers, the State University of New Jersey. I guess my primary area of microbiological expertise is Gram-positive organisms.

DR. SIGMAN-GRANT: I am Madeleine Sigman-Grant from the University of Nevada Cooperative Extension. I'm a professor, and my area of specialty is maternal and child health. I'm interested in how consumers make decisions in their food choices. My training was lab-benched, just so you all know I do have a science background, and am a lot interested in lactation and breast-feeding, in that area.

DR. HOTCHKISS: My name is Joe Hotchkiss. I am a professor at Cornell University with joint appointments in toxicology and food science. My areas of interest have long been in food safety, and particularly the effect of

processing and additives and ingredients and so forth on potential risks in foods.

DR. KUZMINSKI: My name is Larry Kuzminski. I'm Vice President of Technology at Ocean Spray. I've been there just over 10 years, where I've had the technical responsibilities for the cooperative, including the operations responsibilities for some of that time. Prior to that I was with the Kellogg Company for about 15 years, where I had product development responsibility in the United States and technical responsibilities in Canada. And prior to that, I was with the University of Massachusetts at the associate professor tenured level. My training is in food science and technology from the University of Massachusetts.

MR. HARRIS: Hi. I'm Ken Harris, Food and Drug for 30-odd years, a consultant for 25 or so years. Presently I'm retired. I've worked with the government of Spain, loaned by the administration to the government of Spain. I've worked with the government of the U.K. on some problems of contamination and grain losses. Food and Drug turned me loose once for a week or so with the, in effect, the filth group of the government of Canada. I've worked all over the world, 70-odd countries, and I'm here as a resource on questions of filth and contamination and their possible role in the field of public health. That's about it.

DR. TROXELL: I'm Terry Troxell, Director of the Office of Plant and Dairy Foods and Beverages. The two issues you have before you today, the regulation of filth and the patulin action level, are issues from my office.

MS. BARNETT: I'm Alexa Barnett, and I'm from the Office of Chief Counsel of FDA.

MR. GECAN: I'm John Gecan. I'm Chief of the Microanalytical Branch in the Office of Plant and Dairy Foods, and I'm one of the presenters for the filth enforcement strategy this morning.

DR. OLSEN: I'm Al Olsen. I'm the other presenter. I've been with Food and Drug for 27 years, and I'm the entomologist, so insects are my business here.

DR. APPLEBAUM: Rhona Applebaum. I'm Executive Vice President for Scientific and Regulatory Affairs at the National Food Processors Association. In that capacity I guess I could be categorized as a desk scientist. Our principal focus at the NFPA is food safety, focused on microbiology, chemistry, processing and packaging. Prior to being at NFPA, I was 18 months with Distilled Spirits and 11 years at the Chocolate Manufacturers and the Confectioners Associations. My background is food microbiology, food science and nutrition.

DR. BRACKETT: I'm Bob Brackett, professor at the Center for Food Safety and Quality Enhancement at the

University of Georgia. My background is food microbiology, and specialty areas, microbial food safety, most recently with Listeria monocytogenes and Clostridium botulinum. I have been at Georgia for 15 years and was at North Carolina State University for three years as food safety specialist.

MS. RICHARDSON: I'm Donna Richardson, and I'm a consumer representative on the committee. I am at Howard University Cancer Center. I am assistant professor for the College of Medicine and College of Nursing, and my background is as a registered nurse and a regulatory attorney, and my focus is on access to care for women, minorities, and the elderly.

DR. RUSSELL: I'm Robert Russell. I'm a physician. I'm Professor of Medicine and Professor of Nutrition at Tufts University, and I'm the Associate Director of the Human Nutrition Research Center at Tufts. My background and interests, research interests, are in retinoids and carcinogenesis, and my expertise really is in human nutrition science, trying to get that into the medical practice and curriculum, and I'm currently chairing the Food and Nutrition Board's National Academy of Science panel for setting the new recommended dietary allowances for micronutrients.

DR. BUCHANAN: Okay. Thank you, and welcome, everyone, to the committee.

At this point we have the dreaded administrative matters to deal with.

MS. DeROEVER: First, can we change the agenda? I think I need more than 10 minutes.

DR. BUCHANAN: Oh, my goodness.

MS. DeROEVER: Very briefly, in the portfolio you have in front of you there is a calendar. If you have an opportunity before you leave, if you could tell us dates you are not available through the end of the year, if you could put your name on it, this will help us with scheduling. If you have to return to your office, I certainly understand that, but if you could get that back to us at your convenience.

Also in your packages you have the focus, charge and questions for the filth discussion and for the patulin discussion this afternoon. Those are provided just so you'll have them, but I believe either Dr. Buchanan or Dr. Benedict will read those into the record before the discussions begin.

And that's all I have. Are you disappointed?

DR. BENEDICT: You bore false witness.

Okay, let me just say one other thing, that I realize you've had some accommodation difficulties, and having served on the committee for a number of years, I can tell you that that's not normal. Normally, everything runs

very smoothly and you're wonderfully accommodated and treated and it works very well. So you can look forward to several years of smoothness after this little hiccup.

So let's enter into the discussion of filth and extraneous materials. You've all read the briefing book, and I would like to point out that Ms. Barnett, the attorney who is sitting at the end of the table, is here to help us and guide us and make sure that we do or do not discuss the correct things. And if we stray into legal areas that we shouldn't be in, she will pop up and tell us what we should or should not be doing. And you've heard we have Mr. Harris as an expert, and we're going to ask him to participate in our discussions after we've heard our presentations.

And so, as I said earlier, we're going to do some presenting followed by questions. These questions are for you to understand what you've heard and read. And then at the end we'll be asking you some questions.

And I guess this is a good time to ask Dr. Buchanan to give us the charge for this section of our discussion and to alert you as to the questions that we're going to ask you to deal with. Although they're presented in front of you, I thought it would be better just to hear them out loud and get them into the record before we began our discussion.

DR. BUCHANAN: Thank you, Stephen.

Bob Buchanan, FDA. I just want to take a moment to read the charge so that we have it into the record, and I'll give a little bit of background information and then turn it over to the group that will be making the presentations.

The charge is, the working group is asked to consider whether the revised enforcement strategy for filth and extraneous materials will provide an adequate and reasonable basis for a clear, science-based Compliance Policy Guide for regulating filth and extraneous materials in food.

And I'm not going to give much explanation. Our two speakers are going to go into detail, and we have the resources of Terry and Alexa here to help through any policy-related issue.

But what I did want to remind the members of the committee is that while we tend to focus on issues related to things like food safety and other compliance-related issues, we also have a requirement in our food law to regulate in terms of filth and extraneous material, and we're trying to bring the best science we can bear to doing that effectively, both in terms of assuring public health and also to make sure that we're doing it in what for the agency is a cost-effective manner. So we're looking forward to your advice and thoughts on this whole issue of filth.

And with that, Steve, I'll turn it back to you and we can start the presentations.

DR. BENEDICT: We'll now have Mr. John Gecan, who is Chief of Microanalytical Branch, CFSAN, who will start us off.

MR. GECAN: Thank you. Let me turn this projector on here.

Good morning again, ladies and gentlemen. Again, I am--my name is John Gecan, and my co-presenter on this subject is Mr. Alan Olsen, seated next to me. We both work for the Microanalytical Branch in the Center for Food Safety and Applied Nutrition. I work with Dr. Troxell.

This morning Mr. Olsen and I will present the details of FDA's revised enforcement strategy for filth and extraneous matter. Mr. Olsen will cover the two components that represent the most significant revisions of the enforcement strategy. I will provide a general overview on the subject of filth and extraneous matter and a more detailed background on the origin and development of Defect Action Levels.

I have worked for the--in the area of filth and foreign matter for the past 36 years for the Microanalytical Branch. I started as a bench analyst, and spending about 10 years as a project manager to update the science base for Defect Action Levels, and hope to end my career working on

the development of this revised enforcement strategy.

What changed the way FDA has regulated filth and extraneous matter for more than 50 years? Primarily, we initiated the development of this strategy in part in response to the juice and seafood HACCP regulations. The revised strategy provides both the science base and the action criteria that are critical for the development of HACCP critical control points, critical control limits, and standard operating procedures. And also, in response to the Food Safety Initiative, this strategy also provides an appropriate food safety focus on food contaminants.

What do we want to accomplish with the revision of the filth enforcement strategy? The purpose of the provision was threefold: to provide a transparent science base for each of the three components of the enforcement strategy to regulate filth and extraneous matter. Those components include the health hazards, insanitation filth, and aesthetic filth, and you'll be hearing those terms a great deal this morning, and they will be explained in detail.

Secondly, to focus on food safety and emerging health issues related to filth.

And, lastly, to clearly define the action criteria for the different categories of filth: the health hazards, insanitation, and aesthetics.

What benefits will be derived from the revised strategy? For consumers, certainly improved protection by focusing on the health aspects of filth.

The FDA will operate more efficiently, with reduced case referrals from the field to headquarters. We currently receive better than 400 referrals every year from our field offices for subject matter review, and with generally a one- to five-day turn-around time on these referrals. Once the enforcement strategy is formalized and out in the hands of the field compliance offices, many of those decisions will be made on-site in the district offices and not require the subject matter expert review at headquarters.

Industry will realize a turn-around time, a reduced turn-around time for our FDA regulatory decisions, and the related reduced storage costs for goods on hold.

Everyone will benefit from clearly defined action criteria that will result in uniform regulatory decisions worldwide. Transparency of both our action criteria and the science base will enable industry, both here and abroad, to fully understand FDA's approach to regulating filth and foreign matter.

Now, to touch upon the sections of the Act very briefly that apply to filth and foreign matter, the sections of the Food, Drug and Cosmetic Act that are relevant to

regulating filth and extraneous matter are Sections 402(a)(1), (a)(3) and (a)(4).

Section 402(a)(1) states that a food is adulterated when it bears or contains any poisonous substance which may render the product injurious to health. In the area of filth and extraneous matter, this section generally applies to direct hazards such as contamination by hard or sharp objects such as glass or metal which might cause injury.

Section 402(a)(3) states that a food is adulterated if it consists in whole or in part of a filthy, putrid or decomposed substance. This section applies specifically to contaminants found in the product. An example might be rodent excreta pellets in wheat.

402(a)(4) states that a food is adulterated when it is prepared, packed, or held under insanitary conditions, whereby the product may have become contaminated with filth, or whereby it may have been rendered injurious to health. This section applies to insanitary conditions that are reasonably likely to result in contamination of the products, even if adulteration of the food cannot be demonstrated.

A good example would be unshielded lighting over a production line which could result in product contamination, for example, if a bulb would shatter. This is a condition

that would render the likelihood of contamination.

What do we mean by filth? A lay person's definition of filth is contaminants which, because of their repulsiveness, would not normally be eaten. Filth can be a health hazard, but even if no hazard can be shown, its mere presence in a product will render that product adulterated.

Now, in the case of filth in foods, I believe a picture is worth a thousand words. The following series of slides will show examples of contaminants from the three major contaminant categories of filth.

Rodent contamination comes in many shapes, sizes and forms. The most repulsive form of rodent contamination or other mammalian contamination is the presence of a whole or partial animal in a product, such as a rabbit's foot in frozen greens or a mangled mouse from a custard pie or a tuft of rodent hair attached to a piece of skin, as we see in this slide. These are examples that have passed through our laboratory over the last few years. They are uncommon but they do occur from time to time.

