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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

PUBLIC MEETING

TO REVIEW THE CURRENT SCIENCE RELATING TO

SPROUTS AND NEEDED CONTROL MEASURES

VOLUME I

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PUBLIC MEETING

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Volume I

Monday, September 28, 1998

8:30 a.m.

Crowne Plaza Washington Hotel
Sphinx Club Ballroom
1375 K Street, Northwest
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MILLER REPORTING COMPANY, INC.
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PARTICIPANTS

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JANICE OLIVER, Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition (CFSAN), FDA

Panel

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MS. SANDRA LANCASTER, Chairperson, Conference for Food Protection

MR. CARL REYNOLDS, Director, Office of Field Programs, CFSAN

DR. LAWRENCE SLUTSKER, Medical Epidemiologist, Centers for Disease Control and Prevention

DR. TERRY TROXELL, Acting Director, Office of Plant and Dairy Foods and Beverages, CFSAN

MR. MICHAEL VILLANEVA, Program Specialist, Food Safety Program, California Department of Food and Agriculture

Fresh Produce Working Group of the National Advisory Committee on Microbiological Criteria for Foods

MR. DANE BERNARD, Vice President, Office of Food Safety Programs, National Food Processors Association

DR. ROBERT BUCHANAN, Senior Scientist, CFSAN

DR. MICHAEL DOYLE, Department Head, Department of Food Science and Technology, Center for Food Safety and Quality Enhancement, University of Georgia

DR. DAVID GOOLSBY, (recently retired) Office of the Surgeon General, Department of the Army

DR. MARGUERITE (PEGGY) NEILL, Assistant Professor of Medicine, Memorial Hospital of Rhode Island

DR. BALA SWAMINATHAN, Chief of the Foodborne and Diarrheal Disease Laboratory, Centers for Disease Control and Prevention

DR. KATIE, SWANSON, Director, Microbiology and Food Safety, Pillsbury Technology Center

[Not Present] DR. JOHN KOBIOSHKY, Washington State Department of Health

C O N T E N T S

Morning Session

P R O C E E D I N G S

MS. OLIVER: Good morning. If we could take our seats.

[Pause.]

Once again, good morning, and I'd like to welcome all of you to this meeting. Hopefully, there aren't a lot of people wandering around outside trying to find this room. It was a little difficult on the outside for me, but I managed my way here early, so I'm sure anyone else can manage their way here.

I am Janice Oliver, and I'm Deputy Director for the Center for Food Safety and Applied Nutrition of FDA. I'd like to talk first a little bit about the purpose of this meeting. In July of 1997, following several foodborne illness outbreaks that were associated with the consumption of raw sprouts, the Centers for Disease Control and Prevention suggested that FDA's Center for Food Safety seek the counsel of an advisory group to discuss measures that could be undertaken to ensure the safety of sprouts.

We concurred with the CDC recommendation, and we brought the matter to the attention if the National Advisory Committee on Microbiological Criteria for Foods -- actually, to the their Fresh Produce working group. Specifically, in August of 1997, FDA asked the Advisory Committee to review the current literature on sprout-associated outbreaks,

identify the organisms and production practices of greatest public health concern, prioritize research needs, and provide recommendations on interventions and prevention strategies.

The working group initiated discussions on the subject later that year. While it's still FDA's desire that the Advisory Committee provide a written assessment, we believe that it's prudent to expedite discussions on this subject. In fact, on August 31st of this year, following the recent outbreaks in California, FDA issued a talk paper which re-affirmed the guidance from CDC that high risk consumers should avoid eating raw alfalfa sprouts. And in this talk paper we also committed to further consultation on the issue of safety, and I seek this public meeting today, and the consultation with the members of the Produce Working Group of the National Advisory Committee, as a part of that commitment.

Over the next day and a half, you're going to hear from representatives of the Federal and State governments, as well as industry, consumers and academia. National and international scientists who have performed research in these areas as a result of past outbreaks will also be here to discuss possible interventions and the research that they've done.

We'd like the Fresh Produce Working Group to

consider this information and to provide recommended interventions and controls that you believe FDA should consider in the near term to enhance the safety of sprouts. As you know, there are various avenues that are available to FDA for addressing food safety concerns, including guidance, specific good-manufacturing practices, performance criteria, or HACCP.

Some of the specific questions that I have for the Working Group are: Do we have the science to support any or all of these options and, if so, which one or ones? And further, are there additional priority research areas that need to be addressed? And, if so, what are these research areas?

In essence, one of the primary purposes of this meeting is to assist FDA and the Working Group by providing a comprehensive look at sprouts from the farm to the table; to facilitate the development of recommendations to FDA that we might pursue to enhance the safety of sprouts in the future. This meeting is intended to provide a forum for discussion of the scope of the current situation, the consumer perspectives, agriculture and manufacturing practices, the state of the science, as well as possible intervention strategies.

If you look at the meeting agenda, you'll see that we're on a very tight schedule, so it will be helpful if all

of our presenters could keep to their time limitations. And I understand that it may be difficult, but it really will assure that all of the people that are here get an opportunity to speak, and it will also allow the Working Group and the panel time for questions during the meeting, and this will be useful for their deliberations.

We've set aside an hour this morning, this afternoon, and tomorrow morning for the panel and the Working Group to question speaks or offer comments for the record. If there's time available -- and I stress "we may be able" -- that is, we may be able to also allow additional comments and questions from the audience.

Tomorrow afternoon the Working Group will meet in an open discussion to consider the information that they've heard and to develop initial recommendations. This part of the meeting is also open to the public. However, it's important to understand that this time is specifically for the Working Group. While you're welcome to come to the meeting to listen and to attend, it's unlikely that there will be sufficient time for you to engage in substantive discussion at that time with the members.

Now let me proceed right into the meeting, because we're on such a tight schedule, and introduce my colleagues on the panel.

I'm going to start from this side -- first is Dr.

Lawrence Slutsker, Medical Epidemiologist for the Centers for Disease Control and Prevention. Next is Mr. Carl Reynolds, Director, Office of Field Programs for FDA Center for Food Safety and Applied Nutrition; Dr. John Kvenberg, Strategic Manager for HACCP at FDA Center for Food Safety; Mr. Michael Villaneva, Program Specialist, Food Safety Program, the California Department of Food and Agriculture; Ms. Sandra Lancaster, Chairperson for the Conference for Food Protection; and Dr. Terry Troxell, Acting Director, Office of Plant and Dairy Foods and Beverages at FDA's Center for Food Safety.

Now let me introduce the members of the Fresh Produce Working Group of the National Advisory Committee on Microbiological Criteria for Foods, and I'll introduce them in alphabetical order. Mr. Dane Bernard, Vice President, Office of Food Safety Programs, National Food Processors Association; Dr. Robert Buchanan, Senior Scientist, FDA Center for Foods; Dr. Michael Doyle, Department Head, Department of Food Science and Technology, Center for Food Safety and Quality Enhancement, University of Georgia; Dr. David Goolsby, recently retired from the Office of the Surgeon General, Department of the Army; Dr. Marguerite -- Peggy -- Neill, Assistant Professor of Medicine, Memorial Hospital of Rhode Island; Dr. Bala Swaminathan, Chief of the Foodborne and Diarrheal Disease Laboratory, Centers for

Disease Control and Prevention; and Dr. Katie, Swanson, Director, Microbiology and Food Safety, Pillsbury Technology Center. Dr. John Kobioshky, of the Department of Health in Washington State had planned on being with us this morning, but a recent O157:H7 outbreak is under investigation in the State of Washington, and part of the reason I mention it is that the outbreak involves a large state fair, where about 1.3 million people, or about 100,000 people attended each day. So, as you can see, that gave him some concern. But the last communication we had with John was encouraging, in that there were only a small number of cases, but there still is potential for a large number.

We also have a number of invited guests that we have asked to join the working group, and I'll introduce those. Dr. Larry Beuchat, Professor, Department of Food Science and Technology, University of Georgia; Dr. Jeff Farrar, Food and Drug Scientist, California Department of Health; Dr. Nancy Nagle, President, Nagle Resources; Dr. William Sperber, Senior Corporate Microbiologist, Cargill; and Dr. Bruce Tompkin, Vice President for Product Safety, ConAgra Refrigerated Prepared foods.

And, with that, let me just give a few other instructions for the meeting. Our meeting is being transcribed, so I'd ask my colleagues on the panel and the members of the Working Group and our speakers to please use

the microphone, and to introduce yourself to ease the work of our reporter. And as I indicated before, we'll be timing the speakers, because we're on such a tight timeframe, and we'd appreciate your adhering to the times. Someone in the audience will be timing it and giving you the signal if you're going beyond. They'll also give you a two-minute sign for your convenience.

I'd like to thank you for your attention, and I'd like to now introduce our first speaker, and one of our panel members, Dr. Larry Slutsker, Medical Epidemiologist, Centers for Disease Control and Prevention.

DR. SLUTSKER: Thank you very much. I'd like to thank the organizers of the meeting for inviting me here today to speak to you about the problem of foodborne illness due to sprouts. Let me just see if we can -- oh, I guess I'm supposed to introduce myself for the record. I'm Dr. Larry Slutsker from the Centers for Disease Control, Foodborne and Diarrheal Diseases Branch.

Today I'll be focusing on salmonella and E. coli O157 sprout-associated outbreaks in the United States from 1995 through the present. First I'll give a brief overview of reported sprout outbreaks in the last four years, and then focus on those outbreaks due to salmonella. In particulate, I'll use the S. Stanley outbreak in 1995 as the prototype of a multi-state alfalfa sprout outbreak due to

widespread distribution of contaminated seed. I'll then discuss E. coli O157 sprout outbreaks in the U.S., with particular attention to an outbreak in Michigan and Virginia in 1997. I'll then conclude with a summary and some recommendations,.

This slide summarizes the eight reported sprout outbreaks in the U.S. from 1995 through 1998. Six of the outbreaks were due to different salmonella strains, and two to E. coli O157. The number of culture-confirmed cases in these outbreaks ranged from eight to more than 600, and more than 1,200 culture-confirmed case occurred overall. Some of the outbreaks, such as the S. Stanley in Newport, at the top there, involved many states and other countries. The others occurred in one or two states. Alfalfa sprouts were implicated in all, although in two outbreaks, other types of sprouts were also either culture-positive, or were mixed with the alfalfa sprouts.

In all of the reported outbreaks, the likely source of contamination was seed. And, in addition, in the large 1996 S. Montevideo outbreak there, unsafe sprouting practices may also have contributed.

Although we're focusing today on U.S. outbreaks, sprout-associated outbreaks have also been reported from other countries as well, including the United Kingdom, Sweden, Finland, Japan and Canada. Alfalfa sprouts were

often implicated, but mung and cress sprouts also caused outbreaks, and radish sprouts were likely the cause of the very large O157 outbreak in Japan in 1996. As in the U.S. outbreaks, the source of contamination in these was likely contaminated seed.

Let me turn now to sprout outbreaks due to salmonella.

Salmonellosis is an important clinical and public health problem, and the illness is characterized by diarrhea, often with ever, cramps and nausea, and sometimes bloody stools. Infection is usually acquired through eating contaminated food, and illness occurs approximately eight to 48 hours after exposure. There are over 2,000 serotypes -- or strains -- of salmonella. Each year in the U.S., about 40,000 culture-confirmed cases are reported. Because many ill people do not see a physician or have a stool culture obtained, the estimated actual total number of salmonellosis each year is about 2 million, with 500 to 1,000 of these resulting in death. Infants, the elderly and those with compromised immune systems are at greatest risk of severe illness.

As an example an outbreak of salmonellosis due to sprouts we'll focus on the 1995 Stanley outbreak. In that year, unusual increases in the number of cases due to Stanley were noted in Arizona, Michigan and Finland in March

through June. I'll present data now on how, eventually, 242 culture-confirmed cases in 17 states and Finland were documented as part of this outbreak, and how we linked these illnesses to sprouts.

One of the striking epidemiologic features of this and subsequent sprout outbreaks was the sex and age distribution of the cases. Studies in Arizona, Michigan and Finland found that the proportion of patients who were female was around two-thirds in all three studies. Salmonella reports are usually more or less 50 percent female.

The age distribution was also unusual, in that adults in their 20's and 30's were the most affected age group. Salmonella is usually predominantly an infection of children. This demographic pattern of a preponderance of adult females has since been seen consistently in both sprout and other fresh-produce-associated outbreaks.

In Arizona, 22 Stanley cases were identified. A case control study was conducted to determine the source of the outbreak. We administered a standard questionnaire by telephone to persons with Stanley infection, and compared items eaten by these persons in the three days before illness with items eaten by health control persons of similar age and from the same neighborhood. Eating alfalfa sprouts was the only food item significantly associated with

illness. Persons with Stanley infection were about 12 times more likely than well persons to have eaten sprouts during this time period. Alfalfa sprouts were also confirmed as the vehicle by independent case control studies in Michigan and Finland.

We traced back the source of the alfalfa sprouts eaten by patients with S. Stanley infection in Arizona, Michigan and other states. Tracebacks were successfully completed for 50 patients in six states. They had eaten alfalfa sprouts grown by at least nine different sprout growers. Those sprout growers had all obtained alfalfa see from a single U.S. seed supplier who has about a 60 to 70 percent market share -- or did at that time. This supplier did not grow the seed but, rather, bought it from other sources.

96 percent of the patients either definitely or probably ate sprouts grown from alfalfa seed that the U.S. seed supplier bought from a seed shipper in the Netherlands. In fact, 93 percent of the patients could have eaten sprouts grown from seed from a single 20-ton shipment. This Dutch shipper also supplied the seed for the sprouts eaten by the patients in Finland.

Laboratory analyses of patient isolates supported the hypothesis that cases in the U.S. and Finland were related. Outbreak strains of S. Stanley from the U.S. and

Finland had a unique anti-microbial resistance pattern, with a resistance to tetracycline, Bactrim, and Kanamycin, and sensitivity to ampicillin. This pattern had not been seen before in Stanley isolates, or any salmonella isolate from the United States.

Molecular subtyping by pulse-field gel electrophoresis -- or PFGE -- also gave a unique pattern, suggesting that the Stanley isolates in the U.S. and Finland were the same strain. Alfalfa seed and sprout cultures of a small amount of seed remaining from this lot did not yield S. Stanley.

Along with the Dutch public health authorities, we visited the Netherlands shipper. The seed wasn't grown in the Netherlands, but we were unable to determine the ultimate source. An inspection of the processing and shipping facility showed that the seeds were often full of debris when received. There was evidence of rodents and birds within the facility. During seed processing it was noted that smaller debris and dust were distributed through large volumes of seed. The seed processing machinery was not routinely cleaned.

The Stanley outbreak spurred interest in studies to determine what happens to salmonella on alfalfa seeds during sprouting. The sprouting process itself is a very effective enrichment step. Research conducted by Dr.

Beuchat and his colleagues at the University of Georgia, supported by funds from the alfalfa seed industry, showed that the sprouting process may lead to a 1,000 to 100,000-fold increase in salmonella counts, suggesting that even very low level seed contamination could result in a substantial does on finished sprouts.

Dr. Beuchat's group also conducted seed decontamination experiments -- which I'm sure we'll hear more about in detail later. One key finding was that soaking alfalfa seeds inoculated with Stanley in a 2,000 ppm chlorine solution for 10 minutes did reduce the bacterial populations to undetectable levels, however enrichment experiments were not performed, and the authors cautioned that small numbers of Stanley might still have been present on the seeds.

Based on these findings, in March 1996 FDA recommended that sprout growers soak their alfalfa seeds in chlorine at 500 to 2,000 ppm for 30 minutes prior to sprouting.

The Stanley outbreak highlighted several key features about alfalfa seeds and sprouts. The seeds are a raw agricultural product and, as such, could be contaminated with salmonella. Rodents, birds or other animals known to carry salmonella could come in contact with seeds at any point during growing, harvesting, processing, storage or

shipping. Seed processing, shipping and selling practices often involved mixing multiple lots of seeds of different origins. Finally, the sprouting process itself is an effective pathogen amplification step.

Shortly after the Stanley outbreak, in late 1995 and early 1996 an outbreak of S. Newport infections in Oregon and British Columbia was recognized; 133 cases were reported, and case control studies implicated alfalfa sprouts. S. Newport was isolated from both the sprouts -- alfalfa sprouts -- and seeds from which they were grown. Molecular subtyping by PFGE showed that a single strain caused both outbreaks. As with the Stanley outbreak, traceback showed that the contaminated seed came from a single lot from the Dutch shipper. In retrospect, Newport outbreaks due to this contaminated seed lot were recognized in six states and Denmark.

In June '96 an outbreak of salmonella serotypes Montevideo and Meleagridis occurred in California. Over 650 culture-confirmed cases were reported during the outbreak period, and one elderly patient died from overwhelming sepsis. And epidemiologic study implicated alfalfa sprouts. The same strain of S. Meleagridis was isolated from patients and from sprouts from retail stores and the sprouting facility. Seed samples, however, did not yield either serotype. Unlike the multi-state Stanley and Newport

outbreaks, in this instance all of the implicated sprouts were produced at one facility and were sprouted from alfalfa seed grown locally in California.

Investigation at the sprouter revealed unsanitary sprouting practices such as the presence of flies and rodent droppings, and use of the same plastic buckets to collect both finished sprouts and sprouts that had fallen on the floor. Sub-optimal employee hygiene was also noted.

At the farm where the alfalfa was grown chicken manure was used to fertilize the field before planting. Horses grazed in adjacent fields and their manure was collected and stored next to the alfalfa field.

In addition to the problem of contaminated seed, this very large outbreak due to a single sprouter highlighted the need for good-manufacturing practice guidelines and a comprehensive HACCP program for the sprout industry, as well as the need to classify sprouters as food workers rather than agricultural workers.

Three other outbreaks of salmonellosis associated with sprouts have occurred in the last year-and-a-half. An outbreak of salmonella serotypes Infantis and Anatum in Kansas and Missouri in 1997 resulted in 109 culture-confirmed cases. Alfalfa, rose, radish and snow pea sprouts yielded both serotypes, and the alfalfa seeds yielded S. Anatum.

The implicated sprouts were grown at a single sprouter who was noted to have a clean facility. Again, the seed was locally grown and came from many surrounding farms.

Two clusters of salmonella Senftenberg infection occurred in California in late 1997 and June 1998. The 52 culture-confirmed cases in both clusters were shown to be due to the same strain of Senftenberg. The implicated sprouts were an alfalfa/clover sprout mixture from a single local sprouter. Cultures of a sprouter drum at the facility yielded the pathogen. The cultures of clover and alfalfa seeds did not. The type of sprout causing the outbreak was not able to be determined definitively, however clover may have been more likely, because clover seeds from one harvest were used during the entire outbreak period, whereas the alfalfa seed source changed in March 1998.

Finally, an outbreak of 18 cases of S. Havana in California in the summer of 1998 was linked to consumption of alfalfa sprouts produced by a single California sprouter. Shortly thereafter, the California Health Department and the FDA issued their press releases on the risks of alfalfa sprout consumption.

In addition to salmonellosis, sprout outbreaks have been caused by E. coli O157. Infection with this organism causes bloody diarrhea and can lead to renal failure and death. Cattle and deer can be asymptomatic

carriers of O157. It is estimated that in the U.S. the annual incidence of O157 infections is 10 to 20 thousand infections per year.

Now I'll present some information on the 1997 O157 outbreak. In the last week of June '97, the Michigan Department of Health noticed an increased number of O157 infections in several counties. The isolates were indistinguishable on molecular subtyping by PFGE, suggesting a common source. In the case control study, 56 percent of patients but only 8 percent of controls consumed alfalfa sprouts in the week before the patient's onset of illness -- a difference that was highly statistically significant. No other food item was positively associated with illness.

Traceback revealed that all the alfalfa sprouts were produced by a single sprouting company in Michigan. Sprouts grown by the company at the time of the outbreak came from two lots of seeds: one from Idaho and the other from Australia. At this point it was not clear whether the outbreak was caused by contamination of one of the two seed lots or from contamination that originated at the sprouting company.

The investigation then developed a new turn. The Virginia Department of Health reported a concurrent O157 outbreak and a case control study linked this to alfalfa sprouts. Molecular sub-typing of the strains from Virginia

identified the same PFGE pattern as in Michigan. Traceback implicated one sprouting company in Virginia.

Finally, seed traceback confirmed the lab data that two outbreaks had one common source. The Virginia sprouting company was using a single lot of seed harvested in Idaho -- the same lot as one of the lots used in Michigan. Cultures from this lot did not yield O157. As a direct consequence of the investigation, the remaining 6,000 pounds of implicated seed were removed from the marketplace.

An investigation was conducted at the alfalfa farm in Idaho where the seeds were harvested. Possible modes of contamination identified included cow manure and contamination from deer. Even though manure was not normally applied on alfalfa fields, some fields were irrigated with water that was drained from neighboring fields where manure was applied. In addition, some alfalfa fields were directly adjacent to cattle feed lot, and leakage of manure could have also occurred there. Some of the alfalfa was grown next to a deer refuge, and deer were in these fields every day.

Another O157 sprout outbreak occurred earlier this year in California. This was an non-motile, rather than an H7 strain, but it's equally virulent. Eight culture-confirmed cases were linked to consumption of an alfalfa/clover sprout mixture from the same sprouter

implicated in the salmonella Senftenberg outbreak.

Although not a U.S. event, a very large outbreak of over 6,000 culture-confirmed cases of O157 infections occurred in Japan in 1996 and was linked to consumption of radish sprouts. I think we'll hear more about this later today.

In 1997, similar smaller outbreaks occurred, in which an identical strain of O157 was isolated from patients and radish sprouts.

I mentioned previously that in 1996, the FDA issued guidance to sprout growers to soak their alfalfa seeds in chlorine at 500 to 2,000 ppm for 30 minutes prior to sprouting. Shortly thereafter, the International Sprout Growers Association -- or the ISGA -- distributed this advice to their members. In the reported outbreaks that occurred after this guidance that had information available on seed decontamination practices, no sprouters decontaminated their seed according to the FDA recommendations. In the 1997 O157 outbreak, disinfection with chlorine was used, by seeds remained in contact with the chlorine solution for only a few minutes.

The sprouter involved in the Senftenberg and the O157 non-motile outbreak in 1998 in California reported using 2,000 ppm chlorine for five minutes on occasion, but not during the outbreak period. Information on the Havana

outbreak is still being collected.

In summary, since 1995 in the U.S. there have been eight sprout associated outbreaks resulting in over 1,200 culture-confirmed cases. These outbreaks have usually been due to alfalfa sprouts, but there is some suggestion from outbreaks in the U.S. and other countries and other types of sprouts could also call illness. Multiple pathogens, including E. coli O157 and many serotypes of salmonella have been involved. Contaminated seed is the likely source, and contamination could occur at the farm, seed processor or sprouter.

Some efficacy of seed decontamination with hypochlorite has been demonstrated experimentally. Current practices in seed and sprout production do not ensure the safety of sprouts.

There are many challenges to be met in achieving sprout safety. Most alfalfa seed is not grown for human consumption as sprouts, and so may be grown under conditions where contamination is more likely. Seed contamination may be intermittent and low level, suggesting a safety program that relies solely on microbiological testing of seed samples would be ineffective. There are many small sprouters who may be unknown to state or industry groups, who may be difficult to reach for education or inspection.

Finally, the potent bacterial amplification step

immediately before sprouting and subsequent consumption implies the need for a highly effective process for seed and sprout decontamination.

To make sprouts safer it will be necessary to strengthen industry practices at the level of the farm, seed processor and sprouter. It will be critically important to identify methods to reliably and effectively decontaminate seeds and sprouts before they reach the consumer. Registration and inspection of sprouters as food handlers will help to ensure good manufacturing practices. Until these practices are met throughout the industry, in the interim it may be necessary to consider labels on alfalfa sprouts to indicate the risk of illness.

Finally, I'd like to thank -- express my thanks to the industry, to academia and public health agencies at all levels that have contributed to collecting this information. Special thanks to the state health departments, who do much of the difficult and time-consuming field work in outbreak investigations.

Thank you for your attention.

[Pause.]

Are we answering questions now? Okay.

MS. OLIVER: Thanks, Larry. We're going to save our questions until later, and at that time I'm going to ask all of the speakers if they would come up and sit at the

side tables so that after you're done speaking, if you want to take your place at the side table, you can.

Our next speaker is Dr. Hiroshi Takahashi, who is an EIS Officer from the Washington State Department of Health, and he's going to speak on the epidemiological data on E. coli O157:H7 outbreaks in Japan.

DR. TAKAHASHI: Good morning. And, once again, I apologize that my boss, Dr. John Kebyashi couldn't join this meeting again today and tomorrow because of the further investigation of the ongoing E. coli outbreak in Washington State.

The first slide, please?

Today I would like to talk about the current trends of STEC -- siguatoxin(?) producing Escherichia coli -- in Japan, and the Japanese sprouts production manual which has been recently revised by the Japanese government.

Next slide please.

STEC has been a notifiable disease since the outbreak in Sakai in August 1996. Until then, the Japanese Minister of Health and Welfare had confirmed about 100 isolates annually during 1991 through 1995. In 1996, cases increased to 17,877, including 12 deaths. In 1997, there were 1,576 cases, including three deaths. As of June 1998, there were 356 cases, with no deaths.

Would you just turn off the slide, please?

[Pause.]

In Japan, the dominant STEC serotype is O157:H7, comprising 76 percent of the cases in 1996, 67 percent in 1997, and 79 percent in 1998. The next most common serotype is O26:H11. It's percentage has been increasing from 1991 to 1995: 1.5 percent of cases were O26. This has increased to 3.4 percent in 1996, to 13 percent in 1997. There are 47 prefectures in Japan, and this serotype is most dominant in Okinawa prefecture, which is the southwest end of the Japanese archipelago. From June 1996 to December 1997, approximately 60 percent of STEC in Okinawa was O26:H11.

Next slide, please.

STEC follows a seasonal pattern in Japan. The number of outbreaks increasing from April peaks in August and then decreasing sharply after September. Since the Sakai outbreak in July 1996, awareness of STEC has been very high, however number of outbreaks at the school lunch or other facilities for providing meals decreased. In 1996, 13 large outbreaks due to E. coli O157:H7 were observed. In 1997, there were only three outbreaks. This year, there was only one.

Among children, three outbreaks occurred in nursery school and seven in primary school, including the Sakai outbreak, since 1996.

Among adults, two outbreaks were in dormitories,

one in a factory canteen, four in nursing homes.

Hazard analysis and critical control point -- or HACCP -- programs for radish sprout production and other training programs for food sanitation may have contributed to this decrease.

Various kinds of food have been vehicles for STEC outbreaks in Japan. This includes not only beef and its viscera, but those vegetables and fruits, such as cabbage, leeks, buckwheat, melon and radish sprouts. Last May a diffuse outbreak was seen in five prefectures among those who ate sushi. This involved Kaitan-sushi chains, or self-service sushi bars, using belt conveyer. Salmon roe was contaminated with STEC; its concentration level 0.9 to 15 per 100 gram. Seaweed are also sometimes contaminated. We may see more seafood-related STEC in the near future.

In Japan, bean and radish sprouts are commonly consumed. Annual production includes approximately 388 thousand tons of bean sprouts and approximately 13,000 tons of radish sprouts. After the Sakai outbreak, the annual radish sprout consumption decreased to 20 percent of 1995 levels. It has now increased to 40 percent of 1995 levels.

Alfalfa sprouts are not commonly sold in Japan. Bean sprout manufacturers produced alfalfa sprouts on request. Ingredient seeds for bean sprouts are imported from China, Thailand and Myanmar. Radish sprout seeds are

imported from the United States, New Zealand, France, Italy, etcetera.

Bean sprouts have been eaten for centuries, but radish and alfalfa sprouts have been consumed for some 20 years. Bean sprouts are rarely consumed raw, except at some Asian ethnic food restaurants. Radish and alfalfa sprouts are much more commonly eaten raw.

After radish sprouts were incriminated as a source of infection at the Sakai outbreak, there have been only a few outbreaks related to radish sprouts. Bean and alfalfa sprouts have not been observed to the vehicle of STEC outbreaks yet. This may be because the Japanese are still sensitive about their radish sprouts and STEC. Also, sanitary information provided by the health authorities on washing radish sprouts are followed well by the public.

Finally, it has been very difficult to identify radish sprouts outbreaks. There was another diffuse STEC outbreak in March 1997. The Japanese Minister of Health and Welfare couldn't isolate the STEC from the ingredient seeds which are imported from Oregon, however DNA fragments identical to that from the patient were found by PCR.

The Japanese government concluded that the imported seeds were very likely the source of contamination. The U.S. government didn't agree that the PCR could be used to establish and etiologic connection. How much and in

which process of hydroponic cultivation the radish sprouts were contaminated is unknown.

In October 1996, the Sanitary Management Manual of Radish Sprouts Production, hereafter referred to as "The Manual," was developed by the Japanese government and the members from the Japanese Radish Sprouts Association. The first version was based on the lessons learned from the Sakai outbreak which occurred seven weeks before. It was revised in March 1998 by three recent epidemiological findings of STEC. We provided its English translation later.

Major checkpoints of the revised version: seed sterilization, fly control and seed sampling and examination. For sterilization of ingredient seeds, the pooling method, which involves soaking the seeds into a chlorinated water pool was forbidden. Chlorinated running water systems are required.

Preventing entry of small animals and houseflies which may bring STEC into the production area is also emphasized. Houseflies caught nearby the cattle farm in Saga prefecture carried genetically identical STEC strains as those from the patient. In 1997, medical entomology test group from the Japanese Institute of Infectious Diseases and the Prefecture Institute conducted the national fly investigation. They reported that STEC-positive flies were

found at 15 cattle farms out of 270 investigation sites. There was a 7.2 percent fly infection rate at those 15 points.

The revised manual required at least one sampling from each numbered lot of seeds to be cultured for both STEC and salmonella. Immediate notice of contamination to the seed wholesaler is also required.

Since the etiology of STEC contamination during radish sprouts production is unknown, it is impossible to know which hygienic process is most important. In the current manual, seeds, water and vectors, including humans, are especially emphasized, however way may find other more important sources of contamination.

Regarding compliance, the Radish Sprouts Association has been encouraging the 37 member manufacturers to comply with the current manual, however it remains unclear whether non-members are complying. In addition, only 15 manufacturers passed all requirements of the manual. Some manufacturers had voluntary prevention methods in their production process, such as applying lacto-botuli into the cultivation water, however, such techniques are often patented, and it is difficult to disseminate. Thus it is technically difficult to assess compliance of the original manual guidelines.

Moreover, Japanese Radish Sprouts Association and

the manufacturer suspected of shipping the contaminated radish sprouts during the Sakai outbreak is suing the government for damages. This makes objective evaluation of the manual more difficult.

In individual cases of STEC infection, it is difficult to obtain food samples patient ate, because recall bias often occurs. That makes descriptive field epidemiology more difficult. Even if the vehicle is specified, STEC concentration levels are sometimes too low to detect. Frequently, a few dispersed cases occur. DNA fingerprinting is often useful in such cases, however the technique cannot always identify strains from limited samples. The specificity of the identical DNA fragments should be discussed among the experts.

The Japanese government allows different methods of ingredient seed sterilization using sodium hypochlorite, however its reliability remains to be evaluated.

Because radish sprouts should be shipped fresh, it is difficult to conduct sampling examination prior to shipment. Rapid examination methods should be developed.

Both the United States and Japan --

MS. OLIVER: Dr. Takahashi, you have two minutes.

DR. TAKAHASHI: Okay.

Both the United States and Japan are developing these STEC databases, but the choice of enzyme and PFG

procedures are different. Thus, exchange of isolates are required for comparison in order to develop a quick and accurate information exchange at the international level through systems such as PulseNet, international standard protocols should be discussed among the experts.

Thank you.

MS. OLIVER: Thank you very much.

Our next speaker is Dr. Michael Dinovi of FDA Center for Food Safety and Applied Nutrition. He is going to speak on consumption patterns.

DR. DINOVI: Good morning. I'm Michael Dinovi from the Center for Food Safety's Office of Pre-market Approval.

Consumption patterns is a little ambitious title in light of the data that are actually available to me. What I will be able to talk about this morning is a little bit of the gram amount of sprouts that are consumed at an eating occasion, and some of the trends that we can see over the last ten years.

May I have the next overhead, please?

Sprouts are an infrequently consumed food. By this I do not mean to say that there aren't people who eat a lot of sprouts, or eat sprouts frequently. However, the data available to me suggest that there are not many people eating a lot of sprouts frequently.

The data that you'll see today are from the United States Department of Agriculture's two surveys; the continuing surveys of food intake by individuals. The first surveys were done -- well, the first I'm going to speak of, at least -- were done in 1989, 90 and '91. They were three-day surveys. The total number of participants was approximately 15,000.

These data suggest that fewer than 1 percent of respondents report eating sprouts -- and that's an important consideration: we're talking about reported eating occasions here. The only sprouts they were asked about were alfalfa and mung bean sprouts. I suggest further differentiation -- I suspect, rather, that further differentiation would be rather hard. Big sprouts are eaten cooked, and small sprouts are eaten raw, as you'll see.

Approximately two-thirds of the eating occasions consisted of raw sprouts, however, as you've just heard, mung bean sprouts are usually eaten cooked; the reports were that they're usually eaten cooked. And in this survey period -- ten years ago -- approximately half an ounce of raw sprouts were eaten per eating occasion, and approximately one ounce per cooked eating occasion.

Next please.

Where you can see the trend is when you look at the more recent data from 1994, '95 and '96. This survey

was only a two-day survey, which affects average intakes, however on a per-eating occasion basis, the numbers shouldn't be affected by the two-day survey. An approximately equal number -- 15,000 participants.

As you can see now, however, we see more than 2.5 percent of eaters are reporting eating occasions with sprouts. And, again, it's only mung and alfalfa sprouts. The ratio of raw eating occasions to cooked eating occasions, again, is approximately the same. The gram intake is slightly higher, not very much: before it was 28 to 35 grams, depending on which group you looked at. In this period it was 30 to 40, 30 to 45 -- somewhere in there. Not much different. That may be reflected by the change in the survey. I cannot tell you for sure. However, the number of eaters has clearly increased.

If you take into account that you're asking people on three separate days before, you have approximately 50 percent more opportunities to report eating sprouts. So although the percentage increases from 1 to 2.5 percent, you can almost factor another 50 percent increase in there, so it's clearly much higher than it was.

Next, please.

I'll give you some numbers. The reports of mung bean intake among all eaters: the average per eating occasions, 38 grams per person per day, with a 90th

percentile intake of 85 grams -- not per day, per eating occasion. Sorry. When we consider infections such as this, usually we work an eating occasion basis.

The cooked sprouts, however, you'll notice is 44 grams. What this reflects is that there are many people in the whole population eating raw sprouts. So the per eating occasion intake for cooked sprouts is higher than the raw, and then the 90th percentile is 95 grams -- three to four ounces.

Next.

The group with the highest body-weight basis intake were the seven to twelve year olds, so I separated out their data. You'll see, again, the mean for mung bean intake is approximately the same: 41 grams per eating occasion. The 90th percentile is much lower: only 64 grams.

You see the cooked numbers are not much different here. What this suggests to me is that children do not choose to eat raw sprouts as often as adults do. You would consider that sprouts are probably eaten -- raw sprouts are probably eaten in salad bar or sandwich occasions which children may not choose to do. So you see lower numbers here among the children.

This pattern is true, actually, for all ages. As you get to the adults, the numbers balance out, but the approximate intakes are the same until you get down to two

to five year olds, where the numbers are much lower, not surprisingly.

As I say, there's not much data so we can get to the conclusions fairly quickly.

It's very easy to see that the breadth of sprout intake is increasing over the last ten years. There's a perception that it is a healthy, natural food; consequently, we're seeing more movement toward healthy diets. The intake itself has been relatively constant. You don't see much numbers changing. Again, that's not surprising on a per-eating occasion basis. There was one reported intake of 335 grams of cooked bean sprouts at one sitting, but that very unusual.

And, as I noted, the children up to the age of 12 tend to report -- well, it's reported for them, they're not doing the reporting -- but tend to report eating occasions with cooked sprouts rather than raw, and these would be stir-fried or boiled in a -- usually in a mixed meal.

And other than that, there's not much I can say. So thank you very much.

MS. OLIVER: Thanks very much, Mike.

Next, Ellen Morrison from the Food and Drug Administration's Office of Regulatory Affairs. Ellen is really our emergency person. She's the person you get 24 hours a day when you call our 24-hour number, and is

involved with most of our outbreaks. So if any of you have been involved with any outbreaks you probably know Ellen Morrison.

She's going to talk -- her topic is -- as you might assume -- outbreak investigations and traceback.

MS. MORRISON: And since I've been on-call all week, I look a little tired, so I apologize for that -- 24 hours a day, indeed. Good morning.

Since 1973, FDA has knowledge of 16 foodborne outbreaks associated with consumption of sprouts, as Larry Slutsker has just shown us, both in the United States and in other places in the world.

FDA, state and local officials and CDC have been involved in investigating the outbreaks in the U.S. and abroad, reviewing epidemiological and environmental data, determining the pathogen involved and, in many cases, doing traceback to determine the source of the seeds involved.

As Larry has shown in the example of the traceback in the 1997 E. coli in Michigan and Virginia -- and I'll go back to that in a minute -- outbreaks associated with alfalfa sprouts have been occurring the most of all those 16 outbreaks. So let's examine the intent of traceback from FDA's perspective, and examine some of the issues which make traceback of sprouts difficult.

The traceback investigation is intended to be a

method used to identify the source of foods implicated in a foodborne outbreak. We expect that epidemiology should implicate the same food and, indeed, in our work in other parasitic disease such as cyclospora, which we've done extensive traceback work, we see that the traceback data can be a very useful tool as part of an outbreak investigation.

Nonetheless, we expect the epidemiology to match -- it's nice if we have the PFGE, and we expect environmental issues should also be looked at. What we're trying to do is document the distribution and production chain of a food product. In this case we're talking about sprouts.

Ideally, we would be able to go through every step of the process and determine exactly where the contaminated sprouts have come from.

Next.

So how do we do a traceback, and how difficult is it?

Traceback begins with data obtained in the outbreak investigation, including, obviously, the identification of the sprouter. Sometimes there's more than one, as we've seen in some of the outbreaks that Larry alluded to earlier. In a careful investigation we'll be able to possibly pinpoint one more than another.

Identification of the seed lot numbers is also an issue, and this is critical to traceback, as a lot of time

can be wasted, as we have seen in our own work, visiting and tracing back the wrong lot number.

Next slide,

Inspections of the sprouters, as we did in many of the outbreaks -- or the states have done, as well -- in addition to working with the CDC, we need to document the production of the sprouts: how were they produced. And we'll often pick up samples, both environmental, sprout and seed samples, at this level.

We also need to document the seed lot receipt and usage. We've seen confusing data in our tracebacks that we've done in the past few years, that lot integrity is an issue in this kind of traceback.

Okay. Next. Thanks.

What are some of the issues related to traceback of sprouts? Well, identification of which type of sprouts are involved in the outbreak. As we've seen in the recent California outbreaks, mixtures of sprouts may be used. This means we would end up tracing back different types of seeds, different parts of the country, different parts of the world, perhaps, and obviously the use of molecular subtyping methods, like PFGE helps in this process.

And as I said before, integrity of the seed lot numbers, when repackaged, continues to be a concern of ours.

Now, we know in the Michigan and Virginia outbreak

-- which I'll get to, as I say, a little bit more in detail in a second -- that the use of the PFGE methodology linked those two outbreaks. They may not have been linked prior to the use of that technique. We may have been dealing with outbreaks, but we would not know they were linked to a common source. And, indeed, the value of traceback, combined with epidemiology and environmental data, in the future is likely to link more sporadic cases and more outbreaks that we wouldn't have linked before.

Some of the other issues related to tracebacks in sprouts are the lack of complete records of distribution, and we found in the recent California outbreaks -- and I know Jeff -- I don't know if Jeff is here, but he'll -- he is there -- seeds which have been sent back, and presumably not to be used again have resurfaced and been used and caused more than one outbreak.

So traceback is only one tool, and it may not pinpoint the contamination source.

Now, I'd like to go back to Larry's favorite outbreak -- one of the favorite outbreaks that we talked about: the outbreak of E. coli O157 with alfalfa sprouts in Michigan and Virginia.

Larry pointed out some of the things that were done. I;d just like to say how complicated this gets. The sprouter A, the sprouter B, which only used the test lot,

and the sprouter C involved Michigan and Virginia both had cases as we've seen before.

What the state did, what the FDA did, was visit sprouter A, sprouter B and sprouter C -- three inspections. Further, tracing it back to the seed distributor X, another inspection is done. All along the way samples are picked up: both seeds, sprouts and swabs, to try to figure out the cause of the outbreak. Going back even further to seed company Y, which supplied the lot, another inspection is done, both by FDA and CDC and one of the states.

And I think I have one more slide --

What we saw when we went back to the farm and Thomas Brewer of the CDC did a wonderful job going back there. Some of the things that Larry has already pointed out to you: the possibility of contamination existed. There were deer, they were near a cow pasture.

What we also found, though, that the seeds were harvested -- most of the seeds -- in 1996. So when we went back in 1997, we really were looking at harvesting practices near where the seeds were produced. In addition, a good part of the lot -- some 32 percent -- were from seeds in 1984 and 1989.

Now, this causes great concern to us, because even if we visit the field in 1997, how do we know what happened in 1984?

So to look at this as an overall issue, we can see we have a great challenge, and traceback, as I said, is only one tool. Looking at the need for an overall strategy, it's clear to us who try to manage outbreaks for the FDA, working with the Center for Foods on a daily basis -- looking at the conditions in the fields years after harvesting can only provide some clues, in part, to what the harvesting was like at the time the seeds were produced that were implicated in the outbreaks. Is it the seeds or is it the sprouts? Certainly, the PFGE would suggest, in the outbreak in Michigan and Virginia, that it was the seeds. How did they become contaminated we don't know.

A better testing methodology for seeds is needed. Perhaps, I would suggest, that in all the outbreaks, I believe, that we've done tracebacks and picked up seeds from, we have never found a positive sample of seeds.

A more effective intervention technique is needed, such as those proposed recently by the International Sprout Growers Association.

We need to ensure effective recall of seeds and sprouts so that redistribution is not possible. And we need too review the use of old seeds; seeds that have not been treated, and seeds that were never intended for human consumption, for example, because of pesticide use.

So, in summary, out outbreak traceback data

continues to provide clues, but it is further research and cooperation with industry that will provide better answers and hopefully prevent outbreaks in the future.

Thank you.

MS. OLIVER: Thanks, Ellen.

So far we've heard quite a bit from the Federal government and the States, talking about outbreak investigations; the outbreaks that have occurred in the United States and in Japan; a little bit about consumption data.

Next we'd like to hear a different perspective, and this is from the consumer. And the consumer and victims' perspective are both very important, we believe, to this conference and for you to know.

First under the victims' perspective, Laurie Girand will be talking, from Safe Tables Our Priority.

MS. GIRAND: Thank you. I've got a cold, so I apologize. I'll try not to sniffle through this whole thing.

Could I ask if we could turn down the lights in the front a little bit? I don't think my slides will be quite as visible as some of these other slides -- but not so low that the committee can't see anything.

As mentioned, my name is Laurie Girand. Two years ago, in the fall of 1996, my daughter, Anna -- if we could

get to this slide -- this is my daughter Anna -- almost died from complications known as hemolytic uremic syndrome -- or HUS -- as a result of being poisoned with E. coli O157:H7.

Since Anna's illness, I have devoted virtually all of my spare time to understanding foodborne illness. This turned out to be useful when,this last March, my husband picked up a severe and painful diarrheal illness while traveling abroad. When cultured, it turned out to be campylobacter, a foodborne illness commonly associated with poultry that can result in long-term, chronic arthritis.

As a result of my work in this area, I joined an organization called STOP -- Safe Tables Our Priority -- which consists of victims of foodborne illness, their family and friends, who are committed to ensuring that the foodborne tragedies they have experienced are not needlessly repeated. I am on STOP's advisory board, and I run its produce programs.

We are here today to explain the human side of the numbers and charts that you have been hearing about; the human costs of outbreaks that is not typically measured; the experiences that are lost. To epidemiologists and doctors at the CDC and to investigators at FDA we tend to be numbers and percentages, but we have faces and I'd like to share with you some of these experiences.

What is HUS anyway? Between one and ten and one

in 20 children infected with E. coli O157:H7 develop hemolytic uremic syndrome, which is a blood disorder caused by a poison put into the bloodstream by the organism. Red blood cells are shredded, and the number of free platelets falls as clots form and plug up capillaries. Contrary to what you may have read, the kidneys are merely the first part of the body to fail, clogged with clots and overworked trying to excrete the clots and cell fragments. The victim becomes prone to uncontrolled bleeding in all parts of the body. Every organ suffers damage, including the heart, the pancreas and the brain.

Victims can suffer strokes, blindness, coma, death. The average hospital stay is two to four weeks, with some hospitalized for months. The autopsies of those who die describe their organs as having been liquified.

Here is a face for you. This is five year old Haley. One night in June f 1996 Haley, who was three at the time, Haley's seven year old sister Chelsea, and Haley's mom all developed severe cramps and frequent watery diarrhea which continued day and night. Within the next two days, the mom improved, but the two girls got worse. On Saturday, Haley developed some blood in her diarrhea, so her mother took her an Chelsea in to see the doctor. He was not overly concerned and sent them home again.

On Sunday, they again went to see their physician,

and were again sent home. That evening, the parents took the children, who had become quite dehydrated and inconsolable, to the hospital, and they were finally admitted for observation. It was the parents who cautiously and intuitively suggested that perhaps it could be an E. coli infection. Indeed, stool cultures revealed that the children had E. coli O157:H7.

Over the next day, Chelsea improved, but the doctors grew concerned that Haley was developing HUS, and wanted to transfer her to another hospital. The parents were told they could not ride with their three-year-old in the ambulance. Chelsea cried as her parents and sister left on Monday, July 1st.

Haley's mom slept every night at the hospital. Haley's father left his job to emotionally support his family and wife. At the second hospital, Haley stopped urinating. They tried to do peritoneal dialysis, in which doctors cut a whole in the abdominal cavity, insert a tube, and then pour fluid in with the hope that the wastes building up in the blood will leach into the cavity and can be syphoned out. Note that because of severely depleted platelets, surgery is particularly dangerous for these patients because they may just bleed and bleed and bleed.

However, in this case, Haley's diaphragm had holes in it which caused the dialysis fluid to leak into her

chest. So instead, they had to insert a catheter in her neck and perform hemodialysis for three hours every other day.

In this first week at the new hospital, she had been lethargic and she went into shock. She was put on a ventilator. But then, because she was little and couldn't lie still, the ventilator tube kept hitting her windpipe and caused her windpipe to swell, so they removed the ventilator as soon as they felt she could breathe on her own.

Haley needed more nutrients than IV bags could provide. When they went to put in a blood line for intravenous nutrients, she vomited and inhaled her own vomit. This caused pneumonia, which proceeded to respiratory failure, from which only 60 percent of children survive.

She was put back on a ventilator. They inserted tubes into her chest to drain the fluid around her lungs. As a result of the nutritional supplements, Haley's blood sugar level skyrocketed and she was put on insulin. She subsequently became insulin dependent. Sometimes, when they thought the parents couldn't overhear them, even the nurses were crying.

Haley came off of dialysis in mid-August. On August 27, she suffered a seizure which led the doctors to discover that she had massive bleeding in her brain which

required five hours of brain surgery. She remained in the hospital for another month.

When she returned home on October 4th, more than three months after she was admitted, she was blind, and had to take 12 medications every day. Gradually, with therapy, she learned to walk again and her vision improved. Now, two years later, she is on one medication, has significant vision impairment, has some right side weakness, and has fine motor problems. Her kidneys are not clearing her body of wastes at normal rates. Her mother describes Haley as the most wonderful, loving child you will ever meet.

Through epidemiology it was later learned that Haley and her family were poisoned by lettuce contaminated with E. coli O157:H7. The lettuce was certified organic and shipped to Connecticut from California.

You need to understand that if someone you know gets a foodborne illness it is highly probable that he or she will be mis-treated or misdiagnosed. Antibiotics, anti-motility drugs and narcotics are all believed to hasten the probability of this HUS complication in an E. coli O157:H7 infection, yet these are commonly prescribed for diarrheal illnesses in the U.S.

As can be seen in Haley's case, physicians frequently do not recognize the severity of the illness. In the Odwalla apple juice outbreak, at least two children were

turned away from emergency rooms for this reason.

In my own daughter's case, her stool was tested only for shigella, campylobacter and salmonella, because the lab decided her stool wasn't bloody enough to be cause by E. coli O157:H7. We were told that we were not part of a larger outbreak. Later they would find the E. coli O157:H7 in her stool had the same genetic fingerprint as that found in Odwalla apple juice.

Here's another face. This is Ann. In 1988, Ann was a 32-year-old active mother of four whose youngest child was one-and-a-half years old. She was the healthy eater in her family, always eating fresh fruit and vegetables and trying to convince her kids to do the same, although they were much pickier eaters. During this year she had diarrhea off and on for three months, and was losing weight. Though she could still function, she never wanted to be far away from home.

When she was finally diagnosed with salmonella the doctors had to be careful about which antibiotic they prescribed because she is severely allergic to penicillin. Indeed, for this illness, she had to have two courses of antibiotics, because she was still testing positive for salmonella after the first course was completed.

After the treatments she developed a constant ache in her right side below the rib cage. Though she had no

other signs of gall bladder disease, the physicians treating her were convinced it was caused by salmonella which, given how long she had carried it, would have established itself in the intricate network of blood vessels in the gall bladder. Despite her fears of surgery, her gall bladder was removed. The gall bladder is responsible for producing bile and enzymes that aid in digestion. To this day, Ann cannot digest meals the way you and I do. For the rest of her life, if she eats a large meal one night, such as a Thanksgiving dinner, she will feel full the next day because her digestive tract does not move food along the way ours does.

After the surgery, she was hospitalized for a week with severe pain, lost significant weight, and came home, according to her, looking like a cadaver. Thus ended what for her was a year of chronic illness. The pain was gone. Everyone was telling her, "It must have been chicken." This was common in the late 1980s when produce had not yet been associated with fecal contamination.

In June of 1996, Ann is now 40, and has a fifth child who is three years old. She is still trying to get her kids to eat healthy food. They've gone to the swimming pool, and she's taking orders for sandwiches, which she plans to get from a local grocery store deli. She remembers telling her kids: "Hey, guys. Don't you want something

green on your sandwiches? Don't you want a little lettuce or sprouts?" "Thank God no one took me up on it."

That night, after fixing a dinner the whole family eats, she feels a little under the weather when getting the kids put to bed. At 2:00 a.m. she awakens with diarrhea and terrible stomach cramps that she likens to labor pains. She's deathly ill and has a fever of 102. By 5:00 a.m. she's had so much diarrhea that she is hemorrhaging. Her doctor recommends that she go to the emergency room, but she can't finish talking to him because she has to go back to the bathroom.

She and her husband scramble to find someone who can watch the five kids. In the emergency room they give her two bags of IV fluids, even though ten hours before she was perfectly hydrated. They ask for a stool sample, and she remembers handing it to them and saying, "Oh, this won't work. All there is is blood."

Then they send her home. It never occurs to her that it might be salmonella, because the experience is so different from that of the previous illness.

That afternoon they called to confirm that Ann has gotten salmonella again, and to prescribe an antibiotic. The next night, the evening news confirms what the county will soon determine by matching the salmonella in Ann's stool to that of others: Ann is a victim of salmonella food

poisoning from alfalfa sprouts.

Sprout growers in California are briefly shut down and the grocery store where she bought the sandwiches pulls them off of the shelves.

As of today, you might imagine, Ann doesn't eat sprouts at all. If she orders a salad in a restaurant, she tells them she doesn't want the sprouts, and if they give her a salad with sprouts by mistake, she sends the whole thing back and tells them to do it over again.

Let me ask if you're familiar with the disease listeria. No one's mentioned it so far.

There was a listeria-related recall of many different kinds of sprouts in the last month. Listeria can create asymptomatic infections in pregnant women. A woman can have a perfect pregnancy, have an amnio with the results indicating the baby is fine, appear to be perfectly healthy, and then find, halfway through her pregnancy in the second or even third trimester close to delivery that her baby has died. She then has a choice of whether to use a dilation and extraction procedure to remove the baby's body by sucking it out through a tube, or she can experience the pain of chemically induced labor to give birth to a body that is already dead. Live babies born with listeria infection can develop meningitis, a dangerous infection of the lining of the brain.

When autopsies are performed, pathologists may not even test for listeria specifically, because it is considered less common. As a result, epidemiologists largely do not investigate undiagnosed stillbirths, and outbreaks of listeria largely go undetected.

To give you an idea of how far the numbers and data you've been shown today get from the real individuals and their experiences, I tried to get some very basic information about the victims of a single alfalfa sprout outbreak. Guess which ones -- since everyone's been talking about it.

I wanted to understand how young they were, how old they were, and whether the outbreak might have been responsible for maiming children, requiring gall bladders to be removed, or perhaps killing someone. In essence, I wanted to understand the breadth and depth of the victims' experience in a sprout outbreak.

I called the CDC and the Virginia State Health Department to gather further information on the victims of the E. coli O157:H7 outbreak associated with sprouts that occurred in the summer of 1997 in Michigan and Virginia. I asked two simple questions: What were the ages of all of the victims, and what were their final conditions.

The bottom line is that this data is not easily available because, at these levels, victims continue to be

numbers. Epidemiologists study victims only so they can identify the source of the outbreak. They put victims of a common outbreak into two groups, as you've seen here: those they study, and everyone else.

In Virginia, the age of each victim is trapped on a computer of someone who has since moved to another job. Therefore, what we know about these victims is minimal. Their ages range from one to 71 years. Of the 20 enrolled in the state study, 90 percent reported bloody diarrhea; 43 percent required hospitalization. Out of all of the victims, at least one girl developed hemolytic uremic syndrome.

You might wonder why a one-year-old would appear to be eating sprouts. In reality, it looks as though in both states there were secondary infections. For many of these illnesses, victims can go through a phase when they are no longer symptomatic but are still shedding organisms and can be infectious. A secondary infection occurs, for example, when an infected parent touches their child and thereby infects their daughter or son. Or a secondary infection can occur when a parent sends a child to a lake and a child swallows contaminated water in which an infected child has defecated.

So the victim did not need to personally eat sprouts to necessarily share in the impact of the outbreak.

What this means for parents is that there are lots of ways to give your children life-threatening foodborne illness, and all parents need to be vigilant.

The CDC had the ages of individual Michigan victims, but it was easier to find the ages of the victims that were studied, which represented only a third of the total outbreak victims. Their ages ranged from four to 79. Of the 30 that were enrolled in a study, 97 percent reported blood diarrhea, and 53 percent were hospitalized. Out of all the victims, two people, aged seven and 21, developed HUS. One 64-year-old developed TTP, an adult version of HUS. That person was followed up this last April, and was in critical condition and still on kidney dialysis. The opinion of the epidemiologist that was in contact with the victim's family was that she could be dead now, given her condition as of April, but no one had followed up since.

Yet, after the epidemiologists pack up their statistical software and portable computers and publish their reports, for victims of many of these foodborne diseases, the long-term consequences are what matter. As you've seen, a year passed before Ann finally had her gall bladder removed. Haley's recovery is not yet complete. All HUS survivors suffer the risk of complete of complete kidney loss in adulthood, maybe decades later after what can appear to be a "complete" recovery. They can also develop

gallstones, diabetes, colon and intestinal problems and heart problems.

So the information you get from epidemiologists today -- these figures that describe all the victims as recovered are highly misleading. The epidemiologists give you only a snapshot of one moment in time, perhaps even before subsequent severe cases are identified.

So given all that we know -- excuse me, all that we don't know, what do we know? We know that sprouts are only healthy for you if they don't make you deathly ill. We know that in all likelihood, the cases detected by epidemiologists represent a fraction of the total people infected or sickened. Think about how sick you have to be with a diarrheal illness before you go to see a doctor and you get the idea.

We also know that the outbreaks identified are a fraction of those that are actually caused. We know it takes fewer than ten organisms -- perhaps as little as a single organisms of E. coli O157:H7 -- to cause deadly illness. Think about that the next time you shake hands with someone; the next time you use a public toilet seat; or the next time you go swimming and get water in your nose.

We know the FDA and California State Department of Health have issued press releases advising at-risk groups to not consume alfalfa sprouts. We also know that there are

members of the sprout industry who are legitimately concerned and are trying to take steps to improve the situation.

But this is not enough. May I ask for a show of hands? How many of you are parents? And how many of you are children? Trick question -- okay.

We live in a society of warnings which we choose to read or disregard at will. There are warnings about inhaling gasoline fumes at gas pumps. There are warnings about putting a child in a seat with an airbag, and how to secure a child's car seat. There are warnings about the effects of alcohol on a fetus. There are warnings about the side effects of medicines. There are warnings about riding bicycles with helmets, and there are safe handling labels on meats. And obviously there are warnings on poisons.

As a parent, I take each and every one of these into account when I look at my child's long-term health consequences. I suspect you do too. Yet the single greatest crisis in my family's life was the one for which I received absolutely no warning -- that unpasteurized juice could harbor organisms that would try to kill my daughter.

My mother consumed the same juice, and it is by the grace of God that I did not lose both my mother and my daughter in the fall of 1996.

You, as parents, can understand that I was

distraught when I learned that the FDA and CDC had known for years that unpasteurized juices were making people sick. Their respond through that time: fund more research and tell industry to do some clean-up. In doing so, they robbed me of my ability to protect my family, by refusing to share with me what they knew: that more outbreaks were likely to occur. They also sentenced my daughter to a lifetime of health uncertainty.

STOP is united in its efforts to ensure that consumers will not be repeatedly misled into believing that a food is healthier --

MS. OLIVER: Ms. Girand, two minutes, please.

MS. GIRAND: Thank you -- when it can cause potentially deadly illness in a matter of hours or days. We support the FDA and State of California's press release, warning at-risk consumers against consuming alfalfa sprouts until they are deemed safe. We expect the FDA to add pregnant women to the list of at-risk groups, as the recent evidence of listeria has shown they are at risk.

Press releases are good, but we must to better. Information must be placed where at-risk consumers will encounter it, in order for them to be able to execute informed choices about their risks. Until sprouts can be made safely, we are asking FDA to introduce an expedited rule to place warning labels on sprouts -- whether packaged,

sold in bulk, or as part of prepared foods through delis or restaurants.

We are asking that FDA meet with the American Academy of Pediatrics to ensure that parents are warned through their pediatricians that until further measures are taken, alfalfa sprouts represent a serious risk.

We -- and we believe you -- do not want naive parents throwing alfalfa sprouts into a salad at a school pot luck.

STOP's position on any produce that is served ready-to-eat is that there must be a zero tolerance for the infectious dose level of pathogens. As a result, we cannot be supportive of efforts that merely reduce organisms, such as O157:H7 down to a single bacterium, only to encourage it to grow back again 10 thousand or 100 thousand times.

The suggestion that consumers or industry can achieve safe produce by rinsing off pathogens with water defies both scientific evidence and reason when addressing highly infectious pathogens.

We understand that the evidence of sprout contamination points to the seed itself. It is largely recognized that if seed cannot be made safe, sprouts cannot be made safely. If, after the conclusion of this meeting there is a consensus that there is a technology that will result in a dramatic reduction of organisms -- preferably a

complete elimination of them. We would advocate that it be required of all companies immediately.

If a superior technology to this consensus becomes available, we will support FDA moving quickly to implement it.

We applaud the efforts of the sprout industry to introduce sanitary procedures, but we cannot support self-policing alone. All industries have low-quality producers --

MS. OLIVER: Time, please.

MS. GIRAND: -- and this industry is no exception. The slides from California's investigation show rusty ceilings dripping into sprout beds, rodent feces on the ground near seed, dirty bins being stacked on top of open seed containers.

To imagine that all producers will comply with voluntary anything is to waste valuable time and continue to jeopardize consumer safety. And, to be frank, industry economics -- the sprout industry was given guidance by FDA years ago, yet outbreaks continue to be caused by producers.

In addition to pathogen-free seed, the FDA must impose mandatory HACCP on sprout suppliers as soon as pathogen-free seed is available, and not in two years, or three years. We must have end-product testing to ensure consumer confidence in this product. The Western Growers Association and United Fresh Fruit and Vegetables

Association should insist that these steps be taken to ensure safe sprouts. Without these steps, outbreaks are likely to continue.

Multiple continuing outbreaks from sprouts, a supposedly healthy product, will have a deleterious effect on the markets for other fresh produce, especially if other vegetables are mistakenly associated with sprout-caused disease because they are found in salads with sprouts.

Lastly, STOP will be asking for mandatory traceback data which would address both seed lots and sprout batches and lots so to assist investigators in quickly identifying contaminated sprouts in order to pull them off of shelves, and thus reducing the impact of the outbreak that is underway.

Let me suggest that this path might sound hard, but if pathogen-free seed can be achieved, and if the industry executes these steps quickly -- interim labeling, mandatory HACCP and traceback -- it is quite possible that sprouts could achieve a market position that other forms of produce cannot achieve. Not only could sprouts be healthy for the average consumer, but because they can be brown with pathogen-free water and without soil, manure or other accidental animal involvement, they have a potential to be one of the safest forms of produce on the market.

STOP believes that we are all in agreement that we

need to move forward quickly. However we are concerned that exactly how quickly, whether we will apply regulations uniformly to all sprout growers, and whether we will inform consumers may be questions you are still debating. We ask only that government and industry consider the obvious: we should not wait so long to institute precautions and warnings that more people die when we all knew such a tragedy could happen.

Let us all commit ourselves to no more illnesses or injuries from sprouts starting today.

Thank you very much. Copies of these comments will be available at our Web site: www.STOP.USA.org.

MS. OLIVER: Laurie, thanks very much for giving us the perspective of the victim, and for bringing the human perspective of why we're all here trying to prevent future foodborne illnesses such as those you described.

Let me ask a question. Kathy, are we ready for a break now, or should we take the next speaker?

MS. DeROEVER: We are actually about 10 minutes ahead, if you'd like to take the next speaker.

MS. OLIVER: Okay.

Caroline?

Carolyn Smith DeWaal of Center for Science in the Public Interest will talk next on the consumer perspective.

MS. DeWAAL: Thank you, Janice. Is this on? Can

everyone hear me? -- and good morning.

We have a few overheads that we're going to use. And I'm going to try to cut back my remarks a little bit so as to not repeat too much of what's already been said. Clearly we're all working off the same database.

Thank you for inviting CSPI, the Center for Science in the Public Interest, to give this presentation on sprouts, the outbreaks, and the needed control measures.

CSPI represents over a million consumers on issues related to food safety, nutrition and alcohol policy. To prepare for this presentation, we've thoroughly reviewed the publicly available information on outbreaks linked to alfalfa sprouts. And this review has turned up a number of gaps in production that put consumers at great risk.

First I'd like to review one outbreak in particular, and this is the outbreak many others have focused on: the E. coli outbreak in Michigan in Virginia. I'm going to skip much of the material that others have covered, but I think there are a few points that need to be made with this audience.

This outbreak really brought the issue to public attention because it occurred the same summer as the outbreak leading to the Hudson Beef recall. That, if you'll remember is a recall resulting -- it's the largest ever food recall, resulted in the recall of over 25 million pounds of

ground beef. There were 15 E. coli O157:H7 cases related to that outbreak.

The same summer, we had over a hundred cases of illness linked to alfalfa sprouts, but there was only a minimal outbreak -- only minimal public notification that that was occurring. This was a very serious outbreak. There were 36 people hospitalized, out of the total of 100 illnesses, and there were four cases of hemolytic uremic syndrome. So in the scope of outbreaks, this was quite serious. Luckily, no one died. But in both cases -- in both Michigan and Virginia, as we've already heard -- it was clearly linked to alfalfa sprouts.

I want to skip on to -- from our standpoint, the lessons learned from that particular outbreak, and then they tie into some of the other things we've learned, looking at the other outbreaks.

First, contaminated sprouts can cause serious and even life-threatening illnesses. I think we know that now. It was something that was just beginning to be in the conscience of consumers and people like me who represent consumers, but now that's clearly established.

Second, the sprouters may not be the source of the problem. Contamination frequently appears to occur much earlier in the chain of production.

Third, seeds that are grown for human food must be

protected from manure, animals and contaminated water -- and I'll get -- later I'll discuss a little bit about why this is so important, given how we produce alfalfa seeds today.

And, finally, identifying the specific point of contamination in a sprout outbreak is very difficult, if not impossible, because of current sprout production practices.

These patterns are repeated over and over again in our review of ten outbreaks and recalls that have been linked to sprouts since 1995, and that's significant. We're looking at three years of data and a very large numbers -- seemingly a large number of outbreaks; eight outbreaks and two recalls, domestically.

Most of the early outbreaks were linked to salmonella, so it was really a surprise to first hear about the Japanese outbreak linked to E. coli O157:H7, and then to see that nightmare reoccur on a domestic level.

Regardless of whether we are looking at salmonella in alfalfa sprouts or E. coli O157:H7, pathogens in sprouts represent an imminent hazard for consumers that we believe the Food and Drug Administration is duty-bound to address.

I'm going to go on and talk about both the on-farm contamination and the post-farm contamination, and I'll skim this part of my remarks, because much of it's already been covered. But I want to make a point that I don't think anyone else has made yet, and that is that contaminated

irrigation water or contact with manure is really not a concern for the vast majority of alfalfa seeds which are used in agricultural production. So for most agricultural seeds, that contact would never show up; it would never be a public health problem.

However, for the small proportion of seeds that are syphoned off for use for human food, such contamination is highly problematic and has to end. We have -- looking at just two outbreaks -- the Michigan and Virginia outbreak and a California outbreak in 1996 resulting in over 600 illnesses, we've seen that there are inadequate field conditions for the growth of human food currently in use in alfalfa seed production. Cattle lots were located next to alfalfa seeds. Water from the irrigation canals tested positive for both the generic E. coli and fecal coliforms, which indicates possible contamination problems for the water. Chicken manure was used to fertilize the fields. Horses were in the fields next to the seeds, and manure was stored next to the fields. Conditions like these are simply unacceptable for the growth of human foods.

Moving on post-farm contamination problems: because seeds are generally not intended for use as human foods, they're frequently transported in open-weave sacks and other containers that don't prevent contamination after the farm. Contamination can occur in transit or at

sprouting facilities. In one investigation we've heard about rodent droppings, and we've also seen that environmental sampling can actually turn up evidence of salmonella in the sprouting facilities and in the sprouting areas.

There was another example where sprouting trays drained directly into one another, which creates ample opportunity for cross-contamination in the facility. We also have heard about facilities and equipment that was dirty, and employee practices in the sprouting facilities that were unhygienic. Given the warm, moist growing conditions for sprouts, any one of these conditions could have resulted in an outbreak.

Following one outbreak in California, several sprout growers, in fact, met with government officials and asked for greater regulation of their industry, including reclassification from being agricultural workers to being food handlers. And currently the state of California is working on that proposal, and they've developed voluntary guidelines. So there is some progress. And it's being driven, interestingly enough, by the industry itself.

I want to get into an area which I don't think the other speakers have covered, and that's the outbreaks' link to imported seeds.

Seeks are imported from around the world for use

in growing alfalfa sprouts in the U.S., including China, Italy, Thailand, Hungary, Taiwan, Pakistan and Australia. And in 1995 salmonella outbreak linked to alfalfa sprouts that resulted in 242 illnesses in at least 17 states and in Finland, the seeds were traced through nine growers to one U.S. supplier that bought the seeds from a shipper in the Netherlands. The seeds came to the U.S., and they were reportedly a mixture of seed lots from possibly Italy, Hungary and Pakistan. The origin of the seeds and the harvest dates could never finally be determined.

According to the Centers for Disease Control and Prevention's investigation, the product coming into the shipper was full of debris, and there were rodents and birds in the facility and the machinery, and the machinery wasn't being routinely cleaned.

Other outbreaks demonstrate that the same batch of contaminated seeds can cause outbreaks in several countries almost at the same time. In one example, the first cases of salmonella were reported in Denmark in the summer of 1995. Cases occurred in the eastern United States in September through November of 1995, and cases occurred in Oregon and British Columbia in December through late February of 1996. Finally, more cases occurred in Quebec in March of 1996. The contaminated sprouts in Oregon and British Columbia were traced to one lot of seeds that a Kentucky supplier obtained

from a Dutch shipper. The seeds from the Danish cases, which were found to be related to the North American cases by subtyping, were traced to a shipper in Italy. Thus the original source of the international outbreak could never even be fully determined or fully traced back to one country. And we've also seen and heard a lot about the hurdles to traceback and finding the contamination source.

Based on this examination, which is fully outlined in our comments, I think there are a number of actions which need to be taken by FDA at this point. While consumers -- this is always the question, so I'm just going to address it from the start -- consumers have an important role to play in preventing food safety problems. And we spend a lot of time educating consumers about what their role is. However, consumers cannot prevent outbreaks from alfalfa sprouts, or from other sprouts -- implicated sprouts.

We can't tell consumers to eat their sprouts fully cooked. We can't urge consumers to wash all their sprouts in chlorine bleach to ensure their safety -- a question I'm increasingly getting. This is, quite simply, a problem that consumers can't fix. It's up to the industry to deliver a safe product to the consumer. And if safety cannot be assured, the industry should alert high-risk consumers in an effective manner to avoid the product.

CSPI has developed the following five

recommendations to address the problems that we've identified in our examination of the sprout outbreaks.

First: Don't use alfalfa sprouts unless they've been produced under conditions -- don't use alfalfa seeds unless they've been produced under conditions suitable for human consumption. Period. The practice of using seeds that have been grown for agricultural use should stop. While this may have profound implications for the industry, the outbreak data is clear that contaminated seeds are the overriding cause of the outbreaks. While farms can use manure safely on alfalfa grown for agricultural production, it should be strictly banned in the growth of seeds for human production.

I think that farms that supply sprout growers should observe strict guidelines for the growth of seeds, and should dedicate their seeds to the production of human food. In addition, the practice of using seeds that have been grown in other regions of the world should stop, unless it can be demonstrated that the seeds have been produced under suitable conditions.

Second: Let's ban the use of mixed batches of seeds to aid traceback. In our review we found that seeds were mixed from different countries; we had seeds being mixed from different years of production, including some which were ten years old or more. We should simply use

intact batches, and we should mark both the seeds and the packages of sprouted seeds so that we can trace them back easily. This is a step that the industry can and should take. This will help to dramatically protect consumers and allow for sprouts that do cause a problem to be quickly taken off the market.

We encourage the use -- third -- of the development of safe and natural decontamination methods. But I want to make a point here that the methods currently in use are mostly reduction steps. They don't guarantee salmonella or E. coli-free seeds. They're simply reducing contamination that may be there.

We also think that any treatment should be challenge-tested with seeds contaminated with E. coli O157:H7, which is simply more resistent to many treatment regimes than other pathogens. If there are other things, like irradiation that are more effective at killing bacteria, we should test them. But, again, seeds are tricky because you may prevent the bacteria but you also may prevent germination. So we need them effective, and consumers want them safe and natural.

And we want to see greater government oversight for the seed industry -- for the sprout growers. They should be considered food handlers. They should be subject to frequent, regular inspections by both Federal and state

governments. These are wonderful facilities, apparently, for growing bacteria, and we need to make sure they are kept up to the highest possible standards.

HACCP is also a tool that should be considered for the sprout industry. Although there is not now a pasteurization step, there are potential hurdles to contamination that could be incorporated effectively into a HACCP system.

And, finally, I want to get on to the issue of consumer information. Before I do that, I want to show you -- and I found it over the weekend, so it's nothing we could get on the overhead. This is called "Parents' Page," and it's sent home -- I have two children, one of whom is full-time in day care down here. He's at a very excellent Federal day care center that services the White House; a very, very good day care center.

"Parents' Page" -- the send it home once a month. Here it is. "Personal Parenting" -- it's right between "Toddler Time" and "Tips for Parents." "Growing Things: It's fun to grow alfalfa sprouts. It's a two-part process. First you grow them, then you eat them. The trick is to buy alfalfa sprouts that have not been chemically treated -- " -- and then it gives me instructions for how I can grow alfalfa sprouts with my toddler. And then, "After the seeds have sprouted, place them in a jar in the light. The leaves

will turn green and they'll be ready to eat in a day or two in a salad or a sandwich with my toddler."

This was given out April 1998. This year. This instruction was sent home with me and many other parents. This is a national publication that many day care centers send home to their parents.

Consumers don't know that sprouts aren't safe to serve kids. That just -- let's understand that. This is the current recommendations which are being sent home to day care parents.

FDA sent out -- in response to requests and the state of California and others -- they sent this interim advisory on alfalfa sprouts. I called reporters after this went out. They thought it was old news. They threw it in their trash cans. They didn't understand that this was telling parents that kids shouldn't eat alfalfa sprouts. It's not comprehensible as that message.

CSPI, in frustration, finally had to release our own little statement saying: children, the elderly, and immune compromised adults should avoid sprouts until the industry works the bugs out.

That's communication. That's getting the message out. "Interim Advisory on Alfalfa Sprouts" doesn't do it.

CSPI believes that it is time to require consumer warning labels until effective controls are identified and

fully implemented. Labels on sprout containers and products should alert consumers that the product may not be safe to serve children, immune compromised and elderly consumers.

CSPI has proposed a number of labels for high-risk foods, such as unpasteurized apple cider, raw oysters and eggs. This approach was adopted by FDA for unpasteurized juices, and sprouts represent a comparable risk. There have been eight outbreaks linked to sprouts since 1995, with at least one death. It is unfair to leave consumers in the dark about hazards in the food supply. Until effective controls are identified and fully implemented, sprouts should be labeled on the package to alert consumers of the risk.

Thank you.

MS. OLIVER: Thanks very much, Carolyn.

We're a little ahead of schedule, but I'd like to leave time for additional questions if people have them, and then add a little time for lunch. So why don't we take a 20 minute break; come back at 20 minutes of the hour.

[Recess.]

MS. OLIVER: Back together?

[Pause.]

And I had asked Cathy DeRoever to help keep me on time, and she's one of the people who a lot of you know from having been one of the people in charge of getting this

meeting together. And she came up got me and said, "Janice, if you don't come soon, I'm starting the meeting without you." So here I am.

Okay. We're going to have a little change of pace now, and our next speaker is going to talk about seed morphology. And that's Dr. Robert Wick from the University of Massachusetts.

DR. WICK: I'm Robert Wick. I'm a plant pathologist at the Department of Microbiology at the University of Massachusetts. I'd like to thank the FDA's Center for Food Safety and Applied Nutrition for Inviting me here today. I'm happy to have the opportunity to talk to you about my experience and perspective in seed borne microorganisms.

I was asked today to speak to you about seed morphology, and those of us who work in the business of decontaminating seeds are very interested in seed morphology, because it can have a great effect on our success

Now, I should tell you that in plant pathology, we have been concerned about decontaminating seeds from plant pathogens forever, and plant pathogens are very recalcitrant and even more difficult that what you might consider more casually associated microorganisms from seeds. So there's actually been a long history of decontamination of seed and

we have a lot to draw on.

It's interesting to note, especially in context with the meeting that we have today, that in ancient Rome they suggested that you should treat seed in cow urine and manure to try to prevent some plant diseases. I'm not recommending that today, however.

So I was asked to speak about seed morphology today, and we will, but I would like to talk a little bit in general terms about seed-associated microorganisms to give us a little perspective. I don't want you to leave this room thinking that the sprouted seed is the only seed that has a variety of microorganisms associated with it.

If somebody could turn on the projector for me, I think I have a changing apparatus here --

[Pause.]

All right. First thing I'd like to show you are two petri dishes which contains a culture medium that only allow fungi to grow, and not bacteria. But the point that I'd like to make here is that except -- there's 25 seeds of a plant called Dusty Miller on each one of those petri dishes. And my point is simply that expect for two of those seeds, each one of them has harbored a colony of a fungus. And in this case we are looking at fungi, and most particularly, we are interested in plant pathogens. And these wooly looking colonies are from a plant pathogen, of

which there are several seeds contaminated.

If we plant these seeds out, even though there's a relatively small amount of these seeds contaminated, we have quite a bit of disease development in our seedling tray, as we can see here. Now, of course, we have the same scenario with our sprouted vegetables. We only need a small percentage of the seeds to be contaminated for disease to spread, particularly under conditions that are quite conducive.

So here we have an example which is very similar to what we see in the sprout business. And, indeed, we have a lot of sprout rots that occur -- of no concern from a human health point, but certainly we have plant pathogens developing in the sprout industry as well.

And if we put some mung bean seeds on a petri dish -- and this particular culture medium is selected for aspergillus -- we see some aspergillus flavus group fungi growing, and you may know that these are fungi that produce aflatoxins. But aflatoxins have never been seen in mung beans and they have been looked for in mung bean sprouts in particular. And the growing conditions for mung beans aren't conducive to the growth of the fungus, so it's not really a concern.

I wanted to show you again, however, that seeds of any kind harbor a number of different fungi and bacteria.

Some of them, given the unique conditions that they would need to develop, could result in some problems. And you may know that corn, and cereal products are much more likely to be sources of things like aflatoxins than, certainly, mung bean sprouts. In fact, you can get aflatoxins from any peanut butter that you want to investigate in the grocery store.

And other seedborne pathogens we have: this is slingocephalum we can see in the culture dish up there above, causing a rot of mung beans. Again, not of human concern, but the point -- just another seedborne disease.

And here we have charcoal rot -- the fungus macrophamena phasiolii -- again, something that's carried with the seed and results in problems during production.

I should point out that the Daisy Equipment Company, which is represented here today, has developed some technology -- basically high temperature of very short duration -- which essentially eliminates all these fungal problems, and perhaps many of the bacterial ones. And we're very interested in the fact that they are looking at similar technology for alfalfa seed, and we're hopeful that they'll be providing us with an intervention technique to address this problem in alfalfa as well.

In here we have a radish -- this is a radish sprout -- and on one of the cotyledons we can see a lesion

and, again, this pathogen was carried in the seed.

Plant pathogenic bacteria, as opposed to many of the bacteria that -- I should say plant pathogenic bacteria and fungi are much more difficult to remove from seed than the more casually associated bacteria and fungi that occur during contamination.

Here we have some poppy seeds, and there's 25 seeds in each one of these petri dishes, and the top row has been treated with 5,000 ppm chlorine, and the bottom row hasn't bee treated at all, and those dark cultures there are a plant pathogen, again, which kills the poppy plant, and what I want to illustrate here is that the reason we can't decontaminate the poppy seeds from the plant pathogen very well is that they actually infect the seed coat, and in some cases may even infect the embryo, and chlorine doesn't penetrate tissues so that it makes it very difficult to clean the seed up. However the seed on the bottom -- you can see there is quite a difference between the seed on the bottom and the seed on the top, and even many of these pathogens are superficially associated with the seed.

As Dan Caudill will tell us later, seed, including alfalfa seed, is a raw agricultural commodity. And if you take a batch of alfalfa seed, or any other seed, for that matter, you can separate good seed from bad seed -- as we've done here, there's a little pile of dark seed on the top and

nicer looking, healthy appearing seed on the bottom. Just to point out the proportion between seed, which is not so good and seed which is better. And you can see that the not so good seed doesn't germinate very well, either.

But shifting the focus to bacteria, based on everything I've seen and many laboratory cultures I've done myself on alfalfa and radish and broccoli and clover, there are about 250 to 10,000 bacterial cells per gram of seed that you can recover. And if you do the math on that, basically what you'll find is that only comes out to about 30 bacterial cells per seed. It shouldn't be too surprising that bacteria don't find seed a pleasant substrate to multiply on. Its a highly desiccated surface. It's a very hostile environment, and it tends to be stored under conditions that would prevent it from germinating -- fairly dry and cool conditions. So the bacterial seed itself is not a good environment for seeds to multiply on, although they may find themselves occasionally associated with the seed.

Oops -- wrong button.

Of course, the problem is is that those 250 bacteria -- or, let's say, 30 bacteria per seed, multiplies very rapidly under the sprouting environment, and here we can see several hundred million bacteria per gram after and during sprout production.

And why is this? Why do we have such an incredible increase -- exponential growth -- of bacteria on the surface of sprouts?

Well, first of all, we have a very rich substrate. The sprouts are exuding amino acids and sugars and other nutrients, and there's plenty of moisture there in the sprouting environment, so we actually have sort of a solid culture medium to grow the bacteria on. In addition, we have a very high surface area, as we can see in this picture, where the root hairs are prevalent. So we have a tremendous surface area compared to the volume of these, and therefore we have fairly high bacterial loading when we look at the number of bacteria per gram of product.

And, of course, if we drop down on the surface of the sprout we can begin to see the bacterial colonies here embedded in polysaccharide matrix of their own device. But for those of you who prefer lettuce and other raw vegetables, I should point out that all of our produce would look like this if we look at it under an electron microscope. This is not terribly unique to sprouts. In fact, the fresh-cut vegetables have similar bacterial loading.

Just a little bacterial colony that developed, probably, within a few hours.

Okay, then. Let's move on to the seed morphology

and talk a little bit about what seeds look like up close and personal. Here we have an alfalfa seed, and we can see a couple of things. I guess first I want to say that unlike fungi -- and fungi have the ability to actually breach the barriers of a plant -- the epidermis, the seed coats, and they can enzymatically and with pressure, break through walls of plants. Unlike fungi, bacteria cannot do this. Bacteria can only invade a plant through a wound or through a natural opening. They cannot enzymatically degrade their way or physically encroach through plant tissues. However, plants offer ample opportunity to become infected, or invested, rather casually. And here we can see an alfalfa seed with a large break on it. It looks like a large break in this electron micrograph, but it's one that you wouldn't notice unless you were looking at it under a dissecting microscope or something like that. And here we have a natural opening -- the micropyle of the seed -- all seeds have this. Some of these holes are occluded and some of them are not. But the mere architecture of it provides some difficulty if it were to become contaminated with organic material.

Taking a close look at the crack -- the wounded area -- of the seed -- and these cracks in seed are actually very common. Again, if you're looking at seed used for sprouting, or seeds used in the agricultural, if you want to

take the time to roll them under a dissecting microscope, you'll find that there's a lot of damaged seed out there. It has to do with harvesting techniques and so on and so forth. But the point of it is, it's not unusual, and it's not unique to a sprouted seed by any stretch.

But a closer picture allows us to better understand how organic material might become under the seed coat. And in this position it may be much more difficult to reach with aqueous-based kinds of disinfectants.

The far better technique, if it were practical -- and we're not sure that it is -- would be heat, because heat penetrates into the seed coat -- indeed, into the embryo, and if you're careful, one can treat seeds with heat and remove the microorganisms.

Now, just to get a little closer perspective, let's imagine that we're in a little helicopter, and we're going to fly down here and look at this area here where these walls come together. This is -- this wall that we're faced with here is the seed coat, and only part of the seed coat, because we're so close. I wanted to move in here a little closer so you could see how big a bacterial cell might be. In that last picture bacteria would still be invisible. There are no bacteria in this picture, but I'm going to point to an object that would give you an idea of how big a bacterial cell would be. It would be about as

large as this structure right here. Okay?

So the bacteria are very small, and the cricks are like the Grand Canyon, and this prevents -- this poses a challenge for cleaning up the seed. The surface of the seed appears smooth upon examination, but it's actually quite textured. A bacterial cell would be about as big as this -- as the 1 -- where it says "10 micrometers" here. I'm not sure if you can see that, but this "1" is probably about the size of what a bacterial cell would be.

Clover. Clover might be a little smoother on the surface, but it is also cracked. Much of the clover that you would buy for either planting in the field or sprouting is going to be cracked; maybe 2, 3 or 4 percent of the seed would have cracks in it; and again, allowing an avenue for organic debris which may contain to gain entrance into -- under the seed coat.

We look at the surface of a clover seed, now we can see small cracks in it. Those cracks are large enough to harbor bacteria, but again, the bacteria would be only casually associated with the seed because the surface is too dry for multiplication, and we do know that the populations dare relatively low regardless. But if the seed is handled in an improper way, for example seed is allowed to spill out on the floor and one were to sweep it up and use it, even after washing you have this opportunity for organic material

and bacteria to become inserted into places so that it would be very difficult to remove.

So the idea of see hygiene, in addition to sanitation, is extremely important. I think that seed has to be handled carefully from harvest through cleaning to help prevent, not only cracking but contamination.

Radish seed coat -- very similar. This is actually not a very closeup -- you wouldn't be able to see a bacterial cell here, so there's quite a bit of texture on a radish seed coat.

And here we have broccoli seed. Again, we're actually very far away from this broccoli seed. You wouldn't be able to see bacteria. We have quite a sculptured surface, as well as breaches in the seed coat.

Onions are particularly interesting, because they are highly ornamented, and they have large sutures in the seed. Onion, I think, would be very difficult to clean up with aqueous-based type disinfectants.

And if we get a little bit closer to the onion, we can sere how highly textured and ornamented the surface of the onion seed is. And, again, a bacterial colony -- and there aren't any here -- a bacterial cell would be about this big. And so that, again, we have an opportunity for debris to get -- to find its way into fissures that would be difficult, again, to clean with liquid kind of disinfectant.

Certainly, irradiation and heat would be very effective, and perhaps materials that are very wet and can penetrate well would be effective as well.

MS. DeROEVER: Dr. Wick, you have two minutes.

DR. WICK: Okay.

I would like to conclude by making a few points which I've written down here.

First of all, seeds are not inanimate objects; rather, they're living. They're prone to infection by plant pathogens, and they're convenient vehicles for other microorganisms, including spoilage microorganisms and, as we know, human pathogens.

One kind of seed is not of lower risk than another. We can't replace alfalfa with clover, for example. This is not an approach to the problems that will work.

I would suggest to you that seed contamination by human pathogens is a rare event. An alfalfa grower that grows 10,000 pounds of product a week -- which I don't believe is a lot. It certainly doesn't represent a lot for the country -- would use about 10 billion seeds per week. And it seems to me if there was any significant amount of contamination, there wouldn't be an industry today.

To lower the risk of seed contamination, I suggest that the seed people do not scarify their seed. I think this mechanical injury of the seed is a real problem, and

that if it can be chemically done with acids or something else, that would be more appropriate. It might actually eliminate the microbes that we have to deal with.

And, last, to further reduce the risk of contamination by human pathogens, I urge all the sprout growers to use chlorine as a legal -- by whatever Federal or local regulations there are, and these need to be followed. But I encourage that all sprout growers to use whatever appropriate decontamination processes are available.

MS. DeROEVER: Dr. Wick, your time is up.

DR. WICK: Thank you.

MS. OLIVER: What I'd like to do now is to ask all of the people who have spoken this morning to either stay on the panel if you're here, or to sit on the side up here. There are two tables on the side.

[Pause.]

MS. OLIVER: And what we'd like to do next, then, is to take questions from the panel, questions from the Produce Working Group, and questions also from those invited guests and experts that we've invited to help assist the Produce Working Group this morning. And we've heard information about outbreaks from the epidemiological side, through the tracebacks; we've heard some information about the outbreaks in Japan; we've also heard from the consumer's perspective, both on a personal view and consumers in

general. And then, lastly, we've heard a little bit about seed morphology.

And, with that, I'd like to open it up to questions.

DR. SWAMINATHAN: Is this on?

The question is for Dr. Wick.

You mentioned at least two or three times in your talk that aqueous disinfectants are ineffective, and then in your recommendations you suggested that chlorine should be used. And I wanted you to clarify that.

DR. WICK: Yes -- is this on? Am I on? Okay.

Well, I shouldn't say that aqueous-based disinfectants are ineffective. What I meant was that I think that there's a challenge there, when there are surfaces that are difficult to wet entirely so that you're bringing the toxicant to the target.

But I think that -- I believe that the incidence of contamination of seed is extremely low -- by human pathogens -- and it seems that if one were to -- and not only that, but I suspect in most cases it's rather superficial. And I believe that some type of dis-infestation -- chemical or otherwise -- would greatly lower the risk of contamination.

DR. SWAMINATHAN: Could I follow that up?

You suggested heat is a better way of inactivating

microorganisms in seeds. Could you --

DR. WICK: Well, yes, that's been the longstanding method that we've used for agricultural crops. It's tricky to use, however, and the sprouters deal with 25, 30, 50 pounds of seed at a time, so logistically, it's a little difficult. And there's a very fine threshold between killing the organism and lower seed germination.

In agricultural, sometimes there are many situations where we can live with lower germination; we can over-plant, for example, and if we've gotten rid of the pathogen we're okay. I'm not sure if in the sprouting situation, if 10 percent of the seed not germinating would create a problem. I'm not sure.

People have looked at the effectiveness of heat for seed decontamination. And I think the Japanese have demonstrated very nicely that it works beautifully for fungi, and they are continuing to look at alfalfa seed and bacteria as well.

MS. OLIVER: I might ask for those that are asking question, if you'd please introduce yourselves for the recording.

DR. DOYLE: This is Mike Doyle.

MS. OLIVER: Mike?

DR. DOYLE: Dr. Wick, is it practically possible, in your opinion, to produce seeds such as alfalfa seeds that

would be free of harmful bacteria?

DR. WICK: Well, I'm not the expert to ask that, but I would say -- I'd have to say no. I don't know that it would be possible to grow a hundred acres of alfalfa and keep animals from visiting it.

DR. FARRAR: Jeff Farrar, California Department of Health. The question's probably for Larry Slutsker.

Larry, granted, in epidemiological terms the number of outbreaks that have occurred are few, in terms of being able to analyze a large data set, but are you seeing any risk factors -- consistent risk factors -- in these investigations, either on the production side or the seed-growing side; and I'm thinking specifically of drums versus trays; chlorination of seeds; use of uncomposted manure -- some of those types of things.

DR. SLUTSKER: Well, yes, those are great questions. I think we are limited somewhat by a couple things. First, the small number of outbreaks; also the fact that in a couple of these outbreaks there were so many different sprouters involved in the multi-state outbreaks that there was no systematic collection of information of all the sprouters involved in those.

Certainly, in terms of seed decontamination, we know from the sprouters implicated in some of these investigations, that there wasn't systematic use of any

chemical disinfection, but we don't really have controls, and I don't -- you know, we don't know how often it's being used in the -- you know, as a general practice among other sprouters who haven't been involved in outbreaks -- although you have some data on that, I guess.

And in terms of the type of sprouting operation, whether it's drum sprouting or tray sprouting, that information might be available. I don't have that systematically compiled right now, but we could try to go back and look at that.

DR. KVENBERG: I have a question. This John Kvenberg. I guess it would be directed to Dr. Slutsker, but it refers to a point that was brought forward by Ms. Girand, and it relates to chronic sequelae, long-term cost that spanned out over a number of years -- up to 20 years.

I don't know if that's going to be otherwise captured in this meeting, but my question is: does CDC have any linkage, in terms of epidemiology on chronic sequelae that follow after acute disease and tracking relative to cost of disease, etcetera.

DR. SLUTSKER: Well, there have been -- CDC doesn't have an ongoing project looking at that sort of data. There have been studies by state health departments or individual investigators that have looked at outbreak situations and then followed up with the cases that -- at

some point: six or 12 months later, looking at the incidence of chronic sequelae, such as arthritis or something like that.

But, in terms of an ongoing monitoring project, I don't believe that that's being done. And, certainly, in terms of these sprout-associated outbreaks, I don't think that information -- unless the state health departments would be collecting that on their own.

DR. KVENBERG: Thank you.

MS. OLIVER: Peggy?

DR. NEILL: I have a question for Dr. Slutsker.

What would be your best guesstimate on the number of persons -- or expressed as a percentage -- from all of the sprout-associated outbreaks, both in the U.S. and internationally -- who would come under the divisions in the proposed warning statement: children, elderly, immunocompromised? Ballpark would be to take age less than 15, age greater than 65, and I don't know how you would get at immunocompromised.

Your own data had suggested in several of the U.S. outbreaks that the group who was increasingly documented was young -- I presume healthy -- women in their 20s.

DR. SLUTSKER: That's right. And I don't have the precise numbers, although we could go back and look at that. But my best guesstimate would be less than 10 percent,

outside of those extremes.

MS. OLIVER: Terry?

Dr. TROXELL: Hi. Terry Troxell. This is for Dr. Takahashi.

I believe your slide indicated that the Japanese radish sprout production manual recommended culturing the seeds. The other presentations indicated that we have thus far not seen positive seeds.

What's the Japanese experience using this approach? Do you know?

DR. TAKAHASHI: Well, actually, I was not directly involved in the investigation and also the conclusion, but since they couldn't isolate the E. coli itself from the surface of the seed, or any materials which could be used for the seeds production: water, bath or sponges, whatever -- then the only clue to know the etiology of the contamination was using a DNA fingerprinting technique. And still, as I mentioned in my presentation, the reliability of the DNA technique is not having any consensus among the Japanese literature. But actually, the homology of the DNA patterns they isolated from the seed was quite high from that of the -- isolated from the seed itself and the patients, too.

So I personally think DNA fingerprinting technique could be at least a supplementary technique to know the

etiology of the outbreak.

DR. BUCHANAN: Bob Buchanan. Carolyn, this is for you.

Do you have any estimates on how effective you think labeling would be?

MS. DeWAAL: I don't have specific estimates. We did go back and look -- or try to get some information, I think, from Dr. Slutsker on the numbers of people, for example, in the E. coli outbreak, that fell within these high-risk groups.

I mean, this is a close call, in terms of whether you would want warning labels for all consumers, which really is not -- that's essentially putting them out of business, versus warning labels for high risk consumers.

It is my understanding that a large number of the people who were hospitalized in the E. coli outbreak fell outside of the categories of at-risk consumes; but that the ones with the most severe outcomes -- the HUS cases and some of the others with the most severe outcomes -- were within this group. So the warning label will not eliminate outbreaks and illnesses from sprouts. It will simply -- hopefully -- help to eliminate the most severe cases.

And second of all, it's -- from our standpoint, it's a matter of fairness. If you have a known problem, like with apple cider -- if you have a known problem, where

you have documented outbreaks, where we don't have a solution that's largely in place in the industry yet, that you should alert consumers to that. You shouldn't leave them in the dark, and give them the tool that they need to protect their families and their children, the elderly relatives. It's also information going out to nursing homes; it's information going out to other care-givers; day care centers, things like that.

So, it's a matter of fairness, as well hopefully preventing the most severe cases.

MS. GIRAND: If you don't mind, Bob -- one think in the juice labeling economic analysis was they were trying to decide what the effectiveness rate of the juice labelling would be, and they were looking at generic effectiveness ratings for warning labels, and not looking at warning labels targeting parents in particular; so things like air-bag warnings, or car-seat warnings. And they -- and it's my believe that the data on those will show that those labels have a much higher effectiveness rating than, you know, generic cigarette warnings or something like that.

DR. SWANSON: Kate Swanson, for Dr. Slutsker.

Am I on?

VOICES: No.

DR. SWANSON: Am I on?

MS. OLIVER: Yes.

DR. SWANSON: Okay.

In the outbreak investigations, has there been any effort to look at other sprouters that may have received shipments of the same seed, but were not involved in outbreaks, to determine if they're doing something different that could have prevented outbreaks?

DR. SLUTSKER: I would -- probably not a systematic effort in that regard. The best opportunity was in Michigan, where two sprouters received the implicated seed lot, and only one was implicated in the outbreak, but the other actually had not. And they did have differences in the way they sprouted and decontaminated their seed; how they stored their seed. There was a -- the AIS officer investigating that, Tom Broyer, came up with some interesting comparisons, in terms of how one sprouter stored their sprouts at room temperature overnight before they were shipped out the next day, whereas the other sprouter stored it in a cold room. What the prevalence of those practices is, I don't know.

But in terms of a systematic look at sprouters who got seed that was implicated in outbreaks and who did not have cases traced back to them, I don't think that's been done, no.

DR. TOMPKIN: Is this on?

MS. OLIVER: Yes.

DR. TOMPKIN: This is Bruce Tompkin, and I have a question for Dr. Wick.

It's evidence that some microbial growth -- in act, extensive microbial growth -- will occur during the sprouting process, along the sprout -- the surface of the sprout.

Has anyone made any effort, that you know of, to manage the type of growth that occurs at that time? That is, the flora that will develop -- has anyone looked at the use of probiotics, or anything else?

DR. SLUTSKER: Indeed, chlorine dioxide, hydrogen peroxide, chlorine -- these things have been metered into the sprouts during production on a regular basis. And they don't appear to have any significant effects on microbial growth. And, again, if we're dealing with human pathogens, we simply have to prevent them entirely. We can't just reduce them.

There may be products out there, however, that would be appropriate, but so far we haven't seen any good results yet.

MS. OLIVER: I have a question for Dr. Wick, and that is: you were talking about the differences in the seed surfaces, and I think you said that it didn't matter which seed you took; that there is -- you'll find cracks or crevices in all of the different seeds.

I had heard one presentation once where I thought that certain seeds were more likely to become contaminated with bacteria because of their crevices than others. But what I'm hearing you say is that's not true. Is that correct?

DR. WICK: Well, I can't -- I'm speculating, actually. But the point of it is is that the seed is mechanically harvested with combines; it's subjected to a lot of mechanical breakage -- and, incidentally, there's natural openings in the seed, as well. And so I -- it appears to me that what's happening is that we have point contamination in a clover field, or an alfalfa field; we're picking up some contaminant, we're stirring it around. Occasionally the seeds are scarified, which is a process by which mechanically some of the seeds are broken. And so that I just don't see a large difference from one kind of seed to the other with regard to this kind of chance contamination. And I think when you start sprouting tons and tons of seed annually of any particular kind, statistically the chances are relatively good that you're going to pick up even an incidental contamination.

MS. OLIVER: Thank you.

Bob?

Dr. BUCHANAN: This question is for Dr. Takahashi.

One of the recommendations you have for the seed

industry was a pre-soak with .1 ppm chlorine in running water. Can you give us some more details about how long this is for; how rapidly the water has to be changed; and how effective is the technique?

DR. TAKAHASHI: Well, actually, I have no idea. In that Japanese device manual, the government didn't mention about the duration of the washing time and, actually, we have some Japanese researchers here, and is there any comments on the detail about the washing?

DR. ISSHIKI: My name is Kenji Isshiki, from the Japanese Ministry of Agriculture.

Tomorrow I will show you more detailed comments if that's okay?

MS. OLIVER: Fine. Great. Thank you.

Dave?

DR. GOOLSBY: This is Dave Goolsby.

A lot of comments have been made addressing the concerns; the fact that we're dealing with, really, an international market, a highly complex industry. I wonder if there -- to Ms. Morrison -- if there is the opportunity to give consideration to other concerns that were addressed, putting a PulseNet, or some equally advantageous new technology tied internationally, as an advantage to looking at outbreaks and tracebacks?

MS. MORRISON: Well, I think Larry might be able

to address that better than I can, but I can tell you from our own experience in FDA Emergency Operations, where we try to centrally coordinate emergency response to outbreaks, we're getting reports all the time internationally of outbreaks. We just had one recently in Japan that was botulism, implicating a product from another country, and immediately we were checking to try to get more data to see, a) what did we know about in Japan and, b) was that product coming into the United States? Additionally, contacting Canada -- we have very close relations there -- to see, are we dealing with the same product here that has caused illness somewhere else?

So we're getting very fast reporting internationally. It's not really a system. FSNet is one avenue and, I think maybe Carl or Larry could address it. But we're getting a lot of reports through CDC and FDA channels, through out international affairs offices, as well, of outbreaks. And, you're right: invariably, these are international. It's either the beginning or the end: the traceback ends up there, or the beginning of the outbreak's there, and we find products similar coming in here. It's a great challenge for the future.

MS. OLIVER: Larry, did you have anything to add?

DR. SLUTSKER: Yes, just to elaborate. The 1995 Stanley outbreak really was -- there were a lot of valuable

information exchanged at the beginning through SalmNet, which was the European salmonella surveillance system, now called InterNet. But that's really how we got our Finland connection was by exchanging information with them.

So there is exchange of information. In terms of actually exchanging molecular fingerprint patterns, or isolates, that's still kind of done the old way where you say, "Send it to me in the mail," and we're not really exchanging patterns on an international basis right -- well, perhaps with Canada, but not with the European community right now. But maybe Dr. Swaminathan wants to make some further comments on PulseNet in these kind of situations.

DR. SWAMINATHAN: Yes. Larry was right, we are currently exchanging information with the Canadian investigators. In fact, in the recent outbreaks of salmonella Irreninberg in Canada we did exchange patterns with Canada -- our Washington State health department laboratory.

But as far as exchanging patterns by InterNet etcetera, with Japan there are still some problems to be worked out. The Japanese see primarily differences in the smaller molecular weight fragments, whereas we see differences among the large molecular size fragments; among our E. coli O157 isolates. How to reconcile those differences is an important question, because if we change

our methods now, we have -- we won't be able to go back to our rapidly extending -- expanding data base.

We had a researcher from the National Institute of Infectious Diseases at CDC for six months, and we were trying to jointly address those problems and, hopefully, we will be able to resolve our differences and come up with a way of harmonizing our PulseField set-ups so we can compare patterns, say, by 1999. That's our objective.

As far as the InterNet is concerned, as you probably -- some of you may be aware that the people in the InterNet were primarily relying on phage typing until recently, and were not very enthusiastic of PFGE. We had one meeting with the InterNet people at CDC immediately after the SM meeting in May, and there is an InterNet meeting scheduled in Denmark in the middle of November, and I'm happy to report that they are much more receptive to PFGE and standardizing PFGE between the United States and Canada and the European countries, and hopefully we'll see some progress on that in the not too distant future.

MS. OLIVER: Thank you.

Bob?

DR. BUCHANAN: This is Bob Buchanan, and this is for Ellen.

Ellen, alfalfa seeds are divided into two categories: food and non-food use, based on the pesticides

that are use. Is there a traceback system associated with that?

MS. MORRISON: That I'm not aware of, but I think part of the problem that we saw in the outbreak that we were all talking about -- the Michigan and Virginia -- was that the information -- Thomas Brewer's information when he went to the farms -- would indicate that the way that seed was originally packaged was labeled generally not for human consumption. I think that is primarily due to pesticide use. And whether people use the pesticides and just label them generally, I don't think we know. And I'm not sure -- Jeff, maybe you can help here, from your perspective in California -- I don't think we really have a good handle on how seeds coming out of farms are labeled, and whether they're all labeled that way just to avoid potential problems, or whether they actually are tracking pesticide use.

The EPA may be -- I don't know if anyone from the EPA is here to address it.

Jeff, do you have any other data?

DR. FARRAR: No.

MS. MORRISON: Well, maybe someone on our afternoon panel will be able to, and we can, you know, talk about that then at that point.

MR. VILLANEVA: I would just say -- Mike Villaneva

with State -- California -- that we have a hundred percent reporting on pesticide use in California. So I would think, at this juncture -- and it's not commodity exclusive; every application. So there would be data on that.

MS. OLIVER: Good.

Carl?

MR. REYNOLDS: I have a question, perhaps for Dr. Slutsker, or perhaps some of the data that was quoted by Ms. DeWaal and so on. And perhaps -- I may also have to retain some of it to discuss this afternoon.

But in each of the presentations, you had mentioned and quoted some data based on the investigations of the particular outbreaks, and you had talked about findings at individual sprouting firms regarding rodent activity and so on.

And my question is twofold: in what condition, or in what manner, were the seeds received at the sprouters that you mentioned; i.e., were they in bulk? Were they in multi-wall paper? Or were they in woven cloth that was criticized earlier? And closely akin to that particular question, was there any evidence uncovered during these investigations that showed that there was rodent contamination,either with urine or gnawing in any of the bags that was in these sprouting facilities?

MS. OLIVER: Larry?

DR. SLUTSKER: I'll take a first shot at that, which is that the particularly sprouter that I mentioned -- the 1996 Montevideo/Milagreadis outbreak -- the seeds were not received in bulk there. They were received in bags. I do have information on what type of bag it was, although I'm having a hard time pulling that out right now. But I can look that up for you. I have that.

I don't know about other -- whether there was evidence that the bags had been gnawed into, or whether there was evidence of rodent urine on the bags. I don't have that information.

I know -- and Jeff has more information on some of the investigations in California, where there have been sort of a more thorough or subtle look at evidence for rodent contamination in some of the seed bags, and maybe you'd like to comment on that, Jeff.

Dr. GOOLSBY: In the Montevideo Milagreadis outbreak you mentioned, I'm trying to recall, too. It was either polyweave or paper 50 pound bags. I can't remember which. We can look that up.

But in none of the outbreaks have we -- none of the outbreaks we've investigated, have we seen obvious rodent contamination on the bags. I know there was one voluntary recall of a product that we investigated, with no associated cases that we were aware of, in which we did find

extensive rodent urine on the bags.

MS. OLIVER: Caroline, did you have anything to add?

MS. DeWAAL: I actually just had a question -- mostly for Ellen -- and it is: Congress is currently considering country-of-origin labelling for FDA regulated foods. The only benefit I see to this is to traceback, in the case of foodborne illness outbreak. I mean, there's a benefit -- a general benefit for consumers to know where their food comes from, but from a food safety standpoint, the only benefit to such labeling is really in the area of traceback.

Do you see a benefit, based on your understanding of the traceback problems, to any form of country-of-origin labelling for seeds?

MS. MORRISON: Well, I would defer that to Janice for more of the policy issues in this, but we certainly have discussed the issue of traceback and whether there should be Federal requirements. And we have not proposed them. Right now we think it's very difficult to do.

Fresh fruits and vegetables -- leaving seeds aside for the moment -- but fresh fruits and vegetables are a persistent nightmare in traceback, has posed that question to us. And as we've seen in the cyclospora traceback, we had the ability, thanks to the government of Guatemala, to

be able to trace back to farm level when we had outbreaks, and where we lost the integrity of that was when it came into the United States.

So, there's a lot of effort going on in all sorts of quarters, and I think -- we've met with industry groups -- the fresh fruit and vegetable-related industry groups -- to discuss the issue of traceback. But we right now do not feel that we even know the state of the art of the industry. Some people are very good within different parts of the industry in tracing back their product right to the farm, and we've seen in recent traceback -- which is not related to sprouts -- recent traceback information, that you can go back to the farm level. The integrity of your coding system on fresh fruit and vegetables is very difficult, however.

So I defer the larger policy question to Janice for country-of-origin labelling, because I understood that was a requirement of customs.

MS. OLIVER: Yes, Customs -- on the packages that are coming into the country, there's a Customs requirement for country of origin, and you're talking about something beyond that.

But in looking at safety, the country-of-origin labelling isn't -- wouldn't have helped us in tracing back a lot of the things. If you look at the raspberries that were

involved in the Guatemalan -- because the problem that you had then was -- and in '97 -- the containers were labeled as such, it's just the containers, because when you have fresh produce outbreak, the problem is that that is no longer there, and it's not available -- the original containers -- to find out where it came from. That's more of the problem that we have than the other.

Additional questions?

DR. TAKAHASHI: This is additional comment about the Japanese government regulation. In the radish sprouts package, it's not indicated about the origin of the country, but the government regulated indicates the name of the manufacturers and also contact telephone number and address on each package for the quick notice. It's regulated in the revised version of the sprouts manual.

MS. OLIVER: Okay. Good.

Any others? Swami?

DR. SWAMINATHAN: Bala Swaminathan, CDC.

I -- it's important to clear up two items from Dr. Takahashi's presentation, and if you are unable to provide the information, perhaps your other colleagues could.

One think is regarding this Japanese radish sprout production manual, you're recommending that at least one sample per lot be tested, and you have also recommended that the sample be cultured for STEC and salmonella.

Could you give us some details on how much of the seed represents a sample? Whether the seeds will be tested before or after sprouting? And, because you and others -- us and others -- have had difficulty in culturing organisms -- pathogens -- from seeds, if a processor tests these seeds for salmonella and E. coli and finds it negative, what use is it if we are not very -- you know, if these methods are not very reliable as far as the sensitivity is concerned?

I have another question, too, but I would like an answer for this first.

DR. TAKAHASHI: Well, before asking some comments for Dr. Isshiki, my understanding was during our investigation of the contaminated radish sprouts from Oregon, the Japanese government task force group actually isolated not only E. coli, pertussis and salmonella from that seed, and also we saw we saw some of the same trends. And so far we do not have salmonella outbreak due to radish sprouts, but we may have a potential risk of such contamination through the radish sprouts. So that's why -- my understanding is -- the revised the version, they require the culture for both salmonella and E. coli.

And about the technical detail, maybe I would ask some comments from Dr. Isshiki, or --

MS. OLIVER: I would ask Dr. Isshki -- is that something you will be addressing tomorrow also?

DR. ISSHIKI: Our policy is -- first step is detection of E, Coli as an indicator. If the E. coli was detected, next step is detection of the O157 -- other STECs, and salmonella.

If first step is okay, next step is no more needed. And at least one sample of on lot should be detected. If we can more sample could tested, we recommend to the more test.

DR. SWAMINATHAN: What is the size of the sample, please?

DR. ISSHIKI: Maybe the -- it is -- depend on the producers. So we cannot define the sample size.

DR. SWAMINATHAN: Are these tested before sprouting, just as seeds? Or are they sprouted and then tested?

DR. ISSHIKI: Ahh -- before the sproutings, and we recommend final product should be tested.

DR. SWAMINATHAN: Okay.

The second question I have is regarding the particular seed that was PCR positive but cultured negative from a recent outbreak. Now, I take it that the PCR test -- the target was the chigatoxin genes. But then where I got confused was Dr. Takahashi pointed out that the PCR fragment was later fingerprinted, or some type of restriction fragment linked polymorphism was done on this PCR fragment,

and it was found to have the same fingerprint as the case isolate DNA. Is that correct, or did I misunderstand you? Because I think it's important to clarify this point.

DR. TAKAHASHI: Well, my understanding -- Dr. Takada's group conducted that investigation, and I think the most accurate information would be provided by Dr. Takada and his group -- but my understanding is they conducted both and the fingerprinting method was used for the final conclusion. But, again, I hope you will contact with Dr. Takada about the details of the techniques, please.

DR. KVENBERG: I have a question on the same point, referring back to Dr. Wick.

In your remarks, you mentioned -- this is John Kvenberg speaking -- that -- if I got your information correctly -- 10 billion seeds go into a 100 thousand pounds of production? What's your view --

DR. WICK: 10,000 pounds.

DR. KVENBERG: -- yes -- well, you can clarify the level -- opinion of what testing will get you on seeds? Would you care to comment on that again, please?

DR. WICK: Yes, again, I think we're dealing with point contamination of seed -- chance contamination -- and the possibilities of detecting E. coli or salmonella are remote when one looks at the seed.

The best way to test is the way the sprouters do

it. You put it a drum and you turn it around, and if there is any point contamination there, it's going to spread throughout the system; the irrigation and the tumbling and all that will ensure uniform contamination. And then -- I think that sprouting -- I'm sorry, testing the day before harvest would allow that ability to -- you've amplified any possible problems, and you test the day before harvest, and if you have to hold it under cold storage for a day, that's okay, too. But I think that would be far more effective than testing seed.

DR. KVENBERG: Thank you.

MS. OLIVER: Bruce?

DR. TOMPKIN: This is Bruce Tompkin.

The programs -- well, we're going to hear from Radiation tomorrow, and we've heard a little bit about chlorine and liquid disinfection methods, but it doesn't seem that we're going to hear much more information about heat.

And Dr. Wick is the one who's mentioned it. Now, I was curious as to whether you or others could give us some idea as to how much research has actually been done on a method to arrive at decontamination through heat? The approach has been through high-temperature short-time, or low-temperature for long time holding? There have been procedures, for example, for killing salmonella in dried egg

whites that goes back years. And there have been a number of other applications.

Have all those been looked at and rejected?

DR. WICK: Well, Dr. Beuchat has done some of this work, and I'll let him speak for that. And the Japanese have also worked with it as well.

I think that there's been one other research paper before Dr. Beuchat's, specifically in sprouts. But he would be the person, I think, who would best speak to that.

DR. KVENBERG: This is John Kvenberg. If I could interject, too, I think we may have some public commenters today that will be coming in to discuss some of the temperature information at the close of the day, so we may learn more before we adjourn today about the issue.

DR. SPERBER: I'm Bill Sperber. I have a question, perhaps for FDA and the state officials who are here this morning.

We've heard a lot about the sprout outbreaks in the states, of poor manufacturing practices: rodent contamination, things like that. I'm wondering, at least in these eight affected outbreaks, who had jurisdiction for those factories. Did they fall under FDA jurisdiction, or the state departments of health or agriculture? And my fundamental question behind all of this is: to what extent could we actually reduce these illnesses by having better

inspection or enforcement of GMPs in these sprouting operations? And would better enforcement actions against the sprouters with poor GMPs be effective in reducing foodborne illness from sprouts?

MS. OLIVER: Ellen, did you want to start --

MS. MORRISON: Well, I think in some cases it's primarily the state, and it's Federal and FDA went in on joint inspections when there was a problem, We had previously inspected the sprouter in Virginia. I don't recall the one in Michigan -- just talking that one as an example; the one I read most recently, the package again.

But Jeff can answer, maybe, for California; or Mike, about the inspectional activity on sprouters in the State of California, of which there are a large number. I know our office -- our offices in California, Mary Atkins here from San Francisco office, has worked extensively with the State of California to address that.

MS. OLIVER: Let me just add something, too. I think in the work with the State of California, I mean there were just a few recent outbreaks we worked on, but there also was a, you know, a survey that was done. I think, you know, from what we've heard today, and from what Larry has said in looking back that a lot of it is thought to have been due to the seed. Good-manufacturing practices probably would have helped, too, but that the original contamination

seemed to have come in on the seed.

But I'll ask Jeff to expand on that.

DR. FARRAR: I think you hit the point I wanted to make, Janice, about contaminated seeds. You can have the best GMPs in the country, but if you're starting with a contaminated product, GMPs aren't going to prevent that.

We did recently, with close cooperation with FDA in California, complete a statewide inspection and survey of our sprout growers in California. We identified about 45 or 50 of those -- and I'll bring up some of the results later this afternoon, so perhaps I'll save my comments for then.

MS. OLIVER: Thanks.

Dave?

DR. GOOLSBY: A few comments and a question or two -- this is Dave Goolsby -- along the same subject line.

In full agreement that if we start with a sanitary product -- in this case, the seed -- we have a much better chance of a final consumable safe product. However, the likelihood of cross contamination in post production, all those kinds of things, are certainly inherent to the process. And I'm recalling some things, Dr. Takahashi, that you alluded to in talking about the manual that you had produced in Japan, that there seemed to be a decline in the number of outbreaks during the implementation of CCPs and GMPs and those kinds of things.

Would you comment further on some of the specifics that you felt were influential in a positive way on diminishing the contamination of the final product?

DR. TAKAHASHI: So you are just asking about the production, in terms of those activity or consumption of the radish sprout as well?

DR. GOOLSBY: Not necessarily consumption, but during the actual sprouting operations themselves, after receipt of the seed and during the whole evolution of those few days of sprouting and packaging and then delivery, short of the consumer and consumption steps.

DR. TAKAHASHI: Okay. Well, I'll tell you, I will provide the English translation of the revised manual probably tomorrow, but I think a point is not only the sterilization or packaging on such a production procedure itself, but also the -- for example, the temperature during shipment, and also the sample examination of the seed, and also the sampling examination of the radish sprout itself.

And, well, actually producing the revised version of the Japanese Sprouts Manual, I heard that they put into it lots of the idea of the HACCP or related techniques.

But the question is actually some experts pointed out that the idea of the HACCP is too much over evaluated, because some experts say that even if we put in a critical point of each production procedure, it is not 100 percent

sure. And my understanding of during the discussion of the government committee to revise the manual, some Japanese government official gave a rather strong words that the revised version will have much more reliability because we used much of the HACCP idea in each process.

But, again, it's not based on a scientific point of view. So, as I mentioned in my presentation, well, actually, evaluation of the revised version is very difficult and also should be much more discussed among the both U.S. and Japanese experts.

So, anyway, I appreciate if you would read through the English version and give us comments later.

DR. GOOLSBY: Thank you.

MS. OLIVER: Bob?

DR. BUCHANAN: Bob Buchanan. A quick question for Larry Slutsker and for Mike Dinovi.

Larry, I heard you make a presentation a while ago where you estimated -- CDC estimated that there was approximately 10 percent of the population consumed sprouts on a routine basis; whereas the estimates that we received from you, Mike, this morning was about 2-/2 percent.

And that's a big differential there. Any comments on that?

DR. SLUTSKER: Well, yes. That's good point, and I was thinking about that during that presentation, too,

although I think those data that I presented at that meeting were from FoodNet -- the population survey -- and the range of sprout -- alfalfa -- I think it was alfalfa sprouts consumption was 5 to 10 percent, depending on some geographic variables and education variables.

But the recall period was different. The recall period, I believe, was "in the last four weeks." And I think that the survey data that were presented this morning was "during the last two or three days," or something like that?

DR. DINOVI: The survey was only -- the most recent survey it was only two days, and that's the artifact -- the problem with these data is that the survey is so short. Foods that aren't eaten frequently just don't get captured; the percent of eaters doesn't get captured very well in those kind of surveys.

If you had a 14-day survey, we might have seen the 10 percent, or a 28-day survey, because you catch people who are only eating it once in that particular length of time. You don't get very good data on percent eaters here. I was just trying to report the numbers to demonstrate that, at least for this kind of food, it's infrequently consumed, when you compare it to fresh meat, milk and those kind of products, where you see 80 or 90 percent of eaters, every day of the survey. Of all of the people that reported,

almost no one eats it twice in the survey period of two or three days. So that's where you see an artifact in the number. That number is low, certainly.

DR. BUCHANAN: Do we have -- as we sit and consider the risk associated with this type of product -- do you have a ballpark figure that we could work with, in terms of percentage of the population that's likely to be exposed?

DR. DINOVI: I can't, from the surveys that I have. That's -- marking data are better at that. You get better data from the industry.

DR. SLUTSKER: Yes, just the FoodNet data, which you already have. That's the best that we have.

MS. OLIVER: Okay. And we can look further to try to get it.

Dane?

MR. BERNARD: Thank you. Dane Bernard. A follow-up question for Dr. Wick.

There was some discussion a while ago about substituting other types of seeds. Based on our observations that, at least to date, we've had no problems from cyclospora from blackberries, and they're cultivated in the same regions in much the same way as raspberries, is there conclusive evidence to say that possibly there isn't a better alternative? I know we've had problems with alfalfa, we've had problems with mung beans. But is there conclusive

evidence to say that maybe there is some ecological, or maybe even a physiological reason --

DR. WICK: Well, my comment was speculative. However, again, you know when we're dealing with plant pathogens, where there's an intimate relationship between a microorganism and a living -- another living organism, one would expect all kinds of different things to happen. But, again, it seems to me that we're dealing with a chance contamination in agricultural fields, by animals or by manures, and we're running through with combines, and we're picking up the seed, and we're picking up what's in the environment.

I don't think the type of seed has anything to do with this point contamination that's occurring during harvest. And, again -- this is speculation. But we're not dealing with organisms that have evolved with these plants and have a special genetic relationship with them.

MS. OLIVER: Bob?

DR. BUCHANAN: Bob Buchanan. This is for Dr. Wick also.

There have been a couple of recent reports with tomatoes and in several other fruits that exposure of the flower to the organism results in it being incorporate into the body of the fruit itself.

Is there any indication at all that a similar

thing may be occurring with the foodborne pathogens and the seeds that are associated with sprouts, where it's more than a casual relationship?

DR. WICK: Well, that's a good question, and I don't have the answer to that. But, indeed, there is an opportunity for plant pathogens to become established in seed that way, and it's well documented.

Whether or not there is -- the plant pathogens have a certain genetic capability of going through that process, I'm not certain. But, it's a good question, certainly.

MS. OLIVER: Are there any more questions from the panel, from the working group? How about from the audience, since we have a few minutes.

[No response.]

MS. OLIVER: Okay. If there are no more questions, why don't we break for lunch now and come back at 1:15?

[Luncheon recess.]

[Whereupon, at 11:59 a.m., the proceedings were recessed, to be resumed at 1:15 p.m.]

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

[1:16 p.m.]

MS. OLIVER: Good afternoon. If we could --

[Pause.]

MS. OLIVER: Our first presentations this afternoon will be on agricultural practices, and we have three presenters in that area.

First will be Ms. Nancy Snider, from the International Sprout Growers Association, and she will be followed by Mr. Fred Fabre, from Cal West Seed, and then Mr. Dan Caudill, of Caudill Seed.

Nancy?

MS. SNIDER: Good afternoon. I'd first like to thank FDA and CFSAN for the opportunity to speak in front of you, and hope you all had sprouts for lunch.

[Laughter.]

MS. SNIDER: I'd like to start this talk with just a brief history of sprouts. To many people, sprouts mean only bean sprouts or alfalfa sprouts, but any whole seed is capable of being sprouted.

The history of sprouting seeds in the West has been discovered and re-discovered several times during the last few centuries. In the Far East, sprouts have been an important part of the diet for about 5,000 years. Asia sprouted the bean and the Arabs sprouted alfalfa, which they

called the father of all foods.

The Arabs first used alfalfa as a cover crop, and then as a feed for their magnificent horses. When they noticed that these animals grew stronger, ran faster than the others, they began to eat the sprouted seeds themselves with much the same results.

In the West, during the 18th century, scurvy, which was caused by the lack of vitamin C, was a huge problem in sailing ships. Twenty years before the introduction of limes or lemons, to prevent scurvy on vessels captain James Cook became interested in sprouting barley grain as a source of vitamin C. he had read a treatise on sea scurvy by Dr. David McBride in 1767 which contained a recipe for wort, or drink, which was used by Dr. McBride. Captain Cook prepared this drink for use on board the Endeavor. During his three-year voyage from 1768 to 1771, not a single man was lost through scurvy. Although Captain Cook was awarded a Royal Society medal for this experiment, the British government, for political reasons, decided to recommend the use of the more expensive lemons and limes on their sailing vessels.

In the 20th century, during the Second World War, both the British and the U.S. government recommended sprouted seeds as a valuable source of protein and vitamins, especially C. In the U.S., a nationwide campaign was

mounted to teach people how to sprout grains.

To introduce the present, I'd like to give you just a few statistics. They're always kind of fun.

Worldwide sprout sales are approximately one billion dollars, with the U.S. market being about 250 million. In the U.S., we produce probably close to 300 tons of sprouts a year. There approximately 5,000 sprout growers worldwide -- which excludes China. No one knows how many there are in China -- with about 475 being in the U.S. and Canada.

The sprouting industry in the United States and Canada is pretty much an exact parallel to the farming industry, varying in size from 5 million to 50,000 dollars.

There are many, many benefits from eating fresh sprouts. Not only are they rich in vitamins and minerals, but government and independent nutrition and health authorities agree that Americans should increase their consumption of fruits and vegetables to at least five servings a day. These same studies show that generous servings of fresh fruits and vegetables in our diet are protective against many cancers and lessen the risk of coronary heart disease. Also, a recent study by Dr. Tallale of Johns Hopkins shows that broccoli sprouts contain a high level of a powerful antioxidant chemical, saphoriphane, that can help to prevent cancer.

With all the good reasons why we should include fresh sprouts in our diet, there are some minimal risks associated with eating uncooked produce. I have several references here, and I won't bore you with them.

Also, according to the Canadian food inspection agency, both fresh-cut and sprouts are in the medium risk category, indicating that alfalfa sprouts and fresh-cut produce are both safe for consumers.

Because the health of our consumer and the safety of our product is ISGA's number one priority, we have developed a three-step process to reduce or eliminate this minimal risk.

First, based on research at the University of Georgia, Massachusetts and the USDA, ISGA has developed a new proven method of sanitizing seed. Approved earlier this month for emergency use in California on a voluntary basis, it will eliminate harmful pathogens should they be present. Pathogens which are harmful to people are rarely present in sprouting seed, but on occasion they are introduced into the seed while it's still in the field. We applaud the State of California for approving this method and the FDA and EPA for putting it on the fast-track for approval and implementation in the rest of the U.S.

Secondly, ISGA has approved a program which will establish a quality assurance through verification seal. To

use this seal on their products, growers must follow a strict daily sanitation procedure dictated by good manufacturing practices. This measures include appropriate sanitary procedures to ensure that no harmful pathogens are introduced into the sprouts while they are in their facilities. This program will be available to growers starting the first of October.

Third, a nationally recognized third-party auditor will inspect and certify all QATV plant operators. This ensures that the facilities and procedures are within guidelines and nothing is overlooked.

It is important to note that only growers following the three-step procedure will be allowed to carry the QATV seal on their sprout packages. The vast majority of sprout growers have never been associated with an outbreak and are very careful people, eager to implement the new safety procedures as soon as they are approved by FDA and EPA.

Unfortunately, the irresponsible actions of a few bad actors in the industry, inevitable in any industry, have cast a shadow on all sprout growers. ISGA feels that it is unfair to paint our industry with one brush to eliminate these bad actors. We are doing everything we can to self police, but we need backing from regulators who have the responsibility to shut down sub-standard growers.

Members of ISGA are very concerned, as is the public, regarding the safety of food that they and their children eat. Most sprouts, unlike many other types of produce, are not grown in soil or manures, but in water which is safe enough to drink; grown indoors, under controlled sanitary conditions. When grown and treated properly, sprouts provide a fresh, safe, and abundant supply of proteins, minerals and vitamins. They are food that consumers wish to continue to see on their supermarket shelves, and there's no reason for them not to.

In conclusion, I would like to make a wish list.

First, ISGA would like national approval for the use of calcium hypochlorite on sprouting seed -- this is the seed sanitation method that I mentioned earlier -- so that all sprout growers can make their product safe for the consumer.

Second, warning labels on any fresh produce item, including sprouts, are not necessary. However, safe handling instructions should be included on sprout packaging, either on the packaging or on a separate folder, because most sprout packages tend to be pretty small -- which should be available to the consumer. These instructions should include such important items as "Keep refrigerated," or "Must be refrigerated," "Rinse before using," "Use by -- " sell date, and any other instructions

that scientifically make sense.

Third, ISGA requests that all agencies develop better and more accurate means of reporting the numbers of foodborne illnesses and deaths. We ask that they report real numbers, not estimates based on assumptions or models. According to an article in the Columbia Journalism Review, the numbers commonly cited state that between 6.5 million to 33 million people are sickened each year, and approximately 9,000 die each year from foodborne illnesses. These numbers are totally fictitious. They come from a report called "Foodborne Pathogens: Risks and Consequences," by Dr. Bennett. The article further states that 1,000 people die annually from trichinosis, a pork parasite. According to CDC, only one trichinosis death has been recorded in the past ten years. Bennett posits that 28 deaths per year from typhoid fever, which is carried by shellfish. The CDC recorded a total of 21 deaths over a ten-year period.

And, finally, ISGA thanks all of the agencies and universities which have contributed to its research. We are extremely grateful.

On October 5, ISGA, FDA, USDA, sprout growers and their suppliers will meet in Chicago at the National Center for Food Safety and Technology, Illinois' Institute of Technology. This task force will investigate solutions for sprout problems.

I challenges, and I urge, STOP and the Center for Science in the Public Interest, to drop their adversarial stance and join with us in a common endeavor to solve these problems. We need you. Your input would be especially valuable at the October 5th meeting.

I would also ask that all other produce associations join with us on that date, because solutions in sprouts could be extended to all and, besides that, we need your help, we need your support.

ISGA is very grateful for the help of ARS Philadelphia. Without your help and support, our industry would still be floundering.

ISGA thanks ARS Beltsville for its past support. You have given us many good ideas. Our industry is grateful.

ISGA urges Beltsville to reconsider its decision to remove all sprout research from its facility. We have two current projects in Beltsville. One is a post-harvest treatment of sprouting seeds for plant diseases, and the other is examining the use of ozone in sprout-growing water. We need these projects completed, and would appreciate the opportunity of continuing with ARS Beltsville in NCRETA, as was our past arrangement.

And, finally, ISGA needs the help of our Agriculture, FDA and CDC research institutes. We need free

access to the research data as it's accumulated. Our need for information is so acute we cannot wait for the final results to be published. This often takes up to a year. ISGA is not interested in publishing or patenting data. We simply need results so we can grow a better, safer product.

Thank you.

MS. OLIVER: Thank you, Nancy.

And now, Mr. Fred Fabre from Cal West Seed.

MR. FABRE: Thank you.

I have the unenviable job as responding here today as a seedsman. I represent a grower-owned seed marketing cooperative. We have about 650 seed growers in five western states. And one of the seed crops we produce is alfalfa seed.

I immediately kicked myself this morning for not having a slide presentation. After the stories of food poisoning victims and the slides that were shown there, I figure that even the glitziest slide presentation wouldn't have made me more comfortable here today.

Supplying seed to the sprouting industry is of little importance to me compared to understanding how sprouts can be safened. There are a few things that need to be fixed here, and I'm all ears. I'm here to discover, more than I am to defend.

My company was most involved in supplying the

sprouting industry in the late '70s through the early '90s. During that time, the seed my company sold was produced predominantly in California. Alfalfa seed growers are oftentimes young, diversified farms. Let's take a minute to put a face on some of these growers.

Most of them grow a number of crops; alfalfa seed is just one. They might grow the tomatoes you eat, the melons you enjoy; they're diversified farmers. The majority of our members are young, hardworking people with families, and growing alfalfa seed is one of the toughest crops to produce. So if we put a face on these people, they're diligent farmers trying to make a living off the land.

For a number of years, my company concentrated on three quality -- three main quality characteristics in alfalfa seed: mechanical purity, germination and cleanliness; cleanliness by visual inspection and an analysis of rinse-water.

Alfalfa seed for sprouting was simply the best of the best. We needed a large, large of individual straight lots to choose from, because so few lots met our quality criteria. As the industry evolved, many of our buyers -- who, by the way, always purchase on approval of sample -- began testing for molds, yeasts and funguses. In the past three to four years, testing has shifted to include E. coli and salmonella, of course. We have yet to find any positive

results on the seed we sell.

On the production side, alfalfa has moved away from areas where chemicals are used more heavily, to areas where the seed is dried in the sun before combining; so there's been a great shift in both the way people test seed, people pick individual lots for sprouting quality, and even the areas of the west where the alfalfa seed is grown.

Several people have asked, "Why can't you produce alfalfa seed specifically for sprouting?" Well, there's a very good answer for that. Alfalfa seed is one of the hardest crops to grow. In spite of the hard work of the growers, a crop can be lost because of wind, rain, extreme heat during the flowering of the plant. So our customers around the world realize that to put their seed needs on a contract production basis leaves them in a very dangerous situation, because they could, at harvest time, find that they have no seed suitable for sprouting the next year.

A contract production places too much risk on the sprouter. As opposed to this, most of our sprouting customers would rather have a huge inventory of individual lots to choose from.

Years back, maybe one lot in ten made sprouting quality, passed an individual company's quality standards and the standards of a sprouting customer. Now, nowhere that many lots make sprouting quality.

I believe that fresh, clean sprouts -- sprouts of any kind, alfalfa, broccoli, radish -- sprouts in general, are one of the most healthful and nutritious foods people can buy nowadays. But we do agree that some changes are required. Many sprout seed suppliers have, on their own, initiated an affidavit or attestation system, whereby the individual sprouter agrees and attests to -- in writing -- his willingness to sanitize the side. Before seed is shipped, the affidavit or attestation must be signed.

Many sprout seed suppliers have begun a labelling program, where each bag of seed carries both a product warning label and instructions to sanitize. I think that the use of national and regional seed associations to get the word out on this is an important tool to consider.

Like was mentioned this morning, Japan has drastically reduced the incidence of problem sprouts by adherence to strict quality guidelines and procedures to assure the healthfulness of their sprouting produce.

Like I said, as a sprouting seed supplier, I'm here to learn how to safen the product. Alfalfa seed growers are an important part of the farming community in the west, and we want to help and make sure that sprouts are a safer food product in the future.

Thank you.

MS. OLIVER: Thank you.

Next is Mr. Dan Caudill, from Caudill Seed Company.

MR. CAUDILL: Hi. I'm Dan Caudill. I'm the president of Caudill Seed Company out of Louisville, Kentucky.

Our company's been involved in the production of seed for planting and human consumptions purposes since 1947. So I speak a little bit from experience and practicality in the production of seeds and beans.

I'm supposed to tell you a little bit about the agricultural processes that are involved in growing sprouting seeds. These processes are nothing unique for alfalfa seed for sprouting purposes. These same processes are followed in the production of most seeds and beans used for human consumption purposes. And, basically, the seeds are planted in fields; fields ranging in size from 50 acres to square-mile sections, which are 660 acres.

These fields all have their unique eco-systems. These crops, as are our soybeans and our pinto beans and navy beans and other products for human consumption, are grown outside, in the elements and dirt. And each field has its own unique eco-system. Depending on the part of the world that you're in, they vary, but they're all fairly similar.

The soil in which the seeds grown in contain

microorganisms. They contain a variety of different creatures that live in the soils. There are insects int he fields; millions of insects; thousands of different types of insects that feed on the field or on the plant material. On the microorganisms in the field -- I think you all are getting the picture here. We've got a whole eco-system there.

There are reptiles that live the fields; snakes and frogs, lizards and other things, that also find a way to make a living in these fields.

There are animals that feed on the crops in the fields. The deer, raccoons, possums -- there are animals that feed on other animals that feed in the fields. There is a complete eco-system in this field.

Many of the animals and the birds and so on never leave the field. They live in the field, they're born in the field and they die in the field. And the decompose in the field.

This is the way I look at it -- okay? This is my perception, from an agricultural viewpoint, of what we're dealing with. And where I'm taking this talk is the fact that when you look at the whole process of how our seeds are grown, both for sprouting and human consumption beans, there is not a lot we are going to do to clean up the conditions in that field.

The water is used to irrigate these fields come out of rivers and open canals. There are aquatic eco-systems in each one of those canals and rivers. Sometimes we tap underground water sources and underground rivers and so on, and this is the same situation. You've got different types of aquatic life there.

When I took a look at this problem when it was originally presented to me by Dr. Slutsker and Dr. Mann when S. Stanley occurred, and I thought "How on earth can we grow sterile alfalfa seed?" It's just not very practical.

As Fred Fabre said, from Cal West, alfalfa seed is a very difficult crop to grow. It only takes a little bit of rain, or a little bit of wind to lose your crop. It "shatters" as we call it in agriculture, and the seed blows out on the ground. So we need to be able to select alfalfa seeds from a lot of different areas. If I got to southern California to produce alfalfa seed for sprouting purposes, and I plant 500 acres of seed, and we get a quarter inch of rain at the wrong time, we have no seed that is suitable for sprouting purposes.

We produce seed purely from the viewpoint of germination, purity and then, of course, we test for salmonella, E. coli, listeria and high coliform counts. In the tends of thousands of tests that we have performed in our company on all the different sprouting lots, we have yet

to find a positive for salmonella or E. coli.

Now, that's not to say they're not there, but when you take a look at the harvest from a 600 acre field at 500 pounds to the acre, that's 300,000 pounds of seed that was grown in that one field for -- quote -- a "sprouting lot" of seed. Somewhere in that seed could be 50 or 100 spores of salmonella or E. coli. And trying to find them -- well, the proverbial needle in a haystack is an understatement for what we're trying to do. But we feel an obligation to continue to test, to look for these pathogens on the seed.

Going on further with the harvesting of the seed, as with all beans for human consumption, we -- there are basically two techniques: direct combining, where we take large combines which basically have large rotaries on the front, 18 to 30 feet wide, and they run through the field at ground level to swab in everything in that field, everything on those plants, into that combine, ground it up, and then inside that combine are screens and vibrators which separate, by weight, the seed from the plant material, and whatever else has gone in that combine; which is then exhausted back onto the field, which biodegrades into fertilizer for next year's crop.

The seed that comes out of that combine is generally about 85 percent pure seed to a maximum of maybe 95 percent pure seed. The balance is dirt, plant material

and whatever else came out of that field in that seed.

The other method of harvest is, rather than defoliating with gramoxin, which is salt water, farmers will go in and cut the seed at ground level, lay the plants on the ground, and they rake the plants into what we call "windrows." And the windrows lay in the fields for three to five days while the sun dries the plans out, until we reduce the moisture content of the plants, and then we take our combines and we come in and we sweep up everything in the windrow. And whatever's in that windrow goes into that combine. Not very sanitary.

Anyway, so then, from there, once we've separated out the -- the seed is blown out of the combine into a farm truck, hauled to a processing facility, where we further separate the seed by screens, air and gravity, to a purity of about 99.5 percent or better. And up until a few years ago, we thought we did a great job getting seed to that purity.

That's the reality of growing alfalfa seed, and that is why we have focused -- our industry and companies such as mine -- on methods to sanitize the alfalfa seed after it is harvested. When you look at all the variables that are occurring in the environment, I think that's the only place that we're going to be able to attack this problem, especially if we're looking for a very few

pathogens somewhere in that seed.

Our company's been a part of a number of different research efforts, and these are some of the areas that we've worked on: ozone generators, to generate ozone and ozonated water and pre-soak the seed. We did not have good success or consistent success with that. Heat treatments, both through University of Georgia -- Dr. Beuchat's testing -- and so on, which was effective but a very small window. The problem about sanitizing seed is you have to sanitize the seed without destroying the germination of the seed, and this has turned into quite a trick.

Just to briefly run through these, we've tried ultra-violet. It was not a hundred percent successful. It did have an effect but not nearly enough. The heat treatments -- we tried dry heat, wet heat -- at temperatures of 145 degrees for five to ten minutes, would eliminate the bacteria, but the margin of heat and time is so small that we -- for adverse effects on germination. And if you pre-soak your seed two minutes too long, you've declined germination by 20 percent, which, of course, won't sprout. If you got to 155 degrees for five minutes, you reduce by 30 percent the germination of the seed.

These are the things that we -- so that process didn't work out so well for us on alfalfa seed.

We tried a variety of gases under vacuum. This is

a way that they sanitize spices and so on that enter the country. Ethylene oxide, propylene oxide -- add these gases in a vacuum and -- vacuum the air out and vacuum the gas in, and it does destroy all the bacteria. The problem is it adversely affects germination to such a large degree that we didn't think that it was practical to continue to follow those methods.

We tried microwave, but it created a lot of moisture in the seed by evaporating the moisture out of the inside of the seed to outside of the seed, and that adversely affected germination.

Dr. Beuchat's research -- sodium hypochlorite, hydrogen peroxide, ethanol, calcium hypochlorite as a pre-soak of the seed looks very promising, and it seems to be the most effective and practical solution to the problem. When we understand the problem -- and from the researchers and the epidemiologists and so on that have studied this problem, it appears that the problem is a seed-borne problem. These pathogens are entering the sprouting process on the seeds. Therefore, the problem is sanitizing the seed, and these outbreaks should dramatically reduce or go away. Of course, good GMPs are also advisable.

We've got some promising results with calcium hypochlorite; sodium hypochlorite was not a hundred percent effective, but 99.9 percent, I believe, effective. And

you've got to remember we're looking for just a very small number of pathogens in all likelihood that's on the outside of the seed. These tests were performed where we took seed and completely covered it with as much salmonella and E. coli that we could possibly put on the seed, and then tried to sterilize it.

So I really believe by implementing some of the solutions that the researchers have found, and getting them implemented in the sprouting arena, that we should be able to dramatically reduce or eliminate these outbreaks in the future.

Some of the other areas that look promising are irradiation, irradiation with electron irradiation, gamma irradiation, and there will soon be petitions coming to the FDA -- and we would appreciate anything that the FDA can do to speed up the process of approving these methods -- simply that this industry needs solutions, not next year but we need them now; chlorine dioxide we also have worked with; halazone, but none of these were a hundred percent effective.

Another promising treatment was hydrogen peroxide vapor, but from a financial standpoint, we didn't find it economically feasible, and it also was not a hundred percent effective.

MS. DeROEVER: Mr. Caudill, you have two minutes.

MR. CAUDILL: Well, I'm done. Thank you.

[Laughter.]

MS. OLIVER: Thanks, Dan.

Next we have a discussion on sprouting techniques, practices, and equipment, and Earl Hauserman from the Sholl Group will be up first, followed by Bob Rust from the International Specialty Supply.

xx DR. HAUSERMAN: Hi. If I could before I start, I wanted to clarify some of the things that Nancy Snider said and give you a little better sense of what the industry is.

There are about 350 sprouters out there. Green sprouts, meaning alfalfa sprouts, clover sprouts, radish sprouts, they amount to about $80 million a year in sales. We in this country consume approximately 125,000 to 150,000 pounds of alfalfa seed a month to grow sprouts. That equates to about five to six million four-ounce packages a month. Alfalfa accounts for about 75 to 80 percent of the green sprout market. The bean sprout market, which is the largest segment, is about $200 million in sales.

I mentioned there were 350 growers in this country, approximately 350. Of that, there's 20 to 30 growers that range between $1 million and $5 million in sales. There are about 100 growers that are in the $0.5 million to $1 million range. There are about 200 that are less than $0.5 million. These are family-owned businesses.

The alfalfa business started in the late 1960s as an outgrowth of the hippie generation, if you would, and many of the people that are growing alfalfa sprouts today started in that period of time. They've raised families doing this. They're very committed to the industry; they're very committed to the business.

The mung bean business, that goes back about a hundred years. I met a guy in San Francisco whose grandfather or great-grandfather--I can't remember which--was growing mung beans in San Francisco before the earthquake. We've been growing mung beans here for 200 years, some people say, or 100 years for sure.

From what we understand, about 7 to 10 percent of the people in the United States eat sprouts on a regular basis; some people say as low as 5. And that was probably be correct given the overall size of the marketplace. The numbers I've gotten are really numbers that I've gleaned from people that sell seeds and also people that are in the marketplace. For years I sold equipment, and for a number of years before that, I grew sprouts. So I've got some long history in the industry.

There's two principal methods to grow alfalfa sprouts or green sprouts, and one is with a rotary drum, and the other is in a rack system. And Bob Rust, who is going to follow me, has some pictures for you and is going to give

you a pretty good idea how you grow alfalfa sprouts and how you grow mung beans and how you wash them. I figured you only need to see that once.

I've got to say that sprouts can be the safest produce product in this country. They really can if you stop and think about it. You've got one source: a grower. He grows the sprouts, washes them, packs them; he delivers them to the marketplace--unlike lettuce that goes through a number of hands and is difficult to trace. But we need safe product. We need to start off with a safe seed.

You're going to hear tomorrow about irradiation. There's been a lot of conversation about calcium hypochlorite and the 20,000 parts per million. We know that works. We know that can have a measurable effect. But we need all your help to be able to get that through. We've got to have that approved and got to have it approved quickly. And Dr. Beuchat tomorrow is going to talk about the testing that he has, which indicates it's really very, very effective.

Long term, the industry, most of the industry, would like to see irradiation or some other way to clean the seed at the seed seller's location, followed by a step at the sprout grower's location, maybe chlorination or heat treatment; good GMPs and HACCP programs, and then something that Dr. Davis is going to talk about, which is ways to be

able to test the sprouts before they go to market.

And if we do all of those things, you will have the safest product. And the interesting thing is they're all available right now, and all we need is your help to get them implemented.

I'm going to yield the floor now to Bob, and then I'm going to take five minutes out of what I would do here now to ask German Regli to come up after Bob Rust and talk a little bit about this heat treatment process that Daisey in Japan has spent a lot of time and money developing. There was some feedback about it earlier today, and I thought you might want to have a brief overview.

Okay, Bob?

xx MR. RUST: Can you see that or do we need to turn some lights down? Focus?

[Pause.]

MR. RUST: I'm Bob Rust. I'm with International Specialty Supply. ISS is a 19-year-old company that has five divisions that are all related to commercial sprout production.

DR. HAUSERMAN: Microphone.

MR. RUST: Yes. I'm Bob Rust. I'm with ISS, which is a 19-year-old company that has five divisions all related to commercial sprout production. Our Prime Seed Division--is that in focus? Okay. Our Prime Seed Division

contracts the production of seed, tests the quality of sprouting seed, and sells it to commercial growers. Our Sentrex Equipment Division designs, manufactures, sells, and services commercial sprout equipment, and our Prime Packaging Division designs and sells show-pack (?) containers, labels, boxes, and all other packaging needed to run a commercial sprout business.

Our Sun Garden Sprout Division grows a variety of sprouts: alfalfa, onion, radish, clover, broccoli, bean sprouts and others. It also tests our seed and equipment and packaging that we sell to commercial sprout growers. We also have a lab to test seed, develop methodologies used in sprout production, and test the quality of sprouts for our own Sun Garden Sprout Company.

Now, there are two types of sprouts, and there's two types of equipment, as Earl mentioned. There's bean sprout equipment, which the sprouts are grown in the dark, and that would be your mung sprouts and your soy sprouts. And then there's green sprouts, which would be alfalfa, clover, mustard, onion, radish, sunflower, and other sprouts, and then there's your grasses, which would be barley, oats, rye, and wheat.

Both types of sprouts, though grown differently, go through a similar process. You wash the seed to remove the dirt and debris. You sterilize the seed using calcium

hypochlorite. You soak the seed to speed up the seed's ability to imbibe water. You grow the sprouts--excuse me. You grow the sprouts, harvest the sprouts to remove the seed hull, and package the sprouts for market.

Oops. Let's see where I am here.

Okay. The first type of sprout that I would like to talk about is bean sprout production. Now, the sprouts--of course, not all sprout growers have this equipment. This is just equipment that is available. The sprouts are grown in a bin like this that will hold 1,700 pounds of finished product. And, let's see, I think there's a pointer here. Okay. The water will--let's say you wanted to start, say, 20 bins, for example. You would come over here, press a button that says start 20 bins. Then enough water would come into the tank for enough seed for 20 bins. And then the seed would come in from the other room here. It's held in a hopper. It comes in and drops into the water.

Now, you put the water in there first so that when the seed drops in it won't crack. And so for the 20 bins, let's say there's 3,000 pounds of seed, and then it will automatically skim the top of the water to get off all of the sticks, dead seed, and debris. And then it will agitate the seed and wash it with a non-sudsing detergent to get rid of any dirt. That's to prepare it basically for the sterilization. Then it drains, gets rid of the soap, and

automatically adds calcium hypochlorite. Then it agitates the seed with the calcium hypochlorite for 30 minutes, and then it drains and refills, and then the seed soaks in the water, then is continually ozonated and agitated. So it's soaked generally for about four to eight hours. It's not only ozonated and agitated, but it's continually filtered the entire time that it's soaking.

Then you drain the water, and at this point your seed has soaked up water, and so it weighs a lot more than it started out. So the tank remembers that you started enough for 20 bins, and it weighs whatever is in the bin, divided it by 20, and then you put a bin under there and it will drop in 1/20 of whatever is in the tank.

Then you'll pick up the bin with a forklift, and you'll move it to a growing room. Now, the growing rooms generally hold from 4 to 48 bins. The server supplies the sprouts with water and sterilizing agents, and it keeps track of each bin individually, and it remembers when each bin was started, and it changes what it does depending on where the sprout is in the growth cycle.

Now, the Sentrex 2400 has a laterologic (?) controller that controls the server, so it regulates and keeps track of all the parameters needed to grow good-quality sprout, and it gives you a printout of a daily production report. The Sentrex Infinity is a PC-controlled

system, and it can control a lot more growing rooms and give more entailed recording.

Now, ozone is injected into the growing water. The reason that ozone is injected into the growing water is because it improves the quality of the sprouts. All of the time that we've been developing equipment, we have been doing it with in mind improving the quality of the sprouts. So I don't have any data on bacteria levels or anything like that, but I do know that the things that we do improve the quality of the sprouts.

The system is capable of adding sterilizing agents, and some typically used at various stages of growth are chlorine, hydrogen peroxide, and calcium.

The Encore water reclamation system is engineered to recycle the growing water. Now, the seeds have all the nutrients they need to produce a beautiful sprout, but most of those nutrients are washed down the drain each time the crop is watered. The purpose of the Encore is to kill the bacteria in the water without removing the nutrients. The water is filtered, sterilized, and re-used. You actually get a better-quality sprout and higher yields with the recycled water.

Then the sprouts are harvested in about five days. Now, this is a 48-bin growing room in which all the bins are harvested at one time. The sprouts are again lifted with a

forklift, electric forklift or pallet jack, and then transported to a harvest area. At the harvest area, the seeds are removed--or the seed hulls are removed.

Okay. The sprouts then are removed from the bins by tipping the bin over using a bin dumper. This saves labor, prevents back injury, and no one touches the product.

Now, there's two types of bean sprout harvesting equipment, and the purpose of the harvesting equipment is to remove the seed hull. There's the shaker table, which most people will use dry. Some people will use wet, but it's generally considered a dry machine. And then there is a wash tank, which is always wet.

Now, the shaker table--by the way, what you're looking at is just three different pictures of shaker tables here. The shaker table, the advantages of it are that it saves labor, saves water, and is a less expensive initial investment.

Now, a wash tank--what you're seeing here is the bin dumper dumping sprouts into a wash tank, and our engineers are just developing a system here. But the advantages of a wash tank are that the sprouts can be chilled. You put in cold water, as close to freezing as you can, and that will give them a longer shelf-life. Also in this tank, the sprouts can be chlorinated and ozonated and bathed in citric acid. That will give them a longer shelf-

life and a safer product. But you need to remove the water if you use a water bath-type system like this to give your sprouts a longer shelf-life.

The way that you remove the water is that you can spin the water out of the sprouts. Now, this would be something for smaller growers. Basically there's a bucket here. It's got a lot of holes in it. It spins, and the water flings out. Or there's an air knife, and that will--the advantage of an air knife really is it blows the water off the sprout and it reduces back injuries. And it also reduces labor by eliminating the centrifuging process.

The sprouts are either run through an automatic packaging machine or they're packed by hand and weighed. In this case, this is showing just a packing table. The packer rakes the sprouts into the corner there where there's a scale with a bag on it, and they rake it into the bag and the scale beeps when the bag is at its proper weight. And then you seal the bag and date-code it and then place it into a box.

Now, the most common types or sizes of boxes would be a five-pound and ten-pound, and then also a lot of people use an eight-ounce bag.

Now, the next type of sprout that I'd like to talk to you about is green sprouts, and that would be alfalfa sprouts, broccoli sprouts, clover sprouts, mustard, onion,

radish, sunflower, and the grasses.

The seed is washed, sterilized, and soaked using a similar process as the mung bean soaking system. The difference is that instead of putting the seed into bins, it's emptied onto a conveyor that leads to a seed spreader.

Now, another method of sterilizing seed that people use is to put calcium hypochlorite in a quad of a Rototech. They put the calcium hypochlorite right here, put the seed right here, dry; then they'll put a door on, and they will turn it--this thing rotates. They turn it on to fast so it will rotate at about two revolutions per minute, and the water pours through it, and so the concentrations of calcium hypochlorite are very strong in the beginning and go down--it takes about an hour. It depends on how much calcium hypochlorite you put in there. It takes about an hour for all of the calcium hypochlorite to work its way out.

This is just what it looks like when you close the door and it's rotating. It sort of coats the outside of the Rototech.

Now, you can add calcium hypochlorite for the first few watering cycles and hydrogen peroxide later to the sprouts if you want. The growers that do add hydrogen peroxide add at the rate of about 650 parts per million. Or you can inject ozone into the growing water at all times

after the soak. We don't ever mix any combination of chlorine, ozone, or hydrogen peroxide.

There are many ways to grow sprouts. Some growers grow sprouts in a Rototech to completion. This takes about three and a half days. Or they wash--then they wash their sprouts in a washing machine. The purpose, again, is to remove the seed hull, and the water needs to be ozonated in that also.

Okay. Other sprout growers will grow in a Rototech for two days and then transfer the sprouts to show-pack containers. The show-pack containers are designed for sprouts and have proper drainage. The containers are then placed on trays that have ridges to lift the cups above the tray so that the water then comes out of one cup--the water comes through the cups. They're going to put it onto a machine that does this. Right now they're just spreading, but the water will come through the cup and it will--

MS. DeROEVER: Mr. Rust, you have two minutes.

MR. RUST: Okay. It will go down the tray, and it will go under the other cups rather than through the cups. The reason for this is, of course, to prevent spoilage.

The trays of cups are then placed on a track system, and they grow in the track for two more days. The watering bar has an ultraviolet light that travels with it. Again, all the growing water is ozonated. The show-packs

are then placed on a conveyor. This is a conveyor here. This is some sprouts that have grown in the container. They don't have a lid on them yet. They're coming along here. The lids are up here. They fall onto this chute right here where it comes along under it, grabs the lid, and then tamps it down right there. Then from there they are labeled automatically just using an automatic labeling machine, and that's where the date-coding is done. And then they are placed in boxes and ready for shipment to the grocer, and they finally end up at the end user.

Thank you.

[Applause.]

MS. OLIVER: Dr. Regli?

xx DR. REGLI: Good afternoon. My name is German Regli. I'm from Daisey Machinery in Japan. And it has been mentioned today a few times we were working on finding a practical solution for seed sanitizing, and we'd like to present some results on that.

We are using heat treatment methods for sanitizing which has the following advantages: number one, it's easy and safe handling; number two, it's a natural method of sanitizing; and, number three, it's very effective to kill human pathogens on seedborne diseases; and, number four, a practical solution for everyday use in a sprouting factory.

We developed a fully automatic system for

pasteurizing seed which is successfully in use in Japan for several years. This system is patented in the USA. After the good results of mung beans, we have extended our research recently to alfalfa seeds.

In a recent paper, Dr. Jackert (ph) reported that alfalfa seed heat treatment was effective in killing Salmonella instantly, but it caused substantial germination reduction. But our tests and practical experience showed an insignificant reduction in germination on mung beans. We have tested a system using alfalfa seeds, and we determined temperature and time for disinfecting inoculated bacteria without reducing the viability of seeds much.

Seeds were inoculated with the coliforms Klebsiella, E. coli, Salmonella enteritidis, and Listeria. In this study, we aimed it at, in fact, inoculated bacteria on seeds for the following reasons: It is so that coliform originate in animals and possible ways of contamination with this bacteria of feces. We cannot find contaminated alfalfa seeds with pathogens naturally. The method of bacteria inoculation followed the report of Dr. Jackert.

Heat treatment of seeds. Five grams of inoculated seeds were put in Tetoron 80 mesh bags and dipped in 40-degree water for about 10 seconds, then drawn out and dipped again in hot water for exact treatment temperature for exact seconds. Immediately the bag was dipped in tap water of 24

degrees for about 10 seconds.

Effective heat treatments in killing Salmonella on alfalfa seeds. Please note that the initial population was very high. There was no reduction in population of Salmonella of the treatment in 40 degree, 75, 70 degree by 9 seconds was effective for eliminating this bacteria to 99.4 percent. Longer time treatments at 75, 70 degree were more effective, 99.99, 99.992 disinfection. Higher temperatures for 9 seconds were very effective. Treatment at 77 and 80 degrees for 9 seconds perfectly killed the population of Salmonella.

Almost the same results were obtained with Salmonella. Eighty degree for 9 seconds perfectly killed the population of E. coli. Presently, tests on Listeria are being done. We are expecting the same good results since the heat resistance is very similar to the previously mentioned bacteria.

Influence of heat treatment on germination and growth of alfalfa seeds. We counted the germination rate of the four days culture and the percentage of the sprouts growth of two days and four days of cultivation. Germination was reduced insignificant by heat treatment. Little reduction was observed in growth of the heat treatment of 75 degree by 20 and 30 seconds, 80 degree by 9 seconds, and 85 degree by 9 seconds.

Influence of heat treatment on yields. Batches of one kilo of alfalfa seeds were heat treated by using Daisey's heat treating system. Growth and yields were compared with non-treated seeds. Average of yield was almost the same or only a small reduction was observed, minus around 3 percent. The yield figure is without ungerminated seeds.

As a conclusion, the conditions for heat treatment as an effective and practical method to sanitize alfalfa seeds: number one, the water temperature, 75 to 85 degree depending on the bacterial contamination; number two, treatment time between 9 and 30 seconds, exactly equal contact time for each individual seed is very important; number three, it's a three-step cycle which includes preheating and washing, heat treatment and cooling as the (?) methods; number four, the contact of each individual seed in the hot water needs to be exactly the same; and, number five, using ozonized water or chlorine in the cooling stage can be a further advantage.

At the moment, a fully automatic system for alfalfa seeds using both methods is under development, and it will be on the market in the near future. Please note that we have recently started tests on results with alfalfa seeds, and more tests are required, so especially practical test before we can actually launch the system as it is.

At a later stage, after 5 o'clock, we have a video with us which shows actually the system in operation and gives a little bit more information about the conditions in the Japanese bean sprout factory.

Thank you very much.

MS. OLIVER: Thank you.

Next we're going to talk about the practical implementation of food safety programs in sprout operations, and Dr. Art Davis from the Sholl Group will present that.

xx DR. DAVIS: Good afternoon. Is this thing on? I guess it is. Good.

I'd like to express my appreciation for being invited here to discuss some of the things we've run into as we've worked our way into the sprout industry. My name is Art Davis. I'm the Operations Vice President of an entity called the Sholl Group. Our entry into the sprout industry was about a year and a half ago when we were contacted--our background is in the fresh produce industry, and we were contacted by Brassica Protection Products Group from Johns Hopkins University with regard to commercializing their discoveries in the area of broccoli sprouts. And with that, we--and in this case, mostly myself--got involved in looking at the sprout industry, how we could get into it and provide a series of products based around the broccoli sprout that would, first of all, of course, provide safe food products;

second, we're interested in the quality of the food products both from the organoleptic standpoint and also in the quality assurance area of making sure we had the right amounts of the chemicals of interest from the Hopkins patent; and third was to provide a system of national coverage to make the product a viable system.

For operational goals, after reviewing the available literature and talking to people who were knowledgeable in the sprout industry, it became clear that the first thing we had to have was clean seed. Obviously, probably not all but certainly a majority of the issues with regard to food safety in sprouts seemed to originate with the seed.

The second one was to provide a clean environment. A survey of sprouters showed a rather wide distribution of environments for sprouting seed. Those two we came on pretty early in the game.

The third one, the preharvest testing, is much more recent. We really got seriously started on this one probably three months ago, although the initial suggestion from one of my favorite microbiologists a few months before that was, gee, you've got the perfect sampling system here in this drum, you're running water through your product, why don't you see what's in the water. Well, I'm a little slow some days. It took a few months to sink in. But we started

looking at this a few months ago, a couple months ago, and I think you'll find the results very interesting when we get to them.

The next one?

Currently, with regard to clean see--and by currently, I mean right now as we're putting this network together and trying to produce sprouts--chlorine is where we're at. All we're arguing about is the amount. Currently, I believe 2,000 parts per million is generally accepted, with the exception of California, which has recently approved 20,000 parts per million, however only for alfalfa. One of the early things we did in our Brassica sprout group program was eliminate alfalfa. So we're still working on getting that in the other sprouts.

So I think chlorine is where it's at and will be for the near future, although there are certainly other things on the horizon.

We also looked at a number of other sanitizing agents, many of which have been reviewed here this morning, and found that, alone, none of them seemed to quite match chlorine. However, we do have one lab group, commercial group that was interested in pursuing this a little further, working with us on the possibilities for synergy between different sanitizing agents done sequentially. Obviously you don't mix chlorine with a lot of these others things,

but is there any hope for doing it sequentially, and we're looking at that. I don't think that's a real high odds chance, but it's worth looking at.

The third one, of course--and I believe Dan Caudill brought this up, and his company has been kind of in the forefront, as far as I can tell, of pursuing this--is irradiation of seed. I think there's a number of social issues involved in that, but from a safety standpoint, I think there's pretty good data that says it works. There's a petition, I believe, if not prepared, at least in preparation, and I certainly hope it can be pushed through quickly because it comes as close to providing a sanitized or almost sterile seed quickly as anything I've seen to date. And it would certainly be something we would pursue.

Next?

From a clean environment standpoint, when we went out and started working with sprouters, I think it's safe to say GMPs as a formal documented system were not common. Many of these sprouters were doing a lot of the individual acts that we associate with GMPs, but to see it as an organized system where you kept documents to say that--organized in such a fashion that it was clear that you knew what you were doing, you did it every day, and you can prove that you did it last Thursday. That's kind of the presentation we use.

So we were putting GMPs into effect, and we provided each one with a copy of the CFR GMPs. I also provided them with a booklet from one of the nationally recognized third-party audit groups that I've found useful as sort of an operational application of GMPs.

We also set them up with a microbial testing protocol for their environment. This is a testing protocol which involves composite swapping weekly of various areas throughout the production facility to make sure that we're not harboring pathogens where we don't want them. This is for Salmonella, Listeria, and E. coli.

We also have a microbiological testing protocol that's done to check for cleaning efficacy. Initially, most people are starting out with a surface swab for just total plate counts on product contact surfaces taken immediately prior to the start of production. We are encouraging and, in fact, have at least one and I believe two of our producers using bioluminescent testing, which I think is a very good way for them to go, mostly because of the immediacy of results.

Our other handle on the clean environment is a third-party audit by a nationally recognized third-party audit group. This gives us one more set of eyes in the plant, a fairly uniform set of standards that they're graded against, and a somewhat uniform overall view from an outside

party of what's going on in our different sprouters. And it gives us a method of comparison and gives them something to work against in terms of a numerical score.

Now, the interesting one that's most recent is our preharvest testing. The idea of this testing of the irrigation water, we thought about it for a while and then went to--Pillsbury does contract testing. They have a contract lab, and in their laboratories we've set up a group of small, at this point, simulated sprouting drums with intermittent irrigation and the whole works. And we started with some contaminated seed, and you can throw the next one up there. This is hot out of the lab. This was handed to me last Thursday, and I'll also present some data that I got over the phone this morning.

Our first organism of interest is Listeria monocytogenes, and at the top are the contamination levels that we started with in terms of colony-forming units per gram on the seed and the sprout. The water you'll notice is asterisked because it's a six-hour enrichment of one milliliter of the water. The idea was we wanted to be sure we found it if it was there. And that's why the times zero number and water numbers are a little high. That's because it's been enriched.

But you'll notice that even after 24 hours on both the water and the sprouts, the numbers are well above

10,000. And what we're thinking is initially, based on Dr. Beuchat's work, it looked like about the third day. We're beginning to think that maybe if this works out, we can do our testing on the second day, which provides some operational efficiencies.

Next Monday, on the 5th, at the consortium meeting that Nancy Snider was talking about, I'll be talking to those people about working with their drums that they have, full-sized drums they're going to be putting in the containment lab, working on a project with them to, in effect, confirm this data. And if it is confirmed, we will be using it.

Incidentally, we've also gone--I'll have to just do this from a piece of paper because I just got the information. We've also completed the tests on Salmonella for broccoli and clover, and I'll just give you the initial inoculation numbers. On broccoli, it was 20 CFU; on clover, it was 10. And this is two different Salmonella typhimurium--I can never pronounce that right--cultures and one Salmonella enteritidis. After 24 hours in the water, we had 7.9 times 10^3 and 4.8 times 10^3 for Salmonella; 4.1 and 6.8 times 10^3 for clover; and on the sprouts at 24 hours, we had 3.1 times 10^4, 4.8 times 10^4 on Salmonella, 8.5 times 10^3, 1.1 times 10^4 on clover; and in the 48, 72, and 96 hours, it just continued on up. So we're very hopeful that

this will transfer out into or be confirmed in the full-size drums and that we can use this to back up our various sanitation programs.

Thank you very much.

MS. OLIVER: Thanks, Art.

Next, John Farquhar from the Food Marketing Institute will talk about purchasing guidelines and specifications.

xx MR. FARQUHAR: I thought what I would do is to run you down the sequence of how we notify the industry first, the retail industry. Normally, upon a recall or a concern about a product, we go out with what we call a Food Safety Brief, which essentially blankets about 80 percent of the industry. And this essentially sets down the essence of the problem, any solutions, some instructions in regard to controlling the product. If it's a real concern about foodborne disease, we normally suggest the product be put in a predesignated area before the--well, put in a predesignated area for the regulatory people to come down and take a look at it.

Next slide?

Now, in the case of the recent notification on the sprouts, we began to advise our retailers in regard to make sure that they were purchasing sprouts from a reliable source, and actually, the majority of what I'm going to talk

about today is the complexities from a trade association standpoint in actually doing this action.

The other thing that we wanted to advise them was to develop and implement GMPs for handling sprouts, including temperature control, as you would for potentially hazardous foods, and in the case of the National Food Code, the FDA Food Code, this would be to minimize the occurrence above 41 degrees Fahrenheit. So this would mean that any sprouts that were displayed in the supermarket would be immediately considered potentially hazardous and brought over in that section of the supermarket.

Finally, to separate the sprouts from other products to prevent potential cross-contamination. This is, again, vis-a-vis the Food Code, and in some cases I have to admit that there was potential for cross-contamination.

Now, let's talk about FMI and let's talk about where we're going in the whole area of procurement of products and developing stringent buyer specifications.

I must start out by saying that, in the first place, a trade association cannot develop a buyer specification, and this is due to the Robinson-Patman Act of the antitrust regulation; where you would get behind closed doors and design a specification that could possibly put somebody out of business is deemed a no-no by antitrust. So what does a trade association do to inform its members to

bring them up to speed in regard to minimizing their risks and liability?

Well, what we are doing now--and it's interesting--we are working to develop a number of questionnaires, and I'll walk you through some of these questionnaires as fast as I can. I realize I've got about 15 minutes here. But we have general questions that we're suggesting the retailer ask his supplier, and these are categorized by whether or not the product is deemed potentially hazardous or not. Obviously, it's a much stickier wicket if you have potentially hazardous foods coming into a retail food store; therefore, the questions are much more pertinent, particularly as it relates to HACCP, GMPs, routine microbiological testing, this type of thing.

So we look at it from the standpoint of a general questionnaire, but then to go one step beyond that, we have designed questions now specific to certain food groups: meat and poultry, dairy products, seafood, produce, whatever the case may be. And, obviously, when the hammer comes down on something like alfalfa sprouts, it falls into the category of produce under the general questionnaires, and we take a hard look in regard to what are the recommendations from Food and Drug and are these appropriate questions to ask the supplier.

Next slide?

So put yourself in a chair being the supplier of a product to a national chain, for example, like Safeway or Winn-Dixie. And the first category that we want to take a look at is what type of internal controls and standard operating procedures, essentially what do you have in place. And we look at Hazardous Analysis Critical Control Points. Obviously, in the area of seafood, this is a required--it's a mandate. But what are your sanitation standards? We are very interested in regard do you do daily sanitation tours on your operation; is there a record, a dated record of this, this type of thing. Also, we take a hard look at good manufacturing practices and any other control programs, again, like microbiological testing, whatever.

Next slide, please.

Now, again, you've got to look at this from the standpoint of it's a generic series of questions, and this particular overhead has to do with implementation of controls and training. For example, it's now almost a mandatory requirement for a retail food store to have mandatory food handler certification. The same would apply to a vendor or a supplier in regard to--particularly in regard to a prepared food, a food that falls into the category of meal replacement. These are normally foods that are considered potentially hazardous. They're in the chill temperature range, therefore very susceptible to temperature

abuse.

So what you're coming at them in this particular area is to ask questions of that supplier again. Are their employees trained in specific areas, and in supervisory management, food safety training as well? Those could be, for example, the HACCP program implemented by National Marine Fisheries or FDA or some of those type of things.

Next slide, please.

Now, this particular overhead relates really to HACCP, and we want to home in on some of the specific types of testing that may be going on. And this, again, relates to a specific food category. All of the questions are not always the same. It depends on what you're trying to find out about a particular commodity or line of product or whatever. And we also are very concerned about corrective actions. This relates really back to the HACCP program on ground beef. If we see extreme temperature abuse, are there corrective actions that you can take, cooking the product or whatever?

Next slide, please.

When we set these programs up, we're very interested in regard to whether or not they have outside consultation. Do they have a third party that's coming in, like the National Sanitation Institute, or something like that? We are very interested in regard to their track

record on regulatory inspections. This relates to city inspections, it could relate to state inspections, and in some cases, government inspections. Again, these are questions that are asked. Many of our suppliers of prepared foods, foods that go from, for example, a commissary directly into a retail food store are, as a matter of fact, looked at by third-party audits, inspections, this type of thing.

Let me have the next slide, please.

Okay. This essentially is a real concern, asking questions about the flow of the product from that approved source down through the distribution chain and receiving at the retail food store. Much of this has been taken from what we've learned now from the U.S. Food and Drug's seafood inspection program where we have developed HACCP programs in some cases all the way down to the retail food store. We are really interested in this. We want to know are they using, for example, time/temperature loggers where we can actually see a graphic display of what kind of experience or what kind of history that product's experiencing.

Next slide, please.

This really gets into what I just mentioned, transportation, storage after transportation. This is really a very important aspect, as you know, in regard to these products that are in the chilled range, again, that go

directly in the mouth. The only barrier that they have for rapid microbiological growth is temperature, so we are leaning heavily on working with--well, we're doing a project with the University of Florida, Steve Autwell, on fish, for example; Dr. Leek at the University of Florida on ground beef. We implemented this program on Guatemala on the fresh raspberries, or will be implementing it, to name a few examples.

Next slide, please.

This is another very interesting area. We are now getting into categorizing consumer complaints in retail food stores, primarily to see if there are trends there. Are there like kind of situations where we have a rash of complaints, possible foodborne outbreak, this type of thing. We also are very concerned with recalls. How does this vendor or supplier handle recalls? It even gets into their liability insurance in regard to can they actually afford to conduct a recall program and other related activities. And as you know, FMI has developed a very sophisticated recall system, and we are currently looking into the area of developing sort of a trace-back system, if you will, on customer complaints.

Is that the last slide? Okay. Well, I made it. Fifteen minutes is short.

I have to admit that this project, whenever you're

working with legal people, it takes time. We're about halfway through this project, but I would certainly share what I can with anybody that would like to contact me at FMI.

Thank you very much.

MS. OLIVER: Thanks, John.

Next, we're going to hear about organic standards from Ms. Katherine DiMatteo of the Organic Trade Association.

xx MS. DiMATTEO: Thank you. I appreciate the opportunity to be here addressing this group of people about organic standards. The Organic Trade Association represents 850 businesses that range from themselves to processors and packers, retailers, distributors, brokers, importers, the full range of what could be done with agricultural commodities and products.

Organic is about an agricultural production system, and it is a system. There are no parts of it that exist in absence of other considerations, and organic also refers to things that are not food products, because anything that can be grown can be grown organically and, therefore, there are products that also can be produced which are not edible. They would be fibers, for instance, organic cotton, and we can use that first overhead.

These are the basic principles of organic

agriculture: to replenish and maintain long-term soil fertility and provide optimal conditions for soil biological activity; to work with natural systems rather than seeking to dominate them; to reduce pollution that may result from farming; to work as much as possible within a closed system with regard to organic matter and recycled nutrients; to maintain genetic diversity of the agricultural system and its surrounding, including the protection of plant and wildlife habitats; to sustain the land in healthy conditions from future generations.

So looking at that list of principles, you can see that our concerns are based with the system of agriculture and what happens in the environment and in the land, in the practices surrounding farming. We are not exempt from concerns about microbiological contamination of pathogens. For those of us that are in the food part of our industry, this has to be a high priority, and we have to take into consideration those standards that are developed by other food safety bodies and government regulation and see if we can fit it into the system of organic principles that we have.

Now, organic agriculture, as this shows, did start with the farming part of the system, but has extended to include the handling and the processing. It makes it a little difficult when you move away from these basic

principles to talk about soil biological activity and genetic diversity, and when you try to incorporate those same kinds of principles when you talk about processing or packaging or handling, you start to move a little bit away from the principles. But, basically, the Organic Foods Production Act of 1990, which many of you are aware of was passed by the Congress as part of the farm bill that year, said that basically no synthetics are allowed in organic; and that organic does extent beyond the farming practice into the handling practice; and that if any synthetics are allowed in the production system, they have to be approved--recommended by the National Organic Standards Board, submitted for public comment by the Secretary of Agriculture, and also must meet specific criteria about human health and environmental conditions.

So we can't just willy-nilly start deciding what we're going to use in agricultural production for organic, and some new methods and materials would have to go through a screening process.

I guess there's a myth I would like to put to bed right now, and that is that organic isn't about opposing new technologies and methods. We certainly want to explore with the rest of the food and agriculture communities what can work effectively to meet our set of principles and the legislation that we're obligated under.

The next overhead, please.

This is just a summary of the current state system of organic legislation. The industry back in 1988 and 1989 did petition the U.S. Government for this Organic Foods Production Act because even by that time, as a very small industry in agriculture, we were seeing that our voluntary set of standards and systems was very hard to regulate, that there were assumptions made by consumers and other producers about what it meant when you were purchasing organic products, and also that there was a variety of state programs that were coming into being and they all differed from each other quite a bit, from those states that actually run a certification program for organic production to those states who have no laws at all concerning organic agriculture.

The states kind of in the middle with some legislation or ones that have a registration system or use an independent accreditation body, generally, if you look at those rules, they have to do, again, with what are the practices that happen on the farmer and the processing plant, what toxic chemicals are used in that process of growing and processing and transporting goods to the market. So the emphasis, again, has been on what are the methods and materials, what is the long-term environmental impact, and that's been the basis of our decisions.

So, the next overhead.

The purposes of the act were to establish these national standards to assure the consumers that they were getting a product that was grown to these standards and to facilitate interstate commerce.

The next overhead, please.

One of the major components of the federal regulation and also the industry's self-regulating system is the fact that we have to provide for annual on-site inspections by the certifying agents of each farm and each handling operation, require periodic residue testing--again, you can see in the basic requirements of the act and in the basic requirements of the industry, the residue testing of the types of insecticides, herbicides, and fertilizers that were used were our primary concern. Again, this law was written in 1990, and as things have emerged during the 1990s, we will have to be making adjustments with the Federal Government to this program to protect against conflict of interest and provide public access to certification documents and laboratory analysis.

There is an open access part of our industry. We've always felt that this was about choice in the marketplace, it was about choice in your farming system, choice in your processing system, and that to create such a system called organic and to get it regulated, it would also

require that you would have access to the information. The industry itself and some of the states, as I've said before, do require certification. Those are done by state programs and independent third-party certification agents under the federal law, whenever it is implemented, will require that those certification agents are approved by the Federal Government. The state programs, even under the federal law, may be able to add additional requirements.

The next overhead, please.

I think I've covered most of this, that without the use of synthetic chemicals, again, the major point in that legislation, that the last use of chemicals--again, you can see the references to land use, and then to be produced and handled with an organic plan. And I think this was one of the main points I wanted to make was that the whole system of organic agriculture and its products are based on planning. You have to have a farm plan. You have to have a handling plan. The written plan itself is approved. Someone goes out and verifies that your plan is actually in effect. You have to have an audit trail. You have to have documentation. At the beginning and the end of the year, you know, these things would be turned into your certification agent. So there is a lot of oversight; there's a lot of systems approach.

The idea of HACCP we extend to organic practices,

organic critical control points, and in using this kind of system, many people have come to understand what HACCP means and have also begun to apply those systems and good manufacturing practices to make sure that they can meet not only the organic regulations but the state and local regulations that are required of them for sanitation and other food regulations.

Next overhead, please.

I would just want to point out about the farm plans. Again, you can see it's about soil fertility. We talk a lot about manuring in relation to soil fertility, and, again, I would like to put another myth aside, that organic does not only use manure. In fact, we probably don't use manure any more than anybody else, and we do have a restriction on the use of raw manure in our legislation, the national legislation, in our individual certification standards, in our industry standards, and in the state standards. And it's, again, crops for human consumption, very serious oversight over how raw manure is being used.

The next overhead, please.

Again, here I just wanted to point out that handlers, again, are restricted in terms of what synthetic ingredients they can use during the processing or post-harvest procedures. Again, you can see nitrates, toxic residues, and heavy metals are things that we're going to be

testing and looking for, and that there are going to be issues around water. Again, water has to meet the safe drinking water requirements if it's going to be used in organic processing or sanitation.

This brings me to--that's the end of my overheads, I believe, and this brings me to how does this apply to sprout standards. Well, looking at all of that and thinking if you were a sprout producer, you'd have to take all those pieces of what we have in organic that are both limitations and opportunities, and apply them to your system.

So if I could have the lights up a little bit? As I get older, I can't read the page very well.

There are a number of considerations that you would have to verify and write out in your application process for certification, that is, where did you get the seed. Under organic standards, the seed must be grown and harvested and cleaned and processed according to the organic standards for processing. So that seed must also be certified organic. So all the things that apply to the farming practices part of the organic regulation would have to apply to the seed. So your source of your seed would be well documented. There would be an audit trail for it, and sanitation would be a high priority in prewashing and storage, so there would be no pest or volatile residues in your storage and preharvest practices.

The water that you would use, again, would be drinking water quality. It would have to meet all state and local standards. Well water would have to be tested, or you would have to submit a copy of the municipal water test. And some certification organizations are now adding an annual test for E. coli and Salmonella to their list of water, and that has to do with your irrigation water for your planting and then also the water that is going to be used in the processing and cleaning.

In processing, again, you would have to conform to local, state, and federal health codes. Those would all have to be part of your plan. You have to show that, indeed, you're doing that as well as meeting the organic requirements, which limit the types of sanitizers--

MS. DeROEVER: Ms. DiMatteo, you have two minutes.

MS. DiMATTEO: Thank you. --which limits the types of sanitizers that you can use.

If you do have to use because of state, federal, and local regulations a chemical material that would normally not be allowed in organic production, the recommendation is that you have a double rinse with clean water each time on any surfaces or equipment or materials that you're using. And that would in the sprout case be the sprout.

Chlorine use is allowed for soaking sprouts, but

we expect that it is rinsed down so that the residual would not exceed the maximum levels for safe drinking water, which is 4 parts per million. That is also the recommendation that was given to the Secretary of Agriculture by the National Organic Standards Board.

So we do allow sodium hypochlorite. We do allow hydrogen peroxide. We have problems with calcium hypochlorite because that's not food-based at all, a chemical. There are problems with that both in how it affects water--you would not have safe drinking water after, you know, using calcium hypochlorite. Gaseous fumes, harmful to workers. It's a synthetic biocide which degrades into a carcinogen, and there are some concerns that I would raise at this point in time about the effectiveness not as people are saying in terms of reducing the pathogens, but what effect would that have on persons with high risk. If persons at high risk are susceptible to pathogen contamination which is showing up in small quantities, would they not have some sensitivity to high levels of calcium--

MS. DeROEVER: Ms. DiMatteo, your time is up.

MS. DiMATTEO: --hypochlorite. But we are very anxious and willing to look at all of the studies that are coming out about hydrogen peroxide, heat treatment, ozonization of water, et cetera, to see where we can cross over with our organic regulations and public health and

safety.

Thank you.

MS. OLIVER: Thanks very much.

Jeff, since we're running a little ahead of time, would you like to give your presentation now?

xx DR. FARRAR: Sure.

MS. OLIVER: Okay. Next, Jeff Farrar from the California Department of Health will talk about voluntary guidelines.

DR. FARRAR: Good thing I went to the bathroom first, huh?

I want to thank everyone for the opportunity to be here to share some of our experience in California. We think we have some insight through some of our successes and some of our failures that we all can learn from here today.

Can someone adjust that for me, please? It may not be--here we go.

Beginning in 1996, following a major sprout-associated outbreak of salmonellosis, Salmonella montevideo and Salmonella meleagridis, that you've heard several people talk about today, affecting well over 650 individuals in California, we along with the U.S. FDA in California called an industry meeting to express our concerns to the sprout industry about what we had seen within the sprout industry and our concern about the potential for ongoing outbreaks.

We held both an educational session and an informative session, if you will, to try and expose sprouters to some of the basics in microbiology and food safety and some of the interventions that we knew at that time that we hoped would work.

As an outgrowth of this initial meeting in 1996, a California Sprout Working Group was formed. This working group consisted of large sprouters, small sprouters, state regulators and federal regulators, and academicians from the University of California. Our goal, our charge, was to develop a basic set of minimum guidelines for the sprouters in California to follow.

Based upon what we had seen in our investigations and our brief exposure to the sprout industry at that time, we recognized that the imposition of a HACCP program to this industry was not feasible at that point in time. We needed to go forward with a basic set of guidelines, very basic, bring the industry up to that level, and then proceed with a HACCP-type approach.

Voluntary guidelines were developed after a series of meetings with the California Sprout Working Group and distributed to sprout growers that we were aware of in 1997, early 1997, I believe. As part of this meeting with the Sprout Working Group, we asked these representatives, the sprout grower representatives, to give us input for a

planned statewide survey of sprout growers to establish a baseline for the industry. What are the current practices in the industry? In order to assess progress down the road, we had to know where we stood today. So we received that input and from that developed a questionnaire consisting of several broad areas and went forth with the assignment with the help of the U.S. Food and Drug Administration and our state investigator staff and surveyed the sprout grower population in California.

We identified sprout growers with the help of our county health departments, county health inspectors, who on a daily basis are in retail facilities throughout the state. We asked for written--we developed a questionnaire for them. When in the course of their routine inspections, they found a package or a container of sprouts, we asked them to write down the information on the label so we could add that company to our database and include them in our survey. The final numbers that we arrived at were somewhere between 45 and 50 sprout growers in California.

Sorry. Let me go back just a little bit.

The voluntary guidelines that were distributed to the sprout growers in California were very basic, as I said, and consisted of several general areas, including seed receipt, seed storage, water quality, worker hygiene, sanitation, and record keeping.

As I said, we identified approximately 45 to 50 sprout growers in California. They tended to reside or be located in the major metropolitan areas that you can see, the Bay area, Sacramento, L.A., and San Diego, a few sprouters throughout the valley, and a couple up north.

Some very basic results from the survey, we have a whole report of results put together, if you're interested let us know. We found that less than half of the firms that we surveyed were registered with the state as food processors, as they are required to be. Three-fourths of them do sell only within the State of California. Some of the firms sell direct to consumers, but most sell primarily to wholesalers, distributors, or point-of-service establishments. And less than half had refrigerated trucks.

This graph I think is quite telling of what we saw during our statewide survey. We asked the investigators in the course of this assessment, inspection, survey, to subjectively rate the facility, subjectively score the facility on a scale of 1 to 10, 1 being the lowest, 10 being the highest. What we see is that the majority of the facilities scored a 5 or less in our survey.

Now, I did not bring all our slides, very graphic slides from what we saw in these surveys. But suffice it to say that there were numerous serious concerns in the sprouters that we saw. We've taken enforcement actions on

several of these sprouters. Two, as a result of our inspections, have gone out of business. An additional sprouter went out of business after a recent outbreak. Those enforcement actions will continue until we get complete compliance with GMPs.

After our survey, as we promised the industry early on, we returned with the results of our survey to share with the industry. We held two regional meetings in early August, one in northern California and one in southern California, to provide the graphic slides and the very detailed results of our survey. I think from those meetings it was apparent to all growers present that indeed there were significant concerns right in our own state, as there are in each of your states.

The question that resulted from that meeting that we all needed to answer was: How do we improve the safety of sprouts? We suggested a list of immediate short-term actions that had to take place for us to proceed. Those included: registering with the Department of Health Services Food and Drug Branch as food processors; complete and absolute GMP compliance, no debate, no discussion about farms versus processors, had to comply with GMPs; sprout-specific food safety training, which I'll talk a little bit more about, needed to take place, not generic food safety training about how to develop a HACCP program, but what do

sprouters need to do specifically in your operations tomorrow.

We assured the industry that the California Department of Health Services was going to be in their facilities on a very frequent basis until we achieved full GMP compliance. Also, at about that same time, U.S. FDA issued their project for a survey nationwide of sprouters in the U.S., and I think approximately ten sprouters in California were selected for that nationwide inspection survey.

Other immediate actions: With the suggestion from the sprouters, sprout growers, with the, granted, slim data that we had available at the time, we proceeded with an emergency request for short-term approval of the use of 20,000 parts per million calcium hypochlorite on alfalfa seeds. We worked closely with CalEPA, their Department of Pesticide Registration, and achieved that emergency approval called a Special Local Needs Approval. I think it's a Section 24(c), for those of you that are interested. We received that approximately two to three weeks ago. And we committed to the industry to come back and do another survey at some point in the near future to see what changes had been incorporated. Those were the immediate steps that we were asking for.

At those meetings, we also presented a challenge

to our sprout growers. We asked them to come up with a proposal within 30 days of how they were going to assist in making sprouts a safer product. We asked that that proposal include consideration of such items as immediate and continued funding of research in the areas of pathogen-free seed sources and additional barriers or hurdles in the process of sprouting.

Just FYI, we have recently received that proposal from the sprout industry in California. We're in the process of discussions with them. We'd like some more specifics on that proposal. Hopefully, that will be completed in the next week or so.

We talked about education and training. Last year, AB-1559 gave us some limited funding for food safety training. We established a blue ribbon panel, including NFPA and other food industry members, to help us prioritize how those funds should be spent. Almost to the individual, everyone on the blue ribbon panel agreed that sprouters should be our first priority, along with spring mix lettuce processors.

We have developed, are in the process of developing two regional trainings for sprout growers in California. Those should be presented in November of this year. Very sprout-specific food safety training.

As you're all aware, in September of this year, we

issued a press release stating our concerns about high-risk individuals and their exposure to sprouts. We coordinated our efforts with U.S. Food and Drug Administration, and at the same time they issued their talk paper.

Another approach that we think has a lot of merit within our state is working with the California Grocers Association and California Restaurant Association. We recently had a meeting together with representatives from International Sprout Growers Association to relay our concerns about the safety of sprouts and what measures might be put in place or what guidelines grocers and restaurateurs could observe from their sprout providers. These have yet to be finalized, but we discussed several items, such as visiting the grower, either having their produce buyers or a third-party individual that they have confidence in to go on site. You can tell from the label what you're getting. We believe that seed disinfection is paramount. The restaurants and grocers should be buying only from those sprout growers that are disinfecting their seeds.

Sprout growers should have written SOPs and SSOPs, have the basics. That's what we're talking about, a documented pest control program, employee training records, written product recall, and so forth. You've heard that from several speakers today. These are not technologically complex things. These are things that people can do today

and should have in each of your sprout growing facilities.

So, with that, I'll stop and say that, in summary, from California we have a very diverse group of hard-working, very independent sprout growers, diverse in terms of size--not only in terms of size, type of operations, type of sprouts grown, willingness to make immediate changes, and participation in statewide or national organizational efforts to change the industry. We have the whole spectrum.

Voluntary guidance in California, I'd have to say personally that I don't believe voluntary guidance has been a success over the last two years in California. State and federal agencies have been driving for the last two years the industry to embrace these concepts. However, industry is now beginning--beginning--to take a proactive role in this. We hope that will provide more positive changes in the area of voluntary guidance.

As we all know, regulation can be very time-consuming. For the short term, our approach will include emphasis on increased inspections and education of sprout growers in California.

Thank you.

MS. OLIVER: Thanks, Jeff.

We'll take a 15-minute break now and come back at about 3:30. What I'd like to do then is ask the people that were up here this afternoon and speaking if they would come

up and sit at the side tables, and we'll take questions from the panel and working group then.

[Recess.]

xx MS. OLIVER: I'd ask those who spoke this afternoon to come up and sit at the side tables: Mr. Fabre, Mr. Caudill, Nancy Snider, Earl Hauserman, Bob Rust, Art Davis, John Farquhar, Kathy's here, Jeff is up there. And other members of the working group I think will still be coming in.

What this is, we have approximately an hour and 15 minutes for questions of clarification for all the presentations this afternoon, and to refresh your memory, we went through agricultural practices, talking about the seeds, talking about the growing of the seeds; dealt with organics, talked about the makeup of the sprout industry; went into California's discussion on the voluntary guidelines and their survey that they did with FDA; talked a little bit about purchasing guidelines and specifications and about practical implementation of food safety programs. We also had a short presentation on the research on heat on the treatment of seeds, so if the working group or panel wants to begin asking questions, anyone can start.

DR. SPERBER: Yes, I'm Bill Sperber. I have a couple of questions about sprout processing. Many of the presenters made a strong point today that disinfection of

the seeds is the most important thing that can be done to control these problems. And it seems to me that perhaps that might be the only process step to that approach is a CCP in a HACCP program. But a disadvantage of having the seed disinfection as a CCP, if that's what it comes to be, is that it's about the first step in your process, and that there are many subsequent chances for contamination, and you have a very long sprouting process which could be considered an incubation period. If you got a pathogen into that system, you will still have a liberally contaminated finished product.

So I have two questions for the sprout producers. One, have you considered any means to inhibit bacterial growth during sprouting? And, two, have you considered sanitizing the finished product after harvesting?

MS. OLIVER: Who would you like to address that to?

MS. SNIDER: I'd be happy to start off and then let others finish, if you wanted me to.

Yes, we have looked at additives to the growing water. Probably the most promising one at this point is ozone. Unfortunately, the research that was started was at Beltsville, and they've decided to discontinue any further research under Dr. O'Neill. She's gotten pretty far along, and she's rather happy with the results that she's getting.

I don't know if there's someone else that can pick up the project at the point that she is dropping it or if there could be something done to get the research project finished.

The other possibility is hydrogen peroxide enhanced with a UV light which also shows some promise, but it hasn't been explored, and we hope that maybe in Chicago either one of these two products will be further explored.

As to something on the finished product, I believe Dr. Jerry Safer did quite a bit of work, preliminary works on rinses, and apparently the pathogens tend to--if they're there, they're going to tend to stick to the surfaces to such an extent that you're not going to be able to rinse them off, or if they stick--if you find something that's strong enough to kill them, it's going to kill the sprout.

As to your middle question there, you know, once you sterilize that seed and you get it into a clean growing environment, you don't really touch it beyond that point. Those three days that it spends growing, you don't see it, as long as it's got clean sterile water--or I wouldn't say sterile because water is rarely sterile, but clean water going into that sprouting process. You probably won't--there shouldn't be human hands touching it. There shouldn't be anything touching that product until it's time to harvest.

DR. KVENBERG: Thank you. Any other questions from the panel? Dr. Buchanan?

DR. BUCHANAN: Yes, I have one for either Fred or Dan Caudill. We heard a recommendation this morning about not using mechanical scarification of the seeds, that that might increase the damage and then increase the problems. I'd like to ask you, as seed producers, for your response to that recommendation.

MR. FABRE: Well, generally speaking, scarification is reserved for forage seed alfalfa. Scarification does break down the hard seed percentage in an alfalfa seed lot. Any seed lot is really broken down into two germination components. One is quick germination, and one is hard seed. The two of those are added together to make the total germination of a lot of seed. All an alfalfa sprouter is interested in is the percentage quick germination.

Hard seed is viable seed, but it does not adequately imbibe water, so it sprouts slower. And an alfalfa sprouter will ultimately throw out hard seed.

So in the scarification process, one always sacrifices quick germination, so there's an upside and a downside. Generally, I think it's done very rarely because although you will move more of the hard seed into the quick germination category, you ultimately reduce the percent

quick germination in a lot of seed. That's the trade-off. You know, more of the seed sprouts quickly, but what you can do is you can damage some of the seed and reduce the total germination of the lot. So it's done as a last resort, and I don't believe that many alfalfa seed suppliers do it.

DR. BUCHANAN: So you would then support his recommendation that seeds destined to be sprouted for food production not be scarified?

MR. FABRE: Absolutely. And there's another downside to scarification, too. Besides lowering the total germination of a lot of seed, alfalfa seed that has been scarified has a reduced shelf life. It will not carry as well. And it does not sprout as vigorously and make as good a finished product as seed that is not scarified. So in my experience, that's a process of last resort, and I think top-quality sprouting alfalfa is never scarified. Never scarified. It should not be ever scarified.

MR. CAUDILL: Dr. Buchanan, we've handled considerable amounts of scarified seed simply that we buy from areas that are prone to higher hard seed when crops are not available in areas that are prone to having seed with high quick germination. The process of scarification basically is cracking the seed coat so the seed will imbibe water quickly and the seed will germinate in four days rather than in eight or nine days. And from a sprouting

point of view, you naturally want your seed to imbibe water quickly and germinate in the four- or five-day period that you're growing the seed.

As far as what bearing scarification would have on increasing the likelihood of pathogens being carried on the seed, that would be an area I think would need to be researched. I guess hypothetically it might increase the potential as a result of creating more cracks and crevices in the seed where the bacteria could get into and not be reached. But even with the normal seed that we're harvesting out of the field and the mechanical damage that if you put that seed under an electron microscope, maybe 10, 15 percent of that seed is mechanically damaged, which is a result of metal and seed coming in contact, thus cracking the seed coat, which is similar to what the scarification process does.

So I really--I don't think it's going to make a big difference on whether we not use scarified seed or we use scarified seed as long as we are going through the steps of either irradiating the seed or chlorinated the seed at high enough dosages to kill any pathogens on or in those cracks of the seed.

MR. RUST: Can I make a comment here? The thing that concerns me about scarified seed is that it goes through a single machine, and if there were to be some

Salmonella in that machine and it scarified a lot of seed, it could--the part that scarifies the seed could possibly get it in the seed. I have no idea whether that's actually happening or not, but that's a possibility.

DR. KVENBERG: Excuse me. Before we go any further in the record, would you identify yourself so they--

MR. RUST: I'm Bob Rust with International Specialty Supply.

DR. KVENBERG: Thank you, Bob.

Mr. Reynolds?

MR. REYNOLDS: Carl Reynolds. I have a question or two for Mr. Caudill, if I can. I'd like to talk a little bit about the seed itself. It was stated earlier today that we receive seed both domestically as well as from a number of foreign countries, and the first question that I'd like to ask is about that, which is receipt from foreign country. Is that primarily received in the bulk? Or is it received bagged? Is it reprocessed or cleaned in any way before you receive it and offer it for use by the sprouters? And are there any remarkable differences in processing and growing of seed in the countries that import into the U.S. than that which is produced domestically?

MR. CAUDILL: Well, first off, the seed that is purchased from overseas is final-processed at those locations. It is not brought in in bulk and reprocessed

here.

Most of the seed that's being imported is being imported from First World countries, countries such as Australia and countries such as Canada. So the harvesting techniques and the growing techniques are identical to what we use here in the United States.

There is seed of questionable origin that is invariably the lowest-priced seed on the marketplaces that come out of areas of Europe--Italy and Holland. Those origins could be multiple origins, generally coming from former Soviet bloc countries, Russia, Pakistan, Afghanistan. We never know for certain where that seed comes from, which is why we no longer import seed from Europe. And I think most of the sprout seed suppliers have quit importing from Europe because of the potential of buying seed from Third World nations where they could be using--well, less than adequate standards in just handling the seed.

DR. KVENBERG: Dr. Tompkin?

DR. TOMPKIN: Bruce Tompkin. I had a question for the group that deal with the pasteurization system, the high temperature. The system that was described involved pre-heat wash, then followed by the heat treatment, and then cooling. So then would this system be used in place only at the sprout grower level? Or is it possible to cool and then dry so that these seeds could then be distributed in a dried

stable state? And if they are dried, are they stable? Will they still have a high germination rate?

DR. REGLI: The system was actually developed to be used in the sprouting plant for immediate sprouting afterwards, and this system has not been used, actually, for afterwards to dry the seed.

DR. KVENBERG: Again, Dr. Regli, would you identify yourself?

DR. REGLI: I'm sorry. German Regli from Daisey Machinery in Japan.

DR. KVENBERG: Thank you.

Dr. Troxell?

DR. TROXELL: Yes, I have a question for the International Sprout Growers. I believe you said that you didn't think it was necessary to do a warning label, but you wanted the Federal Government backing and state governments' backing to deal with the bad actors and so on.

Do you have an opinion on other federal actions such as the need for guidance regulations, GMP regulations or HACCP, and which of those you think the knowledge base is ready for?

MS. SNIDER: Well, I think safe handling--

DR. KVENBERG: Excuse me. Microphone, please?

MS. SNIDER: Nancy Snider. I think safe handling instruction would be very beneficial, both to the public as

well as to the sprouter. I think HACCP is--after we get good GMPs in place, then I think HACCP would be a very good way to go. At this point, I really only know of one point that you can truly verify, and that would be the chlorination of seed.

Did I answer everything you asked?

DR. TROXELL: So is it your view that you'd like to--you'd want to promote the industry's voluntary GMPs, or do you believe that there is a need for a mandatory GMP for sprouting?

DR. HAUSERMAN: Nancy, could I say something?

MS. SNIDER: Sure.

DR. HAUSERMAN: If we take a look at what we've got in front of us and what we know right now, if we can get radiation fast-tracked, we could get the seed effectively sterilized at the processor's location, the first step, before it even gets to the sprout house. Then we have chlorination and we have heat treatment as options available at the sprouter's location. And then you would growth the spouts.

And, by the way, in seconding the earlier comment, once you've put the sprouts into a sprouting drum or the sprouting room, people don't touch them. You can't touch them.

Much of the problems that you have with spoilage

of sprouts are similar in nature to the problems that you have when you contaminate sprouts. So you can't touch them. You really--you've got to make sure you know what you're doing in terms of air and water because you could lose your whole crop.

So you would start off by having irradiated seed. You would go into the sprout location. You would chlorinate at that step, or you would use hot water. You would grow the sprouts, and then 48 hours into the growing period, you would collect some water. And you could test the sprouts to make sure that there's not a problem.

As Dr. Davis was saying, you know, that technology is coming along. We're really close to being able to announce that. We want to test it again at the FDA facility in Chicago.

If you did all of those things, then you would have a number of HACCP steps. You would have a HACCP step for cleaning the seed. You would have a HACCP step for checking the drums, because you really need to swab your drums before you use them again to make sure that they are clean and you're not carrying over any pathogens. You would have a HACCP step in the growing process, because you could sample the water. And then the last thing would be sampling of the sprouts as they come out and into the packaging process. So you could be very, very sure that you got a

safe product.

You know, if you have good seed, the seed has been irradiated, if you got good sprouting drums and those are clean and you can verify that, if you've verified that the water coming out of the sprouting drums is clean, I don't know what else you could do. Everything else is covered by GMPs.

DR. KVENBERG: Could I ask you, Earl, one time to identify yourself?

DR. HAUSERMAN: Earl Hauserman.

DR. KVENBERG: Earl Hauserman, thank you. Please, when you speak, identify yourself for the record. Thank you.

MS. SNIDER: Dr. Troxell, in response to your question--I'm glad I had a minute to think. Thank you, Earl, very, very much. I'm glad I had a minute to think.

I think mandatory GMPs would be a very good thing because then all sprouters would be along the same level and the public could be comfortable at the level, the quality of the product that they're getting.

DR. KVENBERG: Okay. Dr. Buchanan?

DR. BUCHANAN: I guess I'd like to follow up a question that Bill Sperber had, and in light of the system proposed by Dr. Hauserman and Art Davis, I'd like to sort of ask the question: When you start off with sterile seeds or

you've irradiated them or treated them with 20,000 parts per million chlorine, what is the level of bacteria present on the sprouts when they then come out of the sprouter?

DR. KVENBERG: This is a test, Art. Identify yourself.

DR. DAVIS: Art Davis. I suspect that it will probably be about the same level it is now on a total plate count. I don't see how you're going to keep other critters from showing up.

What we would hope is that by monitoring our environment we can make sure they weren't pathogenic.

DR. BUCHANAN: Okay. And I asked that question specifically because I think that was a point that was sort of brought out, that there was an impression that these would be sterile products, and they're not. They still have around 10^8, 10^9 viable organisms, and unless you have absolute assurance that there were no pathogens in those seeds, you're going to grow pathogens no matter what.

Now, I understand that then to go back and test for them in the water is an option, but I think Bill's question--and I think I'd like to ask that question. Is anyone aware of a technology where you inhibit the growth of any pathogens during the sprouting process?

MS. SNIDER: Yes.

DR. BUCHANAN: And it can be as simple as yes or

no.

MS. SNIDER: Yes, yes.

DR. BEUCHAT: Larry Beuchat. Yes, but not much. Maybe I'll share that a bit tomorrow, but we can reduce populations, perhaps a log by application of sanitizers, but within a very short time we're back right up where we started from before application of those treatments.

DR. BUCHANAN: I was thinking more along the lines in a cured meat system. You add a little sodium nitrite. It's not a great inhibitor, but it works pretty good against Clostridium botulinum. Is there anything equivalent that you could use with sprouts?

DR. DAVIS: Art Davis. Not that I'm aware of. The data I've seen both for sprouts and for other produce that we're involved with says that the various wash programs and so forth are good for a log, and if you're lucky, two.

DR. KVENBERG: Dr. Sperber?

DR. SPERBER: Bill Sperber. A follow-up on that same discussion. Could you manipulate any of the other factors in the sprouting medium, such as the pH and the water activity, to prevent the growth of the pathogens but yet allow germination of the seed?

DR. DAVIS: Art Davis again. I suspect that we're stuck with the water activity in the high nines with continuous irrigation, and in terms of pH, I think you'd run

into a problem--and this is speculation, but you'd run into a problem just with keeping the sprouts growing at the rate that you need to have them grow at. The environment is pretty much optimized for rapid growth, and I suspect changes might be deleterious.

DR. SPERBER: And what is your pH?

DR. DAVIS: In the--

DR. SPERBER: In the normal sprouting operation, say, for alfalfa seeds.

DR. DAVIS: Eight to nine, I'm told.

DR. SPERBER: So maybe you could raise the pH, but you'd have to get up to 9.5 to 10 to keep most pathogens from growing.

DR. DAVIS: There are some species of plants that I know grow better or do a better job at higher alkaline conditions than others, just from agronomic things. Whether that would apply to sprouts or not, I'm not sure.

DR. KVENBERG: Dr. Slutsker?

DR. SLUTSKER: Larry Slutsker, CDC. Irradiated seed has been mentioned a couple of times today. I wonder if Dan or Fred could comment on how acceptable that commodity would be, do they think, to their clients.

MR. CAUDILL: Dan Caudill, Caudill Seed. We've done quite a bit of work with both gamma and electron irradiation. It looks very promising. Ollie Naruthy (ph),

who is with R&D with our company, basically feels that with the R&D he's done so far, we've got the process down.

Now, we've gone forward with work with the commercial irradiators to scale this process up, and that is undergoing--or going on at this time. We've done several scale-up tests. So all that is in the works. FDA will be notified with a petition hopefully that they will accept in the near future that we might be able to use this process.

The concentrations of irradiation are below 3 kilorays. Now, your question as far as whether the sprout growers will accept this, we feel that most of them would. There are organic growers who would be less apt to appreciate the irradiated seed.

The other thing is that the question is would we have to label. We would label the seed as an irradiated food product, but I don't think the sprouts would have to be labeled as irradiated sprouts since they are grown from seed into a plant.

MS. SNIDER: Dr. Buchanan, on an experimental basis, I did some sprouts using hydrogen peroxide in the growing water, enhanced with a growing light, and doing the 20,000 parts per million on the seed, had them assayed, and it came out to like 10^4, 10^3, fairly low, which is, you know, gee, that's great, except, of course, 24, 48 hours later, those counts start going back up because the

survivors, wherever they are, are going to multiply. So that if you come out with a real low count, whoever survives that is going to bring that count back up again. So I don't know what you're really looking for because I'm not a scientist type. It makes it difficult for me to kind of figure out what you're asking.

DR. BUCHANAN: I guess what I'm asking is: Is there some way that you can provide a competitive advantage to the non-pathogenic organisms during the germination process compared to those that are pathogenic? One of the concerns is the amplification step. And can you eliminate that amplification for pathogens?

MS. SNIDER: A competitive non--what is that? Non-exclusive or competitive--

DR. BUCHANAN: Competitive exclusion.

MS. SNIDER: --exclusion. Sounds like a wonderful way to go once you get rid of the pathogens. But I think you've got to do that kill step in there or you're going to have a problem. And, fortunately for us, as I keep saying--and I think Dr. Wick has said--actually, it's Dr. Wick I think I'm echoing, is that it's not the normal thing to have pathogens in sprout seed. It's the abnormal thing. It's the thing, the unfortunate thing that happens every now and again, and when it does, you know, it creates a huge problem and people get sick. That's a huge problem. And I don't

know about anybody else in the sprouting industry, but I've never had anybody get sick from my sprouts, fortunately. Maybe I've been lucky or maybe I'm just doing things right. I don't know which way it is. I would say the law of averages, I probably should have had someone get sick, but maybe I--I'm hoping I'm doing it right.

But, at any rate, to get beyond that, it just doesn't happen that much, and what we have to do is just stop it from happening, period. And that's kind of where we're trying to go in the sprouting industry with the research that's being done by all the wonderful researchers, which we have, I think, most of them around this table or in this room.

Again, I express my gratitude to them because I can't do it. I need them to do it, and it's a very helpless feeling.

DR. KVENBERG: Additional comments, questions? Dr. Buchanan, then Dr. Tompkin had a question, too.

DR. BUCHANAN: I have a question for both of our seed suppliers here at the table, and then one specifically for Fred. Let me give you the general one first.

You have been moving towards an affidavit that sprouters must sign that says that they will sanitize the seed before use. How do you enforce this?

MR. FABRE: Well, I can't personally visit each of

the sprouters that buys the raw seed from my company--and my name is Fred Fabre, and I'm with Cal West Seeds. I represent seed growers in the West. But every time my company sells raw seed to an alfalfa sprouter, we exchange a sales confirmation. We generally know these people fairly well. We've sized them up over the years, and I think it could be a step connective that would be just integral to confirming a sale to someone, exchanging some kind of an attestation note such that they would recognize that there could potentially be some contamination of the seed and that they would agree to go through a prescribed sanitation process; and until the agreement was signed and returned, the sale would not continue.

I think it could really be a two-step thing. We've talked about putting warnings on sprouted seed. We've also talked about the benefits of sanitizing seed from step one. I think several raw alfalfa seed suppliers to the seed trade have begun exchanging an affidavit like that, kind of a promissory notice from the customer that they will adhere to prescribed sanitation processes. A second step--and I think this could be administered, or at least assisted by national or regional seed associations in the country, some labeling of the raw seed such that it would carry both the cautionary note that the seed contained in this bag may contain some level of biological contamination and that it

must be sanitized. And I think a second there could be a sanitation statement on each bag of raw seed. So it would be kind of a twofold thing in my perspective, both a note from the sprouter that they would adhere to sanitation procedures, and then on the package itself a cautionary note and a separate seed sanitation procedure note.

DR. BUCHANAN: Okay. My second question was specifically slated for you, and this one answer as you will. I noted in your introductory remarks that you said that your primary time for selling seeds to sprouters was in the 1970s to the early 1990s, implying that you're getting--you have less activity with sprouters. And can I ask why?

MR. FABRE: Well, far more people sell alfalfa seed into the sprouting trade. I think when the industry was in its infancy in the late 1970s and early 1980s, there were just a few, and our company, my company, was one of the largest. The supply side has been a bit fragmented, and there are a lot more people that vend to the sprouting industry. That accounts for our doing less today than we used to do. There are just more players in the game.

DR. BUCHANAN: Can you give us an estimate of how the numbers of suppliers has increased over this 20 years?

MR. FABRE: Oh, that's tough. Maybe three- or four-fold now, would be my guess.

DR. BUCHANAN: Thank you.

DR. KVENBERG: We had several more questions from the working group. Dr. Tompkin, did you have a question?

DR. TOMPKIN: I just wanted to have a clarification for my own purpose. The growing water, once the drum or the tub is sealed with the growing water, that does not change; is that correct?

DR. DAVIS: Art Davis. The water in the drum is a continuous irrigation that goes into the sprouts, works its way through, and drips right on out. So it's a continuous irrigation process. It does not stay in the drum for any particular length of time. The automatic controllers turn it on and off so many seconds every few minutes.

MR. RUST: If I could add something, I'm Bob Rust. It takes about an hour for the chlorine to get out of the drums. It depends on how much you put in there.

DR. TOMPKIN: I had a question. If you were to chlorinate or ozonate the water, you actually do measure then the exit concentration of chlorine so that you maintain a specific level?

MR. RUST: We don't maintain a specific level. It starts out at very, very high concentrations, and then it works its way down to--in 40 minutes it is down to 75 parts per million; in an hour it's completely gone.

DR. TOMPKIN: So over a process of several days, for example, then actually once it's gone, it's gone. We

don't have any continuing sanitization in a sense?

MR. RUST: No. You can add ozone during the entire time, and the sprouts enjoy that. And hydrogen peroxide you can add during the entire time.

I would like to say something, and that is that we found out that it doesn't appear that there is any level of chlorine that will hurt the sprouts during the soak phase. We've put in very, very high concentrations for up to an hour, even up to--starting when the seed very first starts, it has 650,000 parts per million and then works its way down to nothing in an hour.

DR. TOMPKIN: Okay. And I had another question. This is Bruce Tompkin again. How important is oxygen to the sprouting process?

MR. RUST: It's crucial.

DR. KVENBERG: Dr. Beuchat and then Dr. Goolsby.

DR. BEUCHAT: Larry Beuchat. I'd direct this question to Mr. Regli. Your pasteurization system you have demonstrated will kill vegetative cells. One of the first documented outbreaks of foodborne illness, sprout-borne illness, was associated with bacillus cereus, the spores of which would survive the system that you have described to us. Bacillus cereus that was after the first outbreak, or that outbreak, there was a survey actually, I think, conducted by FDA that revealed that spores of bacillus

cereus can routinely be isolated from seeds destined for--this was home sprouting kits. This was some years ago.

Have you given consideration to the disposition of this pathogen, potential pathogen, in terms of its growth in a relatively low competitive environment once you get rid of or reduce those vegetative cells that would grow to larger numbers and perhaps at least keep in abeyance the bacillus cereus during the sprouting process?

DR. REGLI: German Regli. Sorry, I had to check it out with a microbiologist. This method is not as such effective for this particular bacillus.

DR. BEUCHAT: If I could take that a step further, the same or similar situation may also be in the case of irradiation, if indeed spores were not inactivated by whatever dose it would take to eliminate vegetative cells. So you may be trading one hazard for another in terms of risks of growth.

DR. KVENBERG: Is this to this point?

DR. BUCHANAN: No.

DR. KVENBERG: Dr. Goolsby and then Dr. Troxell.

DR. TROXELL: Can we follow up on this point?

DR. KVENBERG: Sure.

DR. TROXELL: Because you questioned the heat treatment and you questioned the irradiation effect on the spores of bacillus cereus. What about the chemical

treatment's effects on the spores? What do you know about that?

DR. BEUCHAT: Well, I think the spores of this bacterium, as well as a number of others, would be more resistant to the same concentration of chlorine or chlorine dioxide, perhaps ozone, compared to vegetative cells of itself or other pathogens. I don't have the data to share with you, but that would be my guess on that one.

DR. KVENBERG: Now, Dr. Goolsby.

DR. GOOLSBY: Dave Goolsby. A couple of comments to underscore a few things that have been said regarding the GMPs and HACCP-based programs, and these comments are made because, again, we all, I guess, in general tones at least, agree on the necessity of having a sanitary seed to begin with. I go back to underscoring the GMPs and HACCP for processing, production, and all, because I really am convinced that, regardless of what we begin with, we can certainly still end up with many interventions, if not present, allowing contamination of a sterile product. So I would ask for strong consideration on the part of the industry and the agencies for an inclusion of GMPs and HACCP post-sprouting, during the processing, the washing, the packaging, all those other steps before the product arrives to the consumer.

DR. KVENBERG: Dr. Troxell, did you have another

point?

DR. TROXELL: Yes, I wanted to pursue the residue question. We've had a number of--you know, we've talked about chemical disinfection and efficacy and so on, and we had the comment over here that after an hour the residues were completely gone.

One, what does "gone" mean in terms of parts per million? Two, what have you looked at as far as residues in the sprouts, their levels? What are you looking for? Because that's a question that always comes up when you're looking at the public health on the micro versus chemical risk.

DR. DAVIS: Art Davis again. We addressed this early on. We took sprouts where the seed had been treated with 20,000 parts per million, gone through a normal sprouting process, and sent the sprouts out for a test, just the normal--I've forgotten the EPA number, but it's a regular scan for chlorine and chlorine byproduct residues. And essentially there were none. That data was submitted both to the EPA and to the California group as part of their petition.

It appears that, first of all, the chlorine only touches the hulls, and then the sprout--and is gone before the sprout ever appears. Probably 80 percent of the hulls are removed in the washing process, and they've also been

continually irrigated for about four days, and there simply was nothing there in the scan. And I can get you the numbers and the data, for that matter.

MR. RUST: Bob Rust. When I was talking about the chlorine being gone, I meant that the chlorine was gone from the water. After 40 minutes, there was 75 parts per million.

DR. DAVIS: Also, we're talking about very different processes. Bob's talking about a process where they're putting chlorine in with the seed in the drum to begin with, which, at least to my knowledge, is not a real common practice. And we're talking about the chlorination of the seed followed by a rinse and then normal germination.

DR. KVENBERG: Dr. Buchanan?

DR. BUCHANAN: How much is really known about sort of the flexibilities and the conditions in the sprout chamber on the germination rate? What are the temperature ranges that are competitive for germination? What are the pH ranges, things that we could manipulate as microbiologists in order to prevent growth of pathogens?

I haven't heard any real data on this. What's the lowest pH you can use? What's the highest pH you can use? What's the temperature and still have the competitive process in terms of getting it to germinate in the four days that you normally target?

DR. HAUSERMAN: I've gone as low as six and as high as nine.

DR. BUCHANAN: And what was the effect on germination rates?

DR. HAUSERMAN: Minimal.

Bob, what have you done on pH?

MR. RUST: I've never really checked for the high and low ranges. We've always checked for the optimum ranges, and those are generally around 70 degrees.

DR. BUCHANAN: Well, when you get outside those, how far is it non-optimal?

MR. RUST: I really don't know.

DR. HAUSERMAN: We know that the temperature rises when you grow sprouts, alfalfa sprouts, after the second day. The first day--the second day it starts to rise. You'll go up--oh, depending upon the type of seed, because, you know, California mawapa(?) is a fairly hot growing seed. You use it in a colder area to compensate for the drop in temperatures. Some people in California use it all the time. But it grows at a higher temperature. A cooler seed is like a seed that Dan was talking about that they might scarify, coming out of Canada, would be a harder seed. And that will grow at a lower temperature. But in all cases, there's a rise--there's actually a bell-shaped curve, and it just kind of goes up, and then it drops down after the third

day. It rises a couple of degrees, two, three, four, five.

DR. BUCHANAN: Yes, well, I'm thinking about, you know, at what temperature in nature do these seeds start to germinate?

MS. SNIDER: I don't know if this will help or not, but our water comes in normally at 55 degrees. Prior to a couple of years ago, the only problems we had to face were the normal plant pathogen problems like, you know, Pseudomonas and (?)-vicula and that kind of thing. And whenever that started to happen, the first thing we'd do is drop our water temperatures down because it always seemed to help us save our crop. So I know that sprouts will grow-- they won't grow as well at 55 degrees, and since we can play around, since we have to raise our water temperature anyhow, we've played around with that, and we have found that when we get our temperatures over 70 degrees, we start getting what's called rot, which is basically a super-bacteria. So that we find in our particular growing operation that 65, 68, but never over 70, is--

DR. HAUSERMAN: This is Earl Hauserman. Generally speaking, it's 75 degrees. If you get above there, you really have problems. Below 55, it's really tough to get it started and get it going.

MS. SNIDER: The other thing that we've kind of noticed, too, is that we keep a thermometer in our seed when

it's germinating, and we find that if our seed germination temperatures--when the seed first starts to germinate, if that temperature gets above 90 degrees, you might as well just throw it out, you know, because you're not going to get a crop. So it's really important, as the seed first starts to germinate, to keep it cool so that those temperatures never get hot. So, yes, temperature is a big thing with us. Beyond that, I don't know how that manipulates. I used to play around with citric acid because I thought maybe, you know, lowering pH would get rid of Pseudomonas and Erwina(?) and stuff, and we just sort of experimentally--if you get this pH much below three, you're not going to get any--at least I couldn't get any germination.

DR. NAGLE: This is Nancy Nagle. I want to follow up a little bit on one of Bob's questions, and I have another question perhaps for Jeff.

You mentioned these different varieties that germinate at different rates and different temperatures, like a hot growing one or whatever. Is there any data--maybe Jeff knows this, or Dr. Slutsker. Are any of these outbreaks tied with specific seed varieties? This may be something that if we're saying these sources are coming from--you know, if it's seed that comes from somewhere, maybe we can start tying it to these temperatures that Bob is talking about.

DR. HAUSERMAN: This is Earl Hauserman. No. I thought for a while that all the outbreaks were tied to seed coming from Eastern Europe, but that didn't prove to be correct.

No, the seeds--it's pretty well come from across the country.

DR. NAGLE: Well, but I guess the question is, though, but are they different varieties from different parts of the--you know, I think we've heard that there are different varieties that may grow at different times and different parts, you know, different things, and there may be similarities or relationships between some of these varieties. Or are they all over the board, hot starting seeds and cold starting seeds and all of that?

DR. HAUSERMAN: They're all over the board.

DR. NAGLE: Okay.

DR. HAUSERMAN: There is no defined trend that I could pick up.

Dan, did you--

MR. CAUDILL: Dan Caudill. I think the CDC has linked the outbreaks across the board, seeds from Australia, seeds from Holland, seeds from Italy, seeds from California. I mean, it's been pretty well across the board, both hot and cold seeds, as sprouters would call them.

Areas that are hot, dry climates where non-dormant

seeds are grown are called hot seeds. We call them hot seeds for sprouting. They sprout much quicker. Areas that are cold areas, such as Canada, are dormant seeds, and they grow much slower.

Regarding your questions of pH and growing sprouts in low pH, Dr. Gerald Hirsch (ph) in Atlanta was working with us a consultant, and he took pH's down to 4.5 in the hopes that we could grow sprouts at low pH where the pathogens would not grow. Unfortunately, at the lower pH's, we could not get the seeds to germinate and grow.

And, of course, the lower temperatures that you grow alfalfa sprouts in, the slower they grow, but also the slower the potential pathogens or microorganisms will grow.

We also worked on two chemical additives that I just wanted to throw out real quick, and that was a chemical additive of halazone and chlorine dioxide, sodium hypochlorite, and calcium hypochlorite, as additives to the water that were sprayed on the sprouts as they grew. And our results, we never came up with anything more than 1.5 log reduction in those tests. And based on those results, we funded no more research in that direction.

DR. NAGLE: Can I ask one more question of Jeff? It goes along with kind of what he just said.

Is there any kind of correlation between the presence of competing organisms and the outbreaks? I mean,

because we're talking about knocking down--we've just had all these discussions of knocking out all these competing--all the organisms off of there, and now is that just setting this up that there's more likelihood that these organisms will grow? And does Jeff have any insight on that, you know, as to the kinds of operations from which he's seen problems?

DR. FARRAR: Jeff Farrar. In California, we've seen pretty much the whole spectrum of types of facilities, level of knowledge, ranging from places you definitely would not buy from if you saw them, to what we would call above-average facilities. So from a sanitation point of view, that's run the whole gamut.

From numbers of organisms or types of organisms present in the seed, I really don't have that information. Maybe Greg Inami from our microbial disease lab can address that tomorrow in his presentation.

DR. BUCHANAN: Larry, do you have any data on that? When you had a sprout outbreak, what was the level of the pathogen in the sprouts, or do we have no quantitative data?

DR. SLUTSKER: I haven't seen the quantitative data. I know the Danish researchers quantitated the level of--well, actually, they quantitated the level of contamination--this was in the Salmonella Newport outbreak--

on both seed and sprouts. And I have those numbers. I don't recall them. Rather than misstate them, I can look them up. But that's the only sort of data that I know about in terms of quantification.

DR. BUCHANAN: Was it a major part of the microflora?

DR. SLUTSKER: It's actually fairly low in their experiments.

DR. NAGLE: Nancy Nagle. One more thing with Jeff. We talked about the outbreaks that we've had in California. Have they been associated--you said you've seen different levels of sanitation throughout the state and the different sprout growers, but have the outbreaks been associated with all levels of producers, or are they actually with the better producers?

DR. FARRAR: Again, the entire spectrum.

DR. BUCHANAN: I'd like to follow up a couple of comments that were thrown around here. The reason why we're asking a number of these questions is just some physical realities. Salmonella or E. coli O157 doesn't grow below approximately 50 degrees Fahrenheit. At 55 degrees, they're non-competitive.

If we had some more information about what were the extremes you could grow these sprouts under and still get growth, we might be able to design something. But until

that information is available, it's very difficult, and certainly in light of Janice's initial charge, I know at least some research recommendations.

MS. SNIDER: These organisms, would they grow well at 60 degrees? Yes, sprouts would do fine at 60. At 55 they're slow.

DR. BUCHANAN: So will Salmonella.

[Laughter.]

DR. KVENBERG: Dr. Tompkin?

DR. TOMPKIN: We saw some slides, environmental chambers that could be used, but in terms of the germination, the drugs that are used for sprouting alfalfa, are they temperature controlled, or are they typically at ambient temperature?

MR. RUST: They're temperature controlled.

DR. HAUSERMAN: No, they're at ambient.

DR. TOMPKIN: At ambient. You grow them in an ambient room temperature. That's what I wanted to know.

MR. RUST: The water is temperature controlled, and some growers will control the--most growers will control their rooms, also.

MS. SNIDER: I know in my sprout growing operation we control both water and room temperature because we feel that the combined temperatures is what we're talking about and not just one specific temperature.

DR. KVENBERG: A point of clarification from the podium here. Are we talking exclusively about alfalfa sprouts during all of this with the water temperature control? Or are you going between beans and alfalfa? This is all about alfalfa?

DR. TOMPKIN: My question was specific to alfalfa.

DR. KVENBERG: Are the answers and responses to that the same?

MR. RUST: Yes, they are, but it is consistent with both.

DR. TOMPKIN: And I had a question to follow up relative to germination temperature versus growth temperature, and I'm sure that sprout growers want to get a crop as fast as they can so that they get a higher volume and so on without jeopardizing the quality and losing the crop.

So in terms of optimizing germination, let's say that may be 70 degrees, as was mentioned. I'm not sure that that was for germination or for growth. But is it possible then, in reducing the growth temperature say down to 55 degrees, what is the real impact on the turnover of a drum, that is, a crop, in terms of days?

MS. SNIDER: I can speak to trays. If you do it at 55 degrees in just tray sprouts--and I don't know about drums because I really don't deal that much in drums. I use

drums to start my germination, but then we go to trays. If I leave sprouts in a tray too long, I lose my crop because the roots start to deteriorate because they don't have enough nutrition to sustain themselves. It seems like the slower they grow, the more likelihood it is that I'll lose the crop. The idea is to grow them quickly, harvest them, and then cool them quickly, so that whatever got started gets put back to sleep again.

DR. HAUSERMAN: This is Earl Hauserman. I think Nancy is right. You would elongate the growing process. Most alfalfa sprouts are grown in three and a half days, three days to four and a half days, depending upon the seed and the room temperature, four days. But when you start to stretch that out to five, six, seven, you're trading off something, and that's shelf-life. It's been my experience that it would be difficult to do this commercially--not impossible but difficult.

DR. KVENBERG: Mr. Reynolds, and then Dr. Sperber.

MR. REYNOLDS: Carl Reynolds. I have a question for Nancy, if I could, please. I notice in your guidelines that your association recommends, you talk in your labeling to follow federal guidelines. You also suggest a "use by" date and so on.

Speaking for the industry, what is the industry acceptable practice of date-coding individual containers of

sprouts? What is the normal shelf-life period that you're suggesting or is a standard for the industry? Is it a standard practice of the industry for those firms that are actually coding the individual containers of sprouts to include that coding system on distribution records? And, finally, you state in the guidelines that sprouted products should not be stored under automatic misters. And I was wondering in that last part how you control that in a retail setting.

MS. SNIDER: Retailers are difficult to control. All we can do is suggest. We suggest that people start date-coding. I think it's very important, and I happen to be one that has not quite got the equipment installed yet to do it on individual labels. I think it's very important because if ever you do need to do a recall, you'll know what to recall. It's also important because it gives the store an idea when they ought to remove the product from the shelves.

I've had sprouts last 21 days. I've had sprouts last seven days. It depends on how good that seed is. If I've got a good, clean seed, I know I'm going to get at least 14 days out of it, and possibly 21. But I wouldn't code anything beyond 10 days.

MR. REYNOLDS: You mentioned the term "good, clean seed." How do you assess that?

MS. SNIDER: I assess it--well, when I go to purchase seed, I usually have--because I purchase in fairly substantial lots, I usually have my seed supplier send me at least 50 to 100 pounds of seed to test, and I test that in my facility. I used to do plating. I used to literally get the agar plates and plate it and look to see what grew out of the seed. But then I found that I could find out just as quickly by not refrigerating the finished product and leaving it and seeing how long it will last under room temperatures, which, you know, if it lasts two or three days or four days under room temperature without getting mushy, I've got a seed that's pretty clean, that doesn't have a lot of sprout diseases in it.

Unfortunately, pathogens, we don't know how to look for those, so we're just looking at the plant problems, the plant diseases. So I'm always looking for the cleanest possible seed that I can get, but I like a seed--I like a hot seed. I like when it's germinating. I like to get seed, if I can, from California. I like to get it from the Imperial Valley, if I can. Sometimes that seed is too expensive, and then I go to the Australian seed, which is to me the best hot seed that I can find.

That's just personal preference. That's what I do. It's unscientific.

MR. REYNOLDS: From your understanding of the

industry, is it the exception rather than the rule to individually code each container? And is it also the exception to the rule to put the date-coding or some coding system on the invoices that are going to the retailer, to the customer?

MS. SNIDER: I never considered putting that on the invoices. It's actually not a bad idea.

It's hard for me to say because it's something I've never really looked at. I know that our Canadian neighbors all do it. It's required in Canada. And it's something that we should do. I've seen it. I used to do it on a regular basis, and then the little gadget I had broke, and I never replaced it because the retailer never asked for it again.

So I guess we're pretty driven by what the retailers want, and if the retailers tell us they want a date code on it, they'll get it.

MR. RUST: Nancy, could I say something here? We sell labeling machines, and we also own a scrap company, and from our experience in selling the labeling machines, I don't think there's very many people who date-code. Our sprout company does a "born on" date. It's a "born on" code, but it's not a date code that tells when it expires.

DR. TROXELL: Ten days, is that what you would do, or is that any kind of consensus in the industry for ten

days?

MS. SNIDER: Ten days is what I would do, and I think it's--I would guess--what would you say? Is it pretty standard?

MR. RUST: I think it depends on the variety of sprouts. Bean sprouts would certainly be a lot shorter than that, and alfalfa sprouts would probably be longer.

MS. SNIDER: I thought we were just discussing alfalfa.

MR. RUST: Well, as far as alfalfa--

MS. SNIDER: Bean sprouts, I give them two days.

MR. RUST: I would hate to speak for the industry on this one, but I'm guessing somewhere around two weeks or less.

DR. KVENBERG: I think the order of questions was Dr. Sperber and Dr. Neill.

DR. SPERBER: This is Bill Sperber. I have one brief comment and then a question. There was some earlier discussion about the fact of chemical disinfectants on spores, and in my experience, you can kill spores fairly easily with chlorine compounds. They're certainly more resistant than vegetative cells. But the least resistant bacterial spores are only about twice as resistant to chlorine compounds as vegetative cells are. So in the food processing industry, we can get rid of spores even at normal

levels of chlorine use, which is 200 ppm. If you're using 2,000 to 20,000 ppm for soaking seeds, you should easily kill the spores.

My question has to do with the soaking of seeds, and I'd like to address it perhaps to Fred Fabre and Nancy Snider, and Dr. Wick, if he is still in the audience.

It seems to me there is a lot of emphasis--and I don't know how this is going to shake out or where the industry is thinking of this, but it seems to me there's a lot of emphasis on disinfecting the seeds through soaking to get rid of the problem there, and then you're going to keep it clean the rest of the way.

Well, that strategy would work very well if you had a 100 percent disinfection of the seeds. But we heard from Dr. Wick this morning and from other presenters this morning that it's not possible to disinfect the seed because of the seed morphology. So I'm confused as to whether or not this could really be a good prevention step or possibly a CCP for sprouters.

DR. KVENBERG: Who would like to go first in response? Dr. Wick's coming forward.

DR. WICK: Well, I don't have an answer to the question, but clearly, we can't completely disinfect the seeds, and we expect to see 100 million bacteria on the finished crop. I think the question is whether or not we

can remove human pathogens which I would suggest are rather superficially associated with the seed, unless the seed has been handled in an unusual way or maybe in the scarification process, which I feel could embed human pathogens into the seed if they're present.

But it seems to me that certainly the risk would be reduced by these sanitation practices, given the fact that the pathogens are probably incidental contaminants as opposed to some of these more deep-seated contaminants that you'd expect of longstanding association with plants, some of the pseudomonads and so on that are difficult to get rid of.

MS. SNIDER: Dr. Beuchat's data--I don't know that it's been completed--looks--I think the word is very promising, but basically what it said was that out of three replications, he did not recover any pathogens after enrichment. So that looks very good. Maybe occasionally something is going to slip through. Life is never sure of anything, including walking across the street or eating a piece of chicken. But if you can reduce the odds to a very small percentage, I think we've done a very good job.

DR. TROXELL: May I follow up? It seems to me the issue here may have something to do with what Dr. Wick said at one point earlier. It has to do with the wetting of the surfaces, and that also may apply to the vehicle, how well

it wet the surfaces when Dr. Beuchat and other researchers were applying the inoculums to do these tests. So if those tests aren't mimicking getting down to those crevices, then they wouldn't be, you know, as absolute as we all like. But maybe it has to do with the wetting ability of the disinfectant as well as its killing properties.

DR. KVENBERG: Dr. Neill?

DR. NEILL: I have a question, I think for Art. Have you looked at whether there are differences among--whatever the correct term is--varieties, seed sources, for their ability to support the amplification step, whether there are some that seem to support it less?

DR. DAVIS: This is Art Davis. Yes, we even got interested at one point, when we first started looking at--I assume by seed you mean the broccoli versus radish versus alfalfa?

DR. NEILL: Well, I think first that, and then within the seed group species.

DR. DAVIS: Between the species, we got interested in the broccoli because they do exude some isothiocyanates that are--and we had some evidence that they do suppress microbial growth. And even in the data I reported this morning, if you look at it carefully, things don't seem to grow quite as quickly on clover as they do on some of the other seeds.

We were going to pursue that for a while, but when we looked at it a little closer, the differences were small enough--you know, three days into the growth, you're talking a log or two. It didn't really seem like that was going to get us where we wanted to go.

Within the different varieties of a particular species, I don't know.

DR. NEILL: I would just point out, scientifically, the issue then would be whether that's a manipulatable variable that could be further amplified itself, which then might be expected to have a better dampening effect.

DR. DAVID: Possible, but I think we'd have to be looking for several orders of magnitude greater effect than we've seen before it would be--in the list of priorities, it's there, but it's probably not real high at this time.

DR. KVENBERG: Are there any additional questions? Yes, Dr. Swaminathan?

DR. SWAMINATHAN: Bala Swaminathan, CDC. We have talked a lot about seed disinfection. Dr. Buchanan asked several questions about the possibility of manipulating the environment lab pH or temperature or whatever during the sprouting process. And it looked like the sprouting's effect would be affected if the pH is changed too much or the other parameters are changed.

Now, the one that we haven't talked about is after sprouting. Are there specific steps, specific treatments that one can think about after the sprouting process and before packaging that would be useful in controlling pathogens?

DR, DAVIS: Art Davis again. Once the sprouts come out of the drum, they're very similar to other produce. In fact, if anything, it might be a little heartier because they're not cut or cut off from their energy source, as are other produce. And I think if you look at the produce literature, it's clear there are a number of things you can try, many of which will take you down a log or two in microbial count, but it's nothing like the level of cleanup that we would need to have a control point.

The surfaces and the adhesion and so forth, they're just awfully hard to overcome.

DR. KVENBERG: Mr. Reynolds?

MR. REYNOLDS: Yes, I have a question for Dan, if I might. I understand that part of your service is including equipment distribution as well, so my question is to you in that regard.

Do you see any changes or what will be the engineering redesign or the designs of new equipment that might be coming down for a drum or tray sprouting in the next few years?

MR. CAUDILL: Presently, there are some minor changes going on to the existing equipment that is currently being used out there. They're creating ways to unscrew the misters so you can clean back in there. There's going to be some modification of the rotary drum. These are minor changes to help sanitize the equipment, and that will be available in the near future.

Dr. Sizer (ph) in Chicago there, with the FDA research labs there, is working on setting up a sprouting operation, and we expect some results out of their testing that may help us modify equipment to make it more sanitary.

DR. FARRAR: Jeff Farrar. The debate will obviously go on for a while. As long as we don't know exactly how the seeds become contaminated, we're still dealing with looking at artificially inoculated seeds and using that laboratory route. However, I think our lab is one of the only labs in the country that has some naturally contaminated seeds. So researchers can make out your checks to the California Department of Health Services.

[Laughter.]

DR. FARRAR: We'd be glad to entertain those proposals.

DR. DAVIS: Is this an open auction?

DR. KVENBERG: Is there one more burning question before we go on to public comment? Yes, Dr. Buchanan?

DR. BUCHANAN: Just one out of curiosity, and this is, again, to the seed suppliers. I'm left with the impression that good alfalfa seeds for sprouting are hard to come by. On the other side, I have this impression that the demand for seeds has gone way up. And on the third side, there seems to be--I haven't heard of any alfalfa seed shortages. So where is it all coming from?

MR. CAUDILL: Dan Caudill. I'll answer--I'll let Fred take a shot now, and I'll also take a shot at this.

One, demand for seed is not going up. It's going down, and down significantly. Two, there is not a shortage of alfalfa seed as long as we look across the world to purchase alfalfa seed. Alfalfa seed is grown over a very large area in the world.

What was your other question? I'm sorry.

DR. BUCHANAN: I'm just surprised there's no shortfall.

MR. CAUDILL: Not really. And your other question was it's difficult to find good lots of alfalfa seed for sprouting. To that question, yes, it is difficult. Probably 10 or 15 percent of the seed that we look at we find suitable for sprouting purposes.

MR. FABRE: Yes, I might tend to disagree just a slight bit. I think sprouters around the world, sprouters in this country for sure have a hard time finding seed that

they're completely comfortable with, that they have, you know, full confidence in. If seed supplies were adequate domestically here, then seed suppliers wouldn't be going abroad to some of these Western producing countries to buy alfalfa seeds. So I think the U.S. is not even close to being self-sufficient in good quality sprouting seed, seed that's been tested, tested by the grower, tested by the marketer for all of the spectrum of things that sprouters look at today.

So were the U.S. self-sufficient, nobody would be importing seed. So there may be supplies of sprouting seed to go around, but top quality U.S.-grown sprouting seed I think is in short supply.

MR. RUST: I'm Bob Rust. I would like to clarify a little bit of what Dan said. Actually, the sales of seed have gone up. I own a seed company, also, by the way. They have gone up. But recently they have gone down since the news releases have been coming out. I believe that's what you meant. Is that correct, Dan?

MR. CAUDILL: Yes. Since the news release, I'd say alfalfa seed demand has dropped, at least in our company, by half.

MR. RUST: I think that's the same with us.

MS. OLIVER: Okay. I'd like to thank everyone very much for this afternoon's presentations.

Next what we're going to have is those who have registered for public comments. The first one that we have is German Regli from the Sprouting Plant Division of Daisey Machinery, and I think he has a film or something to show. Is he here?

xx DR. REGLI: Yes.

MS. OLIVER: Okay.

DR. REGLI: My name is German Regli. I'm working for Daisey Machinery in Japan.

Just a little bit to clarify, Daisey Machinery has developed since over 20 year equipment for mainly the bean sprouts industry. The alfalfa industry in Japan is considerably small. So before we introduce a little bit our system, seed pasteurizing, we brought actually a small video section which shows a little bit how things are going on in a Japanese bean sprouts factory, which includes also a seed pasteurizing system in action.

I don't know if we're ready to start.

MS. OLIVER: Can someone move the overhead?

[Videotape shown.]

DR. REGLI: This is just a very short video. It starts actually with the seed pasteurizing system, and it shows actually also the processing of the bean sprouts after harvest.

This is the seed pasteurizing system, a rotary

type machine, has a capacity of about up to 1.8 tons of dry seed sprouts. Again, this system was designed for mung beans, and we try and use now the same experience, technology, and redesigning the system for alfalfa using the results I presented before.

It actually works in three steps. Seed is divided in batches automatically, fed into baskets, and then this stage we are seeing here is the washing and preheating stage. As we explained before, it works in three stages.

Then it goes over to the pasteurizing stage. As we mentioned, it is very, very important that each seed is treated exactly for the same time at a constant temperature in order to be effective.

Then what happens here, you see on the right-hand side over there the seeds are then straightaway cooled down. This is a three-step method. Then it's straightaway into the growing bin, and from there it goes into the growing room where the soaking starts and the whole growing process.

Now, what we are always emphasizing on this is that the environment--I mean, it came up before as well. The growing rooms, everything is kept clean. I mean, everything is stainless steel. Of course, after each cycle, everything needs to be able to be properly cleaned.

This system is our growing system, using computer-controlled monitor to detect any problems during the growing

cycle. The temperature, things like that, are monitored constantly. It's indicated straightaway if something goes wrong. Then on harvest, again, as mentioned before, there's no handling in between.

On harvest, the containers of bean sprouts are then taped on the platform, then briefly hand-sorted, and then into the washing tank, and between this stage and until the final product, there's no manual handling again.

So this is the washing stage. I have an overhead later on which will show you a little bit the reduction of bacteria during the washing process. It's just a brief introduction of basically how bean sprouts are processed.

It's very important that they're harvested, they're washed straightaway, and there's no handling in between, and packed and sealed straightaway and kept cool. We heard that before as well from other speakers.

This washing line is using the washing tank, a table, and after washing, bean sprouts are rinsed with fresh water, which is very important as well. Then depending on--it depends on each individual grower. At the moment here, there's a root cutting device, and then bean sprouts are dried and straightaway packed. So there's no handling in between.

This is a device which is actually monitoring the bean sprouts, the quality, and any foreign objects are

actually moved automatically from the belt. Then there's the measuring stage before the packaging takes place, and the bag is sealed. The bag is then placed in a box ready for distribution, and it goes out straightaway and as fast as possible to the shop.

The bean sprouts are packed in retail size bags, which is about 8 to 10 ounces, but there's also the wholesale, which goes to Chinese restaurants, places like that.

Until this point, from the point where the bean sprouts are dropped into the washing tank until this point here, there's no additional handling, which we consider very important. This is the system then for wholesale bags, about 10 pounds.

There's a variety of different packaging systems used in Japan. It all depends on the cost. It depends on the requirements. Also, it is very important, of course, the seeds need to be cleaned and then the handling in between, the hygiene standards need to be high as well.

Now, if I just can get...I've just got actually an overhead as well.

What this shows is just a washing line as we have just seen on the video. It's actually before washing, the count, the total count, 100 percent, 1.8 times 10^7, then after the washing tank, it reduces it down to 56 percent,

which includes a fresh water rinsing, reduced down to 23 percent, and after withdrawing roots, they reduce it down to 9 percent. Our research has found that taking it all through, it reduces the total count significantly.

As you can see, we get it as far down as 9 percent, and it's very important that at this lowest possible level, as with seed, the product is straightaway packed and processed and sealed and cooled. This is just some additional data. Maybe some comments came up before about that.

MS. DeROEVER: Mr. Regli, you have two minutes.

DR. REGLI: Okay. I'm just about done.

As we said, the pasteurizing system, we're in a very early stage of what we're doing in alfalfa. We have quite a few years' experience with mung beans. And we're testing using even higher temperatures, different times, but this is the process which is taking quite a bit of time.

Just two days ago, we did actually the finish test, refusing(?) 85, talking always about centigrade, and 85 degree by 9 seconds, and the germination and yield, again, was not affected any further. So there are possibilities that we can go further, but this needs to be-- research needs to be done and, of course, practical tests as well.

Thank you very much.

MS. OLIVER: Thank you very much.

Next we have Larry Ravitz, owner of Banner Sprouts.

MR. RAVITZ: Good evening, everyone. I'm sorry I'm not dressed appropriately. My baggage is gone, and so are all my notes. So instead of telling you what I came here to tell you, I'm going to give you some of my opinions on some of the questions that were being asked by some of the speakers today.

I've been growing alfalfa sprouts and everything but bean sprouts for 17 years. I'm in Sacramento, California, and I have had, thank God, no epidemics of anything for 17 years.

Recently, I have started using calcium hypochlorite, mainly because I do have concern, like all the sprout growers in this room and all of you have, regarding the health hazards of alfalfa sprouts. I have a few suggestions I'd like to share with you that have been keeping me up for many nights, and this is probably the first good opportunity for having many people that can listen.

First of all, I would think that if we could find out specifically what countries we've been having the most difficulty with in obtaining their seeds and selling them in our country, we should stop buying them from those

countries, such as Italy or Spain.

Second of all, if you didn't know this before, Australia did have an epidemic a number of years ago of Salmonella on seeds that they purchased from California that were grown here in California. Since that time, they have passed a law; their Department of Agriculture requires--seeds that are sent from the United States to Australia have to be treated. And in turn, seeds that come from Australia to the United States are also treated. So if we can look into that, we might also find out exactly what research they have done.

In addition to that, rather than using the calcium hypochlorite, we've heard of many suggestions this afternoon. I heard very little on ozone, and I for one have taken it upon myself to get a few scientists and a few large companies that are involved in ozone generator manufacturing in Canada and here in California to work on a system that could possibly be used as a demonstration unit for testing, which is now in the process of being done at UC-Davis. UC-Davis at this time, which is very close to where I live and where my facilities are, has started doing research using ozone, and the preliminary reports so far look quite good. They have used ozone in small dosages on the finished product, and it has shown no significant decay of the product. They have also used it in the pre-soaking method,

and it did kill all of the bacteria and pathogens in the solution.

They do not have a generator at this time that's large enough to go up to, let's say, two parts per million, so I think at this time they're probably using maybe a half a part per million. They are going to be continuing the investigation of the possibility of using ozone.

I think that we need to keep a very open mind on using chemicals on sprouts because, in my own personal feelings, the reason for people eating sprouts is because it's supposed to be healthy and nutritious. And if we need use any sort of chemicals to save the sprout industry from decay--excuse the pun--or from the Salmonella and the outbreaks that we're having, eventually we're going to probably have to put some sort of label on our sprouts saying that our seeds have been pre-treated. And as soon as we start mentioning chemicals, I think people are going to start backing off, anyway.

In my opinion, if there's any natural method, either ozone, which leaves no residue, and also, by the way, has no difference in taste on the finished product, if we can use something like that or possibly even the pasteurization process, if we can find a way that we can afford a process like that, I think we'd be way ahead than using chemicals.

I think also--I do a lot of thinking, you can tell, because I'm ad libbing, so please bear with me. I think also that it's very important that we do recognize the absolute importance of doing something now regarding the alfalfa issue. There is a good possibility that it isn't just alfalfa that has Salmonella and E. coli, probably because so much more of the sprouts sold in the United States are alfalfa that maybe there has been problems all along that we haven't noticed or observed, and possibly clover. I don't think there's too many growers here in this room that are growing dicon(ph) radish as far as the tall ones. I believe most of the people that spoke today, from Japan, the doctor from Japan, I believe he's referring to the tall dicon radish rather than short sprouts similar to alfalfa in size. There's quite a difference in the growing methods for those.

Furthermore, as far as changes in temperature and what effect it has on the speed of growth on sprouts, my facilities, we produce about three-quarters of a million four-ounce containers a year. So that's a fair number for a small to medium operation. If we use just their city water because we're in the city, in the summer the water does get warmer, so we do have to chill it. Alfalfa is extremely sensitive to water changes. Two to three degrees at a certain stage of its growth is enough to cause the entire

crop to fail. If it's already pre-germinated, as an example, at 68 degrees, and the next day your water temperature gets up to 71, there's a good possibility that those sprouts will decay before it ever reaches maturity in three days.

Those of us that try to extend our yield by approximately 20 percent or 22 percent by growing it to maturity in a drum, in a rotating drum for four days, take a big chance, not only the potential problem of the sprouts overheating in the drum because of the amount of volume in that small confined area, but also the longer it's in that ultimate comfortable environment, the more rapidly I feel that bacteria can grow. I think the shorter the period of time we grow it, the less likely we'll have major problems. I have cut all of my growing cycles down to three days on alfalfa, whereas before, I used to go four.

I don't know what else to say. I've had a lot of things that have been running through my mind that I wanted to bring up with everyone just to share my feelings on the subject. If you don't agree on using chlorine or calcium hypochlorite, at least I beg all of you that are sprout growers, at least start doing something. We have no time left any longer. Every single week, we hear of another problem that's taking place in the country. A decision has to be made on what we're going to do about it, and those of

us that aren't here that you know are sprout growers because they didn't want to spend the money for the trip or didn't feel it was that important, it might be your neighbor next door that's your competitor who didn't show up here tonight that can be the downfall of our industry.

Thank you for listening.

MS. OLIVER: Thank you very much.

Our next speaker is Thomas Mates, general manager of Sterigenics International.

MR. MATES: Good afternoon. Thank you for the opportunity to give my two cents. I've got to tell you, sitting in the audience, as most of you non-speakers have found out, it's a test of patience to listen to all that's going on and not being able to put your two cents in.

My company is a contract irradiation processor. Rather than try to sell my company or the industry, I thought I'd give you two or three statistics about what irradiation is doing so that as you as a committee look to use irradiation as one of the techniques, you should at least go in with some pre-loaded ideas.

Currently, as you're probably aware--and you'll hear from speakers tomorrow, and Dr. Pat Hansen is in the audience--the use of irradiation for this application is currently not approved by the Food and Drug Administration. So one of your greatest challenges--and Dan Caudill brought

it up before--is to petition the Food and Drug to allow the use of irradiation, and the key problem you're going to face is this is not something you can get done in 20 or 30 or 40 days, as you all recognize. Most petitions are in the 3, 6, 9, 12, 15-month terms unless you can get on some kind of a much faster track. So you're going to face a little bit of a problem just getting through the regulatory land mines that are in front of you getting the approval process complete.

Secondly, to give you an idea of the scope of the irradiators in the United States, there are 29 contract facilities domestically. Of those 29, only five are positioned to do non-medical sterilization. The majority is being used to process single-use disposable products, and of those five, to give you another statistic, the American Spice Trade Association uses this technology to sterilize ingredients, and the current domestic use is about 75 million pounds annually.

Now, I don't know where the alfalfa seed total volume comes in, but I think the industry is prepared to handle this volume if, in fact, we can get a dose range that's consistent with the pieces of machinery that are available.

You're going to face a little bit of a problem with the utility of some of the equipment. Using an

irradiator that was designed for medical sterilization and now trying to use it for seed sterilization is somewhat analogous to putting a square peg in a round hole. The irradiators that were designed for medical sterilization were designed obviously for lightweight square boxes that have high doses of 25 kilograde and greater, and the doses that we're talking about to do with the alfalfa seeds is more in the 2 to 3 kilograde range, which, if you do the math, is a much smaller dose and a much higher density product and is a significant challenge for the irradiation operator. So he's going to have a little bit of a problem, and you're going to have a challenge finding facilities that have the capability of doing those finite doses. Not impossible, but there just aren't that many of them around.

With that, I guess that's all. I don't have a film. I don't have a joke. But thank you for the opportunity to talk.

MS. OLIVER: Thank you very much.

Our next speaker is Michael Lalley, president of Living Foods, Inc.

MR. LALLEY: Good afternoon. Nice to have you all here today and be with you. We've been in the business of growing sprouts for 21 years at Living Foods in Michigan. I am the president of the company, and, first and foremost, we agree that the main purpose of being in the food industry is

to provide a wholesome, healthy product to the consumer. That is the number one issue. Nothing will ever be more important.

However, my main concern is with the FDA warning and the accompanying threat of a warning label, which I believe to be an overreaction to a situation that clearly exists in the food industry, and that's specifically to the sprout business.

Quoting from Siliker (ph) Labs, Volume 13, Issue 1, they're talking to their fresh-cut people and they say despite their remarkable gains, all processors share one sober realization, that is, zero risk is not--and I repeat, zero risk is not achievable. Period. We don't care if we're talking alfalfa sprouts, broccoli sprouts, fresh-cut. We've got a list of things that we've had various food problems in the U.S. in the last number of years, of which I'm acutely aware. Amongst the items that have been implicated, we've got raspberries, strawberries, basil, melons, fresh-cut lettuce, to say nothing of the ground beef, chicken, eggs. We can go to any local grocer and pull those samples from the store shelves and test positive results for human pathogens.

With all the testing that we've done both in-plant and federal and state agencies, very, very few contamination problems have ever actually been cultured. The

epidemiological studies that have linked the sprouts to the various foodborne outbreaks I believe are somewhat questionable. The Hudson Beef situation, we had 16 people that were ill. Of the 16 people that were ill, 100 percent, all 16, had swore to God on their studies that they had consumed the Hudson Beef. In the Salmonella Stanley situation in Michigan, 60 percent of those interviewed swore to God that they had never eaten alfalfa sprouts.

In the 1997 Michigan outbreak of E. coli, once we got the questionnaire worded out a little better and asked repeatedly on alfalfa sprouts, unlike other commodities, we managed to get that number up to a 60 percent positive respondents had actually claimed that they consumed the product. However, when the FDA--maybe I stand corrected. When CDC, the Michigan Department of Agriculture, and the Michigan Department of Health came to my plant to check us out on the E. coli situation in 1997, when they arrived, they told me the reason that they had arrived was that a vegetarian community had been struck with the problem.

I understood that that did tip them off, and at that point in time I thought it was a reasonable assumption on their part, because our purpose--I would just as soon be selling pencils on the side of the street as sell implicated food products. I have no desire to be in that business. But by virtue of the fact food is--there's no such thing as

zero risk, then we have to look at the relative risk.

We've heard that 72 million pounds of sprouts are produced in this country annually. If the average serving or dose is, say, a quarter--or let's just say one ounce, then we've got something in the neighborhood of 2 billion doses annually going out into the marketplace. We've had eight situations in the last five years where people have supposedly been linked to problems with the sprouting business. I don't view that--as much as one person sick, I view as a serious disaster. On the other hand, the relative risk I think has been grossly overstated.

What else do I have for you?

Other than that, like I say, the FDA warning, I think you will realize the seed producers said that their sales are off by 50 percent. FDA should be happy to notice that the Kroger Company in my market area has pulled the product even though we've had no problem of any situation in the two years just due to the FDA warning. Farmer Jack, the Great A&P Tea Company has pulled the product from their shelves, and like I say, when we can't test this, when we can't find it, when my family and my employees eat the product on a regular basis and nobody is becoming ill, and yet like I say we grossly overreact like this, I think that the entire food industry, especially food items consumed fresh, ought to take a quick look before they had down the

slippery slope, because my feeling is if we're going to be warning alfalfa sprouts from what Dr. Wick's testimony--what his pictures showed us on the screen today, what the Japanese have indicated to us of their situation with the radish problem, this is not an alfalfa sprout problem. This is a food, a fresh raw food problem, and if you all want to just start eating pasteurized foods--I personally have been a vegetarian for 30 years. My great-grandmother lived to 102 and a half, and I'm going way beyond here, and I'm going to eat these things. And warning label or no, like I say, it's just a sad state of affairs.

I'd be happy to entertain any questions, too. Thank you.

[Applause.]

MS. OLIVER: Thank you very much.

Our next speaker is Jay Louie, vice president, ISGA.

MR. LOUIE: Thank you, Madam Chairperson and members of the sprout panel, for this opportunity to speak today. I'll try to keep this short and reduce some of my notes because it's been a long day.

First of all, my name is Jay Louie. Not only am I the vice president of ISGA, I am also the acting president of the California Sprout Growers Association, which is now being formed in response to some of the outbreaks that have

occurred in the State of California.

The sprouting industry in California goes back as long as 50 years ago. My mother and father started in this business in 1950 in a small back room using the only technology available at that time, which was ingenuity, hard work, and an alarm clock. We grew bean sprouts, which at that time was a specialty product used primarily by Chinese restaurants. My family's background was in farming, but we couldn't afford to buy a lot of land, so we produced bean sprouts, which are grown entirely indoors in a small confined space.

This is probably a typical scenario for a lot of sprout growers. We had a very nutritious food product that could be mass produced in a short period of time without the need of large acres of farmland. Furthermore, this product could be grown and sold at a price that any consumer could afford.

Sprout growing is a life-style choice. It's a seven-day-a-week, 24-hour operation. Most of us have education in other fields. We are teachers, artists, engineers, or, like myself, an attorney. If money was my goal, I would be practicing law instead of growing sprouts.

California growers, like growers in the rest of the country, serve their local areas because sprouts is a highly perishable product. Distribution is very direct, and

not many food handlers are involved.

When most of us started our business, there wasn't a health food market as it exists today. My business produces over 20,000 pounds of sprouts a week, both bean sprouts and green leaf sprouts. There are other growers who produce a lot more and some a lot less. The average consumer has created the demand by buying and eating sprouts. There was no magical marketing plan. The consumers wanted a low-cost, healthy, nutritious food. They just want their sprouts.

For at least the last 50 years or more in California and for thousands of years that sprouts have been grown worldwide, sprouts have been known as a healthy, nutritious food product. The first Salmonella outbreak epidemiologically linked to sprouts in the United States occurred in 1995, less than three years ago. The first Salmonella outbreak epidemiologically linked to sprouts in California occurred in 1996.

The California Department of Health Service Food and Drug Branch and the U.S. Food and Drug Administration invited many sprout growers and suppliers to meet in Sacramento in September of 1996. As an industry, we were challenged to address the sanitation and microbial problems related to sprouts, both mung and alfalfa. In response to this challenge, the California Sprout Working Group was

formed. I became a part of this group. This group consisted of sprout growers who volunteer their time and energy to understand the problem and to work with the various public agencies to produce safe sprouts.

As a group, we began to understand that foodborne illnesses were becoming a more frequent occurrence and that other organizations, like the WGA and IFPA, had developed voluntary guidelines in order to protect consumers. These guidelines were developed and were distributed to all growers in California in late August of 1997.

You must keep in mind that for decades sprouting has been a very secretive, competitive industry. The various methods of growing sprouts were very proprietary. Sprout growers literally did not speak with one another. Less than 20 percent of the California sprout growers at the time were members of the International Sprout Growers Association, which started in 1989.

The California Sprout Working Group was not surprised at the relative lack of response from the industry. A majority of sprout growers never heard of the California Sprout Working Group or good manufacturing practices. Sprouts have been grown to consume for decades. Pathogens were unheard of. Root rot, brown rot, which destroyed crops, yes. But nobody has ever heard of anybody getting sick from eating sprouts. So are we in denial? I

don't think so. Perhaps it's because of the aggressive tactics used to convince sprouters that their healthy, nutritious food product is now suddenly a dangerous carrier of foodborne pathogens.

Organization such as STOP have accused government of failing to warn the public of dangerous, potentially contaminated products. STOP contends that government has full knowledge that certain food products are potentially dangerous for human consumption and that with this knowledge the government has inadequately failed to warn consumers to protect them from life-threatening illnesses. On the other hand, sprouts that have been grown, marketed, and consumed for decades without any problems are now being labeled suddenly a high-risk food product.

Sprout growers are told by representatives of the Health Department that they have interviewed people who have been stricken with foodborne illnesses, and although most people can't recall what they ate two weeks ago, 20 percent do recall eating alfalfa sprouts and, therefore, alfalfa sprouts is a cause of the foodborne outbreak.

It has been less than three years since the first outbreak of foodborne illnesses associated with sprouts. Sprout growers have been asked to jump through hoops with little explanation or blind faith that what the health regulators are saying is true and correct.

As a responsible sprout grower, I don't want to be personally responsible for causing anyone to get sick from eating sprouts. As a responsible sprout grower, I and other sprout growers in California are taking a proactive position in the prevention of foodborne illnesses in sprouts by forming the California Sprout Growers Association.

The California Sprout Growers have worked together to produce Project SOS, Save Our Sprouts. This is in direct response to the Department of Health Service's challenge to present proposals. A copy was given to them, and I delivered a copy to Mary Acton today, who will make copies for members of the panel, and it will be distributed tomorrow.

As an industry, we're committed to making it mandatory for all California sprout growers to put into effect an approved seed sanitation process. We thank the California Department of Health Service for assisting in expediting the approval of this practice. We will train and educate growers on a regional basis on food-handling practices and on control of microbial hazards. We will implement a model safe food and quality control program for the sprouting industry, with certification from a third-party auditor. We will work with the ISGA to enlist growers to produce safe seeds which will guarantee a safe product.

In order for the California sprout growers to

implement Project SOS, we ask for a couple things in return. First, we need full disclosure of the epidemiological studies, including scientific data, interviews, swab results, lab tests, linking sprouts to all past and future outbreaks of foodborne illnesses. The sprouting industry has been tried, convicted, and sentenced for a crime of distributing unsafe food products. We, the sprouting industry, have not been given the right to cross-examine or scrutinize the evidence presented against us.

MS. DeROEVER: Mr. Louie, you have two minutes.

MR. LOUIE: Okay. Secondly, California sprout growers ask government agencies, the media, and STOP to act cautiously and responsible before destroying the industry that has for decades provided a safe food for the public. Unfortunately, press releases, meant to be helpful, have been taken out of context by public media and released in short sound bites: "Health hazard: Don't eat alfalfa sprouts."

Growers all over the state are worried. Many have lost important accounts. Some may have closed down because they can't afford PR agencies to fight the negative media. As an industry, we have been working diligently with regulatory agencies to produce a safe sprout. Don't pull the rug from under us before given an opportunity to act.

Thank you.

[Applause.]

MS. OLIVER: Thank you.

Our next comment is from Rob Carver, director of Carver Research.

MR. CARVER: Good afternoon. It's very difficult standing out or sitting out there all day long and hearing everything that's going on around you and keeping restraint and not jumping up and saying, Hey, I want to be part of this, I would like to make a statement, or, yeah, I think that's a good idea.

At this time, I'd like to take you on a journey. I have the best job in the world. I do food safety consulting, and I have the great fortune of consulting with some sprout growers. The sprout growers that I have encountered are conscientious people. Generally, to quote one of them, the reason why they went into sprout growing was it was a karma-free way of making a living.

I thought about that for a long time. Karma-free. How would they be able to reconcile such demonstrations that were given this morning by the people from STOP? Which I think is an excellent agency. I think they are needed to call attention to cases that are so very tragic. And they have to be inflammatory to spawn some people that would not normally take action. But not sprout growers. These people are very proactive. They are very concerned about the

environment. They are concerned about food products and nutrition. And they are concerned about food safety.

This journey that I went on with the sprout grower, I walked in the front door of his processing plant, which was his farm, by the way, and shook his hand and we went into a turnkey process where we spent a week talking about everything from facility management, preventive maintenance, where's that missing screw of your conveyor belt. We talked about recall programs. We talked about sanitation, SSOPs. We talked about setting up laboratories and doing environmental swabs.

All of this changed his perspective. It changed his life over a week's period of time. He found that no longer was he a simple indoor farmer, but he was actually a food manufacturer and that CFR 21, Part 110, applied to him. That would be the good manufacturing practices in the Code of Federal Regulation.

So once he realized that he was no longer a simple indoor farmer and that he was indeed a food manufacturer with responsibilities to provide wholesome, safe food. They were more than willing to do whatever it took to provide that safe food, to provide GMP training, to provide every item, every aspect of food safety that they could possibly control, whether it be seed sanitizing, vendor verification, HACCP, which, of course, as we all know, HACCP has some very

broad assumptions that are brought along with it that certain programs are in place and they are working properly.

All this is what helped him make the transition from an indoor farmer to a food manufacturer. That is why I have the greatest job in the world.

Thank you very much.

[Applause.]

MS. OLIVER: Thank you very much.

That was the last person that we had signed up for public comments this afternoon. I got a note that a couple of people from the audience had wanted to ask a few questions before. I'm going to see if any of them do at the moment. I'll take two or three questions. There's one back there, if you want to come up to the microphone. I'll take three. So there's one, two, three. I think they had comments or questions for some of the people from before.

MR. FAHEY: Hi. Jed Fahey from Johns Hopkins University. These are quick questions, if I'm allowed to ask questions. Otherwise, they're rhetorical questions.

I've spent 15 years in the agricultural biotech industry and the last five years at Johns Hopkins University where I develop broccoli sprouts, and in that 20-year period, I've done a lot of work with seed surface sterilization, and it has always involved the use of a surfactant to facilitate penetration of bleach of

hypochlorite and wetting of the seed surface. And I've heard that alluded to today a number of times, but in none of the recommendations that I've heard discussed, the 20,000 parts per million, et cetera, have I heard any mention of a surfactant, the additional of a surfactant.

I just wondered if that was something that was being considered at all, because it has always seemed to make sense to me that that's something that facilitates penetration into these cracks and crevices that Dr. Wick so illustrated with his electron micrographs.

MS. OLIVER: I might ask if anyone from this afternoon's panels had considered that.

[Inaudible comment.]

MS. OLIVER: Okay. He said that he used a surfactant but doesn't have any data.

MR. FAHEY: Okay. It's something to think about.

Something else, and these are perhaps devil's advocate questions, but the issue of biocontrol agents has been brought up. I think other words may have been used, such as antagonistic microorganisms or natural sprout colonizers that might antagonize the growth of human pathogens. And while that's a very attractive idea from the perspective of agriculture in general, keeping nasty organisms from growing on plants that one desires to keep healthy, I just wondered if there's any value at all in

anybody spending any time doing research in this area because I find it--I mean, it would be nice if that were possible, but I find it hard to believe that coming up with a proposal to throw a lot of microorganisms on seeds or on sprouts in order to prevent bad ones, human pathogens from growing, would not on the surface sound to me to be something that would be acceptable in terms of recommendations that might be made. So let's call that a rhetorical question, something to think about.

The third question revolves around mandatory GMPs, and I would ask this question I guess to Nancy. Does the ISGA cover a large percentage of the sprouters? My understanding is that the industry is, I think we have just heard, very fragmented. So I'm wondering what percentage of the 450 or so sprouters in the country that I've heard that exist are covered by the ISGA, are members of the ISGA.

MS. SNIDER: Well, I don't have exact numbers in front of me, but I would guess about 30 percent, actual companies, most of the larger companies, those who produce the most sprouts. If you were to reverse that question, do we have the larger sprouters, yes, we do in the organization.

MR. FAHEY: Okay. Thanks.

MS. OLIVER: Thank you.

Laurie?

MS. GIRAND: I had a couple of questions that were raised by Dr. Wick's comment that he thought it was a point source causing the contamination in the field and legitimate comments from Dan Caudill about the ecosystems around an alfalfa sprout field. It struck me that the only thing we can control in a 660-acre space would be whether or not we apply manure or chicken or poultry feces to the actual alfalfa growing field. In fact, I was surprised when Dr. Slutsker said that people don't do this, because I know a farmer who grows alfalfa for cattle feed who specifically uses cow manure to fertilize his alfalfa. And so I was wondering whether the committee thought that you could reduce pathogen load or you could potentially reduce pathogen load on the seed in the first place by not applying manure to the alfalfa field and whether we ought to do research on fertilized fields, fields fertilized with cow manure or poultry feces, and the relative level of pathogens possibly found in seed after that versus fields that are not actually used for--where fertilization with manure is not used.

MS. OLIVER: What I'd like to do is open that question for any of the speakers that we have and leave the committee discussion until tomorrow afternoon on theirs. But if any of the speakers--Larry, did you have any comments, or Dr. Wick?

DR. SLUTSKER: The information I had on the usual practices of alfalfa growing were just through conversations with Dan Caudill and others in the seed industry, but I can't tell you what proportion of alfalfa farmers use animal manure on their fields.

MS. OLIVER: Dr. Wick? Or did anyone else have a comment to that?

DR. WICK: I don't have any.

MS. OLIVER: Okay. We'll keep those questions-- I'm sorry?

DR. FARRAR: There's another component to that question. It's not just whether an individual would use manure or not. There's also another process of composting that needs to be incorporated in this discussion. And the definition of what's adequate composting, of course, rears its ugly head. But that needs to be factored in.

MS. OLIVER: That's a good point.

Did anyone else have a comment to that?

[No response.]

MS. OLIVER: Okay. We'll keep those questions, too, for the discussion tomorrow. Thanks, Laurie.

MR. BATTAGLIA: Janice, I'm afraid I put my name on the wrong list. I'd like to have two minutes, if I could, please.

MS. OLIVER: Go ahead.

MR. BATTAGLIA: Thank you. Good evening. My name is Paul Battaglia. I'm the owner of the Krisp Pack Company in Norfolk, Virginia. I'm the gentleman that everybody was talking about this morning from Virginia that had an outbreak last year in July and August. I'm happy to be here, and I'm happy the FDA would take the time to try to figure out what's going on, because we as growers all want to find the answer.

Like I heard from Mike and other people, no one here would want to get anyone hurt. We all have children. We all have concerns for what it takes to grow a healthy product. We grow alfalfa sprouts. I myself know that I'm a manufacturer. I've got 100 employees. I own Krisp Pack. In the time period that there was an outbreak of alfalfa sprouts in July of last year, in a week's period I sold 95,000 four-ounce containers. We do sell a lot of sprouts, and we do a lot of other items like vegetables, salads, and spinach and so forth. And it's an opportunity to talk to you folks at the FDA and give you a viewpoint of where we're coming from.

Please don't bailiwick all the alfalfa growers in one basket because of one or two problems. Most of the growers that I know and associate with, like Ms. Snider and so forth, are good, hard-working people. We're trying to do the best we can to give a nice wholesome product to people

on the street.

As I said a minute ago, nobody in the room that grows alfalfa sprouts would even think of harming anyone. It's the least--and we are very proactive. We appreciate the efforts that we're seeing today and what we're trying to come about. But if you come out with sound bites or come out with labels on alfalfa sprouts, the industry is going to just dry up and die.

Let's be proactive as a group together with the FDA and us. Let's find ways to certify growers so that we can do it like the gentleman from California said. Let the retailers dictate who they're going to buy from. Let the marketplace determine if alfalfa sprouts are going to be wholesome or not. Let the retailers say I'm not going to buy from that grower unless he's certified. And if the retailer knows, if it's Harris Teeter or Winn-Dixie, knows he won't buy from a certified grower, then the consumer's going to be protected. That's the way it will happen. And then growers who want to grow a certified product will have to become certified. They'll work hard. They'll have HACCP programs.

As I said, I'm a manufacturer. I've got a HACCP program. I'm lucky enough to have Primus Laboratories certify me as a third audit. I've got the FDA all the time, which I appreciate their help and sincere efforts. I've got

the city and I've also got state that looks at my building. We grow a healthy product.

But just for a minute, I want to kind of go over what happened last year. In July, the FDA came in and said that there's an outbreak. You've got the same seed that Michigan has, and we want you to recall your product. I immediately said of course. We pulled all the product off the shelf, voluntarily recalled. We cover about a 500-mile radius with my alfalfa sprouts. We pulled everything out of Carolina and out of Virginia. It wasn't until--because, God knows, E. coli is serious. Kids can die, and the pictures from this morning were enough to make anybody--I'm a little bit antagonistic about it because I felt like they're attacking my industry, and then for the next second, I think, well, that could be my kid.

So don't think for a minute that I'm not proactive and I don't want to put out a good product. That could be my kid that was on the film this morning. So you know I'm on your side. I think STOP is doing a good job, and I support them. I think they're kind of in the wrong direction with the sprouts, but getting back to my point, it wasn't until October of '97 that I finally got the information from the CDC as to what I was looking for. And the State of Virginia said that in the month of June and July we had 48 cases of E. coli. Of the 48 cases, 26 people

had the same RNA strain, the same fingerprint. Of the 26, they were able to contact 20 of the 26 and survey them. Of the 20, eight people said that they think they probably ate alfalfa sprouts.

Well, that's okay, because if one person thinks they ate alfalfa sprouts, I'm going to pull them off the market. Don't worry about it. But to implicate me and to say my industry is out there trying to contaminate people and trying to contaminate a product, you know, I think we need to work together a little bit more.

One-third of the people that had the blueprint for the outbreak of E. coli O157, one-third of them think they ate alfalfa sprouts.

Please don't misunderstand my comments. I'm very proactive. I want to do everything I can. I always submit requests to my customers to come see my facilities, and I have an open invitation to anybody on this board, at this table or down there, to come to Krisp Pack. We're only four hours away in Norfolk. We'd love to have you. You can wear our hair nets and our gloves and see our HACCP programs. I think if this board does anything, if the FDA does anything, please figure out a way to make the retailer make the manufacturers come up with some kind of certification. Make the retailers do it, and that will in turn make the market work like it should.

Thank you for your time.

MS. OLIVER: Thank you very much. I appreciate all of the comments.

I would like to say--I know I haven't said much about working with the sprout industry and the sprout growers, but the sprout industry has been very much working with the agency and has been working with the National Advisory Committee over the past year, has provided information to us in doing research and all, and we do appreciate that.

That comes to the end of today's session. We'd like to start tomorrow morning at 8:00, if you would, and thank you very much.

[Whereupon, at 5:47 p.m., the meeting was adjourned, to reconvene at 8:00 a.m., Tuesday, September 29, 1998.]

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CERTIFICATE

I, **THOMAS C. BITSKO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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