UNITED STATES DEPARTMENT OF AGRICULTURE

PATHOGEN REDUCTION: A SCIENTIFIC DIALOGUE

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P R O C E E D I N G S

8:44 a.m.

Welcome and Introduction of the Under Secretary

DR. HULEBAK: Good morning. Welcome back to Day 2 of Pathogen Reduction: A Scientific Dialogue.

Before I introduce Dr. Elsa Murano, Under Secretary for Food Safety, who's the opening speaker for this second day, David Boden, if you're in the audience, would you please call your office as soon as possible?

Dr. Murano, who's the Under Secretary for Food Safety at the Department of Agriculture, will open today's meeting. I mentioned yesterday she was sworn in by the Secretary of Agriculture Ann Veneman in October of this past year, and as Under Secretary, she oversees the policies and the programs of the Food Safety and Inspection Service. She has extensive public and private experience with food safety as a manager and as an educator, and immediately before joining this Administration, since 1997, was Director of Texas A&M University's Center for Food Safety within the Institute of Food Science and Engineering.

She's a native of Havana, Cuba, and she holds a Bachelor's of Science degree in Biological Sciences

from Florida International University, Master's of Science in Anaerobic Microbiology and a Ph.D. in Food Science and Technology, both of those last two degrees from Virginia Polytechnic Institute and State University in Blacksburg, Virginia.

She's previously served as Professor at Iowa State University in Ames, and immediately before her appointment as Under Secretary, she was a member of the USDA's National Advisory Committee for Meat and Poultry Inspection.

Dr. Murano has defined five goals to guide FSIS as it works towards achieving its mission of protecting the public's health through ensuring the safety of meat, poultry and egg products, both domestic and imported. These five goals are: (1) secure our food supply from intentional harm; (2) base policy decisions on science; (3) improve the management of agency programs; (4) improve coordination with sister agencies; and (5) engage in aggressive education programs.

This scientific symposium, yesterday's and today's meeting, has been planned by FSIS with Dr. Murano's five goals clearly in mind. As an exercise in scientific dialogue, it is an activity that is centrally focused on Goal 2, and with an eye to Goal 4,

it also involves substantive involvement from experts in our sister agencies within USDA, FSIS, ERS, Economic Research Service, and Agricultural Research Service, and with our Public Health Service sister agencies among HHS' agencies, FDA and CDC, and also through participation with our neighbors to the south from Mexico and to the north from Canada.

And now, I'd like to introduce to you the architect of these goals, Dr. Elsa Murano.

(Applause)

Opening Remarks

DR. MURANO: What a nice introduction, my goodness.

Well, good morning, everybody. Very glad to see all of you returning this morning for the second day of our Symposium on Pathogen Reduction.

Well, yesterday, we heard several presentations on how hazards are introduced into the food supply, and I think you will agree that the discussions set the stage beautifully for what will be presented today. In fact, several questions posed to yesterday's speakers revolved around performance standards and intervention strategies, topics that will be covered today. So, Frank Busta, where are you? Get your panel another cup of coffee because you're going

to need it, I think.

Well, this symposium was planned as part of a series designed to address various topics of significance to food safety. Our first symposium was held in January in Atlanta and revolved around the science of epidemiology. There are seven more meetings to follow this one. So, you may ask why is FSIS engaging in these symposia? How are these meetings different from others the agency has held in the past?

Well, when I came to Washington last Fall, it didn't take me long to realize that in spite of the tremendous strides that we have made in food safety over the last few years, there are many challenges ahead. Yesterday, we heard that hazards are introduced into the meat and poultry supply at various points along the farm to table continuum, pointing to the complex task that we face.

We also heard from CDC about a decline in foodborne illness from 1996 to 2001, but due to the many variables involved, it is difficult to attribute this decline to any one factor.

Well, because of these challenges as well as many others, policymakers need to make the best decisions possible; decisions that will address the underlying problems affecting food safety, decisions

that will provide solutions that can be measured in terms of public health. In my opinion, these decisions must be based on science and not on the path of least resistance.