The next slide shows the type of damage and contamination that a nest of baby rats can inflict on stored foods. Common damage from rodents is gnawing of the outer cardboard cartons, frequently into the immediate food package, and quite often in gnawed products.

Rodents also leave behind their excreta pellets

along with the attached rodent hairs. You will note in the lower right-hand pellet the hairs protruding from the pellet.

Foods may become contaminated by digested hairs. The attached hair that I pointed out in the previous slide was digested by passage through the animal's gut. I don't need to say any more about the significance of hairs. Undigested hairs may also be present due to rodent visitations to the raw materials or processing environments or through airborne contamination.

Rodent urine stains, as seen in this slide under ultraviolet light, they fluoresce, indicates rodent visitation to stored food. This happens to be burlap bagging with urine stains.

Evidence of bird activity includes everything from a pigeon roosting on stored products in a warehouse. One consequence of bird visitation is their excreta and feathers, as shown here on a burlap bag. Now, the open weave of this burlap would permit the liquid excreta components, particularly at the time of deposition, to pass through the weave and contact any food that might be contained in the burlap sack. As the excreta dries out and the bag is handled, the particles of the bird excreta will break up and pass through the weave into the product.

Birds also contaminate foods with microscopic

feather barbs, which is a subcomponent of a larger feather, and even smaller microscopic feather barbules, which was one of the strands on the barb.

Insects are also found in consumer products. These insects can generally be separated into field and storage insects. Insect contaminants of field origin include the Bruchid weevils on beans; corn earworm larvae--you can see that right there--on an ear of corn in the field. The pecan weevil larvae from pecans, on the left we have the weevil larvae and in the center of the slide we have the larvae commingled with pieces of pecans. These coffee beans have been bored by the coffee berry borer; they could show up in the gourmet coffee bin in the supermarket, but the industry does quite a good job in removing bored and contaminated materials like this.

Examples of storage contamination includes an Indian meal moth larva entering peanut butter candy after depositing its excreta on the surface of the candy. This slide shows moth excreta in webbing among stored peanuts. Weevils in wheat; and even a predacious mite that attacks storage insects that are infesting stored products.

Mold contaminants can generally be separated into two groups, avoidable and unavoidable. Unavoidable molds of field origin are shown on the tomatoes as they arrive from the field. These types of moldy tomatoes are generally

removed from the lot prior to entering the processing line. If perhaps some of the rotted tomato does enter the line, evidence of this material will show up in the finished product, such as catsup or other fruits and vegetables, as mold hyphae can be seen here. These are microscopic in size.

Avoidable mold such as Giatricum is also known as machinery mold or slime mold. Giatricum grows on food contact surfaces such as in certain processing environments, particularly those environments that are warm and moist, like canning factories, fruit and vegetable processors. The paddle in this slide illustrates the growth of the white Giatricum mold along the center of the paddle.

Giatricum mold can also be seen on this belt in a production line, a food contact surface. The belt is almost entirely coated with Giatricum slime mold. The Giatricum mold being scraped from that belt illustrates why this contaminant is quite frequently called slime mold, and products passing along this belt can dislodge pieces of this mold, and upon analysis the finished product will show clumps of the Giatricum mold that were growing on the equipment or food contact surfaces.

A few examples of extraneous material include fragments of glass, stones, pits in pitted olives, and shell from canned clams and oysters.

As I mentioned earlier, the revised enforcement strategy categorizes filth into three major types: health hazards, insanitation filth, and aesthetic filth. Previous slides showed the universe of filth and included examples from all of these categories.

Mr. Olsen will cover filth that presents a health hazard and filth resulting from poor sanitation. The remainder of my presentation this morning will focus on aesthetic filth.

For purposes of perspective it is important to understand how filth has been regulated up to this point in time. The early regulation of aesthetic filth relied primarily upon FDA's scientific knowledge and case precedents that were generally not available to the public. Over the years, the regulation of aesthetic filth evolved to identifying action criteria in Compliance Policy Guides and later the Defect Action Levels, both of which are publicly available at this time.

In the event you are unfamiliar with the term Compliance Policy Guides, which will also be referred to as CPGs throughout our discussion, this slide provides a definition. CPGs are guidance to our field inspection and compliance staffs. They explain policy and procedures to be applied when determining industry compliance. CPGs came into existence around 1968, and prior to that they were

called the Administrative Guidelines.

Over the years the FDA has issued a number of action criteria for natural and unavoidable aesthetic filth that were included in these CPGs. In 1972 the FDA extracted the action criteria for aesthetic filth from the CPGs and issued them to the public as Defect Action Levels. The cover of the booklet is shown in this slide.

Upon their release to the public, the Commissioner of the FDA specified that the science base for the DALs or D-A-L-s should be updated as appropriate. A multiyear effort was initiated to accomplish the development of this science base. Science base for the DALs consists of retail market and port-of-entry surveys that developed filth contamination profiles for a large number of products.

The results of all these surveys upon which the DALs are based are published in the Journal of Food Protection. A few examples of these publications of the contamination profiles are shown in this slide. An example of the type of data that was published in these journal articles to support the DALs is shown here.

This is an example of rodent hair counts from ground oregano. That was one of the analytes that were selected for the regulation of filth in ground oregano. The rodent hair counts ranged from zero to nine, and the number of samples that contained the respective counts is shown in

the right-hand column.

Defect Action Levels were selected for each analyte at the upper 99th confidence interval of the 95th percentile on a frequency distribution. Looking at the cumulative percent column, that point corresponds to around 97.6, and as you look across to the far left column, that corresponds to five rodent hairs, which is the Defect Action Level for rodent hair fragments in ground oregano at this time. All Defect Action Levels are set following the same approach for all products, for all analytes.

Where do we go from here? I previously said there are three major types of filth covered in the revised strategy: health hazards, insanitation filth, and aesthetic filth which I've just talked about. Up to this point we've gone through the development of FDA's enforcement policy for the regulation of aesthetic filth. We do not intend to revise our approach to regulating aesthetic filth.

We do, however, intend to include in the Compliance Policy Guides revisions of our regulatory approach for the other major types of filth, specifically, health hazards and insanitation filth. Alan Olsen will present the details of the health hazards and insanitation components of the revised enforcement strategy.

At this time I can entertain questions, if that's appropriate.

DR. BENEDICT: Yes, that's appropriate. We're well ahead of schedule, and this would be a good time, if we could have the lights, and if the committee would like to ask questions of Mr. Gecan, this would be an appropriate time. Dr. Hotchkiss?

DR. HOTCHKISS: My question really is generally will--

DR. BENEDICT: The microphone.

DR. HOTCHKISS: Will someone tell us roughly what is the recent past enforcement action level or number of enforcement actions taken for reasons of filth over some period of time, over the last year or two years, somewhere along there? What's the field, what's the incidence in the field?

MR. GECAN: Okay. I guess a figure for filth actions a year or so ago was roughly 5,000 samples were collected and analyzed for filth, and my branch saw roughly, as I said, a little less than 10 percent of those samples. It fluctuates from year to year. So about 5,000 samples just a few years ago were collected for filth analysis. I can't reflect on the findings of those analyses, whether they were violative or non-violative. I don't have that information.

DR. HOTCHKISS: I assume that those 5,000 are collected because the inspector has reason to believe that

there may be a filth issue with them. Is that right?

MR. GECAN: Yes, yes.

DR. BENEDICT: While we're paused, let's take a moment. Janice Oliver slipped in while it was dark and I didn't notice. Let's allow her to introduce herself to us.

MS. OLIVER: Thanks, Steve. Good morning. I'm Janice Oliver. I'm Deputy Director from the Center. I'd like to welcome you here, and sorry for being late. I went in to the office first before I came here, always a mistake. And I came in during the last presentation, so if we continue on, that would be good. I'll see you all around lunchtime and at break time.

DR. BENEDICT: Okay. Are there additional questions? Dr. Applebaum?

DR. APPLEBAUM: And this might be a very naive question, but if you could help me figure this out in my mind, I'd greatly appreciate it. I guess my major question regards, is there a problem, you know, in terms of the current regulatory framework and the flexibility currently available to not only FDA Federal but also the district offices?

I guess I'm just wondering exactly or I need to get a better handle of the problem. Okay, we talked about filth, you went through the Act, we have GMPs. I guess I'm just wondering what exactly the problem is that's not

enabling FDA to do its job to the extent that you feel it's necessary.

I might be missing something. It might be as transparent as the nose on my face, but I--when I reviewed the information, it's--you know, you talk about the benefits, the resource savings, but I'm just wondering why, again, in the current regulatory framework that's currently available, what's--you know, why is this issue being brought to our attention.

Now, the health hazards are a different one. We'll get into that, I realize that. But, you know, because I also have concerns in terms of the focus being placed on HACCP, but can you just briefly outline that for me? And I apologize to my colleagues. If you have this clear, I apologize for being so dense.

MR. GECAN: I believe I understand your question. You addressed the or mentioned the health hazards, and that is one reason that we undertook this revision, was to identify any health hazards associated with filth. And, as I said, the aesthetic filth issue has a sound science base that was developed in the form of industry surveys, retail market surveys and port of entry surveys.

The other types of filth, that filth resulting from insanitation, needed to have the science base clarified and developed to more clearly define what was insanitation

filth and to develop action criteria, clearly defined and transparent action criteria for that type of filth, so that we present a level playing field for everyone here and abroad.

Does that answer your question, or are we--

MR. HARRIS: May I try and answer it?

MR. GECAN: Yes. This is Mr. Harris.

MR. HARRIS: I have worked both sides of the street. In the industry side, what Food and Drug does and has been doing sometimes is really confusing to the industry on the basis of are you going to seize, prosecute, or what are you going to do on this particular--after this particular analysis?

The other day I met with Food and Drug, John and his people, and the way--what they said to me was, they are trying to now provide a scientific basis so that the industry can, in effect, get inside of their heads and know how they came to a scientific conclusion and not just a will-o-the-wisp, "I don't have to like the results of this analysis" conclusion. They're trying to put this on a scientific basis, black and white, written down, so that the industry can come to the same conclusions that the Food and Drug Administration is coming to.

MR. GECAN: That's correct, Kenton.

DR. BENEDICT: Dr. Kuzminski?

DR. KUZMINSKI: Just to build on the points, just from the perspective that I've had in reading the material, I would agree with the comments in the material that much of the objective quantification of these kinds of parameters in the past--and others may agree or disagree with this--has generally been from a particular product or product grouping evolution of knowledge. And the benefits I see here in what the agency is trying to do is to bring objective measures to the entire field.

MR. GECAN: Entirely correct.

DR. KUZMINSKI: I think you may debate the numbers, you may debate the levels, but at least this is an effort to bring objectivity to the evaluation, and that's been my conclusion as I read through this. And I would add that there might be other benefits to various of the constituencies that the agency has described. For industry it would mean higher quality products and fewer consumer complaints to deal with, and hence fewer reworks, et cetera. So I think that might help Dr. Applebaum's question, and I would endorse what Mr. Harris has said, also.

DR. BENEDICT: Thank you. Anyone else?

[No response.]

DR. BENEDICT: Well, let me just ask one small question. Do you foresee any negative effects from introducing this sort of a concept, negative effects with

respect to industry, small companies, anyone, consumers?

MR. GECAN: We don't believe so. We've looked at and tried to analyze the benefits to be derived, and to us, you know, from our perspective, we only see positive from this enforcement strategy.

