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ELWDEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

APPLE CIDER FOOD SAFETY

CONTROL WORKSHOP

VOLUME I

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9:00 a.m.

Room 305A
Hubert Humphrey Building

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P R O C E E D I N G S

MR. SCHWALM: If we could have people take their seats, please, I think as you look at the agenda, we have a full agenda, and we want to try to stay on track as much as we can.

Just a couple of administrative things to let you know about, and then I'm going to turn it over to our people who will start the conference. The first thing is bathrooms. You go back past the elevators, out the door here, take a right through the General Counsel's doorway and they are immediately on your right there. There is a drinking fountain past the elevators on your left there.

As you can see, we are registering everybody. We expected to have maybe 40 or 50 people at the conference. We've got over 70 that have registered, so we'll be using all of the chairs. Maybe we'll have some standing only, I'm not sure, so we are trying to limit this to registered people, and please make all the chairs available.

Handouts, you will have some. I handed out LeeAnn's talk which she will be talking this morning, and if you don't have one, they're up there. We will also have some additional handouts and some materials to add to your notes, and if we could do that at the lunch break, that will I think expedite things. So just kind

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of keep an eye on the table and make sure that you've got everything that you need.

In terms of lunch, there's a cafeteria up on the top floor, which is one floor up, and that's probably going to be your most convenient facility. Otherwise you can go back out the building to the subway stop, if anybody came on the subway, which is going back out the building to the left and then down two blocks to the left, and there are some facilities, restaurants and fast food type places, beyond that, also salad bar type places beyond that. I'm not sure to what extent in terms of time-wise, how long it would take to do that.

Another thing is, for people that we are-- speakers and other FDA people that we have been paying for to attend the conference, Brenda over here is going to be doing your travel vouchers and--

MS. PINKNEY: Wait a minute.

MR. SCHWALM: Okay, let Brenda talk, then.

MS. PINKNEY: What you're going to do is, you're going to do your vouchers. Instead of giving them back to your people at your home, whatever, you're going to FedEx it to me, I'll get it signed, and then you--if you process it through your office, it's going to get lost.

Send it to me, let me get Nicky to sign it, put the

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numbers on it, and it's done. If you overnight it, I guarantee you'll get it back fast.

MR. SCHWALM: Okay, thank you. Let me turn it now over to--are there any questions in terms of administrative types of things?

[No response.]

MR. SCHWALM: Okay.

DR. MILLER: Good morning. My name is Art Miller, with the Food Center here at FDA. I wanted to just quickly run through the program, to kind of give you a blueprint of where we're going, what we hope to accomplish, and with an emphasis on trying to stay on time. You should all have copies of your program in your workbooks.

This morning we'll have some introductions from the FDA, why we're here, what the problem is with unpasteurized apple cider, and current thinking on this question from FDA. And then we'll move into essentially a, you might want to call it an "orchard to jug" scenario of interventions that may contribute to the solution of the problem, so we'll then move into things like Good Agricultural Practices as currently practiced.

We'll hear a talk from USDA, from the Extension point of view, and then we'll move into the plant, with a couple of promising intervention technologies, and then

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continuing into post-pressing juice control measures, and then we'll be having Q and A sessions along the way.

And then starting on Friday, tomorrow morning, we'll talk about quantitative risk assessment and try to pull some of the current thinking together about promising or best control practices, and then try to finish up with a roundtable discussion on regional issues. As I'm sure you're all aware, what's true in apple cider making on the East Coast is not necessarily true on the West Coast or the Midwest, so we tried to bring a variety of speakers, each representing a different part of the United States, and then we'll have a close-out. So we should be done by noon tomorrow.

Let me mention a couple of things. I believe you have an attendance list, registration list. If you look through who's here, you will find a common theme, that the people who are in the audience more than anybody, anything else, represent what I would call Extension and not the actual producers so much, although we have a few producers, but we view you as the conduit. We don't have a--okay. All right. Okay, then let me give you an idea of the demographics.

There are a number of people from the States. In fact, maybe, can you identify yourselves?

[A show of hands.]

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Okay, these would be State government. Okay, how about academic?

[A show of hands.]

Okay, how about trade associations?

[A show of hands.]

See, it's starting to fall off. How about actual juice makers?

[A show of hands.]

See? So that ought to tell you something. The information that you're going to receive today and tomorrow, the handouts that you have, we consider as conduits, and we consider you a conduit for transferring that information to the people who really have the need to know, and that is those who are engaged in producing unpasteurized apple cider.

So we hope to share some information about current thinking, current technologies, promising future technologies, but we hope that you will take that information and transfer that back to the folks who really need to know that information.

There will be a transcript of this meeting, and so we ask that you speak loudly. If you have a question or you want to make a comment, please identify who you are and your institution so that we can capture that in the transcript. We consider all the comments important

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and we want to make sure that it's properly attributed to the source.

Okay, any comments or questions before we actually move into the program?

[No response.]

DR. MILLER: I want to introduce Dr. John Kvenberg who is with the Food Center. John historically was the division director for HACCP, and currently he is the deputy director of the Office of Field Programs. John has been involved in this issue since the onset. John Kvenberg.

DR. KVENBERG: Thank you, Art.

Good morning, everybody. I thought it was very interesting when I saw a show of hands of who is represented here. In a positive vein, we hope that today's conference will be one where we can initiate a dialogue to get to the next phase or the level where we need to be in food safety in the area of juice products, specifically apple juice products.

Taking you back to an earlier history, I think that in the area of apples obviously there was a shaking event in apple juice that caused the initial concern in food safety about fresh juice products. As a piece of history that went along with that, I think we will be hearing today a lot of the work that we have done on the

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science and technology front at the Food and Drug Administration: interacting with regulators at the State level; working with the producers, the industry itself; and, very importantly, the science and academicians that are also involved in tackling these issues.

The idea of microbial food safety is really at the forefront, I think, these days in the news. Obviously we are in the best of times and in the worst of times, in that the resources that are being devoted to protecting the public health in the area of microbial hazards have never been as focused as they are now, and we are on the point of curve of trying to reduce the risk to food-borne pathogens in the food supply.

With that comes change. I will personally recognize the fact that cider production and apple juice production has a history in the United States that probably goes back before the formation of the United States, into our colonial times. The aim of this conference today is to work with people who are presenters and interested parties in this audience to get to the point where we can improve food safety in the very specific area of apple juice production in the United States.

So that's all I really have for general remarks to begin with. I know we have a long program to go

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through today, and I wish you all a successful conference. I'll be here for as much of it as I can, to participate. This is really an important area for the Food and Drug Administration, as Art has said, I have been in this from the beginning and I certainly feel a personal investment in this effort.

Thank you.

DR. MILLER: The first question that we hope to use as a point of departure for the rest of the meeting is, why is there a problem? What is the problem? And I'd like to call up Dr. LeeAnn Jackson, who will talk to us about the food safety hazards associated with apple cider processing. LeeAnn?

DR. JACKSON: Good morning. I don't believe that everyone has a copy of my presentation in their notebook, so if you didn't pick it up on your way in, it is currently laying over here on the table, for those of you who didn't get a copy.

Now really all I'm going to be talking about are just the microbiological hazards, because I think that is what everyone is most concerned about, the ones they are probably having the most difficulties trying to determine what they can do with their product in order to make sure that they're controlling microbial hazards.

Just a brief outline. I'm going to talk about outbreaks that have been associated with apple juice and cider, some juice processing issues in general, and then wrap up with some overall characteristics of microorganisms.

I guess in the past 20 or so years we've had outbreaks associated with apple juice and cider, and they have primarily been associated with three different microorganisms: E. coli 0157:H7, which you have probably heard about ad nauseam; you're probably tired of hearing about E. coli 0157:H7. Also there was an outbreak with Salmonella typhimurium. And we've also had a couple of outbreaks with Cryptosporidium species, which is a parasite.

Back in 1980 there was an outbreak that occurred in Toronto, Canada that was associated with fresh apple juice. They're not quite sure exactly how many people became ill due to the consumption of this product, but they believe that it was somewhere between 13 to 14 children had bloody diarrhea which subsequently developed into hemolytic- uremic syndrome. The Canadian officials were not able to isolate E. coli 0157:H7 from the product or from any environmental samples, so it was strictly based upon epidemiological investigations that they made the link with the fresh apple juice consumption.

Then in 1991 we had an outbreak in Massachusetts that was associated with fresh pressed unpasteurized apple cider, 23 illnesses. Sixteen of those had bloody diarrhea. Four people developed hemolytic-uremic syndrome. Within that outbreak, the processor stated that he did not wash or brush the apples prior to pressing and he did not use any preservatives within his product.

In 1996 there was an outbreak in Connecticut, unpasteurized apple cider, 14 illnesses. Seven of those people were hospitalized. Three of them developed hemolytic-uremic syndrome. The processor stated that he did use some dropped apples, which means they fell on the ground and then he took them from the ground and used them for making apple cider. He stated that he did wash and brush the apples prior to pressing them, and he did use 0.1 percent potassium sorbate within his product.

Probably the outbreak that most everyone is very familiar with is an outbreak that occurred in 1996 in the northwestern United States, in Washington, California, Colorado, and in British Columbia. This outbreak was associated with a commercially produced unpasteurized apple juice. There were 70 illnesses. Fourteen of those developed hemolytic-uremic syndrome, and unfortunately with this outbreak there was the death of one child.

They were able to culture E. coli 0157:H7 from an unopened retail container in this outbreak, but they were never able to determine what the source of contamination was. They did investigations of the facilities, they did investigations at the orchard which supplied the apples; they could never determine the cause for the source of the contamination.

And then also in 1996 there was an outbreak in Washington State that was associated with a church function. They were pressing their own unpasteurized apple cider, and six people became ill in this outbreak.

There was only one outbreak that occurred that was attributable to Salmonella Typhimurium. This occurred back in 1974 in New Jersey. There were 300 illnesses that were associated with the apple juice consumption--sorry, the apple cider consumption. They did use dropped apples from an orchard that had been fertilized with manure, and this was a very large processor.

And there have been several outbreaks that were associated with Cryptosporidium species in apple cider. In 1993 in Maine there was a fair that was held in which they served unpasteurized apple cider. There was a school-organized field trip in which they all went over

to the fair. There were 160 primary and 53 secondary cases.

What they mean by that is that you had 160 people who were initially associated with consuming the product. The secondary cases occurred due to transmission of the microorganism from the initial case to a subsequent case, like through their children or somebody else in their home, and they had been preparing food and they had contaminated the product with the E. coli 0157:H7.

When they were making the apple cider at the fair, they collected the apples from trees by shaking the trees over a truck, and then they collected apples that had fallen onto the ground, that didn't quite make it into the truck. They then stored those apples in wooden crates, and they rinsed the apples the next morning with a municipal water supply. They did find *Cryptosporidium* oocysts in the apple cider as well as in the cider press, as well as in the stool specimen of a calf on the farm that supplied the apples.

In 1996 there was an outbreak in New York with unpasteurized apple cider. There were 20 confirmed and 11 suspected cases. All the apples that had been used for making this apple cider were purchased from one orchard. The orchard owner said that he only used picked

apples that were sold to the cider mill. They washed and brushed the apples with well water prior to pressing the apples. They did not use any preservatives when they were making their apple cider.

They were never able to determine the cause of the outbreak or the cause of the contamination in this, but they postulated that it came from well water which had been used to rinse the apples, and subsequently the well water was found to be positive for coliforms. And there was also a dairy farm that had been located across the street from the cider mill.

Now, to move into some juice processing issues, three broad categories I thought I would talk about are just the issues of pressing/squeezing/grinding of fruits and vegetables into making juice; the aspect of bruises and injuries to the fruits and vegetables and how they can contribute to microbial contamination; and then also the transfer of microorganisms via insects.

Now, with regard to the pressing, the squeezing and grinding of fruits, I know that during the processing of apple juice and cider you maybe wash the outside of those apples before you press them. Recent research has shown that if you place apples in wash water that is cooler than the actual temperature of the water, they're going to internalize the water through the stem scar into

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the apple. So if your water happens to contain any pathogenic microorganisms, you're going to internalize that into the apple, and no amount of sanitizer that you apply to the exterior of the apple is going to remove any internal contamination of the apple.

MR. COLMAN: Matt Colman, Ardens Garden. You said that if the temperature of the water is lower than the temperature of the fruit?

DR. JACKSON: Yes. If the wash water is cooler than the temperature of the apple, yes, you will internalize the water into the stem scar end of the apple.

And also any contamination that you have on the exterior of the fruit, if you don't thoroughly wash it and then you press the fruit, you're probably going to be incorporating whatever is on the outside of the fruit into the juice.

Now, bruises and injuries, if you have any kind of bruise or injury on the fruit, it can serve as a point of injury for pathogens. Bruises can create soft spots which may then allow for the entry of pathogens. If somehow the fruit itself becomes punctured in any way, that can serve as a point of entry for pathogens, and also the actual process of the puncture itself may actually introduce food-borne pathogens into the interior

of the fruit. So you need to be very careful about the types of fruits that you're actually going to be using to make your juice.

And I'll talk to you briefly about the transfer of microorganisms via insects. This is some very recent research that was done by Dr. Robert Buchanan. He has shown that actually fruit flies can transmit food-borne pathogens within cider operations. They took some fruit flies and they allowed them to walk around in a culture, I think, that had some E. coli in it, and then they flew around in a little container that they had, and they actually found that they had the same strain of E. coli 0157:H7 that had been on the fruit flies, they could then find it on the apples themselves. Okay? So you need to be very careful in, you know, trying to control the introduction of insects into your processing facilities.

And then to finish up talking about some general characteristics of microorganisms, microorganisms can be very hardy little critters, and they can develop resistance to a number of different processing aids, such as the use of acid or preservatives, sanitizers, heat, and a number of other control methods that may be used.

So when we're talking about acid, there are some strains of E. coli 0157:H7 that actually have the ability to survive exposure to acidic conditions for a very long

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period of time. Research has found that E. coli 0157:H7 can survive in apple cider with a pH of 3.7 to 4.1 anywhere from two to three weeks when stored at refrigeration temperatures of 4 degrees Celsius, and also 31 days when stored at 8 degrees Celsius. So you can, with E. coli 0157:H7, you can actually enhance its acid resistance by refrigeration.

Malic acid, which is a common component within apple juices, it's one of the most gentle organic acids so it's not going to have much of an effect on E. coli 0157:H7. You can also induce increased acid tolerance with E. coli by prior exposing it to mild acid conditions.

And also in many instances you can have cross protection, and what I mean by that is that if you have a microorganism that has developed some type of an acid resistance, frequently it will also develop a resistance to another type of processing measure, like it may develop a resistance to particular sanitizers or preservatives, or possibly also different types of heat parameters.

And also if you have an organism that has developed a very high acid resistance, it may also actually survive, you know, the route through your

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gastric system, because you do have very high acid, low pH conditions within your gut. Okay?

The resistance to preservatives, most preservatives are ineffective against *Cryptosporidium*, and that's because it is a parasite and it has a very tough exterior surface, so preservatives are generally ineffective against *Cryptosporidium*. And there has been some research that has been done with apple cider and *E. coli* 0157:H7, with sodium benzoate and potassium sorbate and its ability to develop resistance to each of these two preservatives.

Microorganisms can also develop resistance to a number of different sanitizers. Many of them, many sanitizers have been evaluated in the juice industry, and depending upon the fruit or vegetable and the pathogen of interest, some sanitizers will be much more effective than others. So all three of these different sanitizers I think have been utilized within the apple industry, so you just want to try and make sure that you're not going to develop some sort of a resistance to these different sanitizers.

Also with regard to heat, in many instances the storage conditions of the product will influence the ability to destroy a pathogen within it. And as I stated earlier, *E. coli* 0157:H7, you can actually have enhanced

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survival by lowering the storage temperature of the apple juice and cider products.

And in the last slide, these are some new types of technologies that are being looked into as control methods for the juice industry. They're looking at high hydrostatic pressure; microwaves; the use of irradiation; as well as pulsed light.

Now with high hydrostatic pressure, depending upon the pathogen, you may have differing susceptibilities to its ability to be destroyed by this type of a process, and you may also have differences within a genera. So you may actually have some strains of E. coli 0157:H7 that may not be as readily destroyed by this type of a processing parameter as some other strains may be. And also if you have sometimes a high heat resistance, you may also have some resistance to high hydrostatic pressure processing.

Also with microwaves, some bacteria are more readily killed in water and apple juice type products than in apple cider. They say that perhaps this is due to a difference in the pH of the products. Usually with water and apple juice you'll have a much more neutral area of a pH than you will with apple cider. Usually apple cider is much more acidic. And also perhaps there was some sort of an effect seen there with insoluble

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solids. Apple cider, usually you have much more particulate matter within that type of a product than you do within apple juice.

And there has been a lot of work done recently with irradiation and apple juice and cider products, that is still ongoing. You know, depending on the food matrix, you may have differing kilorays that would need to be used in order to ensure destruction of a pathogen.

And lastly, with pulsed light, it's a very new technology and they're finding that there is an increased level of inactivation when you're using light pulses of a very high ultraviolet content.

So these are just some examples of other processes that are being used within the juice industry as a whole. If you have any questions, I would be more than happy to try and answer them if there is time, because I do have another meeting that I have to head off to for the rest of the day.

Yes, ma'am?

MS. : You were saying that the fruit flies in the controlled study, that the E. coli was transferred, and are you extrapolating from that those flies have to be on fecal matter (inaudible) as well as the apples, or that those fruit flies (inaudible) fecal matter (inaudible)? What are you--

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DR. JACKSON: I don't know about the actual, you know, habits of fruit flies. That's not something I'm very well versed in. But there is a possibility that flies themselves could possibly also land on fecal matter, other decaying material, then get into a processing establishment and actually contaminate apples that are going to be used for pressing.

DR. MILLER: I think it's important to keep this all in perspective. This research shows potential, it does not show probability of occurrence, and it's very important to realize that it may be a factor but there's no proof that it is a factor.

DR. JACKSON: Right. It's just an area that you need to be aware of and just thinking about. Yes?

MR. : There was a paper that came out of Japan that showed that flies were a vector, common household flies were a vector of E. coli 0157.

DR. JACKSON: Yes, sir?

MR. : Going back to your history, you said in '80 they didn't, in the Toronto case they did not isolate 0157. Is that true for the '91 in Massachusetts and the '96 in Connecticut, as well, they didn't actually isolate it, it was just epidemics that were reported?

DR. JACKSON: I don't have any information here which actually shows it to be isolated from the product,

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but I can go back to those literature sources and get the information, I can give them to Dr. Miller and he could provide you with that tomorrow.

DR. MILLER: I think very often the smoking gun is not in the product because you have to realize that until all the pieces come together, weeks or months can go by until you actually can put your hand on some of the product, and oftentimes because it's a perishable product, you never get your hands on the lots of product that are actually responsible for the outbreak.

But when you see clusters of hemolytic-uremic syndrome, and at this point it's the number one cause of kidney failure in children, you always--physicians regularly are alerted to 0157:H7, so the epidemiology is often the way to figure out what would have caused this.

DR. JACKSON: In most instances if you have real good epidemiologists within a State, they can pinpoint the food vehicle very quickly. Sometimes, though, they're not notified of illnesses until much, much later, after the product has already been destroyed and it's no longer on the market, so they can't go back and test it.

Yes, sir?

MR. : We need to remember also that in that 1980 outbreak they hadn't recognized 0157:H7 as a food-borne pathogen.

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DR. JACKSON: That's right. It wasn't until 1982 that they actually recognized that E. coli 0157:H7 was a food-borne pathogen.

MR. : But keep in mind, too, that the surveillance systems still are not as good as they should be to pick these things up, because you're dealing with isolated instances. If you did not have the system they have in the State of Washington, they likely would not have picked up the 1996 outbreak.

They picked it up because they were looking for E. coli 0157:H7 from hamburgers, because of the hamburgers. Because they had a required reporting system by physicians, they were able to pick that instance up. If they hadn't had it, you might have missed that. Certainly if that had not come out, the church incident, which was a separate item, would never have been picked up.

DR. JACKSON: That's true.

MR. : There are a lot of those going on, small outbreaks, even here on the East Coast, that we don't have picked up because we don't have that same surveillance system.

DR. JACKSON: Right. Some health departments are a little bit further ahead than others in their ability to actually investigate food-borne outbreaks. I

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think now that most States are actually required to report cases of E. coli 0157:H7 to CDC. They weren't until probably within the last several years.

Any other questions? Yes, sir?

MR. : Yes. Microbiological concerns obviously are in the forefront. 0157 is very prominent (inaudible), but they're running into problems also with heavy metal contamination, copper, lead. Are you aware of any studies going on down that line at the Center or--

DR. JACKSON: I'm not aware that CFSAN is doing any studies in that area. Are you aware of any?

DR. MILLER: No. The one thing that is on some people's radar screens is patulin, which is a microcosm.

MR. : We're running into a situation whereby we have non-food-grade--non-food-grade--non-food product contact surfaces, (inaudible) equipment, and tolerance levels in that is something else that (inaudible).

DR. JACKSON: Any other questions?

[No response.]

DR. JACKSON: Thank you very much.

DR. MILLER: We will have a discussion period, but I think, LeeAnn, you have to leave now?

DR. JACKSON: Well, yes. I have another meeting. I'm sorry.

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DR. MILLER: There's another public meeting on strategic planning for the food safety initiative going on, and I'm sure some of the attendees at that meeting would be here under normal circumstances, but LeeAnn is over across town.

DR. JACKSON: Doing double duty.

DR. MILLER: With that presentation as backdrop, of course the agency recognized that we had a problem, and FDA is a changing agency, moving from command-and-control type of inspection, we're moving to one of an organization that is setting performance standards, which gives processors far more opportunities to choose their own interventions for meeting those standards.

But of course, along with that freedom goes responsibility, and that raises questions about how do you validate your process, what do you use for verification, and we have asked John Kvenberg to talk about some of the thoughts that are going on about these questions and to provide some recommendations to you folks. John Kvenberg?

DR. KVENBERG: I will have to apologize. I'm a low tech kind of guy, so we have overheads here instead of computer mouse buttons, but I'm coming along with the curve.

Okay. Thank you. Back again. Just following on the remarks that were just made by Art, I think in simplest terms the concept of a performance standard is familiar to everybody in the form of standard pasteurization procedures. It's a tried and true way of providing public health through a known set of time/temperature relationships. In milk, you have the ability with heat transfer process to assure thermal destruction of the pathogens in every particle of the milk product.

What Dr. Miller said relative to the concept of the performance standards provides a step back to a little bit more of an abstract system, and a discussion of the concept of cumulative steps also confounds the simple nature of providing control through control steps associated with various avenues of how you can achieve public health safety through operations in a food processing environment.

Just as background, if I may begin there, borrowing from the words of our National Advisory Committee on Microbiological Criteria for Foods in its discussion of identifying hazards under the HACCP or Hazard Analysis, Critical Control Point concepts, they have defined the control measures as something that, when you apply them, must be useful in the process of

preventing, eliminating or reducing the hazards in the foods to acceptable levels.

It seems reasonable to ask the question, well, preventing and eliminating a hazard are easily understood. What is an acceptable level?

A performance standard in its general sense is basically the benchmark or the bar used to control measures that will reduce a hazard when you have an acceptable target level of performance that can be applied. And a performance standard can be applied to a single control measure, such as a time/temperature/heat or an application of high pressure, some of the technologies that Dr. Jackson spoke of in her previous talk.

But there is also the opportunity, although a more daunting task, to assume that through various steps you can have a cumulative process that will allow for achievement of a performance standard. Whether or not that's relevant to a specific commodity is dependent on many factors, including the food itself. Is it amenable to such kinds of treatment?

Performance standards themselves basically, as I would like to say in a common vernacular, sets a level or sets the bar to the level that is expected for achieving the result for public health safety. By doing this, it

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creates an atmosphere for scientific studies on various avenues that may be approached in order to assure that you have a safe product, and it provides latitude in the ability to do it.

Getting into how you can demonstrate the fact that a performance standard is effective speaks to the issue of how you would validate that a particular process that is applied to a system is useful and works. And part of what I would like to talk about this morning is various avenues of looking at how you can validate the ability to attain a performance standard.

This can be accomplished through various avenues of looking at how it can be accomplished, through studies that are conducted; through laboratory investigations, primarily with pathogens themselves; and actual work within in-plant environments suited to the specific structure, whereby you would have to use some sort of indirect measure or surrogate type of observation to achieve the kind of effect that is expected in order to bear out achieving the performance standards.

Within this comes other study design considerations, where you have individual controls, entire process evaluation control systems that are tailored to a specific operation. This gets to the question of a new day relative to flexibility, and how

you can achieve a performance standard dependent on a particular situation, so that's the concept. Yes?

MR. : May I ask what you mean by surrogates, meaning--

DR. KVENBERG: Yes, if you'll bear with me, I'll get to what that means. The short answer is, other bacterial organisms that would behave in a system, including how they would die, that are very similar to the pathogen of concern. I'll get into some specific examples of that in a moment.

What I think really brings us all to a focal point is that FDA last year moved in our labeling requirements, in a specific codified rule, to where the industry that dealt with fresh juice basically was faced with a choice. If fresh juice were to be produced, and in the absence of preventive controls, FDA has called for in our labeling regulations warning statements to be associated with the production of juice products.

Now, I will say that that still does not excuse operation, even with a warning label statement, a departure from Good Manufacturing Practices that must be applied to the food products. We expect these foods to be safe and adequate preventions to be taken, but the actual rule speaks to the performance standard as is mentioned in that rule, and it goes to the concept of a 5

D reduction of hazards as the benchmark for performance standards for juices, and it requires reduction of the hazard to that acceptable level.

Control measures that are being applied in fresh juice, basically in apple juice, to my knowledge we have not got--I have no information on a 5 log reduction on fresh apple juice that I can cite where there's an example. If a question comes up on that, I simply have no answer at this point about how that would be achieved. We haven't addressed the issue.

Well, since I have mentioned the term 5 relative to a 5 log reduction, I think many people in this room understand it, but I feel just so that everyone's on an even playing field, the simplest answer to a 5 log reduction standard as devised by the National Advisory Committee's recommendation was to reduce the organisms by a factor load of 100,000.

In other words, every time you take a number from 5 to 4, 100,000 would go to 10,000, would go to 1,000, would go to 100, would go to 10, would go to 1. Another way of looking at it, relative to the advise we were provided by the Committee, is a reduction of the risk to be less than 1 in 100,000, which was also part of that same enactment from the National Advisory Committee

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for recommendation on establishment of a performance standard.

MR. SANFORD: Would that be FDA's definition of legal pasteurization of apple juice at this point in time?

DR. KVENBERG: Yes. I think the answer to that would be, if you were talking--if I understand your question correctly, will a time/temperature relationship that would give you a 5 log reduction, pasteurization, would that meet the definition, and it would.

And I think that time/temperature relationships for pasteurization requirements are already worked out in the literature relative to what time and temperature would be needed in apple juice to achieve the standard. And I think the industry is--I'm not the technical person to ask that question, but the time and temperature relationships are, I think, defined for 5 D for apple juice.

MR. SANFORD: Would that also include a statement on properly designed and operating equipment?

DR. KVENBERG: Yes. Well, as I basically--

MR. SANFORD: Also, because--

DR. KVENBERG: Well, as I basically--let me answer if I can from that standpoint, from the question

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or the remark I made earlier that we would expect total conformance with our requirements under our Good Manufacturing Practices. That would ensure that you would have a pasteurizer unit that was in operation, in essence in conformance with the requirements that we would have for any pasteurized operation.

You could measure that against our milk basic standards, that basically would look at press type operations with holding tubes that are timed. Ideally, although it's not mandatory, flow diversion valves if you had a deviation in the process, and recording charts, would all be applicable to that heat process.

There is an alternative that can be used in addition to, which is the high temperature/short time pasteurization, which is vat pasteurization, which still is an effective means of control. That's a cooler temperature for a longer period of time, and you've got a static product. I think the folks with the technology background and understanding really basically have the information necessary to get into how pasteurization would work.

MR. SANFORD: Would we really need that? I've dealt with pasteurization for better than 20 years. My background is in dairy processing. And the apple juice

industry, I can find nowhere anything that I can hold in my hands to show me what a legal pasteurizer is.

Can I design a legal pasteurizer? Absolutely. No problem. Do it routinely. But there are no standards that you can adhere to, and there is equipment being sold that is junk, and it is creating a great problem out there for us who are regulators, for those people in the industry who are being greatly misled by equipment manufacturers, and that sort of thing.

So we need something like this. We need something to hold in our hands to say this is what it has to be like. I've dealt with both vat and high temperature/short time.

DR. MILLER: Could you identify yourself?

MR. SANFORD: Oh, John Sanford, Tennessee Department of Agriculture. And it is very frustrating to work on that line, and I'm not venting towards you.

DR. KVENBERG: Right.

MR. SANFORD: I'm just saying we need something in hand, and to this point in time no one within FDA has been able to present that.

DR. KVENBERG: Well, if this is a gap and something--and it sounds like something very useful to do, I think it's something we ought to take as a recommendation and pursue for establishment of minimum

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guidelines for pasteurization equipment and application in pasteurized apple juice.

MR. SANFORD: That would be fantastic, absolutely fantastic.

DR. KVENBERG: Well, thank you. That's exactly the kind of thing--

DR. MILLER: A good recommendation.

DR. KVENBERG: --recommendations of things we're looking for to have done, and I think that is a doable thing.

MR. SANFORD: You're going to find a tremendous number of people are buying systems right now which are nowhere close, and they're being misled that it meets FDA recommendations or requirements, which there are none. So therefore there's a statement that you may say that's true and, I mean, you know--

DR. MILLER: But it could be misleading.

MR. SANFORD: That's right, and when you get into pressure relationships, when you get into the efficacy of the recording devices, when you get into the product contact surfaces, when you get into all the basics, it's simply not there.

DR. KVENBERG: Well, it's I think something that's probably a very positive statement that you've just made, that we can basically come out with minimum--

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with guideline type information so we can work with States on what minimum processing guidelines and equipment behavior is going to be useful, so--

MR. SANFORD: Greatly appreciated and very recommended.

DR. KVENBERG: Thank you. Anybody at any time that would like to ask a question, this is an informal presentation. Please--

MR. : You don't currently do equipment approvals anyway.

DR. KVENBERG: Excuse me?

MR. : You don't currently do equipment approvals.

DR. KVENBERG: We don't do equipment approvals. What we can provide is basic guidance and comments on equipment and, you know, basically I think a minimum standard on the production of juice through a pasteurized operation. At least for evaluation purposes, we can take a look at the performance of the equipment and it's ability to do--

DR. MILLER: We have GMP regulations, though, right now that can do that.

DR. KVENBERG: That's what I said, I said earlier. What I think I heard today was provide some guidance on basically what to look for and how to

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evaluate the process. That's what I think would be useful.

Okay, if I could continue relative to the general discussion of the performance standards, just giving you a general background of the philosophy that was provided by the concept of a performance standard, is it has a good side and it has a side that is difficult. It certainly gives industry the flexibility to use new technology or different control measures as opposed to a strict, "You must do it in a specific way, by rote, with specific equipment," and there is no deviation allowed, there is no variation in the process.

A performance standard says you must meet it and you must demonstrate that it consistently can be done, so it moves away from what has been termed in the past as a command-and-control kind of approach for exactly the steps you have to follow and the equipment you must purchase.

The point that was just made is, FDA in its Good Manufacturing Practices provides general guidance. It doesn't get into the specific prescriptive type of requirements, taking pasteurization as a requirement, that could be done. But I think going too far away from that and providing no guidance or no information on the various technologies is something that we need to work

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on, and that's a good reason for this conference, to get recommendations for where we may move.

One of the great disadvantages, though, if you get away from the old white bread, plain and simple, tried and true single point time/temperature relationship or other simple technology, validation on a complicated system can become more complex and more prone to failure, to where the risk would be increased. So individual controls which are only partially effective, but can be used in combination, have to be thought of in light of how fail-safe is your system, that you are not having a breakdown in a more complicated system as opposed to single point.

Yes, sir?

DR. MILLER: Could you identify yourself, please?

MR. HAXTON: Yes, Bob Haxton, Iowa.

DR. MILLER: Thank you, Bob.

MR. HAXTON: We had the situation last fall where the--you know, we had a processor who had a problem with cider, and we had to have a recall, or they did, and the thing was, we got into 5 log reduction, and I shouldn't say nobody, but we couldn't find anybody who had done any studies to indicate what is a 5 log

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reduction, and how you would sample the apples coming in versus the pasteurized apples going out.

We ended up, you know, they installed a pasteurizer that (inaudible) the PMO, and it has been validated a couple times that it (inaudible) the PMO, but it's--you know, I think the small manufacturers, at least in our part of the country, they want that specific--they would almost rather if you tell them they have to deal with the PMO and exact guidance versus--you know, because a 5 log reduction, when you mention that, you know, they're just not there.

DR. KVENBERG: Well, perhaps what we could do is, following on the previous recommendations, is you can provide maybe a footprint for someone that wants to exactly follow guidance that could be provided to assure they've got the system. That certainly would be attainable as a model for something that they could use, and a regulator at the State level say, or our own people at FDA could say, "Yes, I understand this is in accordance with the 5 log," and they can tackle it directly.

It becomes more difficult when you're getting into a system where there's more latitude in the approaches. No doubt about it, it presents a challenge.

And that I think kind of brings up this slide right here, which is how does a manufacturer achieve the 5 log reductions? According to what's on the books relative to the log reduction control program that's set forth in the requirements of the labeling rule, in order to be effective it has to demonstrate the ability for reduction of the microorganisms to an acceptable level.

The use of control measures have to be demonstrated or known to be effective control measures by accepted information, and I'll go into the specific types of things that can be used in this regard or have been attempted by the industry in this regard.

Either single control measures alone or a combination of things with others to achieve something that can be contemplated under a 5 log reduction. But, as I mentioned in the previous thing, when you get into a combination of control measures, a combination of results and a cumulative reduction, it's something that becomes more problematic and requires tight control, and may not be applicable to processors who have to continually do operations in order to rely on a 5 log operation without much margin of error.

Well, another question that would come up would be sources of information for how one gets at the question of which measures can be effected. Going into

this and looking back retrospectively for a year, there wasn't as much scientific information in the literature that one would hope, launching into this area. I think those facts are changing, and we'll hear a lot today about information in the literature and developing science that's going on now, that will move ahead.

Obviously sources of information and workshops like this, the Federal and State agencies do play a role in talking about effective control measurements.

We would call on the industry associations, where food groups are affected, and I notice that there are several representatives from food industry trade associations that have been active in this regard, and I think there's an opportunity for a partnership with regulators, both Federal and State, and industry associations to work together on sources of information on effective controls.

And also data that could be generated at an operation, by the facility itself or by a consultant, can move for a source of information that can demonstrate effective control.

This slide cites a previous operation that was something like this one, wherein we were involved with a technical workshop in two places, in Florida and California last year, where we held technical workshops

something like this, where industry basically presented its results on the citrus processing information.

Complete transcripts of that workshop are available at our web site, and we have specific information on how to get at that web site, for those of you who would be interested in further information on what was covered in those meetings last winter.

This gives you an example of some of the things that the citrus industry people who worked on this issue, and State agencies that were involved in the reduction control in citrus, were coming up to relative to log reduction systems.

Before I go into this, I think basically one of the things that came out in Dr. Jackson's talk is something I feel the need to mention when it comes to apple products, and that is, one of the very first things one has to look at in the processing of food products is, what is the food itself like and how can you process it?

One of the main theses that was put forth in the citrus apple was that if you had the ability examine and cull for sound product, no rips, no tears, no obvious intrusions into the interior of the fruit, there would be the ability or the possibility of producing that kind of product, under strict controls of sorting, to eliminate

the risk of the problem by external treatment of the fruit.

The information that you'll be discussing today says this may not be the case with products coming from apples because of the situation of the flower end--I'll call it the calyx, I'm not sure what the true botanical term is--and the inability to exclude the organism from the interior of the fruit before it becomes juice.

In any event, the concept of the 5 D, as the industry was looking at it and was moving forward with the citrus juice, included things like reductions that could be expected from what would be considered a normal GMP-based practice of allowable fruit in the citrus area that would be okay for processing according to quality standards that they had established for themselves, down to the irreducible minimum of a true sort with no defects.

This is basically a difficult operation, when culling needs to get down to a zero defect kind of program, and it is labor-intensive. However, industry had done some work to show that this additional sorting operation could reduce the association of pathogens or of surrogate organisms, which I will talk about in another slide, to a reducible level lower than was common practice.

Secondly, the specific cleaning/washing/brushing and, very particularly, sanitizing operations on the exterior of the fruit further reduced a log reduction of the pathogenic or bacterial load on the surface of the fruit, but in specific instances in the area of citrus, that a bacteriocidal production of a waxing process that goes on in orange citrus fruit did provide some lethality. That was documented by a Florida paper that was presented by the Florida Department of Citrus.

Hot temperature control, where you basically have a heat pasteurization through either steam tunnel or hot dips demonstrates, where there were some studies that were conducted on that, and the value of the extraction process, which is different in citrus, where you have a pinpoint or a small extraction as opposed to a general washing of the fruit, did provide some sanitary benefit for a reduction of the level of potential contamination.

That was basically the approach or the attempt by the industry in the citrus group to look at a multifaceted control measure that would speak to the performance standard.

And those people that were involved in the citrus group asked for and were given an extension, I might add, on the application of the rule. They have to have a validation study now currently available, and FDA

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will be going out to look at what efforts have been made by the industry and how that has been applied by the citrus group folks that signed up for an extension of that labeling rule. That's what we're going to be doing now.

All right. Relative to validation or a study design, FDA did not speak to a specific design to require validation, so basically it was viewed by the industry-- and largely this is an experience with the citrus group that worked on this--options that the industry chose to pursue were in-plant studies using organisms that behaved as pathogens would, relative to how they behave to sanitizers, acids, heat control through steam operations, etcetera, so that their specific process could be tracked by specific organisms in the plant to look at a reduction process.

Pilot plant studies were done by some, where the actual plant operations were simulated in an enclosed laboratory environment where pathogens were actually put on the exterior of the fruit and processes were applied to demonstrate the reduction involved with that.

And then laboratory studies using the actual pathogens were involved in a large degree in some of the validation work, to demonstrate the effectiveness of a specific application such as a time/temperature

relationship of exposure to steam or exposure to sanitizing chemicals.

One of the things that is absolutely critical is, it works great in theory but you basically have to make a determination that the laboratory studies, if they are done in an abstract from an actual operating environment in a plant, need to be confirmed that the controls that are being contemplated actually work in the processing environment that is being considered.

On the approaches that the industry have taken to this to gain some additional help is use the expertise of academia or private laboratory support in development of processes and laboratory testing to simulate the kinds of tests that they use to go into this issue of pathogens or pertinent organisms for control, and actually conducting tests to simulate the process, either in the laboratory with actual pathogens or using organisms that were close surrogates to the pathogens of concern in the actual processing environment, to demonstrate what was going on in the actual process operation.

Processors can also use their own particular studies, and it is encouraged that processors do take a look at what their processing environment behaves like in actual operation, without the--obviously without the

introduction of pathogens into their processing environment.

Now we have asked also, and I think Dr. Jackson covered it to begin with, the rationale for the public health concern, but I'll speak briefly to what are the pertinent microorganisms that need control.

And it's not necessarily on the basis that these organisms present the greatest risk to the consumer as they have presented themselves in apple juice products, but more I think you need to know that the specific organism such as E. coli 0157 is more resistant to acid and can handle a lower pH environment than some other organisms, and so would be one that could be considered as a candidate for a rugged test. Likewise, Listeria monocytogenes, with its relatively high heat resistance, would be a good challenge organism to use, and perhaps in combination with E. coli or Salmonella, if those kinds of processes were applied as well, to get a true value of what you are getting as far as destruction values or elimination.

Finally, I come up with a slide with a question that was asked earlier. It took me a while to get down through the talk but I knew I would find this slide sooner or later.

Basically, we didn't define for the industry-- and again referring to the citrus industry that has done a lot of work on this--what a surrogate microorganism might be, and I think it depends on obviously the fauna or the flora or whatever, the micro or whatever, the associated microflora associated with the particular food that's under concern, in this case apples, would be applicable. But in essence any non-pathogenic microbe that has a resistance pattern that is desired to be studied would be a candidate for doing this, and has other characteristics that would be relevant to the study they're wanting to get done.

Some examples that were chosen were the lactic acid kind of bacteria associated with citrus products. One specifically, *Klebsiella pneumoniae*, which is naturally occurring, is an example of the kinds of pathogen--non-pathogen associated with foods that are naturally occurring organisms--it may be debatable if *Klebsiella* is a pathogen, I would say--that were associated and naturally occurring and were in the processing environment, could be measured.

MR. : May I ask, what is G-R-A-S status?

DR. KVENBERG: Oh, I did go over--say that too fast. That's an acronym. It's called Generally

Recognized As Safe. In other words, in the area of food additives there are certain fermenting bacteria that may be applied to a fermented food process. Any microorganism that has a status, that is used as a fermenter. Leuconostoc would be an example, perhaps, or Lactobacillus kinds of organisms, something that would have proper characteristics that we would--would have a status that we would recognize as being safe. I'm not the expert in microbial, but that's what the acronym means.

MR. : Well, wouldn't a microbe that has characteristics similar to E. coli, wouldn't that be just as dangerous a pathogen?

DR. KVENBERG: Normally not, but never say never. Obviously the best thing within a plant operation would be, rather than introducing a new organism into your plant environment, is find one that's coming in on the apple products, that's naturally in the presence without doing anything to your process other than measuring the microbial load that you're dealing with every day, and then identifying what that is and getting a reduction. I guess we'll be talking to that--

DR. MILLER: Another point is, we're not saying an organism that has the pathogenicity characteristics, but an organism that under those food processing

conditions has the potential to grow like E. coli, or under an intervention technology that will die at the same rate of E. coli. So we're not talking about its pathogenicity characteristics but its growth or survival or killing characteristics.

DR. KVENBERG: Now--

DR. MILLER: I think there's another question.

DR. KVENBERG: Yes?

MS. : Wouldn't it be, if you get in some apples that are really dirty and they have a lot of microbes on them, wouldn't it be a lot easier to achieve a 5 log reduction starting with that, and than if you get apples that are washed and cleaned and waxed and--

DR. KVENBERG: Well, I think what basically has to be done, is there has to be established a floor for what's acceptable that you would process. I mean, that's not been done and it's not been done effectively, I don't think, is the starting point for the 5 log reduction has not been adequately addressed.

And that question has come up in previous concepts, and I think that one of the things that ought to be recognized here is, you can't count into a cumulative operation rigging the deck, if you will, to come up with extremely dirty processing.

At least within the citrus industry, and we may have some discussion about this later, there is a minimum level that would be "acceptable" for quality purposes, that at least could allude to a background level of what--you shouldn't be processing filth. That's illegal, number one. Poor processing to begin with is not a good idea, and it ought to--incoming stock ought to be looked at.

But I think that's an area where we need further definition, is where do you start and what's an acceptable starting load if you're going to be doing anything but a conservative heat pasteurization, and that again would have to have some minimum assumptions on how you achieve a 5 log.

DR. MILLER: John, over here.

DR. KVENBERG: Yes?

MR. INGHAM: I think you've got a real good point--

DR. MILLER: Could we have some names?

MR. INGHAM: Yes, Steve Ingham from Wisconsin. I think you've got a really good point, that you're better off using an indigenous organism, but if you've got a low load, you're not going to be able to prove it. My question was, is it GRAS to inoculate in a plant with a fecal non-pathogen?

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DR. KVENBERG: Well, I guess what I'd like to do is--

MR. INGHAM: I'm talking about--

DR. KVENBERG: --I understand, but to defer to the people that have actually done the work of how that's accomplished. I think the short answer is, it's not a good idea to load this stuff and sell it to the public. Okay? Basically, that's why pilot studies were conducted, why things were simulated. There is a difficulty in achieving actual demonstrated reduction of 100,000 down to zero when the load initially is low.

MR. MATTHYS: Allen Matthys, National Food Processors. We've discussed a lot of this with our members, too, setting a baseline. You should recognize that these people are already following Good Manufacturing Practice regulations, which require you to sort out the fruit and wash the fruit and clean the fruit as it comes in, that they're supposed to be doing that anyway--

DR. KVENBERG: Exactly.

MR. MATTHYS: If you don't do that, you're going to be over a 5 log coming in with your bacterial load. You're going to be looking at 7 or 8 log in some of these cases if you don't clean that produce or that fruit.

DR. KVENBERG: Absolutely.

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MR. MATTHYS: So 5 log does you no good--

DR. KVENBERG: If you don't have a decent starting point to begin with and adhere to Good Manufacturing Practices.

MR. MATTHYS: So you have to adhere to GMPs first, and you should not--that's why your GMPs (inaudible). You should start there and then deal with (inaudible).

DR. KVENBERG: Thank you. Other comments? Yes?

MR. : (Inaudible) agree with the concept of a 5 log reduction (inaudible) with industry, you're talking about one unit against 100,000, which is true if you start with 7 million or several million, you're going to have 700 units (inaudible). If you deal with the concept of infectious dose, it's all units (inaudible). Then (inaudible), maybe the concept of infectious dose would be a better guideline than a 5 log reduction.

DR. KVENBERG: I'll leave that to the microbiologists at a later point, to go through the reduction. I'm trying to just basically deal with the concept of the validation studies. You're over my head on that one, I'm sorry. But I think I understand the point. It goes to the risk assessment, of if you had not only the infectious dose but all the other information

you needed, you basically get down to the question that was put forth in the first part of my talk, is what's the acceptable risk, and I think in fairness that's where your question was actually headed.

If I could go on, the validation studies themselves, which is what I was working my way through on this was, the purpose of these studies is to assess whether the hazards were identified to the point and the controls that were selected actually work, that the hazards that have been associated in this case within the performance standard we're talking about, microbial hazards, and the control measures that are put against them actually achieve the performance standard. And that's going to be, in essence, the theory or the basis of the test of acceptance of any proposal that's put forward to achieve the standard.

In doing microbial testing work and what's required, we basically don't have a large list of how you do this or how you do a kit, but I hope that this conference will spawn and stimulate some discussions on it. Initially, when a process is being rolled out, the purpose of the validation is to select the control measures that are critical, and then you have to be able to measure the fact that they are being so that you are providing a safe product.

This also requires that the measures have got specific limits that can be measured and monitored to confirm that you've got a point in the system that's reducing the microbial level to the target. Again, simple is more easy to accomplish than complicated systems where cumulative steps are being attempted.

Now, when it gets down to--and a lot of folks in this room basically are faced with this issue, is verification audits or when you're looking in to assess whether or not the preventive measures have been applied and designed correctly. This prevents actually challenges to the auditors when there is some latitude of how the performance is being proposed by the processor.

The idea of a verification audit moving in to, if you will, inspect the system, is to assure that the preventive controls have been applied as they were designed and intended to operate under the system, and focus on assessing whether these preventive controls have been applied on a basis that has been consistent and verified in the audit or the inspectional operation that has demonstrated that it is being done.

Moving to the end of what I've got to say this morning, is our role at FDA, the way we view it in the concept of validation studies, is provide and work with so that self-validation by the processor itself can

occur, so he can assure himself that he has got a system that will work. And also it's our role to basically inspect or look at the validation studies that are being proposed, to have assurances ourselves that what is being--that what has been put together would be effective.

FDA needs some information on the effectiveness of various control measures and critical limits that have been proposed in a system in order to have assurance that the performance standard has got a likelihood of being achieved and can be measured, and it does require a shift from us, moving from a regulatory-based inspectional operation into examining--into a validation study on a research area which we have focused on heavily with the apple people, on developing how you would approach the issue of validation on certain technologies.

Validation studies themselves basically have fallen into several categories. I won't dwell on this, and I think a lot of it will be reviewed today. A review of specific where others have been before and review of documentation and literature that's available is a start. Specific challenge studies to see if the process that's being applied actually is effective. And then actual product testing in a system to audit the effectiveness of

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the control is also a point of how you can conduct a validation for a specific process.

Now, how you use the data in the process of this validation may rely on scientific studies that have been conducted by others. The question of the reliance of others on the system, I think it's fair to say, has been challenged in recent days on relative to how cumulative a process can be--certain assumptions cannot be made that you can have a reduction standard applied across a large distribution system.

So one of the things that needs to be closely looked at, and we will in our process be looking at suppliers, providers for information of materials that's coming into the process.

Processors may rely on standard controls and utilize procedures and limits that have already been put forth by others. In other words, if there is available information working with suppliers of cleaners or sanitizers at specific concentration that have published information are useful sometimes in addressing the issue of what is an effective process or product to be applied.

I may get back to the pasteurizer question, too, in that we don't regulate the equipment but we certainly need to review what is effective and what's not.

And my final slide is on microbial testing and verification. We don't currently require, but we certainly encourage the use of microbial testing in verifying that the process is under control and working.

Microbial testing certainly has its advantages in keeping the industry itself, the processor, informed on any safety issues that may be cropping up or if he has a problem in his product; to evaluate the effectiveness of the type of applications, either under GMPs or under a control environment, for sanitation and cleaning; to evaluate incoming ingredients specifically. Basically, you can't clean up a dirty product or a contaminated or dangerous product on incoming materials. That's certainly true.

And it provides additional data for revalidating the process on whatever basis, annual or otherwise, that the processor is utilizing; and provides also data for customer reviews for the processor that has nothing to do with the regulatory environment directly, but indirectly does in our food supplier system, because I think that microbial testing and verification go a long way as a positive aspect from what a processor faces with him selling his product up through the food chain to retail environments.

So that's my presentation for the moment. If there any additional questions, I will be available throughout the day as well, in addition to now. If there are no questions, thank you.

DR. MILLER: Well, I think we've pushed the envelope on our discussion period. Are there questions?

[No response.]

DR. MILLER: So we can forge forward. A number of people have walked in the room in the past time, and if you haven't and you are registered, please come up and pick up your ID tags and your handout materials.

Shall we take a two-minute stretch break? But I mean two minutes.

[Recess.]

DR. MILLER: We're going to begin the more technical side of the program now, and one of the things that you should keep in mind, in formulating the program we wanted to keep the technologies, the suggestions, as practical as possible. So there are research activities ongoing that we know of, that are not included. If you are working on things like pulse-electric field, gamma radiation of juices, our apologies, but we considered these to be too far into the future to have a short term impact on the apple cider question.

And so we wanted to really keep our energies directed on what's in the here and now, what's on the shelf, available to be used by processors today or in the very near future. And in that regard, we have limited the presentations to those technologies and the guidance that we feel has the most promising short-term impact on the apple cider industry.

We've had a request that when speakers ask questions, speak louder, project. Perhaps if you stood up, said who you are, your affiliation, and then asked your question broadly so that everybody can hear it, we would have it captured on the tape, as well as the fact that everybody in the room will be able to hear the question.

MR. SANFORD: Just a comment, if I may, alluding to the last speaker.

DR. MILLER: Yes.

MR. SANFORD: Something that we're recommending in Tennessee--Sanford from Tennessee--for evaluating incoming ingredients, we're making people aware that if they would make their suppliers aware to forward them a letter of continuing certification of safety as it relates to (inaudible) on everything that comes in, whether it be a package, a container, everything, it

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works extremely well, and they will find out relatively fast what's safe and what's not.

DR. MILLER: That's a good comment. Moving on, our speaker will be Dr. Michelle Smith, who is with the Food and Drug Administration at the Food Center, and Michelle has been intimately involved in development of the guide for foods and vegetables, the Good Agricultural Practice Guide, and she will talk a bit about that document and some of the guidance that's particularly relevant to the apple industry.

Michelle?

DR. SMITH: Good morning. It's a pleasure to be here this morning. It's also kind of comforting to be the first speaker up after Art said so many things about common sense and simplicity, because I think that's part of what our Good Agricultural Practices guidance document is about. At least that was our goal.

Now, this guide is titled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." It was finalized in October of last year. It was one of the charges to FDA that came out of the President's Produce and Imported Food Safety Initiative. sub-set of the larger Food Safety Initiative. This guide covers general Good Agricultural Practices and Good Manufacturing Practices common to the growing of most

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types of fresh fruits and vegetables in the U.S. and abroad.

I've only got about 15 minutes today, so I'm not going to try to teach you everything in the guide, but I do want to leave you with a clear idea and a clear understanding of what this document is. It is a broad scope document. The recommendations in this document are based on, first of all, identification of common microbial hazards and recommendations for ways to minimize those hazards.

The first goal of this guide is to increase awareness of these potential hazards in an agricultural and packing house environment. The guide is voluntary. It does not impose any new requirements on anyone. It does not supersede existing laws and regulations.

It focuses on risk reduction, not elimination. We understand that the agricultural environment is not a sterile environment. You're going to have a bird flying overhead. It just would not be reasonable to expect the absence of any sort of contamination.

What we're trying to get at is the promotion of Good Agricultural Practices and Good Manufacturing Practices that will eliminate larger sources of contamination, some of which may be a byproduct of

certain practices, and other sources may be unintentional sources of contamination.

Another thing is, I had a call the other day from someone who had heard a rumor, and they were a bit concerned. The rumor they heard was that FDA was planning on going out to farms across the country and monitoring compliance with this guidance document. Again, the guide is voluntary. It's not a regulation.

We put forth the hazards in this document and say, to the best extent or to the extent practical, consider these operations, choose the combination that is the best fit for your own particular operation. FDA is not likely to go out to U.S. farms and start doing inspections without good cause.

We have had reason, both in this country and abroad, when there has been a food-borne illness outbreak, if the traceback continues to the extent of the farm, we have gone back and visited farms, and that is expected to continue, but that would be in a situation where a problem has already become apparent.

Another thing that is going on right now is, FDA is working with USDA National Agricultural Statistical Service to do a survey of growers and packers. We just finished a pilot of two States, New York and California, and later this year we'll get into a national survey of

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the 14 largest growing States in the U.S., and we're encouraging the participation of anyone who is approached as part of this survey. We're trying to collect hard data on what the practices are that are being followed, information on the diversity of practices throughout the country, to help us guide policy development in the future, and also we expect this survey will show us that there are a significant number of good practices that are being followed right now.

Now, the scope of our guidance document, we developed this document with fresh fruits and vegetables in mind, primarily intact produce items. However, the recommendations in here can be applied to other things also that may benefit, particularly items that are likely to be consumed without some kind of lethal intervention step.

Excuse me. And in addition to that, the products where further processing is involved, this guide recommends following GMPs, but when you get into a food processing operation, the GMP requirements are part of what needs to be considered, and the particular product may dictate additional needs for control.

Now, these are the areas of concern covered in the guide. Again, common sense, a lot of these are obvious. Water covers both agricultural water use and

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water in the processing plant or packing house. There are a lot of different sources of agricultural water. Some operations may have a choice of several sources. Some may have only one source at their disposal.

Water is a concern in two regards: first of all, as a source of contamination itself; and, secondly, for its potential to spread contamination both in the farm environment and in the packing house.

In an agricultural situation, the microbial hazards that are present are dependent on many interrelated factors, things like the characteristics of the crop, the degree of contact between the water and the produce. If your water quality is known to be good, then irrigation method has probably very little impact on potential for contamination. But where water quality may be uncertain, additional good agricultural practices, such as irrigation methods that minimize contact, might be considered.

The same is true in a packing house environment. Water quality has a significant impact depending on where in the operation that contact occurs. You may have different water quality needs for flume water as opposed to final rinse water. But the water should be safe and sanitary for its intended purpose, and in no case should

the contact of water with produce cause a food safety concern.

If water is recycled in the operation, we give recommendations on how to do that appropriately to minimize hazards. We talk a bit about the use of antimicrobials, particularly in respect to minimizing pathogen buildup in processing water.

Some of the other things that may be of particular concern, we have talked a bit about temperature differentials and the potential, if you have some types of produce and you immerse warm produce into cold water, for the water to be sucked into produce. Two examples, apples and tomatoes, both have an internal air space that can promote that happening.

Another section of the guide is the use of manure and biosolids. Both of these items can have very beneficial uses as far as soil structure and fertility are concerned, but they can also be a potential source of pathogens.

If manure is used, growers should follow Good Agricultural Practices to minimize the potential for microbial hazards associated with the use of manure. We focus primarily on treatment such as composting to reduce pathogen levels, and maximizing the time between application and harvest of the produce.

Growers also need to be aware of an unintentional introduction of manure into the growing environment. By unintentional, it could be heavy concentrations of wildlife or it could be nearby animal production operations. I visited one very picturesque orchard across a very narrow road from a beautiful pasture, and was informed that that was an area that flooded frequently. And there was a lot of livestock in the pasture, and so it was very obvious that whenever this flooded, whatever was in the pasture could very easily run off into the orchard area.

Sections of the guide cover things like personal health and hygiene. We strongly encourage training programs. Don't assume that people know how to wash their hands. We have a very diverse work force in the produce industry, and their training needs need to be carefully considered.

Field sanitation, more and more operations are occurring in the field as opposed to a packing house, so we have sections talking about cleaning and maintaining equipment, and dedicating equipment for harvest use as opposed to using containers for multiple uses.

Sections on packing facility sanitation, and this precedes getting into the level of requirements that are covered by GMPs, we cover pest control in the guide.

We also talk about accountability. Once Good Agricultural Practices and Good Manufacturing Practices are put into place, it's very important to have someone in charge to make sure that the systems are operating and that they're functioning correctly.

A number of traceback investigations have gone to facilities where, as far as management was concerned, they had done what they could but there was the lack of follow-through and the lack of accountability. Maybe filters hadn't been changed on water treatment systems, or different equipment had been out of operation for two weeks and the facility had continued to run and problems had occurred.

Finally, we talk a bit about traceback. We understand that the produce industry itself, just because of its complexity, has a number of difficulties in keeping track of where some produce items came from and where they go once they leave the packing house.

Now, with a packaged food item, this is much more simplified, but still, if you have control and information on the source of the produce that goes into your item, if there ever is a problem, that helps us trace back to the very source if indicated by the investigation.

Advantages of effective traceback systems are, it allows public health officials to respond a lot more quickly and limit the degree of public health impact. It will minimize the impact on the industry by specifically identifying or helping specifically identify the route of the product. And also, in those cases where the investigation does go back to the farm, this would help us identify the farm and learn more about the kinds of practices that may or may not contribute to a problem.

Now, I've brought with me a handful of these guidance documents if anyone is interested, but it's also available on FDA's web page, along with information about the development process. We held a series of about nine public meetings during the course of developing this guide, and had input from State and public health officials, and a lot of this is documented on the web page also.

And is there time for questions?

MR. : (Inaudible.)

DR. SMITH: I'm having a hard time hearing.

DR. MILLER: Stand up and identify yourself.

MR. : (Inaudible.) On the first you said, would any products cut during harvest be excluded from final processing?

DR. SMITH: Okay. Cut during harvest includes items like celery or asparagus, things that have to be cut just to harvest them. As far as other types of tree fruit, for example, if it was cut during harvest you might choose to exclude that particular piece of fruit, depending on the degree of damage involved.

MR. MOORE: Bill Moore from Tennessee. Have you come out with, are there any recommendations on composting--

DR. MILLER: Could you stand up and--

MR. MOORE: Are there any recommendations that you've come out with on composting specifics, temperatures, times?

DR. SMITH: Okay. The short answer to that is no. Much of the research done from a food safety standpoint was done a number of years ago on biosolids. The information that I found on composting when working with this dealt a lot more with soil fertility and nutrient management type questions.

There is a significant research underway right now, some of it at USDA ARS in Beltsville, also at a number of other locations around the country. The food safety concern relative to manure is a fairly new concern, and research is starting now.

DR. MILLER: Any other questions for Michelle?

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[No response.]

DR. MILLER: Okay. Thank you.

DR. SMITH: You're welcome.

DR. MILLER: It looks like we have a technology here, and Bill Snodgrass I think is firmly in grip of the situation.

Okay. Our next speaker is Dave Bolster, and I need to mention that his affiliation needs to be amended. Notice, I didn't say it was wrong. But Dave is a juice processor himself. He also is an employee of the El Dorado County, California, Department of Agriculture. And another hat that Dave wears is working on an FDA partnership research project that you'll hear about during the course of this meeting.

So Dave has a wealth of experience. Today he is going to talk about the Apple Hill quality assurance program that is quite successful in Placerville, California, in El Dorado County. So, Dave.

MR. BOLSTER: Thank you very much, Art. Let's see if the technology works here.

The quality assurance program that we're going to talk about today was developed in response to the outbreak of October of 1996 in California, in the northwest. We began the development of this quality assurance program in early 1997.

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The program was implemented in the fall of 1997. Our local juice processors began to implement the program. We used it last year, and this coming year will be our third year of actual implementation and use of this program, so it's not a document that's on the shelf. It's been in use now for a couple of years, so it's an ongoing learning program, if you will.

The Apple Hill area is located in northern California, between Sacramento and Lake Tahoe, up in the Sierra Nevada foothills, a beautiful area. The elevation ranges between 2,000 and 4,000 feet. We have about, oh, between 2 and 3 million people in the metropolitan areas of Sacramento and the San Joaquin Valley and northern Nevada that we draw from in terms of direct marketing.

Our area probably looks familiar to a lot of folks in the Midwest and back East here in terms of direct marketing operations. Our growers, we have almost 50 growers in our association, our Apple Hill Association, mostly small growers. Some growers, just a few acres, ranging all the way up to a couple hundred acres in production by some of our growers.

A common profile of our growers, very similar again to farm market operations across the country. A grower will have his acreage, and in our area it's apples, pears and wine grapes. The grower will have a

retail stand, perhaps a packing house, a bake shop, and a number of our growers have cider mills. There are seven processors in our area. Six of those processors still produce fresh juice. One of our processors produces flash pasteurized juice.

The program itself, basically it's a HACCP-based program. The QA program is a HACCP-based program. It's not a full HACCP program. There are elements of HACCP in the program which you'll recognize, but the basic foundation of this program are SOPs and GMPs. That's the essence of this program, in addition to elements, guidelines, processing guidelines that are specific to apple juice processing itself, namely the handling of press racks and press cloths, etcetera, items that are specific to apple juice processing.

So let's talk about the program itself, if the computer will let us. Okay, our title page, this is a typical farm market scene in the Apple Hill area. This is from Boa Vista Orchards, one of our larger growers. You can see the packing house is here on the left, and the retail stand, and the cider mill is back there at the far end on the right.