There are three lessons that I personally came away with from yesterday's sessions. One is that prevalence data derived from regulatory testing is by its very nature biased data and will not provide us with the true incidence of pathogens on meat and poultry.

Secondly, data on foodborne illnesses collected by CDC is incomplete and does not provide adequate information on the contribution of various factors on disease, such as the type of food involved. Both of these are essential if we are to determine whether interventions, HACCP or other factors are making an impact on public health.

Thirdly, yesterday's meeting helped put into perspective at least for me which of the steps from farm to table are the key points where contamination must be controlled in order to improve food safety, and none of these things were revelations to most of us, yet I believe these were facts that we all needed to agree on before moving forward with today's discussions.

Well, since my confirmation last October, as Dr. Hulebak said, I've been going around the country telling people that I want to inject as much science into the policymaking process as the system will take and then some. There are several ways to do this, I believe, some of which have been in use by FSIS for many years.

Risk assessment is one such method which has proven very helpful to us in showing the true impact of several hazards to our food supply. Another is research, and I am happy to see several people here from the Agricultural Research Service on whom, along with academia, we policymakers depend in order to determine the strategies that can be applied to directly control hazards to our food supply.

Yet a third method of injecting science into the process is to avail ourselves of the experience and expertise of the scientific community and to engage in meaningful conversations that may help shed light into trends and thus enable us to be proactive in our decisionmaking.

For this reason, we are having this scientific dialogue, so that we can hear from scientists that have dedicated their life to the study of these problems and who can provide us with the

guidance we need to make sound policy that will translate into positive public health outcomes.

Lately, I've been asked by reporters to define what I mean by science. In fact, they usually ask me about sound science. I tell them that science by definition is sound. Otherwise, it's not science, is it? Still, they want to know what I mean, sometimes implying that what is science to some may not be to others.

Well, since we're at a scientific symposium, I think this as good a place as any for us to define science. So, let's see if we can do that. Well, simply stated, science is a body of facts gathered by observing the physical universe. One question that arises from this definition is: well, what are the facts? Well, a fact is something that is true. What is true, you may ask, and how does one know that a supposed fact is true?

Well, maybe the following story will help us answer these questions. Back in the 1600s, there was a man named Jean Baptiste von Helmont, who proposed that mice could be spontaneously generated in at least 21 days, not 20, 21 days, by putting a sweaty shirt and grains of wheat in a dusty box. The sweat supposedly supplied the active principle which caused the wheat

grains and dust in the box to become mice.

Well, every time von Helmont conducted the experiment, he found mice gnawing out from the box within 21 days. Well, certainly we know that mice don't spontaneously generate, right? Right? Well, as it turns out, the design of the experiment was faulty. von Helmont failed to take into account that the mice might be gnawing into the box.

So, what could he have done differently? Well, was this a controlled experiment in your opinion? In fact, let me ask what should have been his control? I'll go ahead and open it up to anybody who would like to answer that question. What should have been his control in this experiment? A secure box. Good. Say that again. Box without a sweaty shirt. Interesting. Very good. A secure box is Rosemary. Anybody else? You scientists out there?

Well, these are good ideas for sure, and he didn't include any one of those. The fact is that he was attempting to support his widely-accepted belief, you know. He believed in spontaneous generation, and since his results supported his belief, he didn't see the need to restructure the experiment or to include any controls.

Well, thank goodness for Louis Pasteur.

Wouldn't you say that? Because he, around 1800, devised a series of experiments which to this day are valid and which disproved once and for all the notion of spontaneous generation. He prepared several sets of infusions and sealed them in flasks. He then sterilized the infusions by boiling, and he opened one set of flasks along a dusty road, another set in a forest, and another set up on the mountains.

Well, later, Pasteur examined the infusions and found that those opened in dusty places contained abundant and varied microorganisms. Those that were exposed to cleaner air, like the one opened in the mountaintop, had fewer and different microorganisms. Well, these results urged Pasteur to conduct his now-famous Swan neck flask experiment in which he showed that infusions that were boiled and sealed in flasks with long winding necks would remain sterile unless he tipped the flask so that the dust particles trapped in the neck could enter the infusion at the bottom of the flask. He repeated the experiment several times and always obtained the same results.