DR. BENEDICT: Okay. One more time, are there any more questions from the committee? Yes? It's Dr. Brackett.

DR. BRACKETT: In the materials you address that one of the advantages or impacts globally is internal--I mean, excuse me, international harmonization. How does this affect what Codex and some of the--which deal with some of this sort of thing, and other countries are doing as far as import-export?

MR. GECAN: Well, this strategy will be taken to Codex by some of our people in the agency. You know, right now it's in its developmental stages and we're in the process of trying to have it accepted as an enforcement policy. We do intend to address this to the international community, and it certainly will--I've talked to representatives from the Philippine government and generally presented this strategy in very general terms, and they were quite excited about the possibilities of knowing basically what it will take to get their commodities into the country from a sanitation and field standpoint.

But yes, we do intend to address this to Codex.

Dr. Hoskin used to work in my branch, and he's quite familiar with the enforcement strategy, and he will more than likely be our spokesperson for the enforcement strategy to Codex.

DR. BENEDICT: Dr. Applebaum?

DR. APPLEBAUM: And just one more question. In putting together these objective criteria, and again I understand very nicely now--and I appreciate that, Dr. Kuzminski, as well as Mr. Harris, for bringing it, making it clearer for me--but are these going to be commodity-specific, product-specific, or are you talking about as it relates to this some type of general, comma, objective criteria?

MR. GECAN: DALs, or the Defect Action Levels, are product-specific. The action criteria as it relates to insanitation and health hazards will be hazard-specific, as Mr. Olsen will explain to you. He'll define how that will work.

DR. BENEDICT: Okay. Could the FDA address the possibility that the phrase "aesthetic filth" is an oxymoron? Never mind.

MR. GECAN: I'm not sure where that came from.

DR. BENEDICT: Okay, so the schedule calls for us--for this to be 10 o'clock, and it isn't. Dr. Olsen, I assume that your presentation is 30 or 40 minutes in length,

and I suggest that we just go ahead and take our break now, and then when we return--it will be a 15-minute break only--and when we return, we'll press this through and we'll have a little extra time for luncheon.

So let's go away, but not too far away, for 15 minutes. I would ask you to use the time to reflect on the questions that you'll be asked. They were in the folder that we passed out.

And there's a break room for the committee to use, which is the Fairfax Room, and it's on the other side of this building, wandering through the hallway past the gift shop. There you will be provided with refreshment and a quiet place to reflect on the soberness of the issues.

So it's 9:33. We will reconvene 15 minutes from now at 9:48. Thank you.

[Recess.]

DR. BENEDICT: Okay, let's take our seats and get cracking, in the words of Ed Brandt. All right, let's get started. And before we ask Dr. Olsen to speak, Ms. Barnett has a clarification that she's like to render unto us.

MS. BARNETT: Thank you. I just wanted to clarify that this is a Compliance Policy Guide, so the things that we are discussing are going to be guidance to the field and industry, and there will still be a level of discretion in the agency when deciding whether or not to bring enforcement

actions. That's it.

DR. BENEDICT: Great. Thank you.

All right, we'll move to a discussion of the revised enforcement strategy. Dr. Alan Olsen, an entomologist in the Microanalytical Branch of CFSAN, will now speak to us on that subject.

DR. OLSEN: Hi. Okay, I'm Al Olsen, and I'm the insect guy, and you've probably heard that more than once now. I'm going to turn the discussion into the components, towards the components of the regulatory strategy that deal with health hazards and with sanitation. Basically we'll be dealing with contaminants that are collectively called avoidable filth. The aesthetic levels that John discussed were unavoidable, and I'm doing the second half now, the avoidable filth.

As John pointed out, FDA has a statistical market survey approach to regulating aesthetic filth. Statistical approaches work for the aesthetic types of filth because these types of filth by and large reflect conditions in agricultural fields, and the aesthetic types of contaminants are more or less randomly distributed throughout a product. As a result, we end up with things like Compliance Policy Guides, Defect Action Levels, that are product-specific. If you'll notice, they talk about levels for a particular spice or for flour. They're keyed in on the products.

Now we're going into a realm, the avoidable filth, where it's attributable to insanitation. In other words, somewhere along the line a human act happened. These are attributable to a human act such as failing to follow a GMP or failing to follow your HACCP plan or things like that. We're not talking about acts of nature anymore. We're talking about things either that somebody committed or omitted to do, and so we have to take a different approach.

We take a forensic type approach, where we not only try to find out, characterize the cause of the contamination, but also who's responsible for it. So you have to keep that in the back of your mind, that we've got a different priority, a different set of goals here.

To begin with, FDA will rely on what we are calling a transparent science base. The science base that we have in mind, that we're developing, focuses on types of contaminants again, I have to stress that, instead of types of products. So we'll be talking about things such as sharp objects, not sharp objects in a particular product, just sharp objects.

The first challenge that we had was to develop a contaminant-specific science base, little different direction. These are examples of the first three developments that we've had in our transparent science base. These are papers that we've published recently in the area

of health hazards.

To establish this science base, we thoroughly reviewed the literature, and what I'll be talking about from here on in is based on a pretty exhaustive review of the scientific literature. In the case of health hazards, we've already published three review articles. These articles fully review the literature in each of the subject areas. The first one is on hard or sharp foreign objects. We have one on allergenic mites and another one on disease-carrying flies.

Now, in addition to reviewing the literature, we have also, in these papers and in subsequent reviews, are developing what we call profiles of the contaminants. How do you recognize a thing as a physical hazard or as an indicator of insanitation? That's included in these publications.

This is an example of what I'm talking about for a profile. What we're trying to do is, with a good science background, rather define what attributes can be used to recognize a particular type of contaminant. The profiles are basically--they are based on things that are held in common by a particular kind of contaminant.

This profile here states basically what it takes for FDA to categorize a contaminant as a physical hazard. And in putting this out, then everybody knows what factors

we're considering when we say, "Oh, we have this kind of contaminant or that." Basically for physical hazards we're looking in the science base, in the literature, for evidence that physical injury can occur from eating this particular--a particular type of contaminant.

We also rely heavily in the physical--in the hazards area on our Health Hazard Evaluation Board. This is a body of FDA scientists that review reports of potentially hazardous types of contamination. Their primary focus is for classifying recalls, giving a health hazard classification to recalls, but any health hazard really needs the imprimatur of the Health Hazard Evaluation Board before you can go any further.

And in this age of HACCP, the hazard is not a hazard if it's removed before it reaches a consumer's table, and that's item three on the profile.

If appropriate, FDA can develop the specific guidance from these profiles. An example is a recently issued Compliance Policy Guide. We put a policy guide out for hard or sharp foreign objects in food, and the guide is included in your handouts and it's publicly available. It's up on the web and all over the place.

And basically what it has is not only how do you recognize the hazard, but there was enough data in the scientific base to define in this term measurements,

actually, of how small a thing, a sharp object could be, basically drawing a line of 7 millimeters for most people as to whether it's a hazard or not.

That's kind of an overview of the process we're going through. Okay? We do this same sort of thing, develop the science base, develop the profiles, and if appropriate, a Compliance Policy Guide, for the other kinds of filth. And we've basically divided, as John said, the filth into two categories that we're approaching with this forensic, contaminant-specific approach. The two categories are the health hazards and the indicators of insanitation or the sanitation section.

The science base and profiles and eventual CPGs, Compliance Policy Guides, for the first category which is health hazards, really have to answer this basic question: Is the contaminant or insanitary condition an indication of a potential and reasonably likely hazard to the health of the consumer?

And what we're saying is, if the science and literature base says people are hurt by it, and the Health Hazard Board says yes, it's a potential hazard, and it's not removed by processing or intended use of the product, then it is indeed a potential and reasonably likely hazard. You've always wondered how we decided that, right?

I remind everybody that we're basing a lot of this

on the newer HACCP regulations or philosophy which divides hazards into three groups, physical, chemical and biological. And I reiterate we rely, especially for hazards, on decisions by the FDA Health Hazard Board.

For example, the paper on physical hazards, we reviewed the Health Hazard Board decisions from 1972 on. There was almost 200 decisions that they rendered on sharp objects in food, and we reviewed all those and included that review in the publication, and that in large part was used to derive the Compliance Policy Guide. So we rely, in the hazard area, on the Health Hazard Board.

Here again is the health hazard profile, and I just want to reiterate again that it's a profile that tells everybody what I am thinking and what the FDA is thinking when they classify something as a physical hazard. They are saying it takes reports, good, reliable reports of physical injury from ingestion; Health Hazard Board; and we have to always be in mind that if it's removed before--by processing, before it reaches the consumer's table, it's not a real hazard.

An example is baby food in glass--glass in baby food. Okay, glass in baby food. This is apple juice, and it's turned on end, and here's a piece of glass inside. that is a physical hazard.

Now, I also mentioned chemical hazards. The

profile is pretty much the same: evidence of toxicity or allergenicity--allergens are also classified as chemical hazards--from eating. We are also dependent on the Health Hazard Board to declare it a hazard, and also the condition that subsequent processing and intended use does not remove the hazard.

You may ask yourself, what are the chemical hazards associated with filth? Well, we asked the same question, of course. The chief hazard in this area is an emerging hazard and it involves these little critters.

This is a house dust mite. The house dust mites and certain other mites are widely recognized as a cause of respiratory allergy, but these little critters also infest things like flour, baked goods, and seafood. This particular one is Dermatophagoides, I believe it's farinae. Anyway, we pulled it out of shrimp in a sample we ran a few years ago.

Recently, however, these allergenic mites have emerged in the literature as a cause of food allergy by ingestion. People have turned up in the emergency rooms of hospitals with varying degrees of reactions, up to and including anaphylactic shock, from eating food that's contaminated with these mites, and the clinical workups for these cases clearly isolate the mite allergens as the cause of the allergic reaction.

As I said, this is an emerging issue. These reports only started coming out in 1995 and '96, so we're still watching the situation.

Of greater concern to me and to most of us is this mite. This is the mold mite, which is also allergenic, and it's been reported to cause severe allergic reactions when it's eaten in infested food.

The cause for concern is that this particular mite occurs in about 20 percent of the mite-infested samples that we analyze in Food and Drug Administration. It is by far the most common food-contaminating mite, and it infests a broad range of products. It's not limited to flour-type products or any particular type of product. It is a general feeder. And it's covered in one of the reprints that's in your handout.

A quick reminder. The physical and chemical hazards I just talked about are subject to regulation under all three of these sections of the Act: the (a)(1) section, which is the direct hazard; and of course the general sanitation sections, (a)(3) and (a)(4).

Now, the stuff that I'm going to talk about next, the contaminants I'm going to discuss next, are not direct health hazards, so they will only be subject to regulation under 402(a)(3) and (a)(4). The only ones that are really subject to regulation under (a)(1) section are the physical

hazards, the chemical hazards that I've discussed.

The HACCP categories, and in general we have biological hazards, and filth is associated with biological hazards. Now, I'll emphasize this clearly and I'll repeat myself. The actual biological hazard is the pathogen, such as Salmonella, E. coli 015787, those are the hazards. The contaminants we're talking about are pests that can serve as passive vectors for the hazard.

I'm going to say that again. The hazard is the pathogen. We are dealing not with the pathogen but with the pests that can carry the pathogen. Therefore, they are only regulated under those 402(a)(3) and (a)(4) sections, and they are a contributing factor to the hazard but they are not the hazard itself. Is everybody clear? Okay, I wanted to get that clear.