Our QA is a comprehensive, integrated program of voluntary guidelines for apple production and juice/cider processing that enhance the safety and quality of

unpasteurized apple juice/cider from "bloom to bottle." Art called it "orchard to jug," but we like to call it "bloom to bottle."

And obviously the concept there is, if you're going to do a HACCP-based program, a HACCP approach, the principle is that you're analyzing hazards along the entire spectrum of production of the product, from first bloom in the orchard, the cultural practices in the orchard, all the way through to the final bottling and distribution of the product. So from that standpoint, it's a comprehensive program.

There are five basic elements of the program: Administrative guidelines. Production guidelines, and we talked a great deal about that in the last 20 minutes or so. Basically those mirror the guidance that we just heard about. Cider processing itself. A training program. Product labeling; and program verification.

We call it juice/cider processing because our processors, we have people who call it both fresh juice and fresh cider. Across the country there's different uses of terminology. Back East I know it's, I think it's exclusively cider back here. That's the fresh juice product that's unfiltered, unpasteurized. Out on the West Coast people use both terms. That's why we incorporated that.

Each processor must develop and implement their individual QAP, very similar to a HACCP program. There's not one program that fits all. You have to tailor an individual program to your operation.

Designate a manager, employee or employees, as the official quality control supervisor for in-house processing. And a record-keeping system from "bloom to bottle." Obviously this is critical from a number of standpoints. Obviously a traceback, from a traceback standpoint, and if the processor does have a problem, obviously the record-keeping is very valuable in terms of determining what the source of the problem was.

Processors must maintain identification of fruit from "field to bottle," and I think we have a slide here that gives an example of that. Most of our growers have bins that have their names on them. This is an example of a grower that spent a lot of money to put his identification on there, but most of the growers have their names painted on the bins.

And part of the program, part of the QA program in terms of identification is that you must maintain identification when you receive--either if you receive a load from the packing house that you're going to process, or if you've picked your own fruit and you're going to process your own fruit, you'll need to use bin tags, and

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we use bin tags for that purpose, to maintain the identification. Again, for the purposes of traceback and identifying any potential problems, that's the idea here.

Production guidelines, I won't talk too much about that. Again, it mirrors the guidance that was just talked about. Obviously the concept here and the concept of the whole QA program is to minimize the potential for microbial contamination and to exclude the pathogen from the product itself, and obviously these production guidelines are in place to achieve that objective.

Again, water quality standards, part of the QA program is receiving fruit into cold storage. Growers are required to put the fruit directly into cold storage or to cover the fruit. During the peak of the season, some of the growers and processors don't have the cold storage capacity to put that all into cold storage, and so they're required to cover that fruit, obviously to minimize exposure to rodents and other contamination.

Here's a picture of one of our processing plants in the Apple Hill area. This is Boa Vista. Just talking about GMP, you can see the smooth walls, smooth floors. Just the containers are up off the floor, so that's just an example of, you know, some of the GMPs that are required by the program. Again now, GMPs, a facility is required to be fully enclosed. If you have doors, you're

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required to have the plastic strips to exclude dust and flies, etcetera.

In the processing plant we have general sanitary guidelines for juice processing, and again, these are, the guidelines themselves, these are the elements that refer specifically to apple juice processing, handling the racks and the press cloths, etcetera. This part of the program is not necessarily the SOPs.

The next item is follow the daily plant sanitary operating procedures. Item 12, probably a bit controversial back here. Most of the growers back on the East Coast historically had used drops in cider, and I think primarily because of the nature of the varieties that are grown back here. A much higher percentage of McIntosh grown back here than we have out on the West Coast.

Our primary varieties are Golden Delicious, Red Delicious, Fujis, Grannys, so we have a very small percentage of McIntosh and varieties that are prone to pre-harvest drop. So we're in a position where it was fairly easy for us to say we're going to prohibit the use of grounders. We recognize that in other areas of the country, that that's a little more difficult, but obviously if you're talking about excluding pathogens and

minimizing the potential of microbial contamination of the product, this is a critical element.

And number 13, just because obviously you need to comply with the minimum standards for grades of apple processing, we included that in the program. However, I think the grade of apple that's commonly used via processors is far higher than that minimum standard. Both the tree-picked apple, the so-called field-run apples, and also the peeler grade apples that we use in processing, are much higher than that standard.

The peeler grade apple, I'm not sure what the terminology is used back here on the East Coast, but when a processor buys from a packing house there are a couple of different grades of apple. One is the juice grade of apple that's going to have a much higher content of rot and decay, and then there's the peeler grade apple that comes off the packing line, that's going to have--that's going to have--that's going to have only very minor cosmetic decay, or defect, I'm sorry, so it's a very, very high quality piece of fruit. And so that part of our program is peeler grade and tree-picked fruit.

This is the SOP checklist that each of our processors has and is required to fill out as we go through during the processing day. The plant personnel and the plant management is required to fill this

paperwork out as we go. Obviously the value here is not only the steps themselves, but it's keeping the sanitary mind-set in front of the minds of the processing employees.

Obviously we have a pre-processing checklist, a processing, and a post-processing checklist, and part of our program, as a verification element the growers and processors are required to maintain these records on file when the Department of Agriculture comes to inspect the documentation.

Just an example of some of the sanitation products that are used on the Hill. One is, the product on the right is the antimicrobial. It's registered for fruit and vegetable contact, for prewash. Then we have a chlorinated foam material and quaternary (ph) compound that's used for a sanitizer.

Again, an example of the GMPs and the guidelines for washing the press cloths inside. Press cloths are hung up inside the facility and allowed to air dry.

Processing, prior to processing, inspect and grade and wash all apples. Again, all the water in the facilities has to meet drinking water standards. Wash apples in water containing an approved antimicrobial agent in which the levels are monitored at appropriate intervals. We, commonly the processors, we start with

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200 ppm chlorine in the wash water and maintain at 50 ppm.

Establish and conduct a pest control program. Obviously we want to exclude rodents and other vertebrate pests from pest contamination in the facility.

Cider is placed into refrigeration until final distribution to consumer. Obviously temperature abuse is a potential problem.

Conduct an environmental monitoring program in the processing facility. We're very fortunate to have Dr. Kirk Taylor, who is here today, who conducted our-- conducts our environmental monitoring program with all seven of our processors. And I think that's done, what, three times a year, Kirk?

Okay, our training program, again we are very fortunate to have a gentleman with the University of California Cooperative Extension Service who is fluent in Spanish, and so many of the field workers that were trained, and obviously some of the plant personnel, are Spanish-speaking individuals, and so we are very fortunately to have a very effective training program that addresses sanitation practices in the orchard and in the processing plant itself, hygiene practices, and also the cultural and harvest practices out in the field.

Obviously, if one of the elements is to include only tree-picked fruit in your product, you have to communicate that to the people that are working out in the field, and our training program is--I think we're very effective in getting that done. We also want to thank Linda Harris from UC-Davis, who is here today. Dr. Harris presented some of the training programs for us, also.

Product labeling, the label "fresh unpasteurized" is placed on the caps of all juice, and of course now we have the mandated label warning starting this September on the container itself. And there's the label that was placed on top with the "use by" date.

And the verification element of the program, I think Ronald Reagan used to say "trust but verify," our verification element is conducted by the Department of Agriculture, the El Dorado County, California, Health Services, and also the FDA. I believe it's three times a year we have--the Department comes out, inspects the documentation and the record-keeping by our processors to verify that in fact they are complying with the program. And if the processor does that, in fact, they are eligible to continue in the program and they are able to use the program seal.

One of the motivations, obviously, in addition to product safety is that the Apple Hill area is a direct marketing program. We attract about a half a million people a year, and the processors were very concerned about, you know, the potential for loss of sales, and so there was a great motivation to address that problem.

And so the processors I think did a very nice job working together, and were able to develop a program in cooperation with various Federal and State agencies to present to the consumer, to reassure the consumer that we are aware of these problems, that we have made changes in our processing facilities and operations, and I think it has been a very successful program so far.

Our program was modeled after a couple of different QA programs that were developed in California. The Western Growers Association I think was the first trade group out there to have a QA program. The California Egg Commission I think was second. And so our program borrowed from many of those elements of those programs.

I think at that point it was a fairly unique approach, the partnership programs that were being developed at that time between industry, State government, Federal government, and the academic

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institutions. I think at that time it was a unique approach, and it has been very effective.

It was a difficult process to go through. Anytime you talk about bringing industry in together with a number of entities like that, it's a difficult process to work through, but we were able to do it and I think it has been a very effective program.

These are the agencies and institutions involved in the program. We mentioned El Dorado County, California Health Services, California Department of Food and Ag, UC-Davis Cooperative Extension, and U.S. FDA.

We also want to acknowledge Ray Nelson from FDA. Ray just recently retired. Ray was the industry facilitator for FDA in California, and Ray was instrumental in developing the other QA programs in California. Ray really did a marvelous job digging in with industry and slugging it out and having fun developing a program, so we want to thank Ray for that.

Are there any questions? Leslie?

MS. ZINN: I'm Leslie with Ardens Garden. What log reduction do you think you're achieving?

MR. BOLSTER: Well, that's a good question. That's a good question. Based on some of the work that's been done before, you know--well, I don't know if you want to talk about that at this point.

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DR. MILLER: I don't think we can really say, and it's not that I'm trying to hide anything. We just don't have the numbers.

MR. BOLSTER: Yes. Right, right.

DR. MILLER: You know, we're looking at bits and pieces, but at this point we haven't put it all together.

MR. SCHWALM: Well, I think there's a point here, too, that it was not a program that was set up to achieve a 5 log reduction.

MR. BOLSTER: Right.

MR. SCHWALM: This is a quality assurance program, and I think the important part of the program here, that what you've done out there is that you have established some parameters, sanitation parameters that they're operating under. You have a mechanism to get agreement. You've got a verification process. You're using a seal that has got consumer recognition as an enforcement mechanism to that. So what you have, in essence, is the foundation of a HACCP program, and as interventions are developed for 5 log, you've got that. You can have a 5 log reduction process, but unless you have the mechanism, the structure, the system to apply it the way that you have, it won't mean anything. So you've got the foundation for a HACCP program.

DR. MILLER: (Inaudible.)

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MR. SCHWALM: Pardon?

DR. MILLER: Who are you?

MR. SCHWALM: I'm Darrell Schwalm with FDA.

Sorry.

MR. CRASSWELLER: Rob Crassweller from Penn State. I'd like to point out maybe the difference. You mentioned the differences in processing grades, and Pennsylvania is largely a processing State or has a lot of processing. The grades that we established for the processing, that goes to processing fruit, will be fruit that will run through some type of heat treatment. So that's why we have allowance for what we call trim waste, so you can have up to 5 percent damage and still be number one processing. That would never go to unpasteurized juice.

MR. BOLSTER: Right.

MR. CRASSWELLER: That's why we differentiate between the juice and cider, because things that go to cider are fresh fruit, are going to be off size, you know, similar to what you're saying. So we've got to be cognizant of the fact that when you talk about processing grades, you're specifically referring to a different product than what we have for cider. So I think that, you know, because we have regional differentia-- differences, we need to emphasize that.

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The other question I would ask is, one of the things that we're looking at is that juice stock at the bottom. We think it's also important, many of the fruit growers in Pennsylvania think it's important that they have to cover themselves, say here's some information, you've got to take it back to the consumer.

They have to be responsible to store that product, to handle that product in a proper fashion. Otherwise, you can do everything you want. If they go and stick it in the garage, which is a common occurrence, you have no--you know, they're going to come back and say there's something wrong. So we think instead of from, someone said from "flower to the bottle," we think it should go "flower to the refrigerator at home."

MR. BOLSTER: Right. Yes, that's a great idea.

MR. COLMAN: I'm Matt from Ardens Garden. what are the products you're using to sanitize?

MR. BOLSTER: Oh, I can get ahold of the representative for you. There's Zepamine and Foam Chlora and the fruit and the fruit and veggie product. I forgot what the name of it is.

MR. COLMAN: Is there one you're specifically spraying the apples with?

MR. BOLSTER: Well, we use it both in the recirculation tank and our wash tank and our dump tank.

It can be used in both. I'm not--I'm not touting Zep, by the way, if there's any other manufacturers here. We just happened to have that slide.

MR. COLMAN: We use it ourselves. I wanted to know (inaudible).

MR. BOLSTER: Bill?

MR. SNODGRASS: My name is Bill Snodgrass from El Dorado County Department of Agriculture. A little bit of a clarification on how the program was developed in HACCP, and it really was HACCP, because that's where you pull back and you look at all your critical control points.

So the growers sit down and look at, say a critical control point would be grounders that come in contact with manure, so grounders were eliminated. Livestock was eliminated from there. That's a critical control point that was eliminated to prevent contamination.

The other was establishing a grade, because once the bacteria becomes internalized, I don't care what you wash it in, unless you cook it, it's going to be very difficult to get rid of it. So if you have a sound apple, without blemishes on the outside, you stand a better chance of being able to wash it off.

So that's where the HACCP part of it came in. That was the actual basis of the thinking for whole program and setting it up the way it was.

DR. LOCKWOOD: I'm Dave Lockwood, University of Tennessee. One of the things that we're trying to do in a lot of the Good Ag Practices is trying to tie those back into just good practices as far as growing a crop and making a quality product. For example, timing of manure application in regards to effect on ripening and fruit quality; irrigation, trickle versus overhead; or putting fruit in cold storage, you get--it's easier to crush, you get a better return on your apple. So if you can them in to an economic idea, as well, I think it becomes a lot easier to set up a voluntary program.

MR. BOLSTER: Sure. You bet.

DR. MORRIS: Bill Morris, Tennessee. Have you found that your consumers are really on top of this and they're seeking--do you get better response and interest from your consumers on this type of program?

MR. BOLSTER: Yes, I think so. You know, we have the brochures available for distribution at the retail outlets, and I would say that there's, overall there's a fairly small percentage of consumers that do ask about the product, candidly. But, yes, those that are concerned about it, we make them aware that we do

have a QA program underway, and I think most of the people--well, very few people that I have spoken to were concerned about the product after we talked about our QA program, still had concerns after, after that.

MR. SNODGRASS: It's also very--Bill Snodgrass again--it was also a very effective tool when the press came out, because we have a half million people coming each year up to Apple Hill, so we have name recognition. When some news happens with apples or apple juice, that's the first place they come, is Apple Hill. And the growers had a piece of paper they could hand to the news media. The news media could get the word out that the apple industry is active, is proactive in trying to do something to correct the problem out there. It goes a long ways to help your sales.

MR. BOLSTER: Thank you. Thank you very much.

DR. MILLER: Thank you, Dave.

Our next speaker is Peter Chaires from the Florida Gift Fruit Shippers Association, and Peter will talk to us about the experience with citrus products and the validation of unpasteurized citrus juice. Again, a technology shuffle.

MR. CHAIRES: Again, my name is Peter Chaires, and I'm kind of wearing three hats today. I'm here from Florida Gift Fruit Shippers Association, first of all,

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and we are a cooperative and trade association in Florida, comprised of about 136 members, small farm family businesses, about 98 of which produce fresh squeezed, unpasteurized citrus juice.

And I'm also here as a representative of the American Fresh Juice Council. The American Fresh Juice Council is comprised of unpasteurized juice producers around the country, and really our charge and our mission is to promote the value and the development of a safe fresh juice industry through education, communication, and the continuous improvement of GMPs. So naturally we have been very busy over the last couple of years.

And then also I serve as a member of the Fresh Citrus Juice Task Force, which was a group that we put together in Florida to address primarily the concerns on the 5 log reduction verification for smaller scale producers.

And so you'll get a little perspective, I think, from each of these, and I'm going to move rather quickly. You'll find me hopping around my outline that's included in your booklet, just in the interest of time. A lot of ground to cover.

Really we've been focused primarily with the compliance on the warning label regulation, and our focus has primarily been due to the strong nature of that

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warning, to provide the producers a means of keeping the warning off, the warning label off their product or out of point of retail display by coming into compliance with the 5 log reduction.

Our focus has primarily, in Florida, been production-oriented with the citrus, because we have a very active inspection program. It's kind of a dual effort. One side of it really kind of covers--it's all done through the Florida Department of Agriculture--covers the smaller scale producers, whereas we also have a program for the larger scale. But our whole effort has really primarily been to come into compliance with the 5-log reduction, to provide a good solid foundation and move everyone towards ultimately a complete HACCP program.

As far as what the industry has been doing along these lines, really first I wanted to explain that there's a division in approaches because there really are two different kinds of producers on the citrus side. We have what I'm going to refer to as a large-scale producer and a small-scale producer.

The larger scale are really what I would describe as continuous production plants. Fresh-squeezed juice is what they do, and they produce very typically on a year-round basis but not exclusively, but they do

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continuously produce when they're operating, and they are for the most part involved in wholesale distribution.

Whereas on the small-scale side, you have two different divisions in the smaller scale. You have what I refer to as a retail or a grocery store type of application, where fresh-squeezed juice is really a sideline, and then you have roadside retail stands and shops where it can be a sideline, but the preponderance of these, it really is the engine that drives their business. And these are primarily located in the growing regions, probably very similar to what you heard about with the Apple Hill project.

Now the characteristics of the approaches to the 5 log reduction between the larger scale and smaller scale are also somewhat different. On the larger side we've seen primarily either use of private labs for their validation, and then some, there's some consideration of more proprietary information because of the investment in the process that they went through to get that, because there certainly is intense competition in this business, but we've been also at the same time very pleased at the level of sharing that's come forward through the FDA workshops. And there is some use of a cumulative reduction concept on the larger scale, but we've also

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seen some of these producers verifying their 5 log from beginning to end.

On the smaller side, these guys were really forced to work cooperatively. We had to pull them together. They didn't have the means or the know-how to go through and do an individual effort, or to be able to afford the private laboratories, so we worked cooperatively to put together this Fresh Citrus Juice Task Force to do more or less what I'm going to refer to as a corporate validation process. We wanted to prove certain processes effective, whether it be the washing step, the sanitizing, and on surface temperatures to get the time, the temperature, the exposures, all of those types of things, so that they could take that information and implement it privately in their own business.

Now, the Fresh Citrus Juice Task Force was--we made an effort to make it an interstate effort. We haven't had a great deal of involvement in States outside of Florida, but we have certainly been working to keep them in the loop as we went along, and we have had a great deal of cooperation.

It was not intended to validate existing techniques, but rather to work within the knowledge of what these small plants are capable of, what they're already doing, and what they can most capably and quickly

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implement that would be at the same time highly effective.

And we did focus, for the smaller scale operators, on a cumulative reduction using traditional set-ups within the packing house and the juice production processes, with additional research provided in a document that we just published at the end of this past June, that provides some enhanced results for unique situations.

I will talk about this in a few minutes, but this is what called the Guidance Document for Retail and Roadside Pressed Citrus Juice Producers, and this was put together by the Task Force and it was published by the Florida Department of Citrus. I do have a few of these with me that I could send home with you, but certainly if anybody else wants to get a copy of that, I can provide you a phone number on how to do that, and it's a really good guide for our smaller producers.

Now, we did see some real positive or what we might consider more formal changes that have come about. We've seen an improved knowledge and use of SSOPs and GMPs across the country in fresh citrus juice production, both in small and large, and certainly the knowledge sharing within the industry, in an intensely competitive business, is unlike anything that we've ever seen, and

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certainly FDA has worked to facilitate that exchange and we've all benefited from that.

And then the active extension programs and the land grant universities and with the Department of Citrus have been most beneficial to put on education workshops to share what we know. We've had the larger producers come in and share with the smaller producers, and also a lot of what the larger scale producers have learned that they've shared with us, we've been able to implement and include in our guidance document, and that has also been very helpful.

And of course at the same time we hope to see a cross-commodity exchange, which we're certainly beginning this process today. But I'm going to move through some of these overheads rather quickly, so hopefully we'll have time for some questions.

Certainly on our overall objective in the compliance with the warning label rule, a 5 log reduction of microorganisms in the fresh squeezed citrus juice is what I'm going to address, where the target organisms primarily would be 0157:H7 and the Salmonella spp.

Now, the appropriate surrogate, as we heard about, can be used. We've had a number of different ones used in citrus juice. Dr. Kvenberg could probably speak to that very well, or Darrell, but we've seen an E. coli,

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what we call an E. coli cocktail, which is what we use mostly at the Florida Department of Citrus and the University of Florida research in the compliance guidance document, but also Lactobacillus, and we have seen other--at least one other fresh citrus juice use a strain of Salmonella in their laboratory validations. And then of course the cumulative can and in most cases was utilized.

Our traditional treatments include the chemical cleaning, mechanical cleaning, grading and culling. Some--well, almost all of the larger producers have included the grading as an element of their 5 log reduction. Very few of the smaller ones have, just because it was more difficult for them to do a cooperative verification of the effectiveness of the grading. Although it's absolutely a key part of what they do, it's not in all cases included in the 5 log reduction.

Most of our smaller producers are using FMC extraction techniques, which has been a real benefit for us because of the very small percentage of the field that comes into contact with the juice. And then the external sanitizer treatment. Now, we certainly did learn a great deal in the sanitizer research about what is effective for our product and what isn't.

On the chemical cleaning, various fruit cleaners have been used. On the brushwashing step, in most cases as the fruit is moving across the scalloped roller brushes, that is in most cases where we're seeing the application of cleaners and sanitizers, and we've had a number of them tested that I have listed up here.

With the chlorine, in most cases where the chlorine is very effective, it is used in combination with an ORP system. In most of the smaller operations, they're moving on to the use of high alkaline cleaners in the 11.5 to 12 pH range, because that's what we're finding has been very effective for us in the Florida Department of Citrus research on the fight against E. coli.

One of the things that, on the alkaline cleaners, FMC 395 is just an example of one that has proven very effective because it does have a foaming agent for use in the cleaning and the brushwashing process, and achieves, within the pH range that I mentioned for a 30 second contact time, about 2.5 to 3 logs when you're using this in the cumulative process.

No phenyls has become a big issue for us, because one of the high alkaline cleaners that the smaller producers are using is SOPP, and particularly in Florida in a lot of our regions where the small producers

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are located, the fact that it does contain phenyls, and if you have runoff or if you happen to be going into a perk pond or some other system where you're going to have testing, that has become a critical issue for us. And there are cleaners such as that 395 cleaner that don't contain those so it's not as much of an environmental concern.

Now, the mechanical cleaning, the brushwashing with the soap and the cleaner, the log reduction may need to be determined for specific applications. When you see our guidance document, it does list very specifically what you would need to do in order to achieve that log reduction. And if your process varies pretty much one iota from what is described in there, then you really need to go in and verify your specific process and come up with what is best for your application, if your dwell time or the concentration of the cleaner or even the use of a different cleaner or a different pH range might be used.

On the grading and the culling, if it is very aggressive and you're really diligent in what you're doing, it does provide a log reduction. I think we saw up there earlier .6, around the .6 range, .6 log to 1 log is typically what they're finding in the research, but it is very unique to each application, so I think more and

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more of the fresh citrus juice producers are focusing very heavily on that, but they don't include it as an element of their program, except for some of the very large plants.

And then on the extraction, it does vary. We tested at the Department of Citrus the machines that are used in most cases. I believe we tested out several FMC machines with various cup set-ups on them, also the Juice Tree product and the Deli Juicer. We have a number of users on various other machines such as the Bertuzzi, and some research on that is ongoing. But typically across the various manufacturers, 1.1 to 1.9 on the conservative side is what we're achieving with that type of a cup extraction technology.

Yes?

MR. : The FM, does that stand for "foreign material" or what does it stand for?

MR. CHAIRES: Food Manufacturing, yes. FMC?

MR. : Yes.

MR. CHAIRES: Yes, that's the manufacturer, FMC Corp., Food Manufacturing--Food Machinery Corporation.

And on the external treatments, the phosphoric acid and the anionic cleaner, also we have seen some use of chlorine and chlorine dioxide and peracetic acid--I never can pronounce that one right--

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MR. : And iodophor.

MR. CHAIRES: --and ozone. Very, very little use of ozone, and the research has certainly varied on that, but we do see it used on external treatments.

Now, those things that I just mentioned pretty much cover all of the scales, but on the smaller scale producers, we pretty much laid everything out in their typical processes, running it from the fruit purchasing end or harvesting standards. Most of these smaller companies also are grove owners, they are growers, and they have direct control over the harvesting practice.

But, as I mentioned, we are also covering retail and grocery applications, so we also have to cover fruit procurement, particularly if they're purchasing that fruit from a packing house, perhaps already run, brushwashed and graded, and then include the grading process in the line because you're also going to have a regrade, or if you're starting from the very beginning, a pregrade and then a main grade, and probably a grade also going into the extractor, the fruit cleaning process.

Surface treatments, which are going to vary, and we'll talk about a little bit to that in just a minute when I show you some excerpts out of the guidance document. And then sanitary storage, because in some

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cases it's not going to be juiced immediately after it was run.

And some examples of that where you have the grove located maybe on one side of town and the store where the juice is made on the other side of town, but they're doing the fruit washing and sanitizing in the grove location in a packing house. They will run that through in most cases into a lined bin that's lined with a clear plastic liner, and so the clean, sanitized fruit is going in there. It's then closed up and transported to the other facility before it moves. That's very important, of course, particularly in Florida where we have a lot of amphibians and other things that may come in contact with that fruit.

And then the extraction, and the research is provided in there. And we just have some instances where juice treatment with thermal or UV is in the experimental stage.

Now, an example on a smaller scale plant, in what might be the result of what I just showed you, is that they go through the brushwashing step using the SOPP soaping and the clean water rinse, about a 3.5 log reduction. With the high alkaline wax application, and the high alkaline wax is in addition to a high alkaline cleaner, of about 1.1 log.

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And then if you take a very conservative number with the use of perhaps an FMC or a Juice Tree type of extractor that is also--you have to--you have built into this a firm foundation of GMPs and SOPs that are going to keep this clean and sanitary. It's a clean machine run in a clean environment by clean people, and well trained, then you're coming out and that's kind of your cumulative process here.

A lot of our research, though, is focusing on the external thermal treatments, and we have a real advantage with the peel with the citrus fruit. We're seeing more of our smaller operators this summer trying to implement this technology, whether it's either hot water immersion, and in cases here mostly what you have is the dip of the--it's already prewashed, presanitized fruit, but they will immerse the entire pallet bin, a clean pallet bin, in the hot water, for 176 degrees for 1 minute, or two minutes at 158, and that in itself is a 5 log step, and the heat does not transfer, because of the fruit, to the inner flesh of the fruit. And then hot water sprays and steam, we've had some real successful 30 to 60-second treatments for a 5 log reduction on the external fruit using those methods.

MR. SANFORD: Could you just--Sanford with Tennessee--could you describe the steam, the quality of the steam?

MR. CHAIRES: I really, on the steam, I'm not going to be able to speak as directly to that. We've had one application, one large actually and one small, and the small operator that was moving towards the steam application has now gone back and is going to go with immersion.

One of the things that we're finding in the smaller plants in Florida is that these companies really for the most part don't have any other function for a boiler. They're not accustomed to using them. Their people are not trained around them. It scares them a little bit from a safety perspective. And the hot water immersion is a lot easier for them to control.

But what I've seen is, in the steam applications, is an enclosed steam tunnel fabricated out of either aluminum or stainless steel sheets with--well, starting off with PVC rollers, but I think they're going to back up probably in most cases and go to a more durable metal roller, and they're finding they have to use certain special bearings that are going to hold up to the heat. But the fruit will travel through the steam

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tunnel very slowly, but with a good wide belt you can get a good bit of movement through there.

MR. SANFORD: So the steam has direct contact with the fruit?

MR. CHAIRES: Absolutely.

MR. SANFORD: And so your concern from a quality standpoint would be the steam traps and that sort of thing, or the piping, and from a public health safety standpoint would be the descalers that would be used in the boiler room operations, so they would need to be nontoxic.

MR. CHAIRES: Right, right.

MR. : A single layer of fruit going through?

MR. CHAIRES: Yes, absolutely. Absolutely.

DR. MILLER: Could you identify yourself?

MR. MATTHYS: Allen Matthys, National Food Processors. What is it, a single later of fruit?

MR. CHAIRES: It is a single layer of fruit.

MR. MATTHYS: You can't get multiple layers?

MR. CHAIRES: That's right. And it moves into that, in that--I mean, it's moving in as a single layer. It's very much a controlled flow.

MR. : (Inaudible), Food and Drug. Is ozone regarded as (inaudible), is it approved or not approved, (inaudible). Also (inaudible).

MR. CHAIRES: No, I really can't speak any more to the ozone. I could provide you somebody later that probably could give you some information. Yes?

MR. BEELMAN: Bob Beelman from Penn State. What's the basis for the 1 log reduction in extraction? Are you leaving the peel behind or is there something that goes on during extraction?

MR. CHAIRES: No, it's primarily based on the small percentage of the peel. Number one, you have clean and sanitized fruit going into it, but also you have a very small percentage of the peel coming into contact with the juice, and the peel is peeled away and then discarded, and then the core of the fruit is pushed into the strainer tube where the juice then comes out.

MR. BEELMAN: So you're just--

MR. CHAIRES: It's actually the physical process.

MR. BEELMAN: --you're removing the portion of the material that would have most of the contamination. Okay.

MR. CHAIRES: Correct.

In one type of steam application, and this is just one of them, you keep the contact time down, such as--this is similar to Sun Orchards' situation, with the clean graded fruit entering into the steam tunnel, it's one layer of fruit, with 30 seconds at 190 degrees, and then the surface temperature of the fruit is reaching the 155, but they follow the steam with a chlorinated rinse, and this is used in combination with an ORP system, and the remainder of the log reduction contributing from these factors with the wash, the sanitizing and the extraction. And the Florida Department of Citrus has done the research on the steam application.

MR. : I don't understand. Does clean mean peeled already, or does it mean--

MR. CHAIRES: No. It's been brushwashed, soaped--

MR. : But not peeled?

MR. CHAIRES: That's correct.

MR. COLMAN: Peter?

MR. CHAIRES: Yes?

MR. COLMAN: Matt from Ardens Garden. Can I ask, what is an ORP system?

MR. CHAIRES: All I can really explain is, it's an oxygen reduction potential system designed to control your pH ranges, to maximize the potential of the

chlorine. There may be somebody here more technically oriented than I, that could add something to that.

MR. COLMAN; Oh, that keeps the chlorine from like diluting or (inaudible)?

MR. CHAIRES: I just wanted to show you a few excerpts from the guidance document, to give you an idea of what's included in here. It's primarily broken up into fact sheets, and it's divided into parts, one part for the roadside production facility where they actually have control over the whole flow, and then there's another side for the retail or grocery application, where in most cases they'll be buying their fruit from a packing house.

It breaks up the steps. Up here we have basically the cleaning process and then the grading, some things that might be considered GMPs, but are just critically important to put in there, such as if you have a grocery application, fruit previously handled by consumers is not to be used in the production of juice. You might not think that needs mentioning, but we put it in there to cover all the parts.

And then there are some things that are GMPs dealing with personnel and hygiene, extractor sanitation, clean containers. It moves all the way down, and then the storage of the fruit at proper temperatures.

Moving those same steps onto--this is just a very basic start on trying to help those retailers with their record-keeping and their check-off, on a kind of a daily practice. The same type of nine steps, but then move them onto a calendar where you have some direct responsibility of keeping track of that on a monthly basis and verifying that these things in fact had been done. That's not all the recordkeeping that they should be doing, but it gives them a start in verifying in their program exactly what's occurring.

Some examples of some research tables that are included in there. On this one on the top, dealing with the washing and sanitizing treatments for citrus fruit, using the SOPP and the alkaline cleaner, which is primarily what we're using, and then the selected washing treatments on the fruit inoculated with E. coli.

As far as spray volumes--the waxing is a critical part of the process for the smaller operators, not so much for the larger continuous production facilities because they are running fruit that is only going to be juiced. In the smaller ones, they are running fruit, grading out quality fruit that they're going to use for juice, so some of that fruit will already be waxed, but there's also a very effective

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aspect of the high alkaline, the wax and the sanitation treatment.

And the waxing used in combination with the SOPP cleaners, with the contact times and the details down on the bottom, will result in about a 4.6 log reduction in that step. And the Department of Agriculture in Florida, for the smaller scale producers, are going to be auditing and verifying these processors this fall. Most of them are closed for the season at this point.

And very similar to what we have put for retailers, there is a citrus fruit fact sheet that covers essentially the same type of things, but this is done from the perspective of a small scale juice producer, which would be your roadside shop or stand, that has more control over every element in that process than might your typical retailer.

And then as I mentioned earlier, with the hot water and steam applications, this research is proving more and more valuable to us as the smaller scale producers and the larger scale producers are seeking to avoid additional chemicals and chemical sanitizing steps. And this is the nice, clean operation to either go with the immersion, the steam or the hot water spray, all of which have been very effective for us.

Now, there are some other things. I'm running short on time, but you'll see in my notes that are included in your notebook some additional research that is still needed in this area, and we're still working on trying to identify those things that we can provide to the producers of all sizes, that will continue to help them to improve their processes. That's what we really feel that our role is, and we hope that something that we're doing on the citrus side will be of some direct benefit to what you're trying to accomplish.

Yes?

MR. TIERNEY: Paul Tierney, Mass. Department of Public Health. Can you give us any additional information or background on the current recall that's going on?

MR. CHAIRES: No, I really can't. I don't--I'm in the position right now of waiting for some answers on it. Until the investigation is complete and the report is out, there's really nothing that I can comment to it. I'm in the same position you are, waiting for more information.

We talk about it on a daily basis. We've been in contact with the Department of Citrus, University of Florida, the other scientific advisors that we have, and we certainly believe in the processes that we've

incorporated into our guidance documents and what we've been teaching in our workshops, that what we're doing is effective and the science that we've contributed to it is valid. So we're just waiting in fact to find out what occurred there so that we can speak to it, but we really don't know anything else.

MR. : How long do the hot water washes tend to run? Because my impression of hot water--

MR. CHAIRES: Spray?

MR. : No, no. The hot water washing tank. Is that right? You do that?

MR. CHAIRES: On the immersion?

MR. : Yes, because my impression is that if you tend to run those for a long time, you're going to wind up with a thermal--fermentation going.

MR. CHAIRES: Most of--what I've seen in one application is a double-sided pallet dip, is basically the size of a pallet bin plus a little extra room on it. It's run with a natural gas heater with a filter system and it's constantly filtering through.

It has an automatic thermostat. They don't get more than a degree and a half of drop, even during the coldest time of the season when you're bringing in cold fruit and you're running it through the washer and then bringing it in and immersing it, and the heater has been

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very effective at maintaining that temperature. And then in most cases the second side, they can either run it or not run it, but with a filter on it, it has been quite effective.

MR. CRASSWELLER: Rob Crassweller from Penn State. What kind of yield, to put it in the perspective of apples, what kind of yield or how much fruit do you need to produce a gallon of orange juice? How much would that fruit be worth, so we can see--you've got a lot of expense there. Can apple growers do that? Or are you getting much higher yield, so that you can afford that?

MR. CHAIRES: We were lucky enough to have, particularly with hot water application, to have a couple guinea pigs that were just so interested in it that they were basically going to have to spend the research and development dollars to put together the equipment, and they probably spent a good bit more than other plants are going to need to spend. But I know in one application, with the pump and the filter and the heater and the tank, they were looking at I think \$10,000 to \$12,000 on their investment for a small-scale--

MR. CRASSWELLER: So how much would you, if you had a bushel--I don't know, a bushel of--

MR. CHAIRES: I can't give you good yield numbers. I know it's going to vary, too, by variety and by season.

MR. CRASSWELLER: But we can do a rough estimate. We know how much juice will come off a bushel of apples. How much juice will come off a bushel of oranges?

MR. CHAIRES: I could call FMC and probably give you a better number.

MR. CRASSWELLER: We'd appreciate that, if you could.

MR. CHAIRES: Yes, yes. Any other questions?

DR. MILLER: I think need to limit it, so I see Gerry Sapers, Valerie, and one questioner over here. Then we'll have to call it quits for now.

DR. SAPERS: Gerry Sapers, USDA. In determining the log reductions you can get with this sequence of treatments, are you recovering the bacteria from the orange by rinsing or by homogenizing the orange--

MR. CHAIRES: I'm not a scientist. I couldn't give you that, but Dr. Steven Powell at the Department of Citrus, I'd be glad to give you a phone number for him, and he could give you that detail.

MS. : (Inaudible) in the area of hot water treatment, I'm wondering if the research that was

done had considered the possibility of internalizing the organisms. A 5 log reduction, that's a real nice piece of information to produce, but (inaudible) could be internalizing the organisms.

MR. CHAIRES: Certainly that was a consideration, I know, with the temperature of wash water and various things that came into play. That was a consideration, I know, when Dr. Powell had set up that research. But unfortunately I don't have any data from that study, but I know it was a consideration.

MR. MATTHYS: Allen Matthys, National Food Processors. You mentioned earlier that you provided for in some cases cleaning in the field and then transport somewhere else, and you were counting that log reduction. You were putting them into, in one of the earlier slides, that you were putting them into bags and moving them somewhere else?

MR. CHAIRES: The "cleaning in the field" was probably a bad choice of terms. It's an enclosed facility.

MR. MATTHYS: Well, cleaning them in a packing house operation and moving them somewhere else, for example.

MR. CHAIRES: Right.

MR. MATTHYS: Have you looked at whether you're getting any increase in microbial growth during that phase, as to whether there is any liquid carried over and so you get microbial growth which might affect (inaudible)?

MR. CHAIRES: Yes. In fact, we're doing some of that, I mean some of the research right now on how soon that fruit needs to be extracted after it leaves that facility.

MR. MATTHYS: You need to put a time frame in there.

MR. CHAIRES: Yes.

MR. MATTHYS: You need to clarify that, because some of these things can double in 20 minutes under the right conditions, and in Florida you've probably got the right conditions of temperature to do that.

MR. TAYLOR: Kirk Taylor, and I was wondering if this reduction that you're seeing, what is the final (inaudible), seeing that (inaudible)--

DR. MILLER: Kirk, could you stand up and speak louder?

MR. CHAIRES: What are the overall cumulative reductions?

MR. TAYLOR: What's the final counts that you find in that, the final product?

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MR. CHAIRES: I don't know. I couldn't answer that. I'm sorry.

DR. MILLER: Thank you, Peter.

We're running about 10 minutes behind. I have a suggestion for lunch, which is on your own. Right upstairs on the eighth floor of this building is a cafeteria. If you eat there, you should be able to get back and get us back on track. Alternatively, there are some places out on 3rd Street that you can get a quick lunch. So my recommendation is the cafeteria upstairs.

MR. SCHWALM: The only thing else I'll add here, if you want to get these when you come back, then you can just take them to your seat, but you've got some tabs, and the handouts in the back row here are the ones that are new. There should be enough for everybody. So the ones in the front here are from NFPA, and there is some material here on food processing.

[Whereupon, at 11:45 a.m., the meeting recessed, to reconvene at 12:40 p.m. the same day.]

AFTERNOON SESSION

DR. MILLER: Welcome back to the workshop on apple cider food safety, and as we're marching through our--I'm going to coin a new one--"tree to table" continuum, we're now at a point where we're going to take a little sidebar, and we've asked Anne Bertinuson from USDA Extension to describe some of the programs that are out there in the States, administered through the USDA CSREES, and then we'll continue marching through this continuum for the rest of the afternoon.

Okay, Anne?

DR. BERTINUSON: Well, first I want to correct a little--I've made a slight change from what's in the program. I'm not actually in the USDA Extension system. The Federal USDA Extension Services does not exactly exist as a separate entity anymore. The agency I work for with the very long name, the Cooperative State Research Education and Extension Service, is the culmination of a merging that happened, I guess about four or five years ago, between the Cooperative Research Service and the Cooperative Extension Service, for reasons that we think are good, so that things like research results get to the Extension and get sent out to people in good time.

I'm happy to be here for this workshop. I apologize for the fact that I'm kind of blowing in here, talking, and disappearing. Food safety is such an ever-expanding field, that I just finished a grant panel and now I'll run back and clean up on that and do about five other things.

But I am happy to be here, because it's I guess a bit of a coincidence, the very first job that I had as a teenager growing up in Connecticut was working in my neighbor's apple orchard, where I helped sort apples and pack apples, and then do the retail sales of apples and cider to, you know, the folks who drove by and stopped to buy stuff, and so I guess you could say I have a bit of sort of fond memories, and I have sort of an emotional reaction to the idea of small apple producers, small cider producers.

I mean, I think that the Federal agencies like the FDA and USDA recognize that that is, the Norman Rockwell image of the small producer is a pretty powerful one, and we like to support that. But they are also very realistic in realizing that this is an important part of our agricultural economy, and we're trying to find ways through venues like this to see how can we combine consumer preferences for fresh, natural cider and the

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need for food safety. So that's why I'm happy to be here to talk to you.

I mentioned already that I work for CSREES, and that we are part of USDA, and that we have roles both in research and education. And I notice, just looking through the program, that a lot of the folks who are speaking here in fact do receive funds from us for their work, and that's great.

And I'm not really here to tell you about specific research results. I see my goal as letting you know how USDA, in particular how the agency I work at, supports research and extension that can help the issues that you're facing, and how you can access that information in a number of different ways.

So the USDA is a very large agency. Within the agency itself there are, I think, about nine what we call mission areas, and I've left most of them blank boxes because it gets too confusing, but at the level we're talking about, where I'm going to tell you about the Research, Education and Economics mission area, this is the same level as like Food Safety and Inspection Service, Nutrition, those kinds of levels.

The Research, Education and Economics mission area contains, besides a couple of other agencies that I'm also going to not talk about now, the Agricultural

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Research Services and my agency, the Cooperative State Research, Education and Extension Service. I really wasn't going to talk about CSREES, but I wanted to contrast it a little to ARS in terms of what ARS does.

ARS is the in-house research agency of USDA, which basically means that their researchers, whether they're at their main facility in Beltsville or at their research stations scattered around the country, sometimes associated directly with universities, sometimes more or less freestanding, those researchers directly do the research. That's in response to national needs. It's often in response to needs of agencies, regulatory agencies like FDA, FSIS.

And then they get that--the results of that research can be delivered in a number of different ways. It might have an impact on regulation. It might be published in scientific journals just like any other research. It will be shared with folks at the land grant universities I'm going to talk about in a minute, and that's one way it's going to get to you through the Cooperative Extension System.

In addition, ARS does a really good job on getting information out. Their News and Information Service I think is great. I'm giving them a little plug here. Their ARS magazine I read every month and find

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lots of interesting stuff in it. All of these different web sites that I'm showing you are all in the handout over there that I've left, so you don't have to be frantically copying things down. By going to their web site and looking at the ARS magazine every month, you're going to learn something interesting.

So, as I commented, they are the in-house research agency. They have something like 2,000 employees. And what's different about us at CSREES is that in Washington at the Federal level we probably have 300 or 400 employees, but our agency sort of reaches out across the country through our connection with the land grant system.

In the last year or so, talking with people from different--all over the world, for various kinds of reasons, our--the system that we have in this country, I have to blow our horn, that we federally support our State universities, our land grant universities, that we give them money, that there is the connection with the extension service, is just great. I've heard people from a lot of other countries say "I wish, you know, I wish we had a system like yours."

And so we only have about 350 employees in Washington, but really everyone who works at a land grant university or as part of Cooperative Extension is

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connected with us, and in fact what we bureaucrats in Washington do is act as a conduit back and forth to share information with those folks.

Now each land grant university, and these are the State universities in each State that are built on land that was a grant from the Federal Government, free land, get a certain percentage of their funding every year from formula and base funds, and those kinds of funds support research that could be of interest to you.

In the handout I gave you, I just pulled an example of a project at VPI that was specifically on methods of washing apples to decontaminate them, and it has some good suggestions on what could be useful. I believe that research has now been published. I think there might be somebody here today who might talk about it in the comments section, which is what I was told. If not, with the information I gave you in the handout, you could actually find out about it. You could get ahold of these investigators and look for this research.

So that is sort of a formula funding, direct funding. Another--the other kind of funding mechanism we have at USDA and in CSREES is the competitive grant process. We put out a Request for Proposals, which is a description of the kind of research we want done, the research problem we want addressed, and we ask people to

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tell us how they're going to solve that research problem. If they give us a good answer, we'll give them some money.

Now, a lot of the problems that--sorry--a lot of the programs that we run are open not just to the land grant universities but to other universities, private companies. And the idea behind this is, if you can describe clearly enough a specific research goal you want, you open it up and you have a chance that the best possible people are going to do it. That's the idea behind it, and it usually works out fairly well.

Oh, sorry, a little sidetrack here. The way that I pulled down some of the information I put in, in this handout, is from the Current Research Information System. All USDA-supported research is on the Internet at this site. You can go in here, you can search the CRIS database by words, by investigators, and get a feel for the kinds of research that's being done, and in the handout there is a sort of a direct printout for what that looks like. And that is, to my mind, if you have access to the Internet and you're not afraid to use it, that is a great way to get some general information about things that are going on.

Okay. This is one of those presentations where I look at the next slide to see what I was going to talk

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about next. As I said, food safety is expanding like this. Within CSREES we have the National Research Initiative Competitive Grants Program, which is in the \$100 million range every year, and they have a specific program on food safety, and you can see how it has been growing almost exponentially in terms of the money that we are spending on food safety. About \$2.4 million, I think, in '98.

In this fiscal year, about \$4 million for the regular program plus an extra \$5 million that went specifically to one program area, I think. And what is happening in the year 2000 for our proposed budget is, Congress has asked us to combine research--in some cases to combine research and extension activities, in this case simply to combine some of these other programs into one biggie.

So in the National Research Initiative alone we're looking at about \$12 million on food safety. Here again is their web page, if you wanted to go and find out what their programs are. You can also--they will also report the results of who has been funded and what they're planning on doing there.

In fiscal year 1999, from among their requests for funds, I just pulled out a few possibilities for things that might impact on what cider producers are

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interested in. Strategies to eliminate disease-causing microorganisms: washing methods for apples; ways to pasteurize or, let's just say, get the reduction in pathogens in finished cider; improved detection--well, improved detection methods, models for risk assessment, those are more basic research that may help us develop better Good Agricultural Practices or better HACCP plans for juice.

They also support some what you might call social science type research: obstacles to adopting safe food habits. So these kinds of things, in other words, if you give someone some label information on what the possible risks are associated with cider, do they read it and understand it and do they take the appropriate measure that they should?

All of the grant, competitive grant programs I'm talking about here are right in the middle or just finishing up running their competitive grant panels, where scientists look over the proposals and give out the money, and so what is going--the kinds of research that's going to be funded will be reported, I guess, in a month or two.

As I mentioned, in fiscal year '99 an additional \$5 million was added to the NRI specifically for epidemiological approaches to food safety, and these can

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be of interest because they are all looking at basic research on what are the microbes that are out there, how many are there, where are they. And then it helps you make decisions. It helps people plan Good Agricultural Practices or HACCP plans, in terms of what are the best places to look.

I hate to go another level into the complexity of our agency, but within CSREES I'm in a unit called Plant and Animal Systems, and we have two big programs ourselves. One is the Special Research Grants Program for Food Safety, which in 1998 got \$2 million and in 1999 got \$5 million.

And then we also have an education program called the Food Safety and Quality Initiative, which is very much an extension program that funds almost a formula type fund proposal to each State, where they can work on overall food safety plans for their State, food safety education and extension; and also a competitive grants program, that is open to any land grant university, on many aspects of food safety. That program leapt up from a little over \$2 million to \$7 million in '99, and as you can see, in 2000 this is this merging research and extension that Congress has asked us to do, and we've gone from a total of about \$12 million in '99 to requesting about \$15 million in 2000.

So here is--this is my baby, the Special Food Research Grants Program. Here again is our web page, where you can go and see, every year we put out a Request for Proposals, what we're looking for, and we'll also give you a synopsis of what we funded last year. In this program last year we funded two proposals on juice, one specifically on cider and one on cider and other juices, methods to reduce microbes in that.

And in 1999 we asked for a couple of different things. Oh, another thing I meant to talk about was, when we make these RFPs, we don't just sit--we don't have one guy sitting in his office saying, "Oh, this would be nice." We get together, USDA, including regulatory agencies like FSIS and FDA, and we say what are the real needs and how can we write--how can we ask for research that will address them?

So this year we asked for proposals on risk assessment for ready-to-eat foods, which cider would be an example of that. It's minimally processed. The consumer doesn't heat it up at home before they eat it--before they drink it, excuse me. We also asked for proposals that address the scientific base and models for critical control points.

This also could have an impact on cider research, as well. Someone could really say, if this

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washing step is added, does it give you the 5 log reduction we're asking for? Could we study these two things for a cumulative 5 log reduction? And again, as we did last year, we asked--last year was totally focused on the safety of fresh fruits and vegetables, and we included that as a possibility again this year because we think that's very important.

Okay. The Food Safety and Quality Initiative which I mentioned briefly before is our extension program. And this program, as I said, is getting an increasing amount of money. They have funded last year some education programs for basic fresh fruit and vegetable safety, along the lines of the Good Agricultural Practices in the FDA document.

And let's see if I have--I think the next slide shows you, what they've asked for specifically this year is HACCP--among the many things they asked for people to submit competitive grants on was HACCP model development, and they said specifically models relating to the safety of fresh fruit and vegetables. Develop a model, get an education plan, and go out and do it, either in one State or a region or the whole country, if you think you can do that.

They also asked for projects that focus on "train the trainer" programs, and these of course could

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be of interest as well. These are the kinds of things where you might have a "train the trainer" program for a few people from each region of the U.S., and then they can go back to their region and give a HACCP training course. And they asked specifically for use in emerging areas and new target audiences, so obviously developing a HACCP plan for juice is a new area and that could be funded under this program.

That is a very quick run-through of the kinds of different programs that we have that fund research and extension programs that might be of interest to you. I hope I've given you a good feeling for how you can go about getting this information. I guess I should close by saying, as it has always been, the local, the Cooperative Extension in your State, whether it's at the State level or the local level, is a great place to go to get this information.

Long before we had the Internet, you know, we had folks in Washington with their connections out to folks all over the State, to try to get information out to people, to answer people's questions, to bring the questions back to researchers or educators in the Federal Government and back out to folks who need it. And I think that's plenty of time for this topic, and we might have a minute for questions or we might need to press on.

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DR. MILLER: Any questions?

MR. : I just have one note. On page 2 of the examples you have, the first paragraph--

DR. BERTINUSON: Right.

MR. : --there's a statement in there: "Apple cider processors indicated in a survey that most do not wash apples."

DR. BERTINUSON: Uh-huh.

MR. : That's a scary thought, isn't it?

DR. BERTINUSON: Yes, it is. Well, I mean, that was the purpose of the--that was the purpose of doing the research. That was probably a survey in that State, and that's why the researchers' conclusion was, they have developed some procedures that look like they would be cost effective for washing apples, and this could be something important to do.

MR. : Do they allow you to process (inaudible)?

DR. BERTINUSON: Well, you know, it didn't seem like it was a problem.

MR. : (Inaudible) Federal regulators that allow (inaudible), GMP regulations (inaudible).

DR. BERTINUSON: Yes?

MS. ZINN: Are there any grants available to do a study on the health benefits of fresh juice?

DR. BERTINUSON: Probably not. There probably are, but not from my specific agency. That could be Health and Human Services. It also could be the Nutrition Service of USDA, which I'm not familiar with. But, you know, if you just go to www.usda.gov, you know, you can find out about all our agencies and track down some of these.

DR. MILLER: Any other questions? Comments?

[No response.]

DR. MILLER: I want to thank you, Anne.

DR. BERTINUSON: Thanks. It was my pleasure.

DR. MILLER: Our next speaker will be Dr. Gerry Sapers from ARS, that other agency that Anne referred to, who has the good newspaper or magazine, and Gerry is going to--well, let me back up. We're going to hear a series of talks about pre-pressing, potential interventions, and in each instance these are principal investigators who are working at a facility that Dave Bolster referred to in Placerville, California.

It's a cooperative project where FDA is working with El Dorado County, the State of California, UC-Davis, the National Center for Food Safety and Technology, and a variety of industry contributors to try to address this

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question of what does it take to achieve the 5 log reduction. So Gerry is part of ARS, who is part of the partnership, and he'll talk to us about some of the efforts on washing, brushing and sanitizing of intact apples.

Gerry?

DR. SAPERS: Thank you, Art. And before I get very far, I will need the slide projector.

Okay. Thank you. In response to a growing concern about the microbiological safety of produce, and the calls for research and interventions to improve microbiological safety, we initiated a large research program in this area over two years ago. And the major thrust of this program has been, first of all, research on washing and in particular on washing of apples, but it's part of a broader program that deals with a number of different commodities.

Now, we focused on this area because of anecdotal information and some limited published data suggesting that washing was not very effective as a means of decontaminating fresh fruits. Our research has had three main objectives: to compare the effectiveness of conventional and experimental washing and sanitizing agents in removing or killing E. coli in apples; secondly, to determine the efficacy of these washing

treatments using a commercial brush washer; and, third, to identify factors that would limit the efficacy of washing as a means of decontaminating apples. And in today's presentation I'm going to summarize the results of our studies in these areas.

We began this research with washing studies carried out in the laboratory using unwashed Golden Delicious--unwaxed Golden Delicious apples that we had inoculated with a nonpathogenic strain of E. coli designated ATCC 25922. We used this strain instead of the pathogen E. coli 0157 simply because this kind of research is very messy and we didn't want to spread E. coli around a laboratory that was not designed for working with pathogens.

To examine the nature of bacterial attachment to the apples, we inoculated not only whole apples but also apples that had artificial punctures that we had made with a nail and apples that we had cut in half, so that we could see the binding of the organism to the flesh and core areas.

We immersed the apple samples in concentrated suspensions of the bacteria so that we would end up with a population of as high as 10 to the 5th colony forming units per gram, and that's equivalent to bacterial cells per gram, in the inoculated apples. The apples were

drained and then held for at least 30 minutes--and this time is critical, and we'll come to that later--in order to give the bacteria enough time to attach to the surface.

And then we carried out washing trials by placing the apples in a plastic tub containing the particular solution we were testing. This was done under--with agitation. The solutions were either at ambient temperature or preheated to 50 degrees Celsius, which is 122 Fahrenheit.

After washing, the apples were drained, rinsed in tap water, and then homogenized in a large blender, diluted, and plated on brain-heart infusion agar in order to determine the number of surviving E. coli.

Now, this is a partial list of the different washing agents that we compared in these studies. I did not identify them by brand so we wouldn't offend any of the manufacturers, since not all of these performed that well, but we had a number of representative types, including some of the acidic surfactant combinations, including a number that contain phosphoric acid, two alkaline products, a peracetic acid formulation. And in all of our studies we compared these treatments with an untreated inoculated control, and also with a sample that

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had been inoculated and washed with 200 ppm chlorine, that is, a sodium hypochlorite adjusted to pH 6.4.

Now, this next slide shows some of our results. Pay close attention to the log reduction column. A log reduction of 2 is equivalent to a 99 percent reduction. A log reduction of 1 is equivalent to only a 90 percent reduction.

And what you'll see is that chlorine produced, under these conditions in the laboratory, about a 2 log reduction, and most of the solutions, these commercial products that we tested, were very similar. We did get some enhancement of the action against the test organism by heating these solutions to 50 degrees C. compared to 20 degrees C., which was room temperature. But in general we did not exceed 2.5 logs in any one of these treatments in the laboratory.

Now, in further studies we found that 5 percent hydrogen peroxide, applied at a temperature of 50 degrees Celsius, was considerably more effective than chlorine or the other agents that we tested, and in most cases it was better by at least 1 log.

And you can see in this comparison we found that with heating under these conditions we got almost a 2 log increase over chlorine. We got better results in some cases when we added a surfactant combination to the

hydrogen peroxide solution. We got variable results with trisodium phosphate because the trisodium phosphate tends to cause the peroxide solution to break down. But in most of these experiments you can see the substantial improvement over chlorine.

When we applied these treatments to whole apples--I should mention that these previous data were obtained with apples that had been cut in half. Now, in that case we assumed that it was more difficult to attack bacteria on the cut surface, where they adhere better, than on the waxy natural surface of the apple.

But in this experiment here we used whole apples, and you can see that we got a somewhat lower bacterial load on the apples because it was the whole surface. Instead of 5 logs, we had about 4 logs on the apples. We got a reduction of about 2.5 logs to 3 logs, in that range, with the hydrogen peroxide, compared to only about 1.5 logs with the detergent product alone. And the data is not shown, but we got similar results with chlorine, under 2 logs.

To confirm the results of these laboratory studies, we carried out further trials at the Placerville location which you've heard about. These studies were carried out in the cider mill with a flat bed washer, using the entire process. And so to do this we scaled up

our laboratory procedure, using larger quantities of apples in these experiments.

About 40 pounds of Golden Delicious and about-- which we inoculated, and about 250 pounds of Fuji which were not inoculated, were combined in the dump tank, which contained about 350 gallons of water. And what we did in these experiments is to mix the apples in the dump tank for 15 minutes, to be sure that there was a good mixing of the inoculated and uninoculated apples. This would allow us to look for possible cross-contamination.

After 15 minutes we went to the--we scooped the apples out of the dump tank onto the conveyor, going into a brush washer. This was a flat bed brush washer. The apples went through the brush washer. They were sprayed from above with a number of different solutions.

We tested water at both ambient temperature and 50 degrees C., 200 ppm chlorine. We looked at 8 percent trisodium phosphate. We looked at 5 percent hydrogen peroxide at the two temperatures. We also looked at a commercial acidic detergent solution.

The dwell time in the system was 25 seconds. The apples came out of the brush washer. They were spray rinsed with water as they went up the conveyor to the hammermill. They were ground and pressed to make the cider.

We took samples of the apples at each stage of the process, and the cider, and the dump tank water, for microbiological evaluation. These are the results. I'm sorry, I didn't continue on, but anyway, we'll go on. The samples were sampled using duplicate six-apple samples from each stage along the process, and we sampled both the inoculated and the uninoculated apples so that we could test for cross-contamination.

Now, under the data, and the results were very surprising, to say the least, because what we saw was that when we started we had about 5.5 logs on the apples, 5.5 and 6 logs on the apples. Coming out of the dump tank we were still between 5 and 5.5 logs. Coming out of the brush washer there was practically no change, just a few little variations here and there, but basically we got a zero log reduction, we got virtually no log reduction coming out of the brush washer.

When we went to make the cider, we found a small reduction of about a log, which can be explained almost entirely on the basis of the fact that we diluted the inoculated apples with a larger quantity of uninoculated apples, simply to provide enough mass to make the cider, so the actual reduction due to this entire process was probably only a few tenths of a log.

This is very disturbing. We felt that this was due largely to two factors: one, that the dwell time in the system was only 25 seconds, which is not very much time; and, secondly, that the surface treatment, using overhead sprays as the source of the washing agent and the rotating brushes, simply did not get into the areas of the apple where the bacteria were likely to be concentrated, in particular the calyx and stem ends, and I'll show you data in a few minutes to back that up.

With regard to cross-contamination, we looked at the dump tank water and found that we couldn't detect E. coli in the dump tank water. Now, these apples had all been inoculated and held at ambient temperature overnight. If they had only been held for a few minutes, then it would be quite possible to get a lot of detachment of the E. coli from the apples into the dump tank water. With the 18 or 24-hour time interval from inoculation to the time of the experiment, the bacteria bound to the surface of the apples to such a degree that we could not detect it in the water. And I didn't show here, because it would clutter up the slide, but we did not detect significant levels of E. coli on the uninoculated apples as they passed through the system.

But we did identify one major source of cross-contamination, and to do this what we did was to put

through a series of trials with inoculated apples through the system, so that the entire system was thoroughly contaminated. Then we cleaned out the system superficially. We hosed everything down, but did not use a sanitizing agent. We disassembled the hammermill, but again did not use a sanitizing agent after we hosed it down. The press cloths were rinsed but they were not replaced.

And then we put through 300 pounds of uninoculated apples. The apples picked up very low levels of contamination going through the brush washer, but coming out as cider, we were at 3 logs, which is only about 1 log less than had we used inoculated apples. So all of these bacteria were coming presumably from either the hammermill or the press cloths.

This just points out the importance of good sanitation through the process, so that if you do happen to encounter a small quantity of contaminated fruit, that it would not contaminate the entire system and a very large quantity of fruit and cider produced subsequently.

Now, the poor performance of the washing treatments in the cider mill situation caused us to return to our laboratory to look for factors that might explain our poor results, and to point the way to improvements in washing effectiveness.

The first point that I want to make here is the question of rapid attachment. In this experiment, carried out in a laboratory, we held apples after inoculation for as long as 72 hours. Then we measured the numbers of E. coli on the apples, and also after washing with just water, but in the same agitation system that we used at the lab to evaluate the different washing agents.

And you can see that the counts were fairly consistent. There was not an awful lot of change over time. But if you compare them, compared to the inoculated controls, after 30 minutes we had about a 1 log reduction. At 24 hours we had about a half a log reduction. Beyond that point there's no reduction at all, so the bacteria are staying on the apples.

A superficial wash or rinse as might occur in, say, a dump tank, is not going to accomplish very much if the apples were contaminated at some point prior to their going into the cider mill. For example, if it was during harvest, pre-harvesting, or even during storage and handling post-harvest, the apples would be contaminated to such a degree that the bacteria could not be washed off with any surety.

The second point I want to make is the question of binding to inaccessible areas of the apple. In this

experiment we inoculated the apples, waited 24 hours, and then using an ordinary kitchen apple slicer, we divided the apple into wedges and core. We took the core and further subdivided it into the calyx end, the stem end, and the central portion. We did this on composite samples of six apples given this treatment, and determined the bacterial population in each one of these subfractions of the original.

This shows the count, calculated now per square centimeter of surface area. What we did was estimate the surface area at this calyx end, it's conical in shape; at the stem end, it's also conical in shape; and then on the surface of the wedges that we had cut.

So basically what we're looking at is the entire surface area of the apple, broken down into the calyx end, the stem end, and everything else. What we found, calculating the count per square centimeter, is that we had many more bacteria adhering to the core, the calyx and stem ends of the core, than on the, shall we say, the smooth skin surface of the rest of the apple.

When we washed these fruits, now we carried out the same kind of experiment, but instead of cutting it up after, as being a point of the experiment after the 24 hours, what we did in this case was to wash the fruit with 5 percent hydrogen peroxide at 50 degrees C. and

then, after rinsing it off, we cut the fruit in the same way. You can see that on the wedges, the skin on the wedges, which is the bulk of the skin, it was very easy to get the count all the way down to 2 logs.

But you can see that in the calyx end and in the stem end, the counts after washing were--they were reduced by 2 logs, but you're starting at a high point of 7 logs or 6.5 logs. You still have about 5 logs per square centimeter in these areas of the apple. Unless you could get into these areas of the apple by some mechanical means, and either remove or kill the bacteria in these locations, you cannot expect to get a 5 log reduction by washing.

One other complicating factor that may or may not have had a role in our experiment, but would certainly be important in the real world, is the presence of punctures. In this study we inoculated apples with artificial punctures in the laboratory. We found that *E. coli* was able to grow in the area of the puncture. So even though the apple is highly acidic, and in cider you don't expect to get *E. coli* to grow, whether it's acid-tolerant or not, in this case this organism or this strain of *E. coli* was able to grow to the extent of about 1 log within the area of the puncture.

And to make it more complicated, it's much more difficult to decontaminate the E. coli within a puncture than on a smooth surface. It's equivalent to the calyx and stem problem. The bacteria within the puncture are inaccessible. So if you attempt to wash them with some kind of an antimicrobial agent, you'll only reduce a very small part of that population.

Now the last point that I want to make is infiltration, and this is a question that Bob Buchanan visualized previously. In fact, this was done when he was part of our organization. He carried out studies showing that under the right temperature conditions, E. coli could penetrate through the calyx and into the core of the apple, and this was when the apples were warm, the water was cold, and if you put the warm apples which contain internal gases into the cold water, the gases contract, producing a partial vacuum. This draws water into the calyx, towards the core. If that water happens to be contaminated, then you get E. coli into the core.

What we did, just to visualize this, was to make a solution of Red 40, the food dye, and put warm apples into a cold solution containing a tenth of a percent of Red 40. Then we fished the apples out after a few minutes, washed them thoroughly so that we got rid of the superficial dye on the surface, even swabbed out the

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calyx end with a Q-tip so that we wouldn't get some dye in there that we didn't--that was still external to the core.

Then we cut the apple open, and this is what you see. So here, just by immersing warm apples--this was apples a few degrees above ambient temperature--into cold water, you get this much dye into the apples, to make it very, very visible. Visualize these as being E. coli, and you can appreciate the problem of internalization. So if E. coli were able to penetrate into the apple core by some means, obviously no washing method is going to be effective.

We are looking at number of approaches to deal with these potential constraints on the efficacy of washing. Some of these are listed on the slide. We've had some success in preliminary studies, in which we used shaped brushes or abrasive tools to literally scrub out the calyx and stems, and then we apply a hydrogen peroxide wash to that, and we have been able to get substantial reductions, although it's too early yet to predict whether we can get 5 logs or not.

We are also looking at the combination of surface pasteurization followed by application of a hydrogen peroxide wash, and that also is showing some preliminary favorable results, so in time we may be

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making recommendations about these treatments. I should caution you though at this point that while hydrogen peroxide does seem to be more effective than chlorine and some of the other antimicrobial agents, it has not been approved for washing of produce by FDA, and so an apple processor could not go out and use it until it is approved.

So, in conclusion, we have demonstrated in our laboratory that 5 percent hydrogen peroxide is superior to both 200 ppm chlorine and a number of other commercial washing and sanitizing agents in decontaminating apples that were inoculated with a non-pathogenic E. coli. However, even in the laboratory none of our treatments achieved a 5 log reduction, and when we went to the cider mill, we didn't even get a 1 log reduction.

We attribute the poor performance of these washing agents with the flat bed washer to the limited exposure of the apples to the wash solution, the inability of the brushes to reach into the calyx area and the stem area, and possibly to the problem of internalization and punctures within the core, or just the fact that the bacteria bind on and are very difficult to remove.

Washing is not going to be the answer in achieving a 5 log reduction. You cannot depend upon

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brush washing to decontaminate apples that contain human pathogens. But washing still serves a useful purpose, and I don't want to finish without, you know, stating that. If you wash, you will remove soil, you will remove pesticide residues and any superficially attached bacteria that might have been the result of cross-contamination in the dump tank.

So there is a reason for washing, there is a good purpose for washing, but at the present time it seems that other methods of decontamination will be required in order to assure the microbiological safety of apple cider. Thank you.

DR. MILLER: George Jackson.

MR. JACKSON: On your other produce, similar results or--

DR. SAPERS: We've worked with cantaloupe and carried out washing treatments on the external surface of the cantaloupe, then made a fresh cut from the flesh. So we've been looking at reduction of the population on the surface, and we get very similar results. We've also done some work on bell pepper, and again I think we get somewhat similar results, so I think it's kind of a general phenomenon. But of course with each commodity you have a different shape issue, different issues of-- areas where microorganisms can penetrate into the

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interior, so each commodity has to be examined individually.

Yes?

MS. DUFFY: Siobain Duffy, Rutgers. Looking at the growth of E. coli in the punctures of the Golden Delicious apples, did you find that they reached a maximum population per puncture?

DR. SAPERS: Yes, they did.

MS. DUFFY: Could you speak to that?

DR. SAPERS: Yes. If you make a small puncture, you have only a limited supply of nutrients available, and they will grow to the capacity of that little hole and they will plateau. So we typically found maximum growth during the first few hours--well, the first 24 hours. Then it slowed down. Between I think 48 and 72 hours there was no change.

MS. DUFFY: But (inaudible) published a paper last year about fruit fly transmission using a larger wound in apples, and he found maximum populations of approximately 5 to 6 logs.

DR. SAPERS: Yes, it depends on the size of the wound. That work was actually done in Carneysville by Jan Shulwitz (ph).

DR. MILLER: Is there a question over here?

DR. EL-BEGEARMY: Mahmoud El-Begearmi, University of Maine. I have seen also other research results that support the hydrogen peroxide effectiveness in washing. Is there any reason why FDA did not approve that, too, for use with fresh fruit and vegetables?

DR. SAPERS: It's not that they didn't approve it. I'm not--I think perhaps one of the FDA people can address that question better. But it's a question of industry petitioning for it to be used.

DR. MILLER: Somebody has to actually request that it be approved through a petition process. We're going to have a speaker that will talk about that, so if you want to save that question, I think that would be a good question to address later.

DR. EL-BEGEARMY: But that also has some implication on the consumer.

DR. MILLER: I think we have time for one more question.

DR. SAPERS: Yes?

MS. HUMES: Lorraine Humes, FDA. You were saying in your charts here that you were using your at 20 degrees Centigrade.

DR. SAPERS: Yes.

MS. HUMES: And yet they've said that if the apples are warm and the water is cold, that it may go in,

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inside. What is the normal temperature of the wash water that would cause it to go inside apples?

DR. SAPERS: Well, look at this scenario. If the apples are harvested in the summertime or early fall and processed right away, they could be at temperatures at 70 or 80 or 90 degrees Fahrenheit, depending upon the location. The water is coming out of either a municipal system or a well. It's coming up from underground, let's say. The temperature could be maybe 50 or 60 Fahrenheit, so you've got a very large temperature differential.

Now, in the laboratory, of course, you can make it whatever you want. In the cider mill experiments we adjusted the temperature to be exactly 20 degrees, and all of the fruit samples that we work with were at a lower temperature because the experiment was done in March and they were coming from outside, outside storage, so we always had a temperature differential to prevent this internalization process from taking place. But in actual production situations you could visualize how it could happen.

MS. HUME: Well, do you think your results would be better with warmer apples?

DR. SAPERS: Well, normally the apples should be colder. In order to minimize the scenario, you would want to have the apples refrigerated and the dump tank

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water warm. That way, the apples would not cool down, they would warm up, and you wouldn't get this vacuum effect.

DR. MILLER: We will take more questions, so I thought I saw a hand over here. Two hands.

MS. ZINN: What exactly is a flat bed washer?

DR. SAPERS: It's a kind of washer--

DR. MILLER: Could you identify yourself, please?

MS. ZINN: Leslie Zinn, Ardens Garden.

DR. SAPERS: It's the kind of washer in which you have the apples going perpendicular to the direction of rotation of the brushes. The brushes are just on a flat surface, rotating, and there can be different degrees to which they rotate. With some--

MS. ZINN: So it's not a cylinder shape?

DR. SAPERS: It's not a cylinder shape, it's not a U-bed washer.

MS. ZINN: Could you get better results with a cylinder shape?

DR. SAPERS: We did some work at the National Food Processors Association with a Van Mark, which is that U-bed type of washer where the brushes are arranged in a U shape and where the direction of rotation is the opposite of the flat bed. We got essentially the same

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results. Except it was the first time we did it, we didn't believe it, that's why we had to go try it again, and this time we believed it.

MR. GARCIA: If these studies were done--

DR. MILLER: Please identify yourself.

MR. GARCIA: Guadalupe Garcia, FDA. The studies were done with apples, which are natural wax, because apples are waxed right after harvest, would you see the least amount of reduction in--see some protection or greater protection in E. coli population?

DR. SAPERS: Are these--I'm sorry, I didn't--

MR. GARCIA: The apples were not waxed?

DR. SAPERS: They were not waxed.

MR. GARCIA: They were natural state, natural wax, but if you harvested and then waxed, would you at least see a protection (inaudible)?

DR. SAPERS: Well, I'm not sure, because if you used apples that had been previously contaminated and then waxed them, you might seal in the bacteria so that they're permanently there until you eat them.

MR. GARCIA: I'm saying after harvesting, you inspect a pristine apple that has not gone through processing and (inaudible) or whatever, and if it is waxed right after harvesting with a new wax coating, then

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you take it through the processing, would you at least protect (inaudible) against (inaudible)?

DR. SAPERS: I wouldn't think so. In fact, we've seen examples in which the apples are contaminated on the tree by dust blowing from a feed lot or pasture, and you can pick up E. coli. We didn't find E. coli 0157 but we did find E. coli on the surface of apples that were downwind of a feed lot. So that would just seal them in.

DR. MILLER: Please identify yourself.

DR. HIRST: Peter Hirst, Purdue University. In practice it's very rare to wax apples to be used for making cider out of anyway, so that situation probably wouldn't normally arise.

DR. MILLER: Any other questions? Comments?

[No response.]

DR. MILLER: Okay. Thank you, Gerry.

MR. SCHWALM: Bob Merker's talk is up here on the table, if anybody did not--okay, I'll pass some down and then I'll collect them on the other end, and anybody that did not pick up theirs--

While they're working on that, I see we still have a bunch of the ones from Cooperative Extension. Is there anybody who did not get those? Okay. Well, let me pass some of these down, and I'll collect them on the

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other end if you've already got them. This is the talk that you've already heard.

DR. MILLER: While we're waiting for the computer to boot up, I think, just like the issue with fruit flies as a vector, it's important to bring out that there really are no data showing that E. coli 0157:H7 or Salmonella actually become internalized in the natural setting.

And, again, it comes down to a number of things that swirl around this question of risk assessment. Where are the risks? Are the hazards on the surface or are they internalized?

And I think as we move through this workshop, we will see that these are critical questions that need to be answered in the natural setting so that when we, one, choose our interventions and, two, decide where we're going to apply it, it can be used or they can be used, if in tandem, in a way that's most effective. So these are absolutely critical questions that need to be answered in targeting our intervention strategies.

I think we're where we need to be now. Dr. Robert Merker is with the Food Center at FDA, and is one of the principal investigators on the apple cider program at Placerville, and Bob will talk about some preliminary work that was done during the last harvest season on the

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question of tree-picked versus dropped apples and its effect on the microflora.

DR. MERKER: Thanks, Art. The first thing I'd like to do is to acknowledge some of the people who have worked on this project, and I'm not doing this in any particular order, but they are Lauren Jackson, Kirk Taylor, Sue Keller, Valerie Davis, Kathy Melvin, Dave Bolster, Hsu Ling Tau, Mary Wang, Art Miller, and Stuart Chirtel.

The whole question of dropped input apples and their use in cider has become one that has become rather controversial, and at least to this date it's really a question of guilt by association. There really is no firm proof that the pathogens have been primarily from dropped apples at this point.

Again, at this stage the amount of hard data from controlled experiments is also limited, but some conclusions can be made. Therefore, I would like to focus on three different areas: First, what we do know about dropped apples as input apples versus tree-picked. The second thing is what we don't know, and the third is why more precautions are now necessary and traditional practices may need to be changed.

The 1990s have brought us several outbreaks associated with apple cider or unpasteurized fresh apple

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juice. In 1991 and 1996 there were outbreaks with the infamous E. coli 0157:H7, which is an emergent strain that's far more pathogenic than most of the species. Other apple cider associated outbreaks occurred with Cryptosporidium and Salmonella. And in at least one of the 0157:H7 cases the use of dropped apples was associated with the cider that was consumed by the affected individuals.

And even there the actual source of the contamination in the cider is really something that we don't know anything about. It could have been a case that there were a few contaminated apples that were heavily contaminated, it could have been a case where there were a whole lot of lightly contaminated apples, or something that was introduced later on in the process.

Apple cider of course is usually prepared in relatively small lots by commercial standards, and is often produced by smaller processors. Contamination is usually found only to affect a small number of people, and usually it's only one or two production batches that have been found to be associated with a given outbreak.

It is difficult to assess where the entry point of the pathogens is, whether it's a pre-harvest question; whether it's during the harvest by poor agricultural

practices; or whether it's a consequence of the post-harvest handling practices.

And one other point that I'd like to make fairly strongly is that there is a very low likelihood of actually finding E. coli 0157:H7 or Salmonella in apples if you're just trying to find it; that these outbreaks have occurred very sporadically and in several different parts of the country. So it's not something that would be easy to reproduce or easy to actually find. It's a very low frequency event.

This data brings some questions to mind, though, given the initial association between dropped apples and some of the early outbreaks. The first one is, are tree-picked apples less likely to be contaminated with pathogens than dropped apples? And the other is, what are the likely sources of such contamination?

We can talk about the potential sources of the contamination, and this is something that may well vary in different regions where growing practices, climate conditions, and the general microbial ecology is likely to be very different. The sources of microbes on the apples are most likely to come from the following sources: from field contamination, which would be likely to be reflected in higher numbers of microbes in the dropped apples, and that would include microbes that are

just resident in the soil, those from water supplies which may themselves be contaminated, microbes from domesticated or wild animals or insects.

And then there's also contamination due to the less than optimal agricultural practices, and other possible sources are of course in-plant contamination, and these can include handling practices or, as Dr. Sapers was talking about, poorly sanitized equipment. And then post-processing contamination, where perhaps in bottling or transport you might end up introducing contamination, or inappropriate storage of the unpasteurized products could increase very low levels of certain microorganisms.

Then the question gets to be, are dropped apples more likely to be contaminated? We would of course presume to be yes, because they've got a more direct contact with the agricultural environment on the ground.

Within the past month there was kind of an interesting study in the Journal of Food Protection by Dingman, and it was looking at what was happening in commercially produced cider plants in the State of Connecticut. In this study he looked at samples from 11 cider mills and found that six of them produced product that was positive for E. coli at least once during the production season. He also found that the E. coli was

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only found in samples that were produced from mid to late October through January, and that there was no correlation between the presence of E. coli and things like pH or Brix.

And one thing that I want to emphasize is, none of the strains that he found were 0157:H7, which is really the E. coli of concern. And one other thing that he found was that E. coli was found in samples produced from both tree-picked and dropped apples.

The next thing that I want to talk about is what we've been doing at Apple Hill, and this is something that I would characterize as a study in progress. As Art mentioned, Apple Hill is a cooperative venture between FDA and several other groups which are listed, and one of the things that we've chosen to look at is the question of tree-picked versus dropped apples.

The first thing that we noted was that no E. coli or coliforms were detected in the apples and in cider samples during the October through December period, so that at least was one thing that we did find. Experiments are underway to evaluate the natural microflora of apples, and on a set of data on Granny Smith Apples which are reasonably complete, significant increases in both the mean aerobic plate counts and yeast and mold counts were found in dropped apples and cider

produced from the dropped apples, compared to those from tree-picked apples.

Another very, very important study as I see it was done by Lauren Jackson at the MOFFETT Center in Chicago, and she was looking at patulin levels in the cider samples produced from these various apples, and she was able to find patulin at significant levels in cider produced from dropped Golden Delicious apples but it was not detected in cider from the tree-picked Golden Delicious apples or in any of the samples from Granny Smith apples.

Just to illustrate this a little bit further, these are the aerobic plate counts in the Granny Smith apples and juice. The panel on my right shows the apples themselves; the panel on my left shows the juice. And you can see that the tree-picked, which is on your left-hand side, is lower in both cases than the values for the dropped apples. We see a very similar result for yeast and mold content, and again, being on the ground could easily increase the levels of yeast and mold in apples.

This next slide, the graph shows Lauren Jackson's results on the patulin levels in cider produced from dropped Golden Delicious apples. The different colors indicate different sources of apples, and the X axis is indicating chlorine in parts per million, and it

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looks at least on an immediate level that the major difference there was among the different sources of apples, but the drops from some sources actually had more patulin than other sources.

And patulin is a microtoxin that is produced primarily by *Penicillium expansum*, which is an apple rot mold. It is mutagenic and produces toxic effects in rodents, and there should be no more than 50 nanograms per gram in apple product. Well, as you can see from the graph there, that's nanograms per mil, which is relatively equivalent, and 50 is toward the bottom of the graph, so many of the cider samples that were taken in this experiment would not be fit for human consumption.

Again, the levels reflected the source more than the preparation method, and no patulin was detectable in either the tree-picked apples or the Granny Smith apples, and for the Granny Smiths that may be a reason, a suggestion that they may be less susceptible to that particular mold, at least at a given stage in the harvest.

For the 1999 season we are planning to look at these questions a little bit more closely. We are planning on determining the levels of the natural flora in and on the apples and how that relates to the microflora in the cider, and we want to look at a variety

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of quality apples and again look at the question of dropped apples and their effects on the microbial population in the cider itself.

In summary, as far as general conclusions, the emergence of E. coli 0157 and recent contamination with Salmonella and Cryptosporidium and their involvement in cider outbreaks has resulted in the need for certainly more information and improved safety practices in apple handling and cider production.

There has been an association of the use of dropped apples with contaminated product, but the direct evidence for that right now is not present. And in some regions, at least, there is some suggestion that generic E. coli contamination may reflect environmental conditions during portions of the growing and harvesting season, and that the presence of E. coli on apples may or may not reflect the use of dropped apples.

Finally, the Apple Hill project, we have seen a couple of results now that do have some things to say, I think. As far as patulin, we did find patulin present in unsafe concentrations in some cider produced from dropped Golden Delicious apples, and none was detected in cider from the tree-picked apples or in any cider from the Granny Smith apples.

And I at least feel that this data at least is sufficient reason to avoid use of dropped apples from varieties that would be more susceptible to the Penicillium that produces patulin and related molds. Also, we have seen increased aerobic plate counts and yeast and mold levels in both dropped apples and the cider produced from them. And, in conclusion, I think that the exclusion of dropped apples from cider products will yield safer and higher quality products. Thank you.

DR. MILLER: Questions? The gentleman back there.

MR. BOHNE: Your research involved Granny Smiths or Golden Delicious--

DR. MILLER: Could you identify yourself, please?

MR. BOHNE: My name is Keith Bohne from Massachusetts, Your research was on Granny Smiths or Golden Delicious. Will there be forthcoming on varieties like McIntosh that are used more on the East Coast?

DR. MERKER: Well, certainly that's something that we would like to address. One of the things that-- some of these things can be done, of course, in the lab, and other things we could ostensibly send some varieties out to California if necessary, but we would like to extend these results. And I think particularly it would

be a good idea if, if nothing else, the results on the patulin would be extended.

Gerry?

DR. SAPERS: Yes, Bob. Gerry Sapers from USDA. I would just like to comment about patulin. We've been doing some studies in which we're looking at interactions between E. coli and various fungal spoilage organisms. We find some antagonistic relationships between Penicillium expansum and E. coli, so if you did have the Penicillium mold producing patulin, you probably would not have E. coli.

DR. MERKER: Well, that's fine if you want to drink cider that has a mutant in it.

DR. SAPERS: That's not the problem, just that it wouldn't be a good indicator of the presence of E. coli.

DR. MERKER: Yes?

MS. HORAN: Chris Horan, Con Agra Grocery Products. I have been wondering, because the organism is confined to (inaudible), can we reliably count on culling to quantify a log reduction of that? Is that a reliable way of achieving a log reduction?

DR. MERKER: The data isn't in yet on that, and that's one of the things that we're going to be looking at more closely this year. Hopefully at a later time

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we'll have some hard data to report on the results that culling would achieve.

DR. MILLER: Any other questions for Bob?

[No response.]

DR. MILLER: The next speaker is Dr. Sue Keller from the Food and Drug Administration at the National Center for Food Safety and Technology in Chicago, and Sue has been working on a number of areas, too many, too numerous to talk about here, but we've asked Sue to talk about her work on use of hot water systems for decontamination of apples. Sue?

DR. KELLER: Here we are, the title slide. I want to also take this opportunity to thank all the rest of the people who have also done work on this. Can't get away from this part. Can't let Bob do it all by himself.

Carla Bator at--and also this is another opportunity to mention the fact that there are other collaborators. Also the National Center for Food Safety and Technology is a very active player in a lot of these projects, and Carla Bator is from the National Center, who has done a hell of a lot of the plating and things that we need to actually collect data.

Stuart Chirtel, responsible for all the stats, and likes to hide in the back, too. And then of course Bob Merker, friend and colleague over there at the FDA.

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Kirk and Dave out there in California. And Hsu Ling is from the University of California, who along with Linda Harris has been a big help for us. Valerie Davis is here. And Greg Fleischman is our engineer at the MOFFETT Center, with the National Center, also with the FDA, who has done a lot of heat penetration studies with the apples that we need, so that we can tell exactly how far we're heating and how much heat we actually deliver to the apples.

This is my nice little apple picture. These apples are in fact from Placerville. Are you embarrassed? They're pretty. They are not culled, they are not anything, but they are some that were used actually for pressing. I just put them up here because in fact what we want to do is see if we can make apples safe and actually reduce, log reduction. I think there was a lot of discussion earlier on what you start with. Well, duh, this is what some people start with, and the question is, is really how much is here and can we reduce it at all.

I'll go through this fast. Of course, a lot of people have talked about a lot of things. I'm just going to focus just on surface heat treatment. This came up very early in the Placerville ideas, studies that were forwarded, in terms of what we could actually do that

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would work. A lot of work was done in the orange juice, obviously, and we went back and actually looked at some of this.

This is natural flora, natural populations that were done in the lab. All we did is dip apples into a nice boiling or almost boiling water bath and look at the populations. I want you to note that the populations to start with, the natural flora on the apples isn't very high to begin with. These were more like 3.5 logs. Of that 3.5 logs, we actually did get a substantial reduction. What is left over is a lot of spores. There are spores on apples, and obviously we're not going to kill spore formers.

So considering the fact that we don't have enough to start with to really do a 5 log kill on apples for the most part, we do have to go to inoculation studies. So what do we use for inoculation studies?

Okay. We used two different kinds of cultures in our studies. The first one is E. coli 0157:H7; everybody loves this. We used a strep-resistant strain to make the studies easier to do and easier to run. This strain was developed in the lab. The strep resistant is just a lab-developed strain, originally from ATCC 35150, which is a clinical isolate that we purchased. And then of course we also used a generic E. coli K12. That's our

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surrogate strain. It performs fairly similar in terms of heat resistance, and Bob Merker has done a lot of that work, along with Valerie Davis.

So what's the procedure? Essentially we--our inoculation procedure is very similar to what Gerry Sapers uses. It's--we grow the culture overnight to stationary phase in BHI with glucose added, so that the culture is acidified, which makes the organisms more resistant and basically just plain stronger. We give the apples a five-minute immersion followed by drying, and then they're basically refrigerated overnight for use the following day.

There's a lot of controversy, a lot of discussion about how we inoculate, because clearly there is some internalization. And we make, particularly in the lab studies, we took great pains that the apples were in fact at the same temperature as the water bath, and we still get some internalization.

At that point, the following day, we use that particular batch to immerse in hot water baths. Then they are air-dried and cooled under the hood, and what we do is take individual apples and macerate. Generally speaking, we had at least 15 apples for each treatment.

And these are the results, courtesy of Stuart, who crunches all the numbers for me really nicely. We've

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go the controls here. You see we get about 5 log for our controls. This is at 60 degrees at various different time treatments, and all of these are different from the controls, but within the group between half a minute to one and a half minutes, there really isn't any difference over the long period of time, so you get about a--lose about a log.

At 80 degrees, this is again substantially different from controls, and 60, and it drops down. As you go longer, obviously you get better, more effect on the kill, but you get about--what is this?--about 2 log or actually 3 log kill, and then at 95 degrees again you get the same. You don't really get, at least in our lab data, and this is 0157:H7, we do not see any difference between the 80 and the 95 degrees, but you do get almost a 3 log kill with this treatment.

Okay, and this is just another graph, a slightly different way of displaying it. This is different. It's decrease from control levels. Again, you can see that at 60 degrees there's not as much difference from control as there is at 80 and 90 degrees, there's a substantial amount of difference. And of course, the longer you heat it, the more killing you get.

I do want to add that our heat penetration studies indicate that the heat really doesn't go very

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far. You don't get heat penetration past like a quarter of an inch. There's just not much. The apple is not a very good conductor of heat, insulates fairly well, so all we are is really giving a surface treatment to the apples, which really shouldn't affect the flavor of the juice.

Okay. Along with that, we did a real simple, quick and dirty experiment to determine what was really going on, at least at the surface, at the skin, and we ran this whole experiment again at 94 degrees just to look at skin, unblemished skin sections. They were inoculated the same way and they were heat-treated the same way.

First of all, we did find, and this coincides very well with what Gerry found, is that on unblemished surface of the apple, just on the surface of the skin, you don't get nearly as many bacteria to begin with, but after heat treatment we could not find any E. coli 0157 left on the skin. So it appears that if bacteria are on the surface, that is, the 0157 is found on the surface, we are essentially killing everything that's there.

Okay, so what we really wanted to do is verify our nice little lab data at Placerville, and we tried to use a pretty similar procedure, excepting that we went to

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our surrogate, since we really didn't want to throw 0157 all over the pilot plant. Sounds a little hazardous.

So we inoculated apples with an overnight culture of E. coli K12, and the apples were held overnight again, the same as in the lab, and then we enumerated the E. coli on the apples prior to use. We did it a little bit different from the lab. We used individual apples in the lab because I don't have a blender big enough to hold enough apples to make a big composite, but we did these composites at the pilot plant.

We treated basically for two different time periods. We wanted to have more, but we have a prototype heat treatment. This question did come up, and this is important: How much does this cost? Right? Our prototype heat treatment device was, what, only \$2,000? \$3,500? Okay, \$3,500. We had it just put together real quick and it only cost us \$3,500.

It is geared not as well as we'd like, because we had hoped to have a longer residence time. In fact, we only got, on our "fast" treatments, about half a minute to a minute, and our "long" treatment is only about one minute to one and a half minutes. So there's not really a big difference in the residence time with the gearing, so that is one thing we will have to fix.

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But we did try for two different temperatures, and then we removed the apples after the treatment and enumerated for surviving E. coli, and we really have only done this once. I did want to show you a picture of our little device here. This is the whole overall thing. We've got our little heat control things. It's just a pool heater. We were actually able to get the water in this tank boiling, and as you could see, it was boiling.

These are the paddles. The belt actually submerges the apples under the water. The water level stays above the belt level here, and the apples are pushed through by the paddles. There's the apples going in. I think this one's going to miss. And here's the apples coming back out at the other end because the paddles just lift them back out really nicely.

This is the overall, just a schematic of the pilot plant itself. There was the bin dumper, conveyor, dump tank, and elevator, hammermill and the hopper and then the press and then the holding tank. We inserted our little device right in here. Of course you don't even really need a dump tank at that point, if you were going to use this. You could just put it right here.

Okay, so what are the results? Again, we only really gave this like a one-week shot. I would really like to firm these data up more. There were just two

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run-throughs at the highest temperatures, two runs through here, and we only managed one here so I didn't even put the standard deviations up there, per se. But you can see that for these preliminary data, with our surrogate, we did at the high temperature get a 2 log reduction, and at the somewhat lower temperature we got a 1 log reduction.

The other, of course, problem with our prototype is that there was a good deal of play in the temperature because the set point when the heat would turn on allowed probably a good 10 degree fluctuation, which may have affected the results as opposed to the lab results, why they may not have been as well--as pronounced. Also, again, this is not exactly the same strain. This is our surrogate strain, and in the lab we did use the 0157, which may be somewhat more sensitive.

Anyways, so the gist of it is, is that this works. It really does work to kill bacteria on the surface, and this is why it is so critical that we determine what the risk is really of internalization, because we can kill them on the surface but it's the internal stuff that we really need to worry about. And we need to determine what the risk is of the bacteria, of 0157 and other pathogens, truly occurring inside an apple.

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So, in summary, heat treatment of natural populations, we had about a 1.5 log drop in APC. What was left over probably was a lot of spore formers, and the balance was probably what is internalized. Again, we didn't really calculate that, what it was, so I don't know.

Laboratory studies with the 0157, we got a 3 log drop. When we examine skin sections after surface heat treatment, we find no E. coli left on the surface, at least not that we could detect, so it does appear that if it's on the surface, it's dead. And pilot plant surface treatment agrees actually fairly well with the laboratory results, with our surrogate.

And that is really all there is to it. Are there questions? That was quick.

MR. COLMAN: Matt from Ardens Garden. I have a question. I know that if you've got water that's colder than the apples, they'll suck it in. Now, if you do the chilled or apples from cold storage, putting them in hot water, there is no kind of vacuum effect, I guess?

DR. KELLER: Well, there shouldn't be, but the point is, is that when you're dropping it in a boiling water bath, you're going to really fairly quickly kill anything that's there.

MR. COLMAN: Okay.

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DR. KELLER: And--well, Gerry, have you seen anything on that?

DR. SAPERS: No.

DR. KELLER: No.

DR. MILLER: Well, bear in mind, too, that where is the organism in this situation? And there's a good chance in the cold water situation that you have the organisms floating around. I mean, this is self-cleaning other than spores, because of the heat.

DR. KELLER: Yes?

MR. : The hot water, then if the water is hotter than the apples, then there's not as much internalization?

DR. KELLER: There shouldn't be, no.

DR. MILLER: And it should be cleaner, the matrix itself in which it's sitting should be cleaner.

MR. COLMAN: You said that there's no effects on the quality of the cider?

DR. KELLER: The heat penetration is--it's just less than a quarter of an inch. We measured it with nice little probes. I didn't bring that data. I can give you Greg Fleischman's name. He's got nice little modeling results so that you can actually see how much heat and where the heat will be, and determined by how long you deliver it and what the temperature is.

DR. MILLER: And we have (inaudible) sensor, if that's what you're asking.

MR. COLMAN: Yes.

DR. MILLER: Bill?

MR. SNODGRASS: Bill Snodgrass from El Dorado, again. What's really significant about this is, this machinery was built by a local welder, basically for \$3,500, so it has application to all your small cider mills. If you look at the price of pasteurization and things like that, you're looking at a considerable amount of money, so it really does have a lot of potential for use.

MR. COLMAN: Do you think a unit like that could be used for other fruits and vegetables?

DR. KELLER: Probably.

MR. : What is your source of energy to maintain your water temperature?

DR. KELLER: Dave, Kirk, you want to answer that?

MR. BOLSTER: There were four heating elements.

MR. : So it was electric?

MR. BOLSTER: Yes.

MR. : Okay. What was your estimated cost there? \$3,500 is the one-time cost. What's the ongoing cost?

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MR. BOLSTER: I'm sure the meter was clicking very quickly.

MR. : That's the first thing everybody, all the fruit growers are saying when you talk about hot water treatment. Yes, it may not cost much to build, but what's it going to cost to operate?

DR. KELLER: The heater didn't stay on the whole time, mind you.

MR. : Oh, yes, I understand.

DR. KELLER: It gives heat and then it kicks off.

MR. : Right. You have a thermostat, just like a hot water heater.

DR. KELLER: Right.

MR. : And you just adjust that (inaudible), so you don't really need to go (inaudible).

DR. KELLER: The point is that it is possible, it is feasible, and it's possible for small producers to do it.

MR. : I'm just representing what growers are going to tell me when I get back.

DR. KELLER: Yes. Well, we have to measure it.

MR. : They're going to say, "You come back and give me an answer to that."

MR. SNODGRASS: I have the bills.

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DR. KELLER: You have the bills?

MR. SNODGRASS: For peak season time, okay?

MR. : Seriously, that would be good.

MR. SNODGRASS: (Inaudible.)

DR. KELLER: Yes?

MS. ZINN: Well, I'm a little confused, because you talked about a 1 to 3 log reduction and--

DR. KELLER: 1.5 logs is what we get with the natural flora--

DR. MILLER: In the lab.

DR. KELLER: Right, in the lab.

DR. MILLER: With E. coli 0157.

DR. KELLER: No, no. With 0157 we get the 3. The thing is, is with natural flora, the problem with trying to measure log reduction when you're just using natural flora is, number one, there's a substantial number of spore formers there. You're not going to kill spore formers. They're all way, way more heat resistant. But that is not our organism of concern anyway, so it doesn't really matter.

Other than that, there is simply not, generally speaking, that many bacteria on apples, period. When we have done even very bad apples, it's very unusual for us to see anything higher than log 5 on apples, in the ones that we've done with the natural flora. So in order to

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really look at it, we have to put bacteria on there to see if we can really kill them.

MS. ZINN: I saw in some of your results--

DR. KELLER: Right. Those were--

MS. ZINN: --the inoculated ones.

DR. KELLER: Yes, the inoculated ones, they start about log 5, and that's 0157. It has a particular type of sensitivity to heat, that's what, and it also happens to be the target organism. What we want to see, we want to see a 5 log kill in the pathogen. That is the pathogen, and we do get a 3 log kill there. That is with that particular strain.

When we went to the pilot plant to verify this, we can't use that one because it's too hazardous, so we go with the surrogate, and the surrogate, we got a 2 log.

MS. ZINN: Where will the other 2 log reduction come from?

DR. KELLER: Well, one of the things that we're hoping, that may be extremely promising, is culling. Appropriate culling, and also not using drops. There are other intervention methods that we simply haven't looked at yet. We don't know how much we'll get from that.

The other thing is, is we really--again, we have to go back to what Art said originally. We have to look at what the real risk is of internalization, because I

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can tell you right now, if I can put 12 log of 0157 on the surface, and I mean strictly on the surface, not internalized, I'll kill all 12 log with this heat treatment.

But what does that really mean? You're not really reducing the risk, because if you've still got the same amount internalized, that doesn't mean anything. We have to know what goes in and where it goes in.

Yes?

MR. BOHNE: Keith Bohne from Massachusetts. How much E. coli 0157:H7 have you found inside an apple? Have you looked? Have you cultured?

DR. KELLER: You're asking us to find a needle in a haystack.

DR. MILLER: Right, but this is the question. You can't find these organisms very frequently. These are low occurrence events.

MR. BOHNE: So what's the risk?

DR. MILLER: Well, we can't answer that question. All we can do is cite the epidemiology, and we know that people are becoming sick. The problem is where you're trying to isolate a particular orchard or a particular apple and determine whether or not it has E. coli.

I think you have to say that if you look in the universe of orchards and the universe of apples, some of them have E. coli or Salmonella. The question is, where are they located and where are the conditions that promote this? So, once we know that, then we can take measures to reduce those occurrences.

MR. : But even when we talk about this, are we talking about the likelihood of it occurring? And this result shows that even that likelihood of occurrence is way down, and it's effective. So I think we should not minimize the result simply because we cannot or we did not look for E. coli 0157:H7 itself. I think that this result shows that with the consideration of the likelihood to occur, it's a very effective method.

DR. MILLER: But, as Sue mentioned, we don't know if it's being applied at the right spot on the apple. That's the caveat.

MR. COLMAN: Matt from Ardens Garden. Here's a question. What is--is it feasible, if the apples, if there was a way to either cut them in half, so some of that heat could get into the inside to kill that? Is that--

DR. KELLER: No, no. That wouldn't work, because the apple itself has a lot of air. It's a very

good insulator. So, again, if you cut it in half, what are you heating? The surface that you cut. It's a matter of penetration, and besides, at that point you would be affecting the juice quality or the juice flavor.

The beauty of this is that because the heat penetration is not very deep into the apple, you couldn't possibly--you know, most of it is going in and it's cold, and most of it is not being affected, and your flavor should not be affected.

DR. MILLER: Could I interject? There was an interesting comment, and no data at all to back it up, but if you remember the picture that Gerry Sapers showed of the dye penetration, there may be some benefit by coring an apple.

MS. ZINN: How do you do that cost-effectively?

DR. MILLER: I agree. I'm just speculating that this may be a way to reduce risk.

MR. TIERNEY: Paul Tierney, Massachusetts Department of Public Health. I'll be interested in what our discussion is going to be here, but I'm a little perplexed.

I mean, 20, 25 years we're talking, unfortunately, and I don't mean to be callous, (inaudible), and we're talking (inaudible). You know, in shellfish, you have anywhere from 12 to 16 deaths per

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year, (inaudible), and there's no comment about (inaudible), you have it pasteurized if you're shipping (inaudible) the coast.

I mean, I'm just wondering, I mean, if you have good GMPs--GAPs, GMPs, or HACCPs--and you're dealing with apples that you don't even know whether they're contaminated in the first place. I mean, it seems to me that we're spending an awful lot of research and time on something where you really sit down and look at the public health risk, now obviously you have certain populations out there that are more affected than others, and certainly with a good educational program you're hoping to get to these populations and reduce their risk of exposure.

It's more of a comment than a question. I'm just (inaudible).

MR. SCHWALM: You know, just to say a couple of things, one is that certainly the concerns about relative risk of cider to other foods is a legitimate question, and that's something that is being addressed in the proposed rules on juices and other foods. But that's not really the purpose of our meeting here today, those types of issues. They are legitimate issues, but this is not really the forum for that.

And we have tried to pull together some information about risk assessment. That is going to be, I believe, first thing tomorrow morning--whoever has got the agenda--so hopefully we will be covering what we do know about risk assessment with respect to cider production.

MR. : Well, let me respond. I mean, there was something mentioned earlier that was sort of disregarded. I mean, in a lot of our (inaudible), a lot of (inaudible), FDA loves to get its teeth into something, and it loves to get its teeth into something (inaudible), it loves to get its teeth into (inaudible). Extreme cost, extreme aggravation for (inaudible), both.

MR. GARCIA: Guadalupe Garcia, Food and Drug Administration. As for your question, they are pasteurizing most of it now, but considering the fact that 0157 is sensitive at (inaudible), it suggests the only ultimate way to be safe is to pasteurize apple juice products

DR. KELLER: In fact, what we are doing is pasteurization. What we're doing is killing everything on the surface. When it's on the surface, it dies. Again, I have to reiterate, I have to point out, the critical question here is what is internalized, when is

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it internalized, and what is the risk that this will really happen?

When we're soaking apples, that's a hell of an extreme way to do it. I mean, we're soaking them for five minutes. E. coli isn't even motile, you know. How does it get it? Certainly I can't foresee a situation that occurs very frequently in nature where an apple plunks down into a cultured E. coli that's at 10 to the ninth cells and sits there. You know, I just don't see that happening much. So what is the real risk? We just don't know.

DR. HIRST: With some varieties of apples, Red Delicious in particular, they have an open calyx. We have a common problem with moldy core which is caused by fungus in the core of the apple, causing mold on the inside, and it's thought that the fungus gets in very soon after flowering, so it's early on in the growing season. And so it's not perhaps unrealistic to wonder whether E. coli might be getting in very early in the growing season and just sitting there, perhaps.

DR. KELLER: Yes, but your mold is a natural inhabitant of the apple. E. coli generally is not. And as Art and Gerry--

DR. HIRST: Well, (inaudible)
environment--

DR. KELLER: --as Art and Gerry pointed out earlier, it is very possible and there is some evidence that the molds are in fact antagonistic, and E. coli would not survive well in that situation. So, again, we don't know what the risk is.

DR. MILLER: I think the key word here is, there is an opening, and that is probably the mechanism by which organisms get in, assuming they actually do get in.

Gerry Sapers?

DR. SAPERS: I would just like to comment about some work that we have in progress. We know that early on apples, immature apples, grow with the calyx pointing up, and if a source of airborne contamination did blow over the orchard, it would be possible for the orchard-- for the apples to be contaminated fairly early in the growing season.

Now, we have just within the last couple of days obtained some samples that were provided to us by Penn State, of apples, four or five different varieties, immature apples that are about so big, an inch and a half in diameter. We will be analyzing them and looking specifically for evidence of internalization of any organism. We will look for evidence of bacteria in the apple.

We're also getting some similar samples from Kirk and Dave at Placerville, and I want to thank them for all of their work in our behalf. Those apples, I understand, will be shipped to us or have been shipped. So we expect within the next month or so to obtain some data showing whether or not these early apples, these immature apples, do have any bacteria within the core.

DR. MILLER: I think we need to keep moving forward.

DR. KELLER: Okay.

DR. MILLER: Now, we are moving on from the apple to the crushed product, and into the actually expressed juice, and our next speaker is Dr. Randy Worobo from Cornell University, who is going to talk to us about UV treatment of cider. And we need to go through a technology transfer here.

DR. WOROBO: Okay, now the technology is in place. I'll just introduce myself. I'm the microbiologist who has been working closely with two of the engineers who have been involved in developing this new technology for processing of apple cider.

I arrived at Cornell two years ago, and two years ago there was really only one alternative for apple cider producers that has been proven as an adequate process for the inactivation of E. coli 0157 in apple

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cider, and at that point in time and now it's only pasteurization. And just so that everybody knows, it's 160 degrees Celsius for 6 seconds with any apple cider blend less than 50 percent Red Delicious. Anything greater than 50 percent Red Delicious, it's 11 seconds.

The problem that I was hearing back from a lot of the small apple cider producers in New York State was that pasteurization had a couple of flaws that they weren't exactly pleased with. First of all, it was costly. Second of all, it's labor-intensive. It requires a good bit of training to actually ensure that the pasteurization holding time and temperature is what you want it to be. Because the problem if you haven't got the time and temperature matched perfectly, if you have a longer holding time, you can get flavor defects in the cider, and this was a big concern for the apple cider producers.

And, thirdly, a lot of these apple cider mills are over 100 years old, and the buildings that they are housed in, they don't have the space for thermal pasteurization units when they come in on skids, so this presented an additional expense for actually building an additional housing for the pasteurization unit.

So since I have an extension appointment, and the apple cider producers were saying "We need some

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alternative technologies," some of the research that my lab was sort of directed towards was looking at alternatives, and basically to come up with alternative methods to thermal pasteurization for the inoculation of 0157 in apple cider, and to keep in mind the small apple cider producers.

Initially we started looking at ultraviolet light, and we purchased a water unit because at that time that was the only unit that was available. We used an Atlantic UV unit, an SJ-2400. The problem was, when we passed apple cider through inoculated with 0157, we found that it required anywhere from 80 to 145 minutes to actually achieve a 5 log reduction. It wasn't feasible, and we realized very early on that it's because the water units, it has high penetration because there's no solids. We needed something that actually had a very thin film so that you get full exposure of the apple cider.

At this point in time we didn't have the technology. We also didn't have the capabilities to build an equipment such as this. And it was sort of fortuitous because two engineers called me up and asked me, "Could you be interested in doing some work for us on the inactivation of E. coli in apple cider using UV?" I said, "It doesn't work, we tried it," I said, "unless you

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can create this thin film," And he said, "That's exactly what we can do."

So this is really how the collaboration began, and the two engineers, they created a small company called FPE, and we started to work on a single UV lamp, because we had to go from a theoretical to actually build up to a scale to see if it works in a commercial situation.

So we used a fixed speed and a single lamp, and we passed apple cider through that was inoculated with 0157, and we found that it did achieve a 1 log reduction, and this was just a single lamp. At the same time, we wanted to see how--sort of see what the difference was compared to water, so we inoculated at 8 logs, passed the water through it, same fixed rate, and it was completely sterile. It just shows how much solids affect the kill rate of UV.

From this fixed speed rate, we were able to calculate the lethality of UV light against E. coli 0157 in apple cider. And basically what happens is, you measure the ultraviolet exposure in microwatts, and this curve is sigmoidal, and at this plateau at the very beginning, this actually the injury phase because the UV light doesn't kill the bacteria right away. It actually damages a lot of the DNA, and they're still able to--

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they're just injured--they're still able to resuscitate and grow under the appropriate conditions. Okay?

But once you get past this point, you get a very dramatic kill. And we wanted to make sure we got from-- this is in log number of organisms--from 8 down to at least 3, so we knew that it was roughly around 12,000 microwatts of UV exposure that we had to obtain for apple cider.

So from this graph we were able to get sort of a--how would you say it?--a calibration curve that we wanted to try and span across different apple ciders. We also had to scale up now, so that we were trying to achieve a 5 log reduction with a single pass, and we had to make sure that we were accommodating for different cider variations such as the amount of solids, the amount of color that actually--the browning reaction that occurs with cider, and we also had to make sure that there was adequate safety features.

In the final design there are eight lamps, it still utilizes the thin film technology, and it has two in-stream continuous UV sensors which are placed at the back of the housing. The next slide will show you this. It's compact. It's about the size of a kitchen dishwasher that you wheel in. And it has a flow rate that can get up to about 4.5 gallons per minute, which

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for most apple cider producers is in the range that they would require.

So this is basically the unit. You have a computer interface which really takes the calibration curve and it takes the UV readings. You have a UV sensor here and also at the top. The UV exposure is measured every 20 milliseconds, and the UV exposure goes to the computer interface. It tells the pump, which is located on the other side, how fast it should be going, so it slows it down or speeds it up automatically.

The cider comes in through the bottom of this tubing, and this is--what you see inside is, you have outside a stainless steel exterior tube. Next to it is where the thin film is actually going through. You have a quartz tube inside. It has to be quartz because, don't forget, UV is blocked by normal glass, so it has to be quartz. And then you have the lamps on the interior, and that's basically the whole system. Enters through the bottom and goes out through the top.

MR. : Sir, how thick is that channel?

DR. WOROBO: It's less than 5 millimeters.

MR. : Five millimeters.

DR. WOROBO: Yes. It's less than that.

So what we did was, we extensively tested this unit in the lab. We used three different strains of E.

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coli 0157. We also used upwards of 15 different cider varieties and different blends of apple cider, and basically what it came down to is, we got a log reduction of high 5's and above 6 logs with a single pass. And as you can see, the three different strains of 0157 were very similar in terms of their UV sensitivity or resistance. So we were able to achieve a greater than 5 log reduction with a single pass with the final design.

We also had to look at what was actually happening to the taste of the cider, since this was one of the major concerns for the apple cider producers. Dr. Mark McLellan, who was the chairman of our department at the time, conducted the sensory work, and he found that there was no statistical difference between UV treated, raw, and HTST, which is high temperature-short time pasteurized apple cider. So it wasn't affecting the flavor of the cider at all.

At that--and this was about in April, I believe, wasn't it, Dave? In April we were invited out to the Apple Hill project out in Placerville, California. I won't have to go through, but basically it's FDA, USDA, industry and academia. It's a collaborative research effort. It's a wonderful opportunity to have.

So the study we wanted to see was, how was it actually carrying itself out in a typical cider mill

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setting. So we had the same apples that Sue had mentioned, put them through a typical wash, the hammermill, the press, and we took the cider, and we had 200 gallons in the press. We had two different varieties on two different days. We had Red Delicious and Fuji. It was unfiltered, and we divided it into three batches.

We then took 60 gallons and we reserved it for-- just to see what it was doing to the natural microflora. We took another 60 gallons and we inoculated it with a surrogate organism which I had already done research on to identify that it had the same UV resistance and sensitivity as the three strains of E. coli 0157, and the organism is called E. coli, and it's the same one that I believe Gerry used in his studies. It's ATCC 25922.

So this was our surrogate. We inoculated it, and we passed it through, and we took samples at various stages throughout the run. And what we found is that it just basically reinforced the data that we had obtained in the lab. We were achieving high 5's, 5.89 log reduction with Fuji apple cider, and 6.46 log reduction with Red Delicious.

The cider that we used on these days was extremely dark and it had very high amounts of solids because these were just cold-stored apples, and when would you say they were harvested, Dave? October?

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MR. BOLSTER: Yes, early October.

DR. WOROBO: Early October, and this is late April, so they were just about at the very final stage of use. So this basically reinforced the fact that with a single pass in a typical cider mill situation, it is also effective.

At this point I would like to do some acknowledgements, first of all to the FDA, USDA, El Dorado County, and University of California at Davis, the Apple Hill Growers Association, and finally the New York State Apple Research and Development Fund, as well as the USDA, and Anne would be pleased to see that this work has actually been funded by CSREES. We are not only looking at ultraviolet light for treatment of apple cider, we are also looking at potassium metabisulfite and dimethylbicarbonate, and we have shown what those two processing alternatives, that they are also capable of achieving a 5 log reduction.

So if you have any questions?

MR. COLMAN: Yes. I'm Matt from Ardens Garden. I wonder, now, have you tried this UV machine with any other kinds of juices?

DR. WOROBO: Yes.

MR. COLMAN: Or just with water?

DR. WOROBO: No, we've also tried blueberry juice, we've tried orange juice, we've tried carrot juice, we've tried grape juice, wine. It works with all of them except for the orange juice, and the problem with orange juice is that it has a high Vitamin C content, and Vitamin C is actually a UV quencher, so it takes up the ultraviolet light that would actually be germicidal against the bacteria and it prevents it from exerting its germicidal effects.

Yes?

MS. ZINN: What's the cost of a machine, and is there labeling that needs to go on the product if you're using it, and also have you thought about using--is there any usage of UV light on the fruit before it's pressed?

DR. WOROBO: Okay. Your first question, the price is--Wesco, which is a distributor, is selling it for \$13,000.

And your second question was the labeling. Right now I don't believe that--the only regulations that are in is if you haven't shown that it achieves a 5 log reduction, you have to put on a warning label, so--

MS. ZINN: Okay, but I'm talking about does an irradiation label need to go on it.

DR. WOROBO: No.

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DR. HANSEN: Pat Hansen, Food and Drug Administration. No.

DR. WOROBO: Okay, and then the--

MR. : Excuse me. Has the FDA approved this for use?

DR. WOROBO: No, it has not been approved yet. There is a--presently--they had a petition in and it wasn't complete, and now there's a new petition in for a UV process, so it's in--

MR. : Has that been done by you or somebody else?

DR. WOROBO: No, that's done by Day Fresh. You had your hand up. Yes?

MS. HORAN: Chris Horan, Con Agra Grocery Products. Do you know what the limitations are in terms of color or (inaudible) or opacity of the juice? You mentioned--

DR. WOROBO: We've tried it with--are you talking just specifically for apple cider?

MS. HORAN: No.

DR. WOROBO: Okay. For--

MS. HORAN: We do juice blends, for example like in beverage base.

DR. WOROBO: The calibration curve has been worked out specifically for apple cider, so when we

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passed carrot juice through, it's got a lot more solids than apple cider, and we found that it had a 3.5 log reduction using the calibration curve that we had constructed for apple cider. But all you have to do is just do the microbiology and figure out a new calibration curve and you could use it for that. Yes?

MR. : What kind of path (inaudible) does the juice have from start to finish?

DR. WOROBO: In terms of distance or time? Distance?

MR. : Involving distance.

DR. WOROBO: Okay, distance, I believe it's--

MR. : (Inaudible) time.

DR. WOROBO: --the distance is about, I'd say, 75 centimeters to maybe a meter. I'm terrible with inches. I'm Canadian. I grew up on the metric system.

Other questions?

DR. CRASSWELLER: Just a comment. I assume Jim--Rob Crassweller, Penn State--I assume Jim Cranney is going to be here tomorrow?

DR. MILLER: Yes.

DR. CRASSWELLER: Because he sent out a note, I don't know if everybody got it, but he sent out a note yesterday. Did you see that?

DR. WOROBO: I just saw it before my talk.

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DR. CRASSWELLER: Yes. Essentially, what he said, as I understood it, that you got approval or that you got--you showed that you were able to validate it. Yes, he said you validated it, but the problem was, the levels were too high?

DR. WOROBO: Right.

DR. CRASSWELLER: I don't know if the FDA people can comment on that.

DR. WOROBO: I think Pat would be--

DR. HANSEN: (Inaudible.)

DR. CRASSWELLER: Okay, good.

DR. HANSEN: (Inaudible) Cranney.

DR. WOROBO: Any other questions?

MR. COLMAN: Matt Colman, Ardens Garden. Since there are so many FDA people here, do you think maybe you could do something about that petition?

DR. WOROBO: Any other questions?

[No response.]

DR. WOROBO: Okay. Thank you.

DR. MILLER: Thank you, Randy.

The next speaker is from the University of Minnesota, and the presentation will be given by Imme Kersten, who is a graduate student of Dr. Tatini at the University of Minnesota, and this and the next talk, talk about--discuss a very low tech but presumably promising

technology on looking at the effect of thermal fluxing of juice to reduce pathogen loads.

Yes, we've got to do a technology shift here.

MS. KERSTEN: Because of the increased concern that we've obviously been talking about all morning, about the presence and survival of pathogens such as E. coli, Salmonella, Cryptosporidium, possibly Listeria, there has been this talk about mandatory pasteurization, though we know that the smaller--particularly the smaller apple orchards find this quite unfavorable because of cost, and also they feel that pasteurization might alter the quality of their product.

Therefore, we do have increased research devoted to finding alternatives to pasteurization, some of which we have talked about today, but they also include isostatic high pressure, the pulsed-electric field, filtration, ozone, UV light we just heard about, and then my research which is on freeze/thawing.

Freeze/thawing is a viable method for really any orchard which already has freezer capacity or also because there is little start-up capital necessary, you know, compared to pasteurization. One Minnesota orchard told us it would cost them approximately \$5,000 to \$10,000 to install enough freezers for this method, or he

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could possibly pay someone else to freeze at 10 to 25 cents per gallon.

We also know that with freezing there is minimal to no nutritional loss, and quite possibly there is no change in sensory characteristics. However, we have not as of yet done any sensory testing.

I also want to mention about the freezing, that at least in Minnesota, which is what I know, it is already not unusual for the orchards to freeze at the end of the season and then sell it the following season, so it's not an entirely foreign idea to begin with.

The use of freezing to get 5 log destruction of E. coli, which is what I focus on, can be thought of as contradictory because generally freezing is thought of as a method of preservation and not as a method of destruction. Also, the presence of sugar, which is in relatively high content in the cider, is sometimes thought of as a cryoprotective agent. However, in this case it does not seem to protect the E. coli upon freezing. And, on the other hand, the high acid and the presence of preservative do seem to have a supportive influence on the behavior of E. coli in the frozen system.

I'll briefly go over my methods. I have used four different strains of verotoxigenic E. coli. The two

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first strains, OD and 933, are both 0157:H7 strains. OD was a strain isolated from the Odwalla juice outbreak in California, and 933 is generally recognized as one of the more acid-tolerant strains. The 406 and 0104 are just two non-0157:H7 strains. We wanted to use as many strains as possible because we know that there is always this variability within strains, so we can see if freezing generally has--what kind of impact it generally has.

I used fresh, unpasteurized, non-autoclaved cider. That's cider that has not been sterilized, so all of the natural flora is still present when all of these experiments are conducted. I purchased the cider from five Minnesota orchards, and only two of the orchards produce cider without any preservative at all. The remaining orchards use sodium benzoate as their preservative.

Early on in the season the pH ranged from 3.1 to 3.6 and the coliforms from less than 10 per ml to 50 per ml, and no E. coli was detected in any of the cider throughout the entire season.

First we started out with more small-scale experiments in test tubes. Each test tube contained 10 mls of the juice. The test tubes were inoculated with each strain and then frozen for up to eight weeks, so

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then at each week's time a set of test tubes were removed and then defrosted so we could see the progression over time and what the influence--and what damage the freezing had on the E. coli over time. Once we pulled them, we defrosted them in a room temperature water bath, and then enumerated them and held them in a 4 degrees Celsius cooler until gone.

Another experiment we performed in test tubes was freezing them for four and seven days, and then we gave them a light heat treatment, 50 degrees Celsius. And then finally in test tubes we subjected them to 2 and 3 degrees frost cycles and then held them also in 4 degrees Celsius cooler until no E. coli was detected.

After the test tube experiments, we did move on to large container experiments. This is a very similar experiment as with the test tubes. We just used gallons and half-gallons. And just one thing we did differently is that also with the gallons and half-gallons, we inoculated them with cells that grew at a lower pH of 5.2. In all the other experiments, the cells were grown at a more normal pH.

This is data from a Master's student, a former University of Minnesota Master's student, and the most important thing to take away from this data is that at a lower temperature we do see increased survival of E.

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coli. All of the taller white bars indicate 4 degrees Celsius, which is the cooler temperature, and what's important about this is that cider is generally stored at this temperature, so we know then that E. coli at the refrigeration temperatures is going to be hanging around a lot longer than at higher temperatures.

This research that he conducted shows that at pH of--well, that if you--this first one here is that a pH of 3.6 is really what you want, or lower, to have adequate injury and death of E. coli. Otherwise, all the black bars are showing injury, and there is very little injury at these higher pH's.

And what is really important about this is, in my--in all of the orchards in Minnesota, the highest pH I had was 3.6, so it would fall into here. However, other research has shown that the pH of the apple cider can be as high as 4.4. There was some research done in Connecticut. And so this cider is going to even pose greater problems, because if the E. coli--if the cider is contaminated, it is not going to sustain as much injury and will hang around a lot longer.

And one note on these two pieces of data that you saw from this former University of Minnesota student, it was all performed, if you notice the log on the side, it was only at 3 log because it was performed before the

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FDA issued its (inaudible). So this is all my research now, it was all done at 6 log.

This is just an example using strain 933, just to show you how over the weeks, I would freeze up to eight weeks, and you can see how there is a gradual decrease in the survival of E. coli over time, so it shows how just the freezing alone does have--is influenced by the time.

Okay, now some results. First, to clarify so no one gets confused, when it says a week here, that means how many weeks it has been frozen, and when it says a day, that's how many days it is held in the 4 degree cooler until we have (inaudible) as such.

So this is using unpasteurized apple cider that does not contain any preservative at all in test tubes, and you can see with the first three strains, 933, OD, and 406, if you freeze for three weeks and then defrost and hold for three days, you have 5 log destruction. However, in the final strain, 0104, which is one of the non-0157:H7, you need to hold an additional two days to have the 5 log destruction.

So, in conclusion, we say that with the unpasteurized apple cider that does not contain any preservative, you need to freeze for three weeks and then

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hold an additional five days to get the 5 log destruction.

So here is a similar set of data. This time, however, it's the apple cider with sodium benzoate as the preservative. And in all four strains, if you freeze the test tubes for one week and then hold for three days, you have 5 log destruction. So immediately you can see there is a fairly dramatic difference in the length of survival of E. coli, whether the cider contains sodium benzoate as a preservative or does not contain preservative at all.

Then, because it takes a minimum of one week of freezing plus the additional holding to get the 5 log destruction of E. coli, we also briefly looked at some other methods to see whether we could shorten this time, particularly when the cider did not contain any sodium benzoate.

So the first method was applying light heat, to 50 degrees Celsius, to cider which had been frozen, and we did look at one day and three days and four days and seven days periods to give us the best results, and we did see an almost 5 log destruction after one week with sodium benzoate and a 4 log destruction when there was no preservative.

Some possibilities to get up to 5 log would maybe try freezing a little bit longer than seven days,

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maybe eight days, nine days, or to hold it for a couple of days. There was no holding involved this time. Or to raise the temperature slightly, 55 degrees Celsius.

I should note that when we applied the heat, it was only up to the temperature. There was no holding at 50 degrees. It was brought up and then immediately cooled.

The other experiment was the use of freeze/thaw cycles. We first tested two freeze/thaw cycles, but that was not adequate, so we moved to three freeze/thaw cycles, and one cycle in a test tube would be 24 hours of freezing, and then we would defrost it and then freeze it again for another cycle.

So what we saw with this was that with benzoate, if you went through three cycles, you would hold an additional two days for a total of six days of treatment to get substantially over 5 log. And then without benzoate, however, you needed eight days of holding for twelve days total. So, indeed, you can see that this time is shortened.

However, the energy expense necessary to have all of these cycles would undoubtedly even increase with gallons and half-gallons. The cycle time for a test tube, as I said, is 24 hours, but for a gallon it's 48 hours. And then it takes five minutes for a test tube to

defrost and six to eight hours for a gallon to defrost at room temperature, so you are already expanding the time that way, also.

At this point our research did indicate that the test tube--that this freeze/thawing was a viable method, so we wanted to move into more real life situations using the gallons and half-gallons. At this time the season was already past us, so we had throughout the season collected juice and then immediately frozen it, so for the gallon and half-gallon experiments, the juice had already been frozen once.

We did notice at this time in the freezer that there was leakage of some of these containers due to expansion, so when I defrosted them I removed 250 mls from the gallon and 125 mls from the half-gallon prior to inoculation. So this spill volume would definitely be an issue that would need to be explored and addressed if the orchards were to use this freeze/thaw method. Then, once the gallons and half-gallons were filled and sealed, there would be no further chance for contamination until the consumers open them.

So we have a little summary of gallons and half gallons data when the apple cider did not contain any preservative. You can see that even at four weeks time you still had to almost hold for one week. This is

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definitely a problem, because in apple cider that doesn't contain any preservative, the shelf life is usually about two weeks, so you're automatically cutting the shelf life in half. And also during that one week time you have to think about additional growth of yeasts and molds, too, so it's definitely a problem.

And here we have similar data, but this time with the sodium benzoate, and all of this data is at one week, just using different container sizes and two different ciders. And if you look at the length of time, you can see it varies from three days of holding up to fourteen days of holding, and there is variation within the strains, there is variation within the containers, and there is variation within and between the orchards. So that is definitely something that needs to be addressed.

Then, because we know that E. coli can have an adaptive response to conditions of lower pH, including increased survival, I performed an additional experiment in gallons and half-gallons where the cells had been grown at a lower pH. The premise was that the cells would behave differently when grown at a lower pH.

In fact, this was the case. All of this is at one week, and you can see that the time of holding actually shortened. However, we can't really--this was

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only one trial--we can't say anything definitive. Definitely more research needs to be conducted to see whether these kind of cells, grown at the slightly lower pH, are like the cells, mimic the behavior of cells that we see in outbreaks.