So, Pasteur's genius came from having designed an experiment that would prove or disprove a theory, that of spontaneous generation, through the planning and execution of a controlled experiment

followed by data collection, analysis of the data and verification by repeating it and obtaining the same answer.

So, these are the elements of the scientific process, and it is why science should guide our decisions about food safety. It is why we have organized this symposium, to hear from the scientific community so that, along with risk assessment, research, and other science-based activities, we can achieve the goal of improving the safety of our meat and poultry and thus accomplish the mission of protecting the public's health.

Well, speaking of public health, I'd like to say that I believe strongly that one does not need to have a degree in public health to understand what it means or to contribute to it. All of us in this room are food preparers, some better than others, as my husband will tell you, but we all play an important role in protecting the health of our families when we wash our hands, when we cook foods to the appropriate temperature, when we refrigerate leftovers promptly.

There are many in the audience you produce and process food for a living and play an important role in protecting the public health when they follow the tenets of good manufacturing practices of

sanitation and HACCP, and there are others in the audience who engage in research regarding the hazards that can be found in food and how these can be mitigated.

In that way, they are also participants in protecting public health, and some of us play a role when we draft policies based on the answers provided to us by these researchers through the application of the scientific process.

So, let no one doubt that we are all here because we are interested, in fact, we are dedicated to protecting the public's health. This is why our symposium is entitled "A Scientific Dialogue". We must all engage in a dialogue with the scientists who are here to contribute their expertise but without the rest of us, food producers, food processors, consumers, and policymakers, this would just be another scientific meeting.

So, I urge you all to participate in the discussions today, to leave other agendas at the door and to come with an open mind, an open heart, so we can get to the business of making food safer for all Americans.

Before I relinquish the microphone to Dr. Hulebak, let me challenge you with a thought for

today's discussions. Last week, I sat next to a mother who testified before a congressional committee on how her son had been very ill at age 10 after consuming an undercooked hamburger contaminated with E.coli 0157:H7. Well, my opinion for that family, both microbial testing and a zero tolerance policy for this pathogen in raw product, failed miserably. Neither was able to ensure that the product would be safe.

Ladies and gentlemen, I think we can do better, and I think we must do better. We must not allow our policies to be guided by wishful thinking nor by political expediency. So, I would like to submit to all of you the following questions for discussion today.

What should be the appropriate role of microbial testing and zero tolerance of raw versus cooked products, and how could HACCP or other systems be applied best in order to ensure safety of meat to the greatest extent possible?

Well, thank you for your attention this morning, for your commitment to food safety and to public health. I certainly look forward to a great dialogue this morning, and I will relinquish the microphone now.

Thank you very much.

(Applause)

DR. HULEBAK: Thank you very much, Dr. Murano.

I'll now introduce Dr. Gary Acuff, who is the Chairman for Panel 3 for this symposium, which concerns "Performance Standards and Microbial Testing".

Dr. Acuff obtained his Bachelor's of Science in Biology from Abilene Christian University and then went on to get Master's and Ph.D. degrees from Texas A&M. He currently is Professor of Food Microbiology and is the Food Science Section Leader in the Department of Animal Science at Texas A&M University.

His research focuses around microbiological safety and shelf life of red meat. He's also interested in microbiological hazards of fresh produce. He also carries a heavy teaching load for graduates and undergraduates and has authored or co-authored over 75 articles in peer-reviewed journals. He currently serves as a member of the National Advisory Committee on Microbiological Criteria for Food. Actually, he served as a member. A little moment of panic there.

Join me in welcoming Dr. Acuff and Panel 3.

(Applause)

Panel 3: Performance Standards and Microbial Testing

DR. ACUFF: Well, we have an interesting

panel, I think, for your enjoyment this morning.