A prime example of a contributing factor to biological hazards from pathogens is this beast. This is the Oriental latrine fly. I've collected this fly over quite a few localities. There are specimens in there from Samoa and from America and from Mexico and from everywhere.

The interesting thing about the Oriental latrine fly, in addition to its ability to act as a little dump truck for Salmonella--it picks up Salmonella really nice and carries it all over the place--is that it's an invader species. Now, what I mean by that is, this fly's home range

is in the Asian continent. In India it's known as the bazaar fly. But in the past--bazaar, not bizarre, bazaar as in food market--over the past 10 years this fly has spread around the world.

It showed up in Africa, and was transported from Angola in Africa over to South America, has moved northward, and we discovered it in California and Arizona, and it occasionally is intercepted in Florida. It's strictly living in urban environments and it is very fond of food, human food, and very fond of some very unsavory places like sewers and other things like that. It's a much better carrier of pathogens than our native flies, which is also a cause for concern.

So you say, "That's fine. You're the entomologist. You know all about these guys, right? How are our inspectors and our sanitarians and our QC people supposed to know this fly from the 230,000 other species of flies in the world?" Well, to help out we're going back to the profiles, and this is in the paper on the flies, also.

Disease-carrying pets have certain attributes in common, and this is generally agreed in the scientific literature, that these attributes are the ones that they have in common, that help them act out--we can say help--help them act in their role as a disease carrier. So what we've put together is a profile that can be used to

recognize a disease-carrying pest.

If the pest exhibits these attributes and there is no intervening biocidal process--remember, we're talking about they are contributing factors to a hazard from pathogens. If the pathogens are eliminated, then they are not--they have failed to contribute to that hazard.

The attributes or characteristics are synanthropy, endophily, communicative behavior, attraction to filth and human food, and a good scientific literature base that natural populations are known to harbor pathogens. So we're not talking about insects that aren't associated with pathogens, and we're talking about insects or other pests that have behaviors, basically, that make them excellent contributors to the biological hazard. And I'll explain these big words now.

Synanthropy is--and it's a big word--synanthropy means basically living around where people live. It thrives, these synanthropic pests differentially survive in urban, suburban, and rural environments. In other words, they're our companions in civilization. Endophily is willingness to enter indoors, goes inside.

The point of the profile is, if a pest does not live around people and does not live near us, it is not going to be a contributing factor to any pathogen spread. It's not going to be a threat. And from the Food and Drug

viewpoint, if a pest is not willing to enter a factory, it will not carry germs into the factory. So the pest has to have these characters for us to even consider it as a contributing factor.

Now, the inspector out in the field or the sanitarian can look around their environment--and these are green bottle blow flies--they can look around, and if they see a large number of the same kind of pest--these are all the same kind of fly. They were caught within about two or three hours' time at the same location in a suburban setting. They are definitely associated with carrying disease, too.

The point being, the inspector can observe a large number of flies and they all look the same and they're around human settlement, and can conclude that it's a synanthropic species. Don't need a textbook or an expert to tell you. Then, if we see the fly inside the processing plant, we say, "Ah, ha, this is an endophylic synanthropic species." Two of the five profile attributes are already accounted for, and it's not rocket science.

Communicative behavior means oscillating between contaminated environments and human surroundings. Basically, it has to be a pest that moves back and forth between places where people are and environmental areas where it could pick up contamination. And the attraction

behavior is, a pest has to be strongly attracted to sources or reservoirs of pathogens, commonly feces, sewage, garbage, and also has to be attracted to human food.

Now, this again borders on common sense. If you have a beast that is not attracted to human food, it's not going to contaminate it. If you have a beast that's not attracted to a pathogen source, it's unlikely that it's going to pick up a pathogen to carry to a food. And if it's not in the habit of flying back and forth between the two, it's not going to be a very good dump truck for hauling pathogens into the food supply.

Once again, the inspector or anybody out in the field can look around and say, "Ah, ha, here we have a bunch of flies at a garbage bin, and there they are again at a food contact surface. This looks suspiciously like communicative behavior." That's three out of five.

They can look out in a pasture next door and find the beast on animal droppings, shall we say, and lo and behold, the same one on the food. "Oh, oh, oh. We have attraction to food and attraction to a source of a pathogen." That is four out of five on the profile, and that's how the profile is supposed to work out in the real world.

Now the fifth element is wild populations harboring the pathogens. Okay. These are the insects that

are reported in the literature as harboring either Salmonella, E. coli, or Shigella, and most of them harbor all of those, by the way, in wild populations, not being inoculated in laboratory studies, but you go out and catch them in the wild and they have found these pathogens are existing. Populations of these insects are actually harboring the pathogens in the real world.

It's important to note that the number of pests that are reliably associated with the spread of food-borne disease is currently limited to these. It is a short list. We're not talking about 750,000 species of insects. We're talking about four species of cockroach, estimate maybe a dozen species of flies, a couple of species of ants.

You saw flies. Now I'll give you a cockroach. Nobody really thinks that these aren't dirty little beasts, but I just thought I'd reinforce that with you.

Also, the commensal rodents, the rodents that share our houses and tables with us, such as the roof rat and the Norway rat and the house mouse, fit the same profile. And in some cases, some of the birds, the pigeons and those types of things that are pest birds will fit the profile for a contributing factor to a biological hazard.

So there you have one of the essential components of how we are revising the strategy. Now, to my knowledge nobody has come forth and assembled the science base and put

together a profile. This is sort of--put your Quincy hat on--this is sort of, this is forensic types of things. We're profiling what it takes to recognize something as a possible disease-carrying insect.

Okay. It has to meet all five of these attributes. Now, I've shown you one through four and I've said, gee, in the literature, number five. Okay? The question is, how does an FDA case reviewer or an inspector or a sanitarian determine whether the bug they saw or the pest they saw do one, two, three and four, actually qualifies as actually one of the insects that carries these pathogens in natural populations.

One way is to go to the literature, and we've done that. We're in the process of preparing a review paper that gathers all of this information at one place, so there will be only--there will be a single source for people to look at, to find out whether it's a pathogen--as a matter of fact, there's going to be a single source for all of these. We're publishing them in Regulatory Toxicology and Pharmacology, and that is the same journal as the reprints that you have.

So we have consulted the literature, and wild populations of those insects do indeed carry everything from Salmonella to Shigella to emerging pathogens such as E. coli 015787. The review will be published by the end of the

year, so case reviewers and others need only consult that one source, and it will be available publicly.

Another way to find out if natural wild populations carry pathogens is to directly observe. These are house flies that I collected at an egg farm that was implicated as the source of eggs that caused a Salmonella outbreak. At the time I collected these flies, I saw them do one, two, three and four. They were inside/outside; they were going over to the pastures; they were doing all those things. And when I collected some and we brought them into the lab, we found that indeed those flies were harboring Salmonella enteritidis, so they fit the profile all the way down to number five.

That still leaves us with the problem of how can the inspector of sanitation, sanitarian, complete the profile without waiting for lab results. Well, we're working on that one, too. What we're doing, a colleague and I are developing a field guide. Now, remember this is a small list. It's a short list of pests. And as it turns out, they can be recognized in the field if the proper information is given to the people in the field.

What we're doing is, we're in the process of identifying--preparing single sheet Field Identification Guides for all of the pests that I showed you before, that are known to harbor food-borne pathogens in natural

populations. The identification guide is designed to be used in the field. The identifications can be confirmed with a decent quality hand lens; it's going to be designed that way. And it will cover all of the contributing factor pests, insect pests, to allow people to recognize at least.

Now, that is a key factor in preventing diseases, to be able to recognize a situation quickly and react to it. And I think what--we're approaching a point where we've taken a lot of the guesswork out of it. These will also be publicly available, so anybody can do them.

And this is our little friend, the Oriental latrine fly, kind of a showcase. That was the first one I put in there.

Now we get down to, okay, what's Food and Drug going to do about it? We are recommending that in the case of health hazards, immediate action, immediate corrective action if you're under a HACCP plan, or appropriate regulatory action, is the appropriate response; unless, of course, the hazard is removed by subsequent processing or intended use of the product.

In some cases, such as the hard or sharp objects, the body of knowledge is large enough and definitive enough that we can actually compose a compliance policy guide for a specific contaminant. In other cases such as the allergenic mites, we are not there yet.

Now, the other category is the indicators of insanitation. The science base and profiles that we're developing for these have to answer the question, is the contaminant or insanitary condition an indication of failure to observe Good Manufacturing Practices or other types, that type of guidance, specifically things in a firm's sanitation standard operating plan if they're under a HACCP plan, that kind of thing. The good sanitation practices. We're talking now about things that indicate a lapse in sanitation, indicate poor sanitation.

We're basing our profiles and our regulatory action criteria on the scientific literature, again, which we are preparing the manuscript now, and believe me, there's a lot of literature out there; and also on Good Manufacturing Practices and related regulations, and there are a couple of existing FDA Compliance Policy Guides already in place, notably the warehouse guides which define how many insects or how much rodent damage is reasonable or unreasonable in a storage situation.

I want to emphasize that the strategy will not change existing regulations and guides. What we're doing is providing an updated science base that is reasonably oriented to new developments in HACCP and action criteria profiles for enforcing an existing body of regulation.

Moving on, indicators of insanitation, there are

three major groups. I'll be focusing on the center group because that's the most complex, but we basically have things that are very large and visible and just about everybody in this room, if they saw one in their soup, would say, "Ugh, what's wrong with Food and Drug that they don't fix that?" And they are also indicators, really, of a major lapse in sanitation somewhere along the line.

The second group in this category are the commensal pests. These are the animals, the insects and the rats and the mice, that basically share our table, that seem more or less dependent on us, even though they come in and steal our food, that we don't keep them as pets, but they are the common pests: the flour beetles, the cockroaches, those kinds of things.

And when you look into the natural history of these animals, they fall out into three natural groups, what we call--and I'll explain these in detail--the opportunistic, the obligatory, and the inadvertent, and I've listed examples of what types of pests fall into each of these groups.

The other major indicator of insanitation we deal with is machinery mold, the Giatricum mold that John talked about in more detail, and I won't get--I won't reiterate that discussion.

Now, when we get into what kind of action levels

for these pests, we are basing--we will base our recommendation on samples for right now, because that's what we're working with, of six analytical portions, and somebody's going to ask where the number six came from. That's the minimum number of portions that FDA inspectors normally collect, so we are just expressing it in terms of six.

For the highly visible contaminants which are evidence of egregious breach of sanitation, it's recommended that FDA consider taking appropriate legal action based on finding one of them in a sample, if there's additional evidence of insanitation. In other words, if the inspector has seen something that would contribute to that type of contamination, and you do indeed find the contamination, it's time to consider some sort of legal action, or if you find the same thing twice.

Basically, there have been a number of surveys of public attitudes that show that consumers react strongly to one or two of these large, egregious things. I mean, one roach is enough for most people to want to do something about it.

So we're basing this in part on those public surveys also, that show that one or two incidents of this large, visible, egregious type contamination is just about the limit for most consumers. And a typical reaction is to

discard the contaminated product, spray, try to get rid of the pest, or call Food and Drug Administration and complain, and that's a legitimate reaction.

These large things include large foreign objects of any kind, big bugs, big pieces of anything; live infestations; visible evidence of a lot of insect activity or pest activity, such as nesting, webbing, excreta, that kind of thing; or other visible or egregious contaminants that are not classified as unavoidable natural defects. In other words, we're not--we're separating this out from the Defect Action Level types of contaminants.

And this is an example. For anybody who was planning to have a hamburger for lunch today, you might want to leave the pickle out because sometimes you get pickle worms in there. I love to spoil people's lunches with some of these. Here we go.

And there are also smaller things, and for the smaller things we're saying we should consider taking legal action or corrective action based on finding any of this, any combination of this in three of the six analytical portions. And I'll shortly get into defining the stored product, filth, insects.

We're basically saying if you find some of these commensal pests or if you find large pieces of them, sometimes they get broken in half; a few hairs from

commensal pests, now we're not talking about field mice; or machinery mold exceeding 2,200 mold fragments in 500 grams of product. We're talking about over 600 species of insect pests. There's a large number of stored product insects and that type of thing. And we're talking about disarticulated body regions, head, thorax, abdomen, the same bugs; or hairs or other evidence, mainly hairs, from the Norway rat, roof rat, house mouse, and two Asian commensals, the bandicoot rat and the commensal Asian shrew. And of course excessive slime from that machinery mold.

Okay, you say, fine, you're talking about opportunistic and obligatory, what do you mean by that? Well, we developed the profiles based on the science literature, and I put them up here comparing them with the disease-carrying. We've already gone through this one, the one, two, three, four, five of disease-carrying pests.

The next group is the opportunistic. These are the rats and the mice and the roaches that basically what we're saying is, when you eliminate number five, the guys up in this category become--naturally fit into the opportunistic pests. In other words, a roach devoid of the pathogen hazard is still an indicator of insanitation. The difference is, the pathogen hazard is either absent or eliminated.

And I've tacked another one on here which will

make sense from the next slide. These pests are opportunistic in the sense that they come into places and steal food, but they don't live or breed in the food. They carry it away. A mouse will take something and carry it away somewhere else. Or they come, eat, and then leave.

The inadvertent pests are the pigeons, bats, spiders, things like that that end up in buildings because they are synanthropic like the other pests, and they are endophylic, they will go indoors, usually to nest, though, but they lack communicative behavior and they aren't particularly attracted to the food that is in the building. They're more attracted to the building itself than to the food.

Again, with the inadvertent pests, the pathogen hazard is either absent or eliminated. If it's not, we will consider it--we should try to match it to the profile for the contributing factors. And they again are not found living in the food product itself. They're roosting somewhere or building a web or nesting or doing something else in the building.

The obligatory pests are the true storage insects. These are the flour beetles and the Indian meal moths and those types of things that are earmarked. They're very obvious because they normally live and breed in the food. In other words, when you have flour beetles you're going to

find larvae, eggs, pupae, adults. You'll see the life cycle. You will see little babies and moms and pops and everything. They're making their home inside the bag of flour or whatever food it is.

And because they remain in the food, they are not particularly associated with any pathogen hazard. They're an indicator of poor sanitation, somebody is not paying attention to cleaning up, but they are not particularly known as the types of pests that would spread disease. And they are not particularly communicative. They tend to stay at home in the box of cereal, wherever they are, but they are definitely attracted to human food, big time.

And there you have category one, health hazards; category two, indicators of insanitation; and the profiles that we've developed for the major groups within those categories. The reason we're doing this, of course, is so that even though I know what I'm doing and I can go out and do this, we wanted it to be able to be open so that everybody knows what I might be doing, and in fact can second-guess me, which is fine; and they can apply them on the job, in the factory, in the home, wherever they want to. It is transparent, in a word.

John went through category three, which is the aesthetic filth, and covered it very well. I just remind you that the regulatory action criteria, Compliance Policy

Guides, Defect Action Levels, for aesthetic filth were established literally decades ago.

And I remind you that these were based, had a different basis than the indicators of insanitation and health hazards that I talked about. The aesthetic filth criteria are based on science but also on statistical marketplace surveys, and not on forensic type of information. But this is an example of a transparent strategy that has been successful for decades.

These are just examples of the DALs, but what I want to say is that while the DALs are successful and they're in place and they've been used for quite a long time, our task is to develop a parallel science base, parallel profiles that are forensic in nature rather than statistical, and where appropriate, Compliance Policy Guides or other guidance that is contaminant-specific, not product-specific. The profiles and guidance that we're developing will be similar to those already in effect for the aesthetic filth, except they're forensic in nature, they're contaminant-specific.

Who can use the strategy? As I've said, if we're successful and if we are transparent and we are making this all available to the general public, the strategy can be used by anybody in the industry and by consumers. And this is just a partial list of the people that have actually

expressed interest to me in getting this done because they're waiting for it.

Review time. There'll be a test in five minutes. Never mind. In summary, this is an outline. What we're doing here is, first we're assembling a science base. We're reviewing the literature, seeing what conclusions can be drawn from the science that is known about a particular type of contaminant.

Then we're developing these profiles so that everybody can recognize that type of contaminant when they come across it. They're organizing, they've organized the profiles, we've organized them into three major categories: health hazard, insanitation, and the aesthetic, which was there to begin with.

And, finally, where it's appropriate, where there is sufficient science and where it is fully supported by the science base, we can establish action criteria such as Compliance Policy Guides.

Down the road, we'll publish the remaining science base. That should be out to the public by the end of the year. We have been directed to develop a Compliance Policy Guide for category one and two, and we're in the process of doing that.

That's why we're here today. We presented all this to the committee, and we're really asking the committee

if they agree that the transparent science base that we're putting together with all these reviews, and going through all the literature and the profiling procedure, if you agree that this is an appropriate and proper approach for developing the Compliance Policy Guide that we've been told we have to develop for filth and extraneous materials.

And of course we're also asking if you think it's appropriate to expand this beyond sample analyses. products, collecting samples of products and analyzing, into the areas of investigations and inspections. One of the things that I really try to aim for is to put tools out there that sanitarians, HACCP planners, inspectors can use to make the decisions that they have to make in the modern world about food safety.

They have to be able to decide quickly whether to take a corrective action, whether to consider a corrective action, or whether to conclude that there is no imminent hazard, that it's a sanitation clean-up action that has to be done, or nothing has to be done. They have to be able to decide these things.

And as much information as we can put out to them, and as much structure as we can give into our thinking so that we are predictable, I think we will all have done what we intend to do as far as food safety comes, is assure that the really hazardous and really egregious and really poor

sanitation types of contamination are prevented, and that we focus ourselves in those areas.

Thank you very much.

DR. BENEDICT: Thank you, Dr. Olsen. If we could have lights, this is now the time for us to question Dr. Olsen, and if we have additional questions for anyone else who spoke, I think that would be appropriate as well.

Let me encourage the committee to be as analytical and critical as we can. This is how the FDA gets as much as they can get out of our appearance here. So even if you agree with what they're saying, if you can think of something, ask it anyway.

So let's open the floor for questions. Dr. Russell?

DR. RUSSELL: Yes, I have two questions. And this probably reflects my ignorance of the area, but one of the questions is, if an investigator, a lot of insect parts are found in a product, will the investigator through the field guide or through some other way know whether or not those insect parts are from one of these bad insects that transmit disease such as Salmonella? In other words, will there be sort of a way that they can tell whether the legs that they're seeing are from one of these bad insects or not?

DR. OLSEN: Right now, no. You'll have to deal with the whole insect. Once it becomes disarticulated past

the major body regions, you really need a laboratory and a microscope in a laboratory setting to make those determinations, because they are very, very small. So fragments are still a matter for--we will need laboratories to do the fragments, definitely.

DR. RUSSELL: So just seeing a certain number of fragments would tick off possibly some--without knowing what the fragments were from--would tick off some kind of action, possibly, if there were--

DR. OLSEN: No, you have to know what the fragments are from, and the fragments are identifiable. In other words, the short list there of insects that are a potential health hazard, we can identify those fragments and people with training can do that. If it's a nondescript fragment that isn't identifiable, then it becomes a category three aesthetic type of contaminant.

DR. RUSSELL: Thank you. And my second question has to--I just came back from Belgium during this food crisis they had, and I became quite aware about the problems of packaging and that some people can become sick by the--not from the food product itself but from touching the packaging. I suppose this is possible with at least a biologic hazard, if the packaging is contaminated with a lot of insect excreta itself.

And I was wondering, do these guidelines cover not

just the food, what's in the food, but also the packaging? Realizing that, you know, a lot can happen to packaging after it leaves the manufacturing plant, but are there some kind of guidelines for packaging, at least to the point where it leaves the plant?

DR. OLSEN: Right now we're at the--in the food stage of development, and the packaging question is--I'm not too sure there's a whole lot of science behind that. I'm not exactly--there are--you know, if the--I'm trying to visualize a situation where the contamination would be in the packaging and not the product, and I'm having a difficult time there.

DR. RUSSELL: Well, in Belgium, you know, it was a fungicidal or thought to be, part of it was a fungicidal agent, so this is different from what you're talking about, about insect parts.

DR. OLSEN: Right, that's totally different, yes.

DR. RUSSELL: But I'm wondering, I suppose if you had a lot of flies around the packaging plant, it would be possible, probably not as likely to get into the food, but be possible that you could have Salmonella contamination of the packaging.

DR. OLSEN: Oh, yes, definitely the packaging. The food contact surfaces, yes. In that sense, yes, food contact surfaces will be covered by the strategy.

DR. RUSSELL: But not if it's on the outside of the packaging--

DR. BENEDICT: Why don't we--let me just interrupt for a minute--why don't we ask Dr. Troxell to clarify if you could, please.

DR. TROXELL: Well, if I can here. I mean, we have a whole set of indirect additive regulations that assure the safety of packaging. Now, if a packaging were contaminated by a fungicide, gasoline, or some other contaminant, say if somebody tried to recycle an inappropriate material, then that recycled material probably would not comply with our regulations. But also, if even we had another situation of, say, a fungicide contaminant whereby it would contaminate food, it would adulterate the food per se under 402(a)(1).

DR. BENEDICT: So do you feel, has your question been answered? Or at least addressed?

DR. RUSSELL: I think so.

DR. BENEDICT: Okay, we have Dr. Hotchkiss.

DR. HOTCHKISS: Thank you. A couple of questions. One, I wasn't quite clear, did you say that a Compliance Policy Guide has been written, a proposed one, in this area? I thought you had said that there was one and that we had it, but I don't recall--

DR. OLSEN: The only guide we have is, we've

published the Compliance Policy Guide for hard or sharp foreign objects.

DR. HOTCHKISS: I see.

DR. OLSEN: And I believe that was in the handout.

DR. HOTCHKISS: I don't think we did have that, but I assume that your thinking, you have given us these action categories, one, two, three, and so forth, that's your thinking towards the--towards a potential compliance policy?

DR. OLSEN: Yes. A potential Compliance Policy Guide will focus on one and two, because three is already pretty much covered.

DR. HOTCHKISS: Good, because I just wanted--because I thought you said we had it, but I don't think we do.

DR. OLSEN: No, we only have one small part. In some cases, and this is important to realize, in some cases the science and the other information, such as with health hazards, the Health Hazard Evaluation Boards and the clinical literature, clearly support a contaminant-specific Compliance Policy Guide. I mean, in other cases the science is not that developed.

In the case of the hard or sharp objects, it is very clear from the clinical literature, from the surgical textbooks and from the Health Hazard Board that, for

example, an object 7 millimeters or longer was a definite hazard to anybody. Objects 2 to 7 millimeters could be a hazard to special risk groups. And it was so convincing that we just could not fail to publish that out.

In other cases, such as the allergenic mites or that, there is no dose response data available yet so it's impossible to formulate a compliance policy guide at this time.

DR. HOTCHKISS: No, I understand. I just wanted to make sure that the committee is not able to comment on a proposed policy guide because--

DR. OLSEN: Right. We're asking for comment on the strategy for making guides.

DR. HOTCHKISS: Okay. I just wanted to make sure I was clear about that. More substantive, at least to me, you've laid out five criteria for action or proposed criteria for health hazards. They seem very logical to me, having been actually involved with this a little bit throughout my career.

The only one that I wondered is, my real question is, in practice, do you feel confident that this is not going to overly burden the field people at FDA? I can see the situation where you have these five criteria, you inspected my plant and you got down to the first four criteria and you found flies on my food, and I said, "Yes,

but these are not disease-carrying flies, these are non-disease-carrying flies."

And I guess your answer to that is, you're going to give the inspector a field guide and that's going to be the difference. He's going to look at these flies and compare them to the field guide, and make a decision whether or not they are disease-carrying flies. That's going to be a very critical decision, in my view, because that's going to take you from a category one to a category two kind of thing.

DR. OLSEN: Exactly.

DR. HOTCHKISS: And I just wonder if you think that--are you confident that the field people who have to make that very critical decision at that point will be, even with a field guide in hand, will be capable of making that decision?

DR. OLSEN: Yes. We've tried it out with a few inspectors already, and it's not rocket science. It's doable. Of course we have to realize that for any legal action, the inspectors would normally collect what we call an investigational sample, not a product sample but a sample of essentially forensic evidence showing or to confirm.

A good example is the rodent urine that John showed. They would normally black light it and say, "Ah, ha, this glows under the black light like rodent urine." We

will collect a sample as part of our forensic evidence, and then we confirm it in the laboratory.

A lot of the decisions they'll be making is, should we swat that fly and collect it? Or it doesn't look like one of the ones we swat and collect; we'll just list it on the list of observations. So the mechanics of it will not overburden our investigators by any means.

DR. HOTCHKISS: Let me make sure I understand what you told me a second ago. You have tested this, field-tested this?

DR. OLSEN: Yes, we've taken it out in the warehouses with--out in California.

DR. HOTCHKISS: And my third question is related to that. This seems to me to be a fairly significant departure from past practices in this area. I assume we all agree to that; probably wouldn't be here if it weren't. We wouldn't be talking about it if it weren't.

I wonder if you have or someone in the agency has taken the proposed criteria and retrospectively looked at inspection reports or incidences over some last period of time and made a decision how this would or would not affect the outcome of inspections. In other words, how many of incidences of filth over the last year would now have been categorized as category one, compared over some historical period.

DR. OLSEN: Yes, yes. We have been doing that for the last year. All of the case referrals that come into our office have been getting a double evaluation by the traditional precedents, where we would look it up in product-specific files and see how it was going, and by this process. And we're talking a couple hundred samples here over the past year.

The agreement is over 90 percent. In other words, regardless of which system we used, the outcome, the decision would have been the same. And with the other 10 percent, we've used those to fine-tune, so they would now be in agreement. They were out of agreement. We just had to fine-tune the strategy.

So basically we are not--this will not cause more or fewer decisions in a violative or non-violative category. In other words, it will not change the mix. How else can I say it? If a sample that came in five years ago was violative, and it comes in next year under this strategy, it will still be violative. We have not changed that mix at all. It's fairly consistent.

DR. HOTCHKISS: So the net effect in terms of protection of health generally will not change.

DR. OLSEN: The same, remain the same.

DR. HOTCHKISS: It's essentially--

DR. OLSEN: The difference will be, we will have

the tools to approach the HACCP needs that we're in, where we have to define critical control points and that. This is information that those people need.

And the other difference will be that we will have it out there in front so that these decisions, a large number of them at least, can be made without sending them in to our office, with confidence, by district offices. And there's an element of predictability in there from the industry's viewpoint.

DR. BENEDICT: Let's have a comment from Dr. Troxell.

DR. TROXELL: Yes, I'd just like to add one thing. The health impact would be to enhance the public health here, because we're setting up a system for prioritizing our focus. And with that prioritization of focusing of resources on the most important areas, then we'll get a greater health impact. And we'll have also, because we'll have better guidance out for industry, they'll be able to focus on things that have the greatest health impact.

DR. HOTCHKISS: Thank you very much.

DR. BENEDICT: Okay. Next on the list is Dr. Kuzminski. The microphone, please.

DR. KUZMINSKI: Thank you very much. I'm sorry. I have some general comments and some specific comments or questions, and I'll start with the specifics and go to the

general.

Help me understand the use, your use of the word "transparent," please.

DR. OLSEN: Okay. My use of the word "transparent" is, first, it's published. Everything is out to the public. And, second, it is revealing so that I am predictable or whoever makes the regulatory decisions is predictable. You can take this information and, with a fair degree of confidence, say that, "Well, Food and Drug is going to be very concerned about this, or moderately concerned, and I should also be."

DR. KUZMINSKI: Thank you. That's helpful.

What has been the peer review reaction to the three papers that have been published? I've read them. I found them interesting. I thought they would probably be very difficult to write.

DR. OLSEN: Thank you.

DR. KUZMINSKI: What has been the reaction there?

DR. OLSEN: The reaction among my peers has been overwhelming support, honestly. And before I sent it to the Journal, I shared it with some pretty high-up colleagues, Bernie Greenberg out in Chicago, who is the dean of dipterists, of fly people. He wrote "Flies and Disease," which I've cited quite extensively. And he was very much in support of it. And a few of the universities.

And the reprint requests are all voluminous. We're running out of reprints already. And the comments I've been getting back from just about every sector is support: Yes, this is good science, it's logical science, and it's--it hits the mark, yes. I've been getting very little negative at all.

DR. KUZMINSKI: That's very good. You mention and the materials mention--

DR. BENEDICT: Could you get just a little closer to the microphone?

DR. KUZMINSKI: I'm sorry. Thank you, Dr. Benedict. I'm sorry.

You mention and the materials mention intentions to write two more later this year.

DR. OLSEN: Yes.

DR. KUZMINSKI: And what topics might--could you share the topics?

DR. OLSEN: The one will be on--will be a study of--it's called an organoleptic panel, where we took large objects, in this case hairs, and had a bunch of, a number of people see if it was objectionable, if they could discern it or not. We were basically determining how large is large.

DR. KUZMINSKI: Yes.

DR. OLSEN: And the other one will be a comprehensive review of the indicators of insanitation--the

rats, the mice, the roaches, the ants, those things--basically putting together the science base of why a particular contaminant should be in category two and which group of pests, is it opportunistic or not, opportunistic, inadvertent? Why would the major types of pests fit into one of those profiles, and why the profiles are developed to begin with. So it's basically the science base for the profiles, and then putting all the little critters in their proper bins, as it were.

DR. KUZMINSKI: Thank you. So this compendium of five papers, then, in the agency's view would provide the science base for the entire horizon, of the area that's trying to be regulated

DR. OLSEN: Science base and the profiles, yes, and the profiles.

DR. KUZMINSKI: I guess it's related to a question that Dr. Hotchkiss asked. The new strategy, in the material there's comment made on decreasing the number of referrals to the Center.

DR. OLSEN: Yes.

DR. KUZMINSKI: Might there be a rerouting of costs in the strategy from the Center to the field, and hence no net decrease?

DR. OLSEN: Probably not, because the compliance officers in the field district offices are already doing

extensive reviews of these cases before they send them to us, and the conventional wisdom in the field has been, if we can make the decision out here, it's more efficient for us.

DR. KUZMINSKI: Overall--those are the specific comments, a couple more but I can cover them off line--overall I think the whole strategy going back to, Mr. Chairman, if you're addressing the question, address it to the committee--Does the strategy provide an appropriate scientific base for an enforcement strategy?--I think it's a good start. It's trying to quantify and bring out--

DR. BENEDICT: We're actually going to ask you to say that a little bit later, if that's okay.

DR. KUZMINSKI: Oh, all right. But I see some--and this relates to some questions--there are potential overlaps between these priority sections. Dr. Hotchkiss has referred to it. I believe the speakers have referred to it. between category one, where there is health hazards, and category two, where there are not so.

But there are potential overlaps, and this is where I see the implementation of this strategy, especially when I hear it combined with HACCP implications, where the implication there is clearly hazard. The first letter of HACCP is Hazard Analysis, hazard.

And I feel the--there could be implementation challenges for both training and education in the field, not

just for the agency and the agency personnel but by those that the agency is dealing with, the industry people, to deal with this new information. So I think overall the initiative brings objectivity, but there should be a recognition of real potential overlap between a very key area, category one, and a less key area perhaps, category two.

DR. BENEDICT: Thank you.

Dr. Montville?

DR. MONTVILLE: I have two questions that are--I don't know if they're very specific or very trivial. One is, we go back to the question of category one versus category two, and the fifth criteria, is it a disease-carrying type insect or not? There's quite a bit of coverage in the documentation on recognizing versus identifying and the qualifications you need to identify an insect versus recognize an insect.

I thought I understood until we started thinking about field guides, where if you use the analogy to field guides for identification of birds, I think we're talking about a field guide for recognition of insects.

DR. OLSEN: Recognition, yes.

DR. MONTVILLE: Can you speak to that? I mean, what is the real objective difference between "recognize" and "identify" and what people would have to be trained in

to do that?

DR. OLSEN: Yes, you're exactly right. The field guides are by and large tools for recognizing something rather than making a definitive taxonomic identification. From the field standpoint of the sanitarian or the inspector or the HACCP planner or those people, recognition is an important skill to have, because that is information we use to make decisions out in the field. From a regulatory standpoint, however, as far as taking a regulatory action, identification will still be required.

In other words, recognition is also a component of, "Should I collect it for identification or not?" Because you cannot walk in with partially developed evidence, especially since, as I've stressed, this is a forensic endeavor, you definitely need to take the latent prints and identify them and match them up and do the more complex science before you take any legal action.

DR. MONTVILLE: The second question again may be trivial. When we're talking about three out of six samples having indicators of insanitation, do they have to be the same indicator or could it be different indicators?

DR. OLSEN: Very good question. We debated this one around, whether it had to be same or not, and one would think--your intellect and logic tells you that if it is the same pest throughout, then this is a larger lapse somehow.

But in reality, neglecting a population of say, for example, flour beetles to the point where it spreads into three bags or four bags of flour, how much different is that than allowing flour beetles access to one bag and flat grain beetles access to another? In a sense, the difference between the two situations, at least in our estimation right now, is sort of trivial. They are parallel in importance.

DR. MONTVILLE: Thank you.

DR. BUCHANAN: Dr. Applebaum, and then we'll do Dr. Brackett.

DR. APPLEBAUM: Just a few comments and a question, and again this is echoing off of Dr. Hotchkiss's point in regards to don't think training is going to be--just a warning, you know, training is not as easy as one might think, and we have had our experiences just with HACCP issues. So I'm hoping that there are resources available to ensure that that training is going to be done, not only with FDA, but as you know, a lot of your guidance documents are also used by the States, and any effort that you can have or plan for as it relates to providing education for the States, that would be I think very beneficial for everyone across the board, not only the agencies, both Federal, State and local, but also for the industry.

A question I have in terms of--and it gets back to something that's probably near and dear to all of your

hearts, and that's the integrated approach that everyone hears about and the need for communication, collaboration, and coordination, and I was just wondering if you could perhaps share with us some of the efforts in that regard as it relates to your sister agencies responsible for food inspection and food safety?

DR. OLSEN: Oh, yes. Actually that's a very good question. We have had a number of conferences with U.S. Department of Agriculture Food Safety Inspection Service, Dan Engeljohn's office and also their recall people, and they have been on line with this. And we also are working with them to, as much as possible, align what we're doing here with their instructions to their inspectors out there, and we are pretty much in line. The last meeting they had was a rather large one, and they in fact are supportive.

DR. BENEDICT: Okay. Dr. Brackett?

DR. BRACKETT: Thank you.

DR. OLSEN: Can I make a quick comment about the training and your comment there? This field guide concept that I flashed up here is not a new thing. This is tried and true. Basically it's the way CDC has done things for many, many years, and it's modeled after that. So, yes, people need a little bit of training there, but it's not like we're saying, "Oh, this is a great idea, let's try it out." It's been tried before in many different venues.

I'm sorry, go ahead.

DR. BRACKETT: Okay. Your talk was quite interesting, I think--

DR. OLSEN: Thank you.

DR. BRACKETT: --and generated a lot of questions in my mind, and really too many. So what I'm going to do is actually lump them into two separate areas, one dealing with policy and one dealing with science, and I'll deal with science because I think it's the easiest ones to answer at this point.

And I wonder if I could ask you a little bit more about the state of the science for identification of these. Specifically the guides and everything are relying on field guides and on more art and traditional ways of identifying. Is there not a more quantitative or more objective way of identifying, first of all, allergens, allergenistic insects? And also perhaps rapid methods or something a little more objective for disease-causing insects, something that would be less subject to error by the field inspectors, and also more unequivocal in court?

DR. OLSEN: Yes. Very good question. We'll take the allergens first. The jury is still out as to whether we should measure the mites or directly measure the allergen, both of which are possible. As I mentioned, there is no dose response data for either one, and I won't predict the

outcome, but we are working currently--as a matter of fact, George Ziobro is in the room here--on developing a method for measuring the allergens in a product from mites. So in some cases, yes, there definitely are good signs, there are quantitative methods we can apply.

When you get into insect taxonomy and live, moving animals such as large flies and roaches, there have been a number of attempts to get away from the physical morphology of these beasts as far as identification, and there are no applications that I know of right now that are that definitive, that get that level of precision when applied to a food product or the food matrix.

There has been some work on trying to sort out the protein mix in the exoskeleton, and in some cases--well, the good example is the Asian roach, where they did quite a bit of GC work. The Asian roach is a dead ringer for one of our native roaches, and it's an invading species. The big difference between it and the local roaches is, it flies a lot.

And originally when it invaded this country, into Florida, they started doing some GC work on trying to identify them out because it's an invading pest and you have to tell. And it was good work, but it turns out that it's much easier to say, "If it flies, it's an Asian roach," than to go through all that. In addition to which, one of our

people in Baltimore recently published a paper that said they're not dead ringers, there are some pretty obvious physical characters that you can use to separate the two.

So in many cases with--what I'm trying to say is, with the whole animal, the morphology is pretty generally keying out to be the easiest way to accurately identify them. With the Oriental latrine fly they're doing some interesting DNA work and sorting out strains. They're trying to sort out the migration patterns. They asked the question, "It showed up in California. Did it come from Hawaii, did it come from Mexico, or did it come from Japan?" And the answer is being sorted out at U.C. Berkeley by comparing DNA from the different populations.

So these things are possible, but still insect morphology is the quickest way.

DR. BRACKETT: I'm just wondering if some of that isn't just because there hasn't been a need to look for something to do that.

DR. OLSEN: That, too.

DR. BRACKETT: And you touched on a little bit, which is the next issue that I had, which are some of the policy issues, one of which is again measuring mite parts versus the allergen and coming up with action levels. I see an issue emerging with these sorts of things, not unlike Listeria monocytogenes, that you have a latent problem that

you may not see early on, but through storage you may end up having a bigger and bigger problem, where one might need to take a risk assessment approach in order to find out exactly what the risk is to a sensitive population. And I don't know if you've got plans to do that or how that's going to fit in with what the policy is going to be.

DR. OLSEN: Well, with the case of the allergenic mites, it's such a new issue that, no, we don't have firm plans laid yet. But you're absolutely correct, that's a good direction to consider, because this is something brand new that's just coming out, so there obviously will be more activity in that area, and that is--we just haven't had the time to decide which direction to go. The scientific community actually hasn't figured out which direction to go on that. But risk assessment types of approaches are definitely something we should consider with those, especially with the allergenic mites.

DR. BENEDICT: Dr. Buchanan has a question.

DR. BUCHANAN: To ensure that we get a full consideration of the issues before the committee, what I did want to ask and bring out on the table is, in your description of your criteria, much of this was based on observations in the actual processing environment, the identification of species that fulfill your profile.

What I didn't hear was any kind of quantitation of

how many of these insects would be needed to have a hazard. Would you be concerned if you had one fly, one Oriental latrine fly, or would your concern only be when you had more than 100 in that environment?

Likewise, when you get into the second category, ones that were not particularly associated with transmission of disease but examples of insanitation, where is the criteria, what is the criteria before you would elicit an action? Certainly one house fly could come in with an open door; a hundred might be indicative of someone's broken screen. Do we have any consideration of quantitation?

DR. OLSEN: Well, at this point we have thoughts of doing research in that area, as far as deciding how many flies is too many, how many roaches is too many from a pathogen transmission point of view. On the other hand, in the meantime it's not like we're unprotected, because the fact that we're taking a forensic rather than a statistical approach to food sanitation means that we're not relying strictly on numbers of flies, we are relying on the bulk of the evidence and whether the evidence shows that there was indeed a lapse of good sanitation.

What we really are doing here is deciding whether in fact the Food, Drug and Cosmetic Act, Sections (a)(3) and (a)(4), have been followed. So we have the protection in place, and it would be nice to have the quantitation so we

can draw that line a little finer, and we'll be working towards that.

DR. BENEDICT: Dr. Applebaum?

DR. APPLEBAUM: But then I have a concern, because you're--and, again, this probably goes back to the training --because how are you going to control the subjectivity of current inspectors as well as new inspectors who are geared towards the protection of public health, and we applaud that, I applaud that, but for qualitative reasons they're going to err on the side of safety when a hazard in this regard, or even a strong indication of sanitation, doesn't exist? So if you could just share with us, how would you control an inspector's subjectivity if you don't have, if you will, those quantitative indicators in place?

DR. OLSEN: I think a Food and Drug inspection, a sanitation inspection, is not a numbers generating type of activity. It's an investigational type of activity, and that's where we're at today, where the combination of observations of the inspector make the case for or against a significant violation of sanitary laws.

And when an inspector, for example, goes into a plant to do a sanitation inspection, they walk through the entire operation, they make their observations, and at the end they give the plant manager a list of those observations. That same list goes back to the office to

evaluate as to whether it is enough to justify some sort of legal action.

At the same time, the dynamic working there is that the manager of the plant at the same time will take that list and do some corrective actions. And when you get into that sort of dynamic, they are already putting screens on the windows, regardless of whether it's one fly or a hundred flies, because in essence they realize that if you see one fly and the window is open, you could see more, and let's not count the flies, let's shut the window.

And I think that's the attitude or that is the approach that most of our inspectors in fact do take, is this indicates a problem, and can we correct it before it becomes a big problem? And if it is not corrected, then the dynamic has to be evaluated again to see if we require legal action to get the desired behavior that will shut the window.

DR. BENEDICT: Mr. Harris, is your comment pertinent to--

MR. HARRIS: Just to this point.

DR. BENEDICT: So please address that.

MR. HARRIS: Yes. As a practical matter, you should never turn the Food and Drug inspector loose in your plant. You should accompany him as an adjunct inspector.

DR. BENEDICT: Thank you.

Dr. Hotchkiss?

DR. HOTCHKISS: I'm trying to understand how this science base policy then gets turned into regulatory policy. You've given us these action categories, one, two, three, in our handouts, but they didn't quite match what you had said up there. For example, you had one that said "if three or more," and I can't find that in here. And it says, "If the above criteria are not met, proceed to step six of the strategy flow chart." We don't have that strategy--

DR. OLSEN: We don't, no.

DR. HOTCHKISS: --so there are some parts of this I assume that we don't have.

DR. OLSEN: Actually, yes. The flow chart, we got caught up in some graphics difficulties with it, but it is no more than a decision tree for arriving at category one, two or three. And basically it's a logical progression, where it's the flow of the decision.

You ask yourself first, is there a HACCP plan in place or some other overriding document or agreement or plan, and check those records out first, then decide whether or not it's appropriate to collect a sample. If a sample is collected and analyzed, then go into the decision tree of the analysis. Is it a potential hazard? And if so, is it a situation where the hazard is not removed, neutralized or eliminated?

If the answer is yes, it's a potential hazard and it's not removed, neutralized or eliminated, go to category one. If it is not a hazard, go to the next decision tree that says, is it an indicator of insanitation or is it an aesthetic type, and for those answers it just directs down to category two and category three. So it's basically just a decision tree, and those are the questions that you have to ask yourself every time you inspect a plant or analyze a sample.

DR. HOTCHKISS: Yes. My real question--

DR. OLSEN: Just putting them in priority type of order.

DR. HOTCHKISS: So this is really still an evolving policy?

DR. OLSEN: Yes.

DR. BENEDICT: Okay. Are there other questions? Dr. Kuzminski?

DR. KUZMINSKI: I just have one.

DR. BENEDICT: Microphone.

DR. KUZMINSKI: Thank you. Help me understand. Under action category one in the provided materials, and it goes back to my point on potential overlap between the categories--

DR. OLSEN: Yes.

DR. KUZMINSKI: --reference is made to, under

action, HACCP corrective action or seizure, detention, et cetera, for either one of the two options described in the provided material.

Mindful of the fact that there could be an overlap, mainly in the area of pests and the potential of pests to carry disease, I go to the area on frequently asked questions, responses to frequently asked questions, and the question that addresses what are the HACCP applications. And the last statement made in that section is that the strategy clearly enforces the concept that under normal conditions, CCPs, critical control points, are not an appropriate means of controlling pests in a HACCP environment, including pests that carry pathogens.

While I agree with that statement, I find a little bit of confusion in my mind, trying to correlate and clarify that statement with the action as described in Section 1 an the potential overlap of some material in Section 1 with Section 2, which may not be HACCP-related.

DR. OLSEN: Yes, that's a long question. When we get into the pests that are disease-carrying pests, the most--the normally--normally the appropriate control points for those are in the sanitation standard operating procedure, but the control point for the pathogen must be present there also. If the control point--if the control for the pathogen is being circumvented by the insect, then

you still do not make a critical control point for the insect. In other words, you do not put "fly control" as a critical control point. It still remains in the sanitation standard operating procedure.

I don't know how responsive that is, or did I--

DR. KUZMINSKI: I'm not sure I've done a good job in asking the question.

DR. OLSEN: Okay, let's do the question.

DR. KUZMINSKI: Enough for now. I just see a potential conflict there in terms of how do you resolve action level in two where it may overlap with an issue that's in action level one, category one.

DR. OLSEN: Okay. Yes. And the confusion comes, yes, exactly there, because I think basically what you're saying is, a roach can be in either category, and how do you decide which category it goes into? And the key factor there is whether or not there's a reasonable likelihood of that roach transmitting the pathogen. If there is, it belongs in category one. If the HACCP control point is going to intervene and the roach doesn't get past it, then it's an indicator of insanitation and it falls--it sort of is demoted into category two.

DR. KUZMINSKI: My point--

DR. OLSEN: The key is that we have to make sure that we understand that we're focusing on the contaminant,

and the critical control point is not controlling the contaminant, it's controlling the pathogen.

DR. KUZMINSKI: Yes, and that reflects my fundamental concern, also: Is that the appropriate use of the HACCP concept?

DR. OLSEN: Right. Yes, yes.

DR. BENEDICT: Dr. Buchanan has a comment on this, I think.

DR. BENEDICT: Just one point of clarification in terms of HACCP concepts. Typically these types of activities would be handled under a prerequisite program, Good Manufacturing Practices, et cetera.

However, in those instances where the hazard analysis has indicated that a higher level of control is necessary because insects have been identified as an important source of microbiological contamination in this instance, and there are no subsequent controls that would take care of this problem, then it might elevate insect control up to the point where it would be a critical control point and treat it as such. But this would be highly dependent on a very detailed hazard analysis before, in most instances, this would be considered a critical control point.

DR. BENEDICT: Mr. Harris?

MR. HARRIS: I'm an importer of dried nectarines

from Iraq. Food and Drug has never had an inspector--well, someplace where Food and Drug has never had an inspector. An analysis shows up in a Food and Drug laboratory with some rodent hairs on it. Are you still going to go, as in the past, on the types and numbers of hairs, or are you going to say we don't know the significance of these materials being imported from this particular country?

DR. OLSEN: The rodent hairs example is an interesting one. If it is a Norway rat, roof rat, one of--pretty much Norway rat, roof rat and house mouse, that are known to be indicators of insanitation, then it would be a category two problem. If it's not one of those specific fit-the-profile pests, then it becomes an aesthetic issue.

MR. HARRIS: Thank you.

DR. BENEDICT: The Chair will just ask a couple of questions. The first one is almost trivial, and that is, with respect to the allergenic substances in these mites, is this similar to respiratory things where fecal material has the bulk of the allergenic--

DR. OLSEN: In the case of the mites there are three separate allergens involved, and chemical identities there; and of those three, one is known to concentrate in the feces, the other is known to concentrate in the bodies, and the third one, they're still trying to figure out where it's coming from.

DR. BENEDICT: So that means that identification of the presence of a mite gives you a probability of finding two out of the three. And if the mite has visited, in your words, and left, the mite dung might not be identifiable and you still might have a difficulty. Is that--

DR. OLSEN: Exactly. That's why we're looking into direct testing of the allergens, because in fact the feces of the mites have the highest concentrations, also. Yes, exactly.

DR. BENEDICT: And then the second thing that I wanted to ask was with respect to the field guides, which I think are an exciting thing to provide, but one begins to wonder how far these things will be driven, in the sense that you can publish a very nice field guide to distinguish the 15 organisms or so that you have, and then that may become inadvertently some kind of regulation, in the sense that now people must be trained to use the field guides. At what level will FDA insist that the field guides, helpful though I'm sure they are, at what level will the FDA insist that these field guides be used? That everybody has to buy them, the suppliers--

DR. OLSEN: No, no.

DR. BENEDICT: --the producers. Who?

DR. OLSEN: No. If there's another way to--as a matter of fact, they're put out as a help. There's other

materials available already. They're just not as user-friendly as what we've designed these for. As a matter--actually, Bernard Greenberg's book has excellent keys and excellent identification aids, and CDC has put out some material that can be applied to the same purpose, even though you have to realize that you're also dealing with some of the carriers of blood diseases in there and you have to sort those out.

DR. BENEDICT: Okay. Are there additional questions? Dr. Applebaum?

DR. APPLEBAUM: Just one more question, if I could, and this goes back to the allergenic mites. Because the field of allergy is continuing to evolve, and at this point in time answers regarding thresholds are nonexistent, and when I'm considering, you know, the potential for regulatory control of a mite, and at this point in time, because we don't know what that threshold is, you have to consider that if you see a mite or a piece of a mite, there's a potential for anaphylaxis to occur in a person who is sensitive.

So I guess I was just reading the paper, Mr. Olsen, in terms of this avoidable contaminant, as you called it. And then I started thinking, okay, the methods that might be proposed for control, and then getting back to risk assessments that have to be considered, because you have to

address concerns regarding risk substitutions and risk comparisons, I was wondering if you can share with us some of the agency's discussions or considerations on this particular issue?

DR. OLSEN: It's really such a new issue, we haven't had extensive discussions in that area. I mean, quite honestly, we just became aware of it in delving into the literature for this strategy. It's just coming out now.

The only thing I can say that's reassuring is that, you know, as far as allergenic mites, it will take a decision by the Health Hazard Evaluation Board. It's not going to be let out to anybody to say, "Ah, ha, a tenth of a mite and you've got a problem." There will have to be careful consideration if that issue comes up.

There is a lot of--there is a volume of literature regarding the respiratory allergies, and people have proposed thresholds in that area, but they are expressed in terms of square meters of bedding or things like that. But they give you a feel for that it's a very small number of mites that can actually invoke an allergic reaction in sensitive people.

The only other thing we have for comparison is carmine dye, which is also allergenic, and there has been research done in that with published levels that are threshold levels for carmine dye. I can't bring them out of

my head right now. But for right now it would take a board of experts, really, to decide that.

DR. APPLEBAUM: I guess my concern is, you know, the food industry has been dealing with the issue of allergens as it relates to it being essentially impossible to guarantee with 100 percent certainty any type of cross-contact that might occur, and the agency has realized this, and the issue regarding labeling is something that we are--you know, is very much on the screens of industry. And I'm just wondering that perhaps if these mites, the prevalence of these mite allergies continues to increase or increases, that that might just be another means of looking at this particular issue.

DR. OLSEN: Yes, yes.

DR. APPLEBAUM: Because the last thing you would want to do is to use perhaps some type of a control that raises a bigger risk than perhaps--

DR. OLSEN: Right.

DR. APPLEBAUM: --to more of the population than perhaps these mites do. Okay.

DR. BENEDICT: Okay, so we reach the point where we asked for your opinions, and perhaps before we do, we'll ask Mr. Harris if he'd like to make a comment about--or maybe not, if you don't wish to.

MR. HARRIS: No, I was--there's really nothing I

should add at this point. Thank you.

DR. BENEDICT: Okay, so I'm going to look over to the boss here and make sure I'm doing this right. Customarily, we will ask you a question, and the appropriate response would be yes or no, and we'll collect everyone's responses at one place on the tape. And then we will ask you for comments, if you wish to elaborate on that question, and then--in other words, to state your reasons why you voted yes or no--and then we will move to the second question. And so we will ask members of the Food Advisory Committee for their responses to the questions.

And question one: Based on what you have heard at this meeting, and on your expertise, knowledge and experience, do you believe that the approach described provides an appropriate scientific basis for an enforcement strategy that would include a Compliance Policy Guide for filth and extraneous materials?

And why don't we start with Dr. Applebaum?

DR. APPLEBAUM: The benefits of having a last name with an "A".

DR. BENEDICT: And being a senior member.

DR. APPLEBAUM: Thank you, Mr. Chairman. My short answer, because you could have qualifications from now until the end of the day if not tomorrow, my short answer is yes.

DR. BENEDICT: Thank you. Nicely done.

Dr. Brackett?

DR. BRACKETT: Yes.

DR. BENEDICT: Ms. Richardson?

MS. RICHARDSON: Yes.

DR. BENEDICT: Dr. Russell?

DR. RUSSELL: Yes.

DR. BENEDICT: Dr. Montville?

DR. MONTVILLE: Yes.

DR. BENEDICT: Dr. Sigman-Grant?

DR. SIGMAN-GRANT: Yes.

DR. BENEDICT: Dr. Hotchkiss?

DR. HOTCHKISS: Yes.

DR. BENEDICT: And Dr. Kuzminski?

DR. KUZMINSKI: Yes.

DR. BENEDICT: Thank you. Now, if anyone would like to elaborate on your enthusiasm for your "yes," this would be an appropriate time. If not, we can move--yes, Dr. Hotchkiss?

DR. HOTCHKISS: First of all, one of the questions was, does this move towards establishing a scientific basis for this, and particularly the papers that Dr. Olsen has read, he should be congratulated for. They I think very nicely summarize the science currently.

Dr. Brackett's point, though, about the science needing advancement I think is very well taken, that reading

those papers, I came to the conclusion--and having started out in this area actually 25 years ago or more, having to set up such a procedure for a grain products company--that the science has not advanced very far and does need advancing and the use of some more modern techniques for identifying biological materials is probably very appropriately applied here. So--and I also agree that it's time for FDA to revise its policy in this area, probably past time for that.

In my mind, then, the question becomes, how well has the agency to date translated the science into policy? And I've got to point out, as I've already said, that we really haven't seen the policy. The policy is still being formulated, and we really don't know, and so any responses, at least that I have, have to be formulated in the light of not really understanding for sure how the science is being translated into policy.

Certainly I think setting three levels of concern is appropriate. I would point out to the agency that consumers don't make such differentiations, though, and that last category is exquisitely important to consumers, and--

DR. BENEDICT: I haven't asked you about question two yet.

DR. HOTCHKISS: --and I would hope that the agency does not sacrifice concerns or interests about the

aesthetics, if you will.

The question in my mind is how well these three levels then translate into policy, both from the standpoint of protecting consumers and operating in the agency, but I think the agency should be encouraged to move forward with this and see what works.

DR. BENEDICT: Does anyone else have a comment on question one? Dr. Kuzminski?

DR. KUZMINSKI: Thank you. I've been involved with food processing for about 25 years now, and I think this is, for those of you who haven't been that close to that area of the food chain, I think this is huge. I think it's a good start. It's a difficult area to bring science to, out of which policy can form. It has traditionally been based on experience and knowledge of those people involved.

I do believe it takes the agency approach in this area to a new level. I would encourage the agency to use the terms "public" and "predictable" rather than "transparent," because of the need for collaboration, especially in this area, as has been pointed out. And I can't over-emphasize, I think, the challenge of implementation that will be and the training requirement to fulfill that, and I dearly hope that the resources for that training will be provided.

DR. BENEDICT: Dr. Applebaum?

DR. APPLEBAUM: And you--this is just a little bit of forewarning, I guess, for lack of a better term. But what will constitute scientific basis will be probably debated at some point in time, similar to what we have all gone through as it relates to what constitutes "significant scientific agreement," tomorrow's discussion. But just as a little bit of a heads up, there is the strong potential that the scientific basis, whatever is identified, whether you're on the side of the angels or not, will still be an issue. So I'm just preparing counsel for that one, because that's surely to arise.

But I agree with everything Dr. Kuzminski has said, that this is an excellent example of a new--of the new millennium for the agency, if I could use those words. We've always been a strong critic, as many of you know, in terms of the need for FDA to prioritize and the FDA to be scientifically based as it relates to regulation, so I personally applaud this effort.

DR. BENEDICT: Anyone else? Just as a brief interjection, it would appear certain members of the committee are suggesting that more funds, more resources, are necessary. In case Congress reads this transcript, and I'm sure they will be pouring over it this weekend, I just thought we'd put that in.

Question number two: From a public health point