So, in conclusion, one of the most important things I think to take away from my research is that sodium benzoate definitely contributes to death and injury of cells. There was a substantial difference between when we froze cider without preservative or with preservative.

Also, we noticed that the behavior of E. coli in the test tubes was different than the behavior in the larger containers. We really don't know the cause of this variability. Some possible explanations would be that the--generally it is considered that if you freeze slow and defrost slow, that it's going to be most damaging to the cells.

So in this experiment the gallons would be thought of more as the slow/slow method, and the test tubes would be fast/fast, so therefore we would think that we would expect to see more damage in the gallons and half gallons. However, this is not the case. We see just the opposite.

Some possible explanations for this would be that the distribution of liquid water to ice is greater in the gallons for some reason, due to a concentrating effect in the gallons, or if there is--they just aren't freezing as completely due to their larger size, and therefore the cells are not going to sustain as much damage in the liquid water as they would in the ice.

Also, we don't know the size and number of crystals that are formed on, in, or around the cells when they're freezing. All we do know is that at high cooling rates, which is what we would see in the test tubes, we do know that small internal ice crystals are formed, and that at slower cooling rates, which is what we see in the larger containers, externalized crystals are formed, which tends to lead to dehydration, and we do know--so that the internal ice crystals are in fact more damaging than dehydration. This could be a possibility. Also, the freezing point of the apple ciders can vary between varieties of apples, between times of the season, between orchards.

And, finally, the distribution of pectin and pulp, it's quite evident when you begin purchasing apple cider from different orchards, there is variation. Some orchards have a lighter cider with barely any sediment on the bottom. Another one is thick and very dense.

And there has been some research that has indicated that perhaps this particulate is protective of the E. coli. That could be one reason we're seeing that difference. And then when transferring into a test tube, if you don't have exactly even distribution, you may not have as much pectin and pulp in the test tubes and therefore the E. coli would not be as protected.

So it's definitely safe to say that more research needs to be conducted in various container sizes, different pH's, different times of the season, and from diverse agricultural areas. We're seeing so much variability between the producers, between strains, container sizes, that at this point no real definitive time can be given for length of freezing and length of holding.

And if you wanted to implement some sort of freezing at this point, you would have to pick a longer time to encompass all of this variability, and then that longer time would undoubtedly push further into the season and possibly further into a profit loss. However, it's--particularly I think if you are going to add preservative to your cider and then freeze it, that does look promising.

DR. MILLER: Any questions?

MR. SMITH: Durward Smith, University of Nebraska. Not really a question but maybe something. Have you finished your research on this?

MS. KERSTEN: No.

MR. SMITH: So maybe you could look at this as kind of a post-treatment here, would be to freeze in some larger containers, gallons for instance, and let them sit for two or three months, and then centrifuge and refrigerate and centrifuge, and take the fluid component and look and see what you get, because some of the sugar is going to protect the microorganism.

As a matter of fact, you'll have some of that that in effect never will freeze. You'll have a fluid component with a little sediment at the bottom of the container, and if you were to wait six months, you could actually separate that syrup out. It would be a fluid syrup at the temperature, and you would have almost pure ice at the top of the container. You might want to do a quick test by centrifuging and take a look and see what microorganisms you have.

DR. MILLER: Any other questions or comments?

MR. : How severe is the leakage that you mentioned in the gallons and the half-gallons?

MS. KERSTEN: It depends on how you want to rate "severe". You know, it's messy, you know, definitely.

And I would say that maybe 15 percent of the containers leaked. I wouldn't know how to say how severe the leakage was. It was definitely on some, almost covered the whole container and then pooled on the bottom, you know. Because I would pick up the containers themselves and there would just be pools of juice on the bottom then.

MR. : The reason I asked, and I had an ulterior motive, is could you recommend that to the consumer that buys those gallons and half-gallons, and freeze it and, you know, if there is sodium benzoate added, then you're talking about a week, and this way then you avoid the risk of--especially when we would consider children, at a high risk. A lot of homes have those freezers where they could, you know, just put the jug in there and, you know, a day later or two days later they could use it.

MS. KERSTEN: Right.

MR. : So that's what I was wondering, you know, if that's something that we could do (inaudible) until capacity to--until they're going to (inaudible).

MS. KERSTEN: I think quite possibly, and like I said, I mean, some of these gallons didn't leak at all. Some of the orchards filled to the very top, and those

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were the ones that leaked. But some filled, even if it was three-quarters of an inch, you know, from the top, those ones didn't leak.

DR. MILLER: Any other questions or comments?

[No response.]

DR. MILLER: Okay, let's take a 15-minute break, and then we'll resume.

[Recess.]

DR. MILLER: Can we take our seats, please?

We're going to amend our program for one presentation given by Dr. Allen Matthys, who is the Vice President for Regulatory Affairs at the National Food Processors Association here in Washington, and Dr. Matthys is going to address us on--his title is Apple Cider Food Safety Solutions. So, Dr. Matthys.

DR. MATTHYS: Yes. Well, thank you for providing me some time here to discuss this.

When the apple cider outbreak occurred in 1996, NFPA had already been working in the situation of possible solutions to this with our member companies and reviewing options, going back to some outbreaks that had occurred in orange juice in 1993 and '94. We convened our Juice Committee members again to evaluate the 1996 situation, and they determined, based on their knowledge of the industry, that all juices should be pasteurized or

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receive an equivalent treatment, and authorized NFPA to communicate the following position to FDA:

"NFPA's overriding position is that juice or juice ingredients should receive pasteurization or an equivalent process sufficient to render the juice or juice ingredients free of vegetative cells of microorganisms of public health significance. In this regard we recommend that FDA initiate an appropriate regulatory proceeding to address this and other relevant issues."

There are alternative processing methods. You have seen those presented here today. We agree for the most part that those can work, if scientifically reviewed so that we can prove that they have the same effectiveness as heat pasteurization. We communicated that position to FDA at public hearings and again in various documents filed in proceedings pursuant to their proposed HACCP regulation.

In developing our position, NFPA considered several options, including current Good Manufacturing Practice regulations; the possibility of labeling unpasteurized juice, including possible warning statements; and juice HACCP. We concluded that the only means of assuring that juice did not contain potentially pathogenic microorganisms was to include a microbial

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control step or steps that have been scientifically proven to be effective in providing a level of protection equivalent to pasteurization in the process.

A warning statement was not deemed sufficient to communicate the potential for illness to consumers. Indeed, if we look at some of the products that have warning statements on them today, they almost have a disclaimer up above that product saying "This is all safe and wonderful for you. Never mind the warning statement down below." That is a problem that we see out there, very confusing to consumers, on how to address that warning statement that's out there now.

In addressing how to expeditiously incorporate mandatory pasteurization or an equivalent process, we looked at the current regulations that are in place, specifically the Code of Federal Regulations, Title 21, Part 110, Current Good Manufacturing Practices in Manufacturing, Packaging or Holding Human Food. All food products produced in the U.S. other than USDA products are covered by this requirement, and I'm a little surprised today not to see that document in our packet. I would hope that it would be provided to all the participants here, because we all have to comply with that document.

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That document, under 110.80(a)(2), states that "Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the Act," the Act of course being the Federal Food, Drug and Cosmetic Act.

That regulation I think gets to the heart of the matter. It is a "shall," not a "should." That means it is a mandatory requirement. And our feeling was that all FDA really needed to do was to enforce this regulation for those products which had been shown to be potentially pathogenic to consumers via the data we already had out there in the field.

Twenty years ago we didn't worry about Salmonella or E. coli 0157 in juice products because we thought it died. Well, we're wrong. We knew 15 years ago that it could survive. The data is out there in the literature when you go back and look for it. Ten years ago we knew for certain it would survive.

That's what proceeded us to do a white paper internally to our member, and why in the spring of 1996, when marketing for three different of our member

companies, three different companies had marketing come forward and say, "We want to put out an unpasteurized juice product," three major companies. In one case they went so far as to have five vice presidents, the CEO, and the quality control director in a room for two and a half hours, going through a story board presentation.

When that was over, the quality control director said, "We will not produce that product because we cannot assure its safety, and here's why," and he pulled out the white paper on Salmonella and handed it to his CEO, and his CEO said, "If you can't assure the safety, based on what we know about it now, we will not produce that product."

Similar situations happened at the other two companies. That's the spring of 1996. Now, their stock was very low with the sales and marketing people until November-December of 1996, when the situation occurred in the apple juice and they were borne out, and they are in much better situations now. People do listen to their quality control people.

There is no excuse for not knowing that that organism could grow, if you are in fact in quality control in a company. It's your responsibility to know that, and to take the action to assure that that does not get through into your product.

That's probably why currently in the U.S., although all of our companies at some point have what is an unpasteurized juice--we produce that product from raw apples and oranges and grapes and berries--why are 98 percent of those products pasteurized? This is one of the reasons. That's why the major companies are not putting out these products. That's why they are looking at alternative methods that will provide an equivalent kill step, but until they get that, they're going to continue to pasteurize those products.

Within the past six months alone we have four major outbreaks: In fresh Mamey puree, which by FDA's definition of the HACCP proposal would have been regulated under their HACCP group as a drink, 13 cases, Salmonella, Florida. Raw apple juice in Canada, E. coli 0157:H7. Raw orange juice in Australia, 345 cases, Salmonellosis; that's this spring. And raw orange juice in Arizona, the latest case and I think, what, 104 cases and counting at this point.

And FDA's own estimate is, there's something like 6,000 to 6,200 annual cases of illness only from the 2 percent that's not pasteurized, and zero percent from the 98 percent that is. How many cases would we have if nobody pasteurized? I don't even want to think about that.

Bearing this out, and looking at the need for perhaps looking at a minimal pasteurization, as opposed to pasteurization for a shelf-stable product which does not need refrigeration, or a longer term refrigerated product where you knock the yeasts down and kill those out, those types of products--with the shelf-stable products you're dealing with several thousand D heat put into that product to get it shelf-stable, because you're killing off yeasts and molds that might spoil their product.

The refrigerated product is still lesser, but if it has been pasteurized, usually to increase its shelf life, you're still dealing with several hundred D. So how do we deal with something that's about a 5 D, or maybe a 6 or 7, if FDA changes what the baseline should be, based on what they expect those to come in at?

Under the direction of our Juice Products Technical Committee and our Microbiology and Food Safety Committee, we developed a research project and conducted research that has just been completed into the heat resistance of E. coli 0157:H7, various Salmonella species, and Listeria monocytogenes in various juice products. We looked at three different juices.

That research has been completed. It is undergoing a peer review now through our Juice and

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Microbiology and Food Safety Committee. We were told at our June committee meeting that they want this published and in the public record as soon as possible, so our idea is to have that published in a peer review journal as quickly as possible. It is being written now. We hope to have it submitted to a journal within 30 to 60 days, and once that is done, we may be in a position to meet with FDA and go over those results and give some of the data to you.

Do you have any questions?

MS. ZINN: It's possible to get contamination, is it not, from fresh cut fruit or an apple that you buy in the grocery store, correct?

DR. MATTHYS: Yes.

MS. ZINN: Wouldn't you like to get rid of that also?

DR. MATTHYS: It's going to be more difficult because, one thing, if you have a contaminated apple, the only person who's going to be ill from that apple is the person who eats it. And if you have internal contamination of the apple, you probably won't eat the core so you may never get it. So if you clean off the outside, you reduce your risk.

But if you take that same apple and make juice from it, you contaminated maybe 10,000, 20,000, 100,000

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apples out of that one apple. That's the problem you have with dealing with the juice. You can't pick out all the defectives because you're dealing with so much product.

And you're looking at products that may have been bitten by an insect. You won't see that little hole that goes in there, stung by one, that goes through the top, that goes through the bottom. You have so many means for that to get in there.

It's one of the reasons that, in one of the papers I put out here, that we are supporting a 50 ppb limit on patulin. What that will help us do is get rid of lower quality fruit. It also helps exclude the drops that may be in there. It's coming out.

Now, our members right now are using that limit. They are testing product offered for sale to them. If you don't pass the 50 ppb limit, you will not have product accepted by those companies. In fact, if you're between 30 and 50 on the first test, they'll retest, because the variability of the test is about plus or minus 10. So if you're over 30, you're going to have a second test. If you go over 50, then you're out, too. So you've got two chances to lose your products right there.

MS. ZINN: We are the processed nation, and we are the most obese nation in the world, you know. And we're going more and more towards fresh, and there's going to be more and more outbreaks, because when you're dealing with a fresher commodity, there's going to be some contamination.

DR. MATTHYS: What's the difference in the core value of the juice, whether it's heat treated or not? There's no difference in that core value.

MS. ZINN: There is a difference.

DR. MATTHYS: Take a look at the true nutrition numbers. Look at the numbers. How many of those products have nutritional labeling on them, by the way? Compare some of those numbers, and you'll see that. Look at the real numbers.

MR. TAYLOR: Kirk Taylor from El Dorado. You're talking about introducing equipment into processors that can't afford it, you know, 10,000 gallons or less. How do you intend to deal with their product?

DR. MATTHYS: Well, the question is, if you're producing a product that's potentially unsafe, should you be producing that product? Should you be permitted to produce the product?

If we're dealing with a small restaurant, for example, and some of the State guys go out and inspect

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that restaurant and find they have unsanitary conditions, are they going to say, "Well, this is a small mom-and-pop operation, it's not big like some of these chain things," so we're going to let them continue? Or are we going to close them down until they get hot water. They'll close them down.

MR. TAYLOR: Yes, but some of the mom-and-pop organizations are run better than some of those big restaurant chains, if you want to use that analogy.

DR. MATTHYS: If they're putting out good, safe product, but can they agree that they're doing that?

MS. ZINN: So then we can die of heart disease.

DR. MATTHYS: The problem that you have is--and, you know, the answer to the problem is, if you're a small processor, how do you know you haven't caused somebody to be ill if you have not been taking the proper steps. When I read in that article that the majority of the people producing apple cider were not even washing their apples, that leads me to believe, were they cleaning anything else either?

The presses, were they even changing the press cloths? If they get one sample through there that's got E. coli in it, they're beginning to contaminate everything, and I can't guarantee that it won't grow in the press cloths because that pH may not be low enough to

keep it from growing in that particular environment if you're not changing those things. You have to look at that operation.

Yes, sir? I'll be here tomorrow. If somebody wants to talk to me individually, we'll be happy to do that.

MR. SCHWALM: The point was not to try to get into a debate or anything, but I think that there is a very important point that is being made here--thank you, Allen--in the sense that from a regulatory standpoint this is not an easy issue.

And as you apply some scientific data, some risk analysis data to make these kinds of decisions, the gentleman here from Massachusetts before was talking about oysters versus juice. You've got 16 people on the average that are dying from one product, and you have one death in another product. How, from a regulatory point, do you handle this type of thing?

You've got 98 percent of the industry that is producing a product that is subject to treatment that will make it a safe product. You've got another small portion of the industry that is not. From a regulatory point of view, how do you juggle these things?

These are important issues. These are some of the reasons why FDA and other regulatory agencies have

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had difficulty deciding what is the best way for public health, for our consumers to move forward on this, why we are not rushing out with a HACCP rule, that these are some of the issues that we're trying to deal with. So these are real issues, and there is not a black or white, yes or no, right or wrong.

MR. : You can't (inaudible).

MR. SCHWALM: That's right.

DR. MILLER: Thank you again, Allen.

One other comment or question?

MR. GARCIA: Garcia with FDA. (Inaudible) that small batch processing, (inaudible) not allowed in large batch processing, (inaudible) risk analysis and say contaminating 50,000 gallons, why not contaminate 10 gallons producing, and then you're better off on your risk, your total risk.

DR. MILLER: I want to make sure I understand your question.

MR. GARCIA: If a person eats one apple, that's all they eat, is one apple.

DR. MILLER: So, you--right, it's the same comparison, except expanded on one person eats one apple and gets sick, that's a lot different than if you take that one apple and put it into--dilute it into a large batch of juice.

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MR. GARCIA: (Inaudible.)

DR. MILLER: And that, actually that rationale has been used in the agency for where some of the cutoff points have been made.

Okay, let's move on. Our next talk is again discussing the--well, in this case warming/freezing cycles, and it's going to be presented by Dr. Steve Ingham from the University of Wisconsin.

DR. INGHAM: Well, I've got to admit I feel a little bit like I do when I do meat HACCP courses, because usually in the first 30 minutes of those courses we have an argument like we just had about why do we have meat HACCP, and then I have to come up and be the straight guy.

Anyway, if we can move on, my talk I think you'll find follows very nicely after the one that was right before the break, and what it deals with is again trying to look at some low tech options that you might have to be able to get this 5 D kill. Now, in case some of you are a little drowsy late in the afternoon, I'm going to try to give you the punch lines near the start, and then we'll fill in the background.

We basically looked at three different types of treatments, alone and in combination. We looked at freezing and thawing. We looked at addition of organic

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acid preservatives such as sorbic acid or benzoic acid. And we looked at warm short-term storage. Basically, what we found in our systems was that it was very rare that a single treatment would work, but it was not rare for combinations of treatments to work, and I'm going to fill in the information on that as we go along.

Another key point or punch line that I would like to say right at the start is that it's my opinion that one of the most important decision-making tools a small apple cider maker could get is a pH meter, because we found that the pH of cider is really, really, really critical to what you can do to get a 5 log kill. And if you're up at the high end of the pH range, which we define as 4.1, there isn't much that you can do to get a 5 log kill; and if you're down at the low end, there are a variety of options.

The final punch line, and I think the speaker before break would agree wholeheartedly with me on this, is that it's really tricky to choose your microbiological validation methods. And I've learned the hard way how tricky that can be, and I'm going to point out as I go along here some of the things I might have done differently, if I were validating or trying to validate a process for commercial use.

Let's just set the perspective a little bit. Wisconsin is not a huge apple growing state. We have about 90 licensed apple cider makers. I would guess, from a survey we've done, that the combined production is probably about half a million gallons. Of these 90 processors, probably a handful, somewhere between 5 and 10, produce the majority of the cider. Those few processors are going to pasteurization or have gone because the grocery stores require it.

So really my work has been for the other 95 percent or 80 percent of these folks that still want to stay in business, and I at least value, from an esthetics point if nothing else, the role that these cider operations and these orchards play in Wisconsin. We have a lot of rural areas yet in our State, and I think it's an important quality of life thing.

I'm part of a team. We have three people who are Extension specialists working on the cider issue. Teryl Roper works with the growers. I work with processors, and I've been trying to come up with the equivalent of "farm to table." The closest I could come up with is, I work from "lug to jug." And my wife Barbara, who is also on faculty, works with the consumers.

We also cooperate really closely with the Wisconsin Department of Ag, Trade and Consumer Protection. We're trying to get grant money to give some web-based inspection training for those folks, and hopefully on August 1st we're going to have a video out that you folks might want to get about orchard and cider plant sanitation. We'll have the English version out this year, and we hope to have a Spanish version out; I'm guessing it will be ready for next season at the latest.

Okay, so what am I going to talk about? Well, we got started in this kind of like the folks at Minnesota. We were looking at freeze/thaw treatments and we had some interesting results. Then we pulled in some other approaches and looked at multiple hurdles. I'll cover that in depth. Another thing we've looked at, and it has been brought up a few times here today, is the question of is E. coli 0157:H7 truly the target organism? We've done a little bit of work looking at some other target organisms, and I'll tell you about that. And then, finally, we've looked some at if E. coli 0157:H7 is so rare out there in apples and in cider, what should a cider processor test for to try to get a handle on sanitation and their intervention strategies?

Okay, so freezing and thawing in cider, we've worked with typical cider, pH 3.5. A key methodological

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decision we made early on in all these studies is, we were going to work with previously sterilized cider. Now, as I said, I learned the hard way. I might not do this if I did it over again.

But our concern was that the typical enumeration method for E. coli 0157:H7 from a mixed flora was sorbitol MacConkey agar. There's a pretty good record in the literature that injured E. coli do not grow well or do not form colonies on sorbitol MacConkey agar. So we wanted to be able to count injured and uninjured cells, so therefore we used sterilized cider, spiked it with our cocktail, and then recovered survivors.

In this particular study we worked with two test strains, and again, the more strains in your cocktail, the better, when you do these validation studies. So what we did, it was a test tube study. We froze it for 24 hours, minus 20 degrees Celsius. Then we thawed it out either in the refrigerator, on the lab bench, or in a microwave. Then we recovered organisms.

What we found is that if we recovered our organisms with a nonselective medium, we had anywhere from about 0.7 to 3.5 logs of kill, and the big variation was mainly between the two strains. We had one that was tough and one that was wimpy, as it turned out. If we

used sorbitol MacConkey agar, we had a much greater kill, from about 1.4 to 5.6.

So, now what can you take from this? Yes, there is some lethality associated with freezing and thawing. If a consumer called me and said, should I do that, I would say it certainly will improve safety. Will it get 5 logs? Probably not. Okay, and particularly in this system where we heated, the pulp tends to flocculate when you heat that severely, and I think the pulp is really protective.

Okay, so we moved on. We decided to try to combine treatments, and really we had an idea that we got from doing some other acid tolerance work that I thought was really kind of a--well, in a way it's not a new idea, but it requires a new mind-set. And that is the idea that you might want to actually, on purpose, hold this cider at what we would call an abusive temperature. Organic acids are more lethal at warmer temperatures; that's well known.

And what we came to realize is that immediate refrigeration is not best for cider safety, and in fact I had a few cider makers at various meetings come up to me, kind of on the sly, afterwards and say, "Well, you know, sometimes we leave it overnight." Enzymatically, that makes sense, right? They have more time to operate.

Compounds are produced. From a microbiological point of view, if you ignore yeasts and molds, it might be safer.

So we decided to look into this. The range of temperatures we were working with is 25 to 45 degrees Celsius; for our people who grew up here, 77 to 113 Fahrenheit. Okay?

Now, I recognize this would require a big mind-set change for regulators, because you folks have it engraved, "Keep it hot, keep it cold, keep it moving." Okay? This is saying, "Oh, keep it warm for a while, then cool it down." But let's look at the data and see how it goes.

So the protocol we used, we had a range of heat-sterilized ciders, pH 3.3 up to 4.1. We tried to cover the range in what the folks at Geneva in New York had described earlier as a typical pH range. We put 7 logs of E. coli in. It was a cocktail. We again enumerated survivors by plating. Our treatments were freezing and thawing, sorbic acid at .1 percent, and then short-term storage. At 4 degrees C it was zero to 12 hours; at 25 degrees C it was zero to 12; and at 35 it was zero to six. Thirty-five, incidentally, is 95 Fahrenheit.

So did this work? Again, this is a test tube study, heat-sterilized cider, one type of cider. At pH 3.3, a couple of very simple things worked to get a 5 log

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kill: Hold it at six hours at 35 degrees C, or freeze it and thaw it. Okay? And the freezing and thawing conditions are up there. Now, that's at the low end of the cider pH range.

If you look at the mid-range, pH 3.7, we had a handful of things that still worked. Again, six hours at 35 still worked; got a 5 log kill there. If you wanted to use less severe heat treatments, you could combine those with freezing and thawing. And what we think happens is, is this warm short-term storage sensitizes the cells to the stress of freezing and thawing. So you could go six hours at 4 degrees, 2 hours at 25, 1 hour at 35, and then freeze/thaw. Or you could add sorbic acid, let it sit for 12 hours at 25, and avoid the freezing and thawing. So those all worked for pH 3.7.

pH 4.1, you have to do a little bit more, and I hope you notice the trend. The higher the pH gets, the more you have to do. So here what worked was six hours at 35 plus a freeze/thaw; or sorbic acid plus a couple of different heat treatments plus freeze/thaw; or sorbic acid plus six hours at 35 degrees. The main thing to note is that six hours at 35 degrees C by itself no longer worked, so you needed to do more as the pH increased.

How did it taste? Well, we tried our best to get a handle on this. We used pasteurized as a benchmark, and I need to explain the pasteurization. It was somewhere between low temperature/long time and HTST. In other words, we got it up to 162 Fahrenheit and held it for 15 seconds, but we did that batch-wise. It wasn't in a plate pasteurizer. So there was a pretty significant come-up and come-down.

We did this partly because of equipment constraints, and also because our taste panels were open to anyone coming in off the street to get Babcock Hall ice cream, which is famous throughout Wisconsin. We didn't want to kill anyone and lose an ice cream customer.

So, anyway, we tried these treatments that have been shown to get the 5 log kill. The six hours at 35 degrees kill was preferred over our pasteurized cider; so was the freeze/thaw alone; and so was the combination of those two. Okay? And those were the treatments, remember, that would work at 3.7, pH 3.7 or pH 3.3.

If we added sorbic acid, and those were the treatments for the higher pH cider, consumers preferred the pasteurized. They can pick up that sorbic acid when it's a head-to-head comparison. Now, what we didn't do is just give them sorbic acid by itself and have them

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evaluate it, and I should point out the average scores for all of these are above the mid-point. I mean, people like cider, okay, and even with sorbic acid in it. They just liked our pasteurized more.

Now, the weakness of that study, a couple of them. One was the heat sterilization, and the other is, we only used one cider.

So we are in the process of writing up a second study that we did where we used a different type of sterilization that wouldn't coagulate or cause flocculation of that pulp, and that was through a radiation sterilizer. Okay? Which of course I'm not advising as a commercial thing, but again this was to knock out our background flora. So we shipped our samples over to our friends at Iowa State, they irradiated it for us, sent it back, and we did our studies.

Again, the same pH range, just more pH's. We also added benzoate as a treatment, benzoic acid, sodium benzoate actually. We added some more warm holds, and this time we did three ciders instead of just one.

In addition, we used a much more sensitive method for detecting survivors. We used a broth-based method and a microtiter plate. It would very simply tell

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us, yes or no, whether we got a 5 log kill. If we got growth, we didn't. If we didn't get growth, we did.

Now, you ask, why did he do that? The reason is, if you do all this math out, there were something like 2,056 combinations. We had to miniaturize the study in order to keep that many ciders and that many other variables.

Now, the short news, the treatments did not work as well when we used the non-heat sterilized cider, the different enumeration method, and so on. There are some that worked, though. Generally speaking, what we found, though, was you needed to have sorbic acid or benzoic acid in the cider to get the 5 log kill.

So what you see there, the first one, for example, you could use sorbate or benzoate if it was pH 3.3, and then use that six hour, 35 degrees C hold. That would do it, in all three ciders. You could get a 5 log kill at a little bit higher pH, the second treatment shown here, if you used the 45 degree C hold for six hours.

You could--as we move down, you see a pH 3.9 and there was a treatment that worked with that. You also see the last treatment on this slide involves four different hurdles and less heat. So there's a variety of

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things that work, but with more steps comes more complexity and more cost.

Here are some other treatments that worked. The first three are four hurdle treatments that involve lower pH cider. The bottom one up here is the only treatment that would work at the high end of the range, that is, 3.7 to 4.1. If you added benzoic acid, four hours at 45 degrees C, and a freeze/thaw, you would get the 5 log kill even at that higher pH.

Now, we have not done any taste panel work with this. The student would really like to finish.

So I think, given what I've found, even though it's lab-based, even though we've used sterilized cider, the take-home message is that it's really important to know what the pH of your cider is, and to mix your apples so that you keep it as low as possible. And this slide just shows a very small operation. That's about half a day's cider, apples for about half a day's cider production, that have been premixed.

Is *E. coli* 0157:H7 the best target pathogen? I think so. We looked at *Salmonella typhimurium* DT104, which is a kind of hot new bug, multiple antibiotic resistant. It's surprisingly acid tolerant, but we found that anything that would knock out 0157:H7 would also knock out DT104.

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Listeria has been mentioned a lot here today. We found that Listeria had actually quite amazingly bad survival in apple cider. In fact, we put I think it was 7 logs in, and by two days of refrigeration it was gone. We couldn't even find it sometimes with enrichment. So, yes, it's more heat-resistant. It might be--you know, if you pasteurize to knock out LM, you'll get some other things, definitely, but I'm not sure we need to use LM as a target for these other intervention strategies because it just doesn't survive well in cider.

What should processors test for? You've already heard that looking for a pathogenic E. coli is kind of fruitless, to make a bad pun. What do we do? We need some indicator organisms.

Well, we did a study where we looked at different groups of indicators and how they survived in cider. And, you know, we've all been told 0157:H7 is amazingly acid-tolerant. Well, there's actually quite a range of acid tolerance in just regular E. coli, and some of them are pretty acid-tolerant as well, and we found pretty good survival in refrigerated cider with generic E. coli.

We found some coliforms that would survive well and some that wouldn't. They are certainly more prevalent, but there's the problem of course that they

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are of potentially non-fecal origins. And we also looked at Enterococci, another group of indicators, and they survived poorly, so you can scratch them.

Now, we heard earlier today that there wasn't a smoking gun for E. coli 0157:H7 on drops. We did a small survey, three different visits last fall. We did occasionally find generic E. coli on drops. We never found it on tree-picked apples or in cider, but our N is small. I mean, I think we had two out of fifteen positives with drops.

Okay, so testing for indicators, we found that testing rinse water might be a good idea. We visited one plant where the counts on apples actually went up, coliform counts rose after rinsing. It was a recirculation system, and I think it was very recirculated. So you might want to test wash water.

If you're going to test cider, I think it's very important, first of all, to do it quickly, because even though E. coli will survive fairly well, you want to maximize the chance of finding it, so I would say do it within a day if possible. Some of the methods require you to neutralize the cider before you test it.

For example, if any of you have ever used or recommended Petrifilms, you can't put cider straight onto a Petrifilm and have it work well; you need to neutralize

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it, which is kind of a headache. You have to figure out how much sodium hydroxide to add. Another alternative is simply dilute the cider some, but then you lose sensitivity.

We also found that there are a lot of--well, there were a handful of coliform kits out there. They varied tremendously in numbers of coliforms detected, and I think basically they were using different criteria for what is a coliform.

Well, that's a quick tour of what we've done for research. We're certainly committed in Wisconsin to helping these small processors. We grapple with the argument that we heard earlier about should small processors be in business if they can't do what's right. We think, by and large, we want to help them and at least give them the tools to succeed. And with that I'll stop and take any questions.

MS. : I haven't read the journal articles here. Are there D or Z values associated with the pasteurization steps? Do you know of any heat treatments with D or Z values?

DR. INGHAM: Okay. Well, the paper that everybody references is Splittstoesser at Cornell, or McLellan and Splittstoesser. I don't know if Randy is

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still here. He could correct--okay. And he has got a range of D values because there's considerable variation.

We also published a paper where we've got estimated D values that are in line with what he found. And then the Z value, if I recall, I think we used a value of 4.8 degrees Celsius. Does that sound right, Randy? It's four or five, somewhere around there.

Those heat--the thermal death studies are actually kind of tough to do in cider, and again I think it's because of that pulp. We actually filtered the pulp out a few times and ran D value studies, and the pulp is definitely protective.

MR. GARCIA: Garcia. When you're talking about microbial load, would APC be a better (inaudible) for pathogens?

DR. INGHAM: The question is, would APC be a better indicator? Personally, what I recommend to people is E. coli, because it does survive and it's an indication of something bad. High APC may not indicate anything bad.

MR. GARCIA: But if you're looking for a 5 log reduction, would it not be a better study (inaudible)--

DR. INGHAM: Well, if you want to avoid a spike study, maybe. It really depends on what those organisms

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are. I'd have a little trouble just carte blanche agreeing with you.

One thing I forgot to mention, real quick, yeasts and molds with those hot holds. We checked yeast and mold counts after six hours at 35 degrees C in unsterilized cider. They did not go up. In fact, if you have sorbate in there, the warm hold actually enhances the action of sorbate, and we've checked that out with several other experimental conditions as well. So I don't think these warm holds are really going to cause a shelf life problem that's significant.

Okay, I'm probably way over--oh, one.

DR. HIRST: Peter Hirst from Purdue University. Did you try a combination of benzoate and sorbate?

DR. INGHAM: We did not. We didn't try the combination of benzoate and sorbate. We did look at lactic and propionic. They're already food grade and they have a little less of a bad aura. They didn't work as well.

DR. HIRST: We tried a combination of benzoate and sorbate, and at room temperature they work extremely well.

DR. INGHAM: Okay. I know it was either Chuck Casper or Mike Doyle had done a combination in original shelf life studies.

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MS. : Doyle.

DR. INGHAM: It was Doyle? Okay. Okay, I need to sit down and give somebody else a turn up here.

MR. SCHWALM: Let me pose a question. We're running a little bit behind time, as you can see. Next we have Pat Hansen, who's going to be talking about the food additive issue, and there have been some questions so hopefully she will address that.

The question is whether we would like to postpone having Felicia talk about the labeling issue. We anticipated that some of these questions were going to be coming up, and that's why we wanted these people. So we kind of have a choice here.

I wanted to kind of get a hands-on or a voice vote here on, we could continue on with the next two speakers and that's going to put us towards 5 o'clock; or the alternative is that we could have the talk on the labeling issues tomorrow morning, and perhaps even could start a little early so that we won't be rushing tomorrow morning. So if we can agree to start at 8:30 and have the labeling, then we'd be real fine for tomorrow to get out of here by noon.

So those are kind of the two choices. We could go tomorrow with the labeling or continue on today. If I can see a show of hands, how many would like to continue

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on today? Okay, and tomorrow? Of those people that want to continue on today, how many would not be here tomorrow?

Okay, then I think the majority would like to put it off until tomorrow, so we'll do that. And then tomorrow we'll start at 8:30. Anybody that's not here wouldn't have heard her anyway, so it won't matter if they don't know, and we'll have that.

DR. MILLER: I'll make a quick introduction. Dr. Pat Hansen is with our Office of Premarket Approval, which is the group responsible for receiving and contemplating and making decisions on all food additive petitions and many of the other submissions to FDA. And Pat will be talking today about questions about the approval of technologies, which technologies do require premarket approval, and what it would take to get it through the process. Pat Hansen.

DR. HANSEN: Thanks, Art. First, a little proviso. I've got bad allergies and my voice tends to fade away, so if I can have the back row, if I start to fade away and you can't hear me, somebody back there wave their arms.

Oh, we've got a funny guy. These also weren't set up for short people.

As Art mentioned, I'm going to be talking about the routes to regulatory clearance for some of these new intervention processes, and I'll start out at the outset--try to get myself arranged here --I'm going to be talking about some material that some may find fairly dry. There's going to be a fair emphasis on the legal aspects because we are operating, for premarket approval and a lot of regulatory procedures, within a strong regulatory framework.

I'm going to try to minimize some of the legalese, though, and hit the highlights for you of which agencies you might need to deal with for various technologies or parts of your technologies; what procedures are applicable to different types of technologies; and also to emphasize really the heart of the matter for us, which is reaching a science-based safety decision on the technologies or the components; the questions that need to be answered by sponsors of the technologies, petitioners or other applicants; and also the types of data and information that can provide the answers to those questions.

And then I'll run through, if we have time and people aren't falling asleep or on the floor, a few examples of how you might tackle deciding, for a given technology, which is probably the appropriate pathway.

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And I'll end up with names and telephone numbers of contact people.

First, I spoke about food safety, health protection and food safety. It provides for scientific judgment and the use of agency discretion in some cases. A whole lot of laws. I just put a couple of the major ones up, and you'll see by the list there we've got the Food, Drug and Cosmetic Act. Basically the next lowest one that EPA administers has to do with pesticide chemicals.

For antimicrobial chemicals, the EPA factor is something that folks may need to think about, depending where they're going to apply a given technology. And a couple of other statutes that, again, all concern basically antimicrobial chemicals. Two agencies you see there are FDA and EPA.

And the first breakdown I want to give to you all of is that for the physical types of intervention technologies, the ones that involve radiation, you know, hardware, electric field based methods, basically your more high tech stuff, you're looking at an FDA scope of authority. For your antimicrobial chemicals, it depends where and when you're applying the chemical. Are you applying it to a food or to a raw agricultural commodity?

And here you're either dealing with FDA for the food itself; and raw agricultural commodities, and there are some niceties there sometimes deciding what you've got, you're dealing with FDA for commodities--or EPA for raw agricultural commodities and FDA in certain other cases, minimally processed produce.

I'm not going to spend too much time here. The goal I think is the mutual of government and industry, is protecting public health. We're going to apply science to reach our decisions and consider a whole lot of different types of testing, different types of data, calculations, the scientific literature, but we're operating within boundaries, the boundaries that are given to us by the legal framework.

And I'm going to focus on FDA here, obviously because I'm from FDA, and I'll start with the premarket area because it's sort of where everything starts. That's the default assumption. Now, FDA doesn't regulate processes per se, but substances or components of things that a processor might use in an overall processing scheme.

So it might be the components of a food contact surface, say an equipment surface. It might be the components of packaging materials that contact food, if that's involved in your overall intervention technology.

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Antimicrobial chemicals, where they're not governed by EPA, come within FDA's scope of authority.

The scope is very, very broad by intention. Anything that is deliberately added to food or might unintentionally become a component of food through addition, or use of a source of radiation in food treatment, all of these things fall under the scope of FDA's premarket approval authority at the start. Then the law proceeds to carve different things out of that and say, "No, you don't need premarket, you don't need FDA premarket approval authority," not for pesticide chemicals. Of course, then you're not out of premarket entirely; you're over to EPA for the registration process.

Prior sanctioned ingredients, these are things that basically have been in common, safe use prior to 1958 and had on paper a sanction or some kind of approval or statement from either FDA or USDA that the use is safe. That's basically what those are.

A category about which there's a lot of confusion, and I'm going to discuss a bit later in the talk, is the Generally Recognized As Safe category. And the fourth category relates to dietary supplements, and I'm not going to talk about that at all.

So the law lays out a broad scope, carves out exclusions, and then offers up a couple of cases where FDA has authority to exercise discretion. And the one that's most relevant to our topic today is the area of food contact materials that meet certain criteria, and FDA can exempt those from the requirement of premarket review and regulation.

And we do this under something called the Threshold of Regulation Policy, which is a formalized way of looking at a food contact material that folks want to use and going through and deciding, based on the data, the information they give us, that this is a case that's too trivial to merit the whole rulemaking process.

In some other cases FDA has no discretion, and the key one here is in the use of sources of radiation. People can't stick that under a GRAS exclusion. It doesn't come under the threshold of regulation. We're with the full market approval process here, where typically folks come in with a petition containing scientific data and information needed to establish the safety of what they want to do, and our scientists go through a review and eventually a rulemaking process where we actually publish a regulation and a decision.

So to hit a little bit of a stopping point, if you were out there wanting to use a new technology, a new

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intervention technology, or are the purveyor of one of those, there are a couple of questions that you ought to ask yourself right at the start.

Number one, are you using a source of radiation in your technology? And this isn't just ionizing radiation. Ultraviolet also comes under this.

Oh, shoot, that green does not show up. I will read this. The first question is use of source of radiation, and under that I guess I would ask everybody to write down another question: Is it already covered in FDA's regulations? Because if it is, you don't need to come to us with another request. As long as you're operating under the regulations, you're okay.

The next question to ask yourself, and usually this is with the physical processing methods, is do I have--am I using equipment with food contact surfaces?

The next question would be, are these surfaces already covered in FDA's regulations? If they're not, is it covered under a previous exemption? And there are ways to get that information, and I'll give you some sources later.

And last but not least, you know, if it doesn't appear to be covered by anything on the books, does it appear to meet the criteria for Threshold of Regulation,

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because then there is an abbreviated procedure where you can come to us for an okay.

Antimicrobial chemicals, you really need to sort out first if you're talking about a pesticide chemical, something that's under EPA's authority, because you need to go talk to them. If it doesn't appear to be the case, again, there are a few regulations on FDA's books where you want to look to see, is it already covered? Because if it is, then you don't need to come to us for an okay.

And the last category there would be to examine whether that substance is GRAS, and again I'll talk about that a little bit more later. Last but not least, also, is the situation unclear? And then just give us a call.

So if you are in the premarket approval side of things, the way that that process operates is basically through a petitioning process. The sponsor of the technology or the component of the technology, be it a chemical or a source of radiation or any of the other things I've discussed, needs to come with a petition containing data and information that establish the safety of what they want to do.

And what you need to remember here is, we've got that uneasy--I guess an uneasy marriage of science and the law. You may look out in the literature and say, "Well, my goodness, you know, all this stuff is out

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there, it's safe." But what the law says is, the burden is on you to show it's safe.

So the way to think of it is, you're the expert witness presenting the testimony. You gather up the information. You come in and make the case. We'll look at it, and if we agree with you, what we'll do is approve it and go ahead to issue a regulation.

So what FDA is responsible for is conducting a full and fair evaluation of all that data and information you submit, and then issuing a regulation if we concur that it's safe. A kicker in the law is that FDA is not legally permitted to consider benefits, and I know this is always a real head-scratcher for people, but we can't trade off, under the food laws, we can't trade off some increase in one aspect of safety against other areas where there might be a decrease.

And it's not a risk/benefit type of equation, either, where yes, we're reducing pathogens, but maybe we're putting chemical contaminants in. That's no good either. What we're doing is comparing to make sure that, using the technology, you haven't made the food any less safe than the foods that are on the market.

The process itself, again, involves submitting a petition. When that comes in, FDA staff give it a quick screen to check if it's okay to file, if indeed it has

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the information it needs to even get started reviewing it. We notify the sponsor by letter within 15 working days, and also proceed to put a notice out in the Federal Register that essentially tells the world that, hey, we've got this petition and we're working on it now.

So what does the petition need to have in it. Well, we need to know what you want to use, how you want to use it, and why you want to use it. Those are the first three bullets. Makes sense. The fourth item, a method for determining quantity, that's most easily understood with antimicrobial chemicals. You have to include in the petition a method for measuring how much you've got, say, in wash water or as a residue in the food.

The most important part--and, again, I wish I had not done this in green--is data and information establishing safety. That's the real key here, and that's where most of the data and information are typically in petitions and what we spend the most time actually reviewing to make sure people have covered all the bases.

And last, as a result of another law, there needs to be some information regarding effects on the environment, and typically that's minor information and doesn't take much time to review.

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Safety means a reasonable certainty that no harm is going to result from the use of the components of your technology. It doesn't mean absolute certainty. The law is reasonable in this regard. It leaves a lot to the discretion of agency scientists to reach their decisions.

So we're talking about these new intervention technologies. What are the general areas that FDA is looking for in the petition? What do folks need to address? They need to address three main areas. One would be toxicological concerns. Possible nutritional considerations is the other. And last but not least is microbiological considerations.

It may be that there are in fact, when you get to the end of the analysis, no real issues in any of these areas, but what the petitioner needs to do is make that argument, put a narrative, write it down. Why are these not issues? Why is the technology, why is the additive safe, based on considerations in each of these main scientific areas?

I'll go real quick through here. For toxicological considerations it can basically be expressed as, what kinds of chemical changes can occur using your technology? If you're adding a chemical, that's easy, you're adding a chemical. If you're using, say, ionizing radiation, you may have radiolitic (ph)

products. You want to know what they're likely to be, what kinds and in what amounts, because what you're really trying to decide are whether the products of any of the changes, these chemical changes, can be toxic in the amounts that are going to be consumed.

Again, a lot of judgment involved here and different ways of getting about these questions. There may be information in the literature that can be assembled on a given technology, or you may have to go out and actually do analyses or testing. It really depends exactly on what you're going to do and what you want.

In the nutritional area, the main questions are these: Is the food a significant source of any particular nutrients, and which ones? Secondly, does the technology result in any nutrient losses? Now, it may, and the real question is, do these matter in the context of the daily diet?

You may be reducing, say, Vitamin E in a juice, but if juice is not your major source of Vitamin E in the diet, that's unlikely to assume any kind of significance. On the other hand, if you're significantly reducing Vitamin A and you've got a product where that's your major contributor of Vitamin A to the diet, that's more

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of a concern and we would need to look very closely at that.

And the micro stuff is not--it's two-fold. The first question is whether the intended effect of the technology is microbiological. Of course, in this group that's what we're talking about. Of course it is. And then we want to see information that demonstrates that the conditions you want to use the technology under, you're actually going to achieve something.

Importantly, though, I want to say here that in the premarket approval arena when we're evaluating these petitions, food additive petitions, for different components of technologies, we're not evaluating the power of the treatment against a performance standard. We are not making a finding in this particular type of evaluation as to whether you can actually achieve a 5 log reduction.

What these type of regulations are, are permissive. They allow people to use the technology, the additive, the component, to try to achieve what it is they want to do. The approval is not a sign from FDA that in fact you've actually achieved it in practice, and that's an important thing to keep in mind here.

The second bullet is not so relevant for the things we're talking about here today, and mainly relates

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to uses of ionizing radiation. Generically the question can be expressed, if your treatment isn't sterilizing the food, have you altered the microbial profile in such a way that you're going to allow virulent pathogens to grow faster, produce toxin faster, toxin in greater amounts, than they would have if you hadn't treated the food? And like I said, more of an issue for users of ionizing radiation and less for the technologies we're talking about.

So once we've got the thing and have the information present in all those areas, our scientists are going to get to work on it. They're going to review that data, evaluate the safety argument in the petition, and document their findings.

If questions come up, and they frequently do in the course of review of these petitions, we may need clarification on a few things. We may have more involved questions. Sometimes we even need people to do additional testing. What we do is communicate with the petitioner promptly so that we can resolve any of these problems, any of those deficiencies, and be able to reach a final decision.

The key here is, the FDA staff is trying to reach a scientific conclusion. This isn't a research exercise. We're looking at what we have in front of us

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in the petition, other information in our files, and our wealth of scientific background knowledge, to reach a decision and make a recommendation whether to approve or not.

So what happens after the review of the petition is complete? Well, this is where the full premarket approval process isn't just reaching the conclusion in your mind, and it isn't just, you know, the reviewers, the staff level scientists at their desks reaching a conclusion. The agency has to prepare a draft decision document. Again, this is because we're in a legal procedure here. We're using science to reach a legal end point.

So the decision document discusses the scientific basis for our decision, thumbs up, thumbs down, and it will also include a discussion of any necessary policy considerations. At the very end of it, it also includes the actual text that will appear eventually in the CFR, in the Code of Federal Regulations.

After the document is drafted, it has to go through additional technical review. That is generally not as lengthy, not as involved as the original data review, obviously. There is policy review, and

importantly, there is legal review. Our attorneys have to give it more than just a once-over, in fact.

And eventually the Government Printing Office publishes the decision document in the Federal Register, and that's when it's for real. That's when the gun goes off and everybody can use it, when it appears in the Federal Register.

There is a period in which people can object to the decision, send in written objections. There is a 30-day period for that, and FDA is bound under the law to consider them. However, only in cases where they raise an immediate, serious and obvious issue that the decision was wrong, have we ever stayed a regulation. I could probably count the instances on one hand where we've stayed a regulation in this area. Most of the time we just look at the objections and evaluate them, and the regulation remains effective.

I mentioned there are some other routes to regulatory clearance. One of the more important ones is this area of food contact materials, that is, equipment surfaces or packaging material. We have a policy for dealing with cases where the dietary exposure to any components of those things would be very low, and where some additional criteria are met, namely that there be no evidence of carcinogenicity from the components.

The dietary exposure level is pretty low. The concentration in the diet of any of the components has to be less than a half a part per billion. And in those cases we don't go through this full-blown rulemaking process. We issue a letter that says, "You are below the threshold of regulation." I mean, this is a case that is so trivial, in fact, that we won't go through rulemaking even though technically we could.

There are some requirements for information. Generally these packages are far slimmer than a petition. The first three things are the same, really, as any application to us. We want to know what you're using, why you're using it, and how you're using it. Why you're coming to us with this request, what's your rationale, and then the data that support your rationale.

We like this policy because it allows us to really direct our limited resources away from the trivial situations, spend them on the things that count. We have a couple of teams that look at these Threshold of Regulation requests. They've been up and running for some time. They work together very well. They work together very quickly, and have a wealth of experience in this area.

Typically they can take on 10 to 20 of these in a meeting that occurs every couple of months, and

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requests to get a final letter out is on the order of a couple of months. In some cases it's quicker, but I hate to over-promise, and that's about the time frame.

So this reduces the time needed to reach regulatory decisions. We don't have to invoke that whole big rulemaking process and involve a lot of upper levels in the agency, in case this work doesn't merit it. It takes less out of the sponsors, too, to prepare those packages. The requirements are much lower.

Another route that some of you may be familiar with is the route for Generally Recognized As Safe substances. The law itself in this regard is pretty reasonable. If you look at the legislative history back when the Food, Drug and Cosmetic Act was put in place, there's a lot of discussion, the transcripts of all of the hearings and the committee meetings that were held.

And one thing that did come up over and over was the clear acknowledgement and realization that you needed to have a common sense exemption. That definition of the scope of premarket approval authority I showed you at the beginning is so broad that it could literally cover everything under the sun.

Clearly not everything under the sun should be brought under that. What about things like salt, vinegar, other items that might fall under a strict

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interpretation of that premarket approval authority, but clearly there is no reason? And so, you know, they memorialized the category called GRAS, Generally Recognized As Safe, things that any collection basically of scientists could look at, where there would be data and information, where there would be a common history of safe use, and you could call those Generally Recognized As Safe.

FDA has made Generally Recognized As Safe determinations or affirmations, but the law doesn't limit that to just FDA. Others in the industry, academia, just other experts can make a determination that something is Generally Recognized As Safe. When they do that, they are on their own, of course.

We used to have a procedure where folks could petition us to look at their determination and either affirm it or deny it, and then we would go ahead and publish a regulation. In those cases they weren't on their own because we bought into it. This was really resource intensive. We were spending a lot of time reviewing petitions for things that were not in the end any kind of a safety hazard.

And in rethinking what we were doing, we said, "Yes, we're offering a service to folks," because the industry a lot of times just wants an assurance that

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their determination is right. Well, we shouldn't be spending all this time on something that doesn't warrant it.

And we came out with a proposal that would both clarify the criteria for GRAS status, and also did away with the old petition process and put in a new notification process that would allow folks--give them some boundaries for how to construct and present their determinations, make it easiest for us to look at it. And we could respond by letter, the tone of the letter being either, "Yes, we think you're on target," basically, or "No, you really haven't shown that the substance is GRAS."

I probably made that clear as mud, but basically, if folks come in and they want to take advantage of this notification process and get a letter back, you know, a security blanket saying yes, we're probably on track and okay, then they need to come in with information to us. Don't get something for nothing.

And there are two elements to demonstrate that something is GRAS. One, you need to show it's safe, and you have the same safety standard as all of the other things that are premarket approval authority, that is, a reasonable certainty of no harm. But you also have to demonstrate the general recognition part, that there

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would be common knowledge, information generally that is published and available to other scientists, to other people, other experts in the field. And when you come in, you have to show that both of these criteria have been met.

Again, as I mentioned before, these GRAS procedures, this new one in particular, it's optional. A processor could make a decision on their own, a determination on their own that something is GRAS, and not come to us. Then they would indeed be on their own. They'd be running a risk we might disagree, but they really under the law don't have to come to us.

Lots of folks want to take advantage of the optional procedure and get some feedback from us, and in that case they can come in and notify us, give us the information. Rulemaking isn't required out of us. And we'll send back a letter.

We're still operating under a proposed procedure and trying to fine-tune some of the details before we go out with a final version, but we liked it, folks in the industry generally liked it, the public generally liked it. And that's why we're currently in a long-term pilot, just using it and working out the details until we finalize and ultimately formalize the whole procedure.

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Should I go through some examples, or is everybody ready to hit the floor?

MR. SCHWALM: What examples do you have?

DR. MILLER: Yes, I think that's important.

DR. HANSEN: I will skip one of them and I'll go right to the one that everyone is interested in, UV treatment of juice. Surprise, surprise.

MR. BEELMAN: It's getting difficult to hear you.

DR. HANSEN: Okay. Thanks. I'll take some water.

If you remember, way, way back at the beginning I gave you a list of questions that you might run through in your mind when you're trying to select a regulatory pathway, and I'll just walk down these now and really read again my poor choice of green.

Here you want to use a UV system to treat juice. You're using--you ask yourself, "Am I using a source of radiation?" Well, yes, I am. Okay, that says right away that I'm in the premarket approval authority area.

The next question I ask myself is, is this use already covered by an existing regulation? And no, in general the treatment for juice, at the intensities that are effective for what people want to accomplish in juice, is not covered.

There is a regulation for UV on the books. However, that existing regulation limits the use to rather low intensities, and from everything I've seen from folks in the industry, the levels, the intensity levels that are needed to effect any kind of significant reduction in microbial load in cider or juice requires a much higher intensity. And so higher intensity uses are going to require premarket approval.

The current status is actually pretty promising. We have a petition in from California Day Fresh Foods. We received that and filed it in June. It has been selected for a relatively new procedure that we have, expedited review or priority review. This is where we screen all the incoming petitions, and those that are for pathogen reduction technologies, we take them and put them to the front of the review line for our scientists.

We get a lot of petitions. Some years we've had in typically 50 or so. Last year I think we had in something like 80. Many of those are not pathogen reduction petitions, and so I think you can see the advantage to giving some of these technologies where there's a potential public health benefit a jump to the front of the line.

We have a couple of teams, again, of scientists who deal with these technologies. We have one team

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that's really the experts in antimicrobial chemicals used for food treatment. We have another group who are basically expert in the physical methods. And when the petition comes in, we designate it for expedited review, we gather that review team together right away, get through and brief them on the contents, give them a little bit of time to look it over, and then reconvene and try to develop a timetable and a good notion of where we're headed.

We commit to the petitioners, too, in this case to be--basically to be in good contact. If minor questions come up, we will call them right away. We're not waiting to get to the end of a review to raise every last question. Sometimes you may have a couple of questions come up early, and if they're answered promptly, we clarify things with the petitioner, we may have no further questions. If you wait and gather up a whole big long list, then sometimes you can't see the forest for the trees. So in these expedited petitions we try to meet frequently with the review team, or as needed, and get in touch with the petitioner, and do as much by telephone and meeting as possible.

The other important thing to remember, though, about the expedited review petitions, they're not a shortcut in terms of the safety standard. Petitioners

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have to meet the same standard for demonstrating safety, the same standards for data presentation, quality. Format, that's more trivial. But they have to meet the same standard. They need to establish the case.

So, as I said, this petition for UV treatment in juice is--it has been screened, it has been filed. The review team has it in their hands and are working on it. At this time I don't think I can project a timetable. I'll lose my shirt doing it, probably. But I would be hopeful that we would be looking at something on the order of months, certainly.

In the past I know people have raised many concerns about the length that premarket approval procedures can take. Sometimes it can take a long time. We have had petitions that have, in the past, taken years. In fairness, often that's because the petition was not in good shape to begin with and we had to go through a lot of question and answer cycles. And so the other feature, too, with these pathogen reduction petitions, is that we're investing a lot of time and energy in providing up-front guidance.

I'm very encouraged in this case. As in the case of another example that I skipped over, we interacted quite a bit beforehand, had meetings, looked at materials in draft form, before the petition came in

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officially. The previous example where this worked well was in the case of pulsed-light.

And so in this case with UV, even better, we had a good example to point to and say, "Look at that petition. That petitioner did a good job. This is a very similar technology. Issues and considerations will be similar. Follow that, adapt it for your own case, and talk to us."

So I'm feeling pretty positive about it. I know out in the audience we've got somebody who worked on that petition, the engineer, and he may want to say a few things about that. But I think it has been positive overall, and I'm looking forward to positive interaction and getting a speedy decision.

I think I'll just stop there, actually.

DR. MILLER: Say something about--

DR. HANSEN: There are materials in your handout that talk about pulsed light, pulsed electric fields, that step through the kind of decision tree I've gone through and give you a notion of where they're at. There is a regulation for pulsed light on the books. As long as folks stay within all of the limitations or boundaries in the regulation, they can use it to treat cider. Pulsed electric fields, again, some of these are costly,

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capital-intensive, but pulsed electric fields is there and available.

Various antimicrobial chemicals are on the books either for treatment of--mainly of the fruit or vegetable that's used to make the juice. Those can be found in the CFR, and I can talk to people later if you want.

There are two, though, that are of interest I know to people, ozone and hydrogen peroxide, and in both of these cases I want to make you aware of something. Both of these have listings as Generally Recognized As Safe Chemicals, but the listings have limitations. Because of the limitations that they have, in fact, and the way that's worded, further self-determinations are not possible for these two chemicals.

The reasons for the original limitation are kind of a little bit shrouded in history to me, and at this point I have to say our scientists have looked at a lot of information on these two chemicals and don't see a lot of red flags, but what we need are folks in the industry to come in to us with a petition. I can see a couple of different ways to tackle it.

And so what we are, above all, encouraging people to do is to gather up information and gather your colleagues together and come in and talk to us, so we can work out the best way to approach the problem. And I

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won't go into more, because it's a lot of legal and regulatory minutia of how the thing is worded.

Questions?

DR. MILLER: Questions for Pat Hansen? Bob?

MR. BEELMAN: Have there been very many antimicrobials approved recently?

DR. HANSEN: Actually, yes. We just approved one under our expedited review process back in May. It was not for produce use. It was acidified sodium chloride for use as a poultry wash. We have a few other petitions in house right now. Most of them have not been with us for very long. We have a couple that are through technical review, though, and headed towards closure.

We have a list of them at our web site, but just to hit the highlights, we have one for peroxyacetic acid, hydrogen peroxide, and hydroxyethylidene-1,1-diphosphonic (ph) acid as an antimicrobial wash for fruits and vegetables, which may be of interest to folks washing apples. I don't know. We have acidified sodium chloride solutions. That petition came in just in the winter this year. Again, the California Day Fresh petition back in June. And then we have a couple of others that more relate to foods of animal origins.

MR. BEELMAN: (Inaudible) primarily referring to antimicrobials like benzoate or sorbate that we have (inaudible).

DR. HANSEN: A lot of those have regulations on the books.

MR. BEELMAN: (Inaudible) anything new on those?

DR. HANSEN: Sometimes there's no need for a new one because it's a broad use regulation. Maybe we can talk a little bit later and I can show you. Some of our regulations are very specific, specify commodities, use levels, everything else. Other regulations are very broad, just say you can use it on food. You've got to do your homework.

MS. HUMES: Lorraine Humes, FDA. You were saying that by you giving approval, you're not guaranteeing the method would work; you're just saying from the data, from the procedure, it seems like it would work. In the food industry, have you okayed, can you remember any that you've okayed that turned out later not to work?

DR. HANSEN: In my limited experience, if folks are using the technology intelligently, they can get it to work. What we encourage people to do in the premarket area is, when they're naming their technical effect, for

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instance, to come in to us for something for use as an agent to reduce microbial load.

I don't want to see a petition from anybody that says, "I want to use this" and pegging it to 5 log reduction, because what we would need to see from you then would be all of the validation that you would need to be doing, ongoing, in order to even give you permission to use it, which doesn't make sense.

What these food additive type regulations do, they are permissive. They allow people to use substances and materials for, you know, like broadly defined effects to try to achieve a goal that they might want. So I never want to put a performance standard in these things, because if we decide later we want to change it, then we've got to go through the whole process again.

DR. MILLER: Any other questions?

DR. CRASSWELLER: Rob Crassweller, Penn State. Should I put the million dollar question together? Will your approval be done before or after FDA makes its hazard ruling for cider?

DR. HANSEN: I couldn't tell you.

DR. CRASSWELLER: That's what I was afraid of, yes.

DR. HANSEN: Flip my coin, yes. I couldn't tell you that.

DR. MILLER: Are you talking about the HACCP--

DR. CRASSWELLER: Right. Correct.

DR. MILLER: Really you're talking two independent processes.

DR. HANSEN: Yes, they're not coupled.

DR. CRASSWELLER: I know. That's what I'm saying, but we've got FDA--we've got people who are doing both here. I just wondered if you have a--so I can-- because that's what is going to happen when they ask us, "Well, is UV going to come through, or are you going to come down with HACCP first? So therefore, if you come down with HACCP first, then the UV process is not going to do me any good because I've got to switch to pasteurization."

DR. MILLER: I would characterize that as two locomotives on two different tracks, and each one has its own inertia.

DR. HANSEN: Well, it has its own pace. I think the point that I can make is, these antimicrobial, these pathogen reduction technologies, we want to get those petitions done. That's why we have dedicated teams for them and why we have this process.

DR. MILLER: I think one of the key points is that--Pat, correct me--the approval of an additive is fundamentally an internal process, while the regulation

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for HACCP, that needs to go over to the Office of the President, to OMB, so that gets swirled around a lot more in political considerations.

DR. HANSEN: It's two different types of rulemaking.

DR. MILLER: Right.

DR. HANSEN: The HACCP one is notice and comment, and is a lot more paper and resource intensive than--

DR. MILLER: I don't know if Rebecca is here.

DR. HANSEN: No, she's not.

DR. MORRIS: Bill Morris from Tennessee. It's my understanding that UV light is being used in some States. How does that happen? How does that occur?

DR. HANSEN: I could only speculate. I believe that some people--

MR. : Could you use the microphone, please?

DR. HANSEN: --some people may believe that the old regulation, which is in fact a very limited one, gave them a broad scope, and it doesn't. People have been using UV for quite some time for surface decontamination in different systems. If you've got an open container, you can have contamination.

UV has been used for a very long time to decontaminate surfaces of food, and it's generally effective at the low intensities that are in that old regulation. Interest in achieving the dramatic kinds of reductions that we're talking about now is a relatively recent phenomenon, and these systems are all recent, and many, many years after that first UV reg was put in place, which was right in the early '60s, very early days in this whole process of premarket approval.

They oughtn't to be doing it. I've given people advice that they oughtn't to be doing it. Legally they can't. Legally they can't. They're running a risk.

DR. MILLER: Any other questions?

MR. SANFORD: Sanford from Tennessee. What do you envision as far as labeling of a product? How do you see that?

DR. HANSEN: I'm not going to speak to labeling, actually. Ms. Satchell, who is going to speak tomorrow--

DR. MILLER: She's going to lecture on that tomorrow.

DR. HANSEN: We'll go at labeling when we're fresh. One thing I can be clear about is that we do not have a labeling requirement for use of UV similar to the one that's in place for ionizing radiation, so that

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radiation labeling requirement only applies when you're radiating with ionizing radiation, isotopes, x-rays.

DR. MILLER: Last word from anyone?

[No response.]

DR. MILLER: Thank you.

DR. HANSEN: Thanks a bunch. Troopers to sit through that.

DR. MILLER: Okay, 8:30, everybody.

[Whereupon, at 5:00 p.m., the meeting recessed, to reconvene at 8:30 a.m. on Friday, July 16, 1999.]

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