I will chair and give you sort of a brief introduction, then we'll hear from Dr. Elise Golan, Dr. Buchanan, Frank Busta and finish it up with Loren Lange, and I have reviewed all of these guys' presentations just a little bit and they all look very interesting. So, I think you're going to really enjoy it.

All right. Well, you remember how hard it was to stay awake in that 8:00 history class? Well, I don't want you to flash back but that's what we're going to do. We're going to talk about some history.

This is a piece of art by Pisarro, and this is depicting a poultry market about the turn of the 20th Century. This is the early 1900s, and, you know, yesterday, we were talking about custom slaughter, and boy, this is as close as you get right here. So, you go in and pick out what you wanted, and you could take it home and slaughter it or they would do it for you right there, and microbiological criteria and HACCP had probably not entered their mind at this point. HACCP may have. You know, I think HACCP actually has been around for a long time. We just never called it that, but maybe they had HACCP plans, but I'm not sure they'd meet the regulation.

Well, things have changed. We have mass production of products. The consumer demands precooked products. They want lengthy shelf life on everything, and there are new expectations of safety by the consumer that we all have to deal with and that we all need to meet.

Well, the other thing is we have a lot more data than we used to have. The Centers for Disease Control have provided us with extensive information on foodborne disease, and as we know, there are lots of holes in the data, but considering the information we used to have, we have a boatload of information here that we can use to try to ensure the safety of our products.

Well, when we began to collect data and when we have these pressures to produce a safe product, one of the things I think that naturally comes to mind is there should be some sort of number that we can use to determine whether this is safe or not because we don't want to make subjective decisions. We would like to have everything black and white, and by golly, there should be a number that we can use to take care of things, and this has been around for a long, long time.

If you look back in the 1950s, the City of Portland, Oregon, established a retail meat standard

with an APC of 10 to the 7th per gram. They didn't enforce it because they didn't have any money to enforce it, but it was a nice idea, you know. They put it out there.

In 1971, the state actually established standards, and this followed a baseline survey that they did. They went around and collected data and they said, you know, we're going to do this baseline survey and figure out where everything's at and then they said, you know, I believe we could set some standards and remarkably again they picked this greater than or equal to 10 to the 7th per gram for APC and less than 50 per gram Escherichia coli, and again it was published but not enforced and most likely because of a lack of funding to provide enforcement.

Well, later on in the '70s, there was a big push from consumer groups, and actually this is a picture of Ralph Nader talking to Upton Sinclair. Whenever I was looking for a picture of Ralph Nader, you had to pay copyright stuff on that. So, it just happened to be about the time he was running for President and his picture prices went way up. So, all I could find was this one with the top of his head talking to Upton Sinclair that A&M could afford, you know. So, this is the best we can do. Actually, I

think from that angle, he kind of looks like Mike Doyle a few years ago.

All right. Well, anyway, there may be something there, Mike. Is there any? I don't know. Well, these consumer groups were doing some studies on their own collecting samples, you know, and looking at what was available in the deli case and the retail meat market, and Consumers Union got involved and they published in Consumer Reports a little report that talked about how deli meats and retail meats were really out of control, and they had dangerously-high levels of bacteria.

Well, I've always wondered, you know, I see that in the papers all the time, I've always wondered what dangerously-high levels of bacteria are and maybe we can define that in our science meeting today. When we get that figured out, I think we'll all be in good shape.

But they recommended standards for ground meat again, and you see this time, it was less than or equal to 5 times 10 to the 6. They're getting a little more accurate there and less than 50 per gram for E.coli. They held a public hearing. Consumer groups were very supportive of the microbiological criteria. The industry said very little about it, and they were

passed.

Well, when these were implemented, they had a system where they would come in and sample, and if you were in violation, then you had to resample in 60 days, and they had a three-strike system. On the third strike, you were issued a criminal citation.

So, in between '73 and '76, they filed criminal charges against 27 retail store managers, and they published a list of markets that were found in violation every other month. Well, there was a big outcry by the industry, and the legislature in Oregon decided that they should look at this. They set up a hearing and someone from the Oregon Department of Agriculture came in and explained that this was simply a tool to force sanitation improvement, a hammer, if you will, and that this force of enforcing microbiological criteria improved quality in public health, and his data to support that or evidence to support it was that they had 16 percent of samples in violation in 1974 but yet in 1976, only nine percent were in violation.

Well, the legislature didn't really know what to do. So, they set up a committee to look at this, which is standard procedure, I guess, and this ad hoc committee reviewed the situation and ultimately decided

that the standards should be revoked, and they had several reasons for this. I picked out three that I thought were interesting.

First, they said the standards were not enforceable. Secondly, they said there was no reduction in foodborne disease or improvement in quality, and third, they said that there were erroneous consumer expectations of improved quality and safety.

Well, based on that, the standards were taken away, but there has been activity internationally and nationally as well in microbiological criteria, granted with more data and with more information at our fingertips to begin developing these.

In 1981, Codex published a document called "General Principles for the Establishment and Application of Microbiological Criteria for Food", and they said that "criteria should be established and applied only when there's a definite need and where it's both practical and likely to be effective". Their recommendation for raw products regarding pathogens is that it's going to "meet limited success because of the extreme variability of the organism on the product".

In 1985, the Green Book was published, and they looked at the possible application of microbiological criteria to 22 different food groups

and food ingredients, and in this report, they stated that criteria were not recommended because they wouldn't prevent food spoilage or foodborne illness, and if you can't comply consistently with the criteria, it makes no sense to set them.

Well, their recommendation was that you implement HACCP because we had low numbers of pathogens present on raw products, criteria were not likely to prevent that, but their control would be possible through a HACCP system.

Well, there are a couple of texts that are published by the International Commission on Microbiological Specifications for Food. The first of these is a first edition of the Book 2, which recommended that we establish criteria for certain foods. In the second edition, that was discontinued because they said commodities frequently failed criteria and that there was no relationship to quality or safety.

Now, these texts were primarily designed for international trade, and so we're looking at port of entry products. However, it is stated in the text that while that is primarily for international trade and port of entry-type products, the principles are the same across the board and are not different between

international and local products.

Well, that brings us to pathogen reduction HACCP regulation. The pathogen reduction HACCP regulation established HACCP to ensure safety and this is through, of course, process control. Associated with that, the HACCP rule established testing to verify that we did have this control. Now, these criteria are performance criteria which I've never been crazy about that term. I always wished they'd called it performance criterion since that's the singular form of the word, but anyway, they're called performance criteria, which now, you know, is accepted in the dictionary as a singular form.

You know, if you use things wrong long enough, they finally accept it. Anyway, performance criteria for E.coli and we had performance standards for Salmonella. Now, these are designed in the system to verify the control that we have in the HACCP system, and, of course, there has been a lot of discussion and heartache about how some of these have been applied and how they've gotten established, but we're working through those roadblocks and problems and trying to get things on line.

Well, our panel today contains some people who have been active in ICMSF, some gentlemen that have

been active on the National Advisory Committee and commenting on some of the HACCP regulation and standards and criteria. We have some people on our panel today who are probably considered some of the world's experts on microbiological criteria.

So, we're privileged to get to hear what they have to say to us today, and our first speaker is going to be Dr. Elise Golan, and while I'm introducing her, let me get her slides up here.

All right. Dr. Golan is an economist at USDA's Economic Research Service. She received her Ph.D. in Agricultural Economics from the University of California at Berkeley in 1989 and was awarded a post-doctorate fellowship by the Israeli Higher Education Council from 1991 to '93 for work at the University of Haifa in Israel.

Before joining ERS, she did consulting work for, among others, the World Bank, International Labor Organization, the California Department of Finance. She served as a senior staff economist on the President's Council of Economic Advisors in 1998 through '99.

At ERS, Elise's work has focused on the distributional consequences of food policy, the economics of product differentiation in food labeling

and domestic and international food safety policy.

So, join me in welcoming Dr. Golan, and she's going to make our first presentation.

(Applause)

DR. GOLAN: Good morning. Thank you for inviting me to join this panel. Quite an honor.

My job this morning is to give the economist's point of view and standards and why economists seem to be so enamored with performance standards versus process standards.

We know that policymakers have a wide array of tools with which to try to influence the behavior of private firms or consumers to achieve a social or policy objective. A policy objective could be anything from reducing pollution, reducing foodborne illness, improving nutrition, reducing obesity or smoking, and the policy tools range from those that are less intrusive to those that are quite a bit more intrusive.

Information, like labeling or education programs, are at one end of the scale. They're much less intrusive than other policy tools. For food safety, examples of education programs include FightBack and Thermi, the FSIS walking thermometer. Label information for safety include safe handling labels for fresh meat and poultry, and also in many

states, another example is they'll have labels on oysters telling you the dangers of eating raw oysters during certain times of the year.

One of the most intrusive types of policy tools is prior approval, and with prior approval, each product must be approved by an official agency, a regulatory authority, before being released into the market. For food safety, I really couldn't think of an example of strict prior approval. I'm hoping that maybe for airlines and huge jumbo jets, there's some type of prior approval but that could be wishful thinking on my part. I'm not really sure.

Now, safety standards allow suppliers to release products into the market without any prior control, but the supplier who fails to meet certain minimum safety standards are out of compliance and they're subject to regulatory or legal sanctions.

Now, standards or at least standards that I could think of for safety take at least three forms. The least intrusive are target standards. Now, target standards do not prescribe any specific safety standards for a product or process, but they impose criminal liability for prespecified harmful consequences which arise from the product. For food safety, that would be you make someone sick, you pay

the consequences. Of course, for food safety, that's a big problem because it's very difficult to draw the link between the foodborne illness and the specific food that made you sick. So, target standards are pretty unworkable for food safety.

Performance standards require certain levels of safety to be achieved in a product that lead suppliers or manufacturers to choose the mechanisms through which they meet such conditions. We have many standards for food safety. Salmonella standards for powdered milk is one example.

Process standards are probably the most intrusive of the type of standards that we could use, and they specify the type of production method, the exact procedures to be used to produce a good. These specifications could be either positive or negative. They could either be compelling or prohibiting on a firm to use certain processes or particular methods.

Examples of process standards for food safety include milk pasteurization or specific product washes that may be specified in a HACCP program. In many cases, process standards are just equivalent or equivocated with best manufacturing processes.

Now, the fact that performance standards specify requirements in terms of results and not

production methods has pushed them to the top of economists' most favored policy tool list. The flexibility of performance standards gives them a number of very good qualities.

First of all, performance standards encourage efficiency on the part of those firms being regulated. Each firm can choose the production method best suited for their firm's particular characteristic. Even within this industry, and we talked about this a little bit yesterday, different firms face different challenges meeting food safety requirements. For example, technologies that are efficient solutions for small firms may not be so efficient for larger firms.

With performance standards, the individual firm is given the flexibility to choose the most efficient process to achieve a particular standard, and in the best case, this flexibility leads to innovation, resulting in completely new technologies and new approaches to production. This pushes out the production frontier, creating more with less, hopefully, and this is much preferable to being stuck in a situation where each firm must use the same approach.

As Michael Porter from the Harvard Business School noted, past regulations have often prescribed

particular remediation technologies, such as catalysts or scrubbers for air pollution. The phrase "best available technology" and "best available control technologies" are deeply rooted in U.S. practice and imply that one technology is best, discouraging innovation. The regulators' challenge is to create maximum opportunity for innovation by letting industries decide how to solve their own problems.

Now, in a HACCP situation, HACCP without performance standards runs the risk of turning into a process standard, a best practices standard, and it loses its ability to encourage efficiency and innovation.

Now, it's important to note that the logic that leads economists to conclude that performance standards encourage efficiency and innovation is built on the premise that the firm is ultimately responsible for the safety of the product. Recalcitrant firms, firms who are not interested in food safety, will only have an incentive to be efficient and innovative if violation of performance standards means that the firm will incur real costs and that the firm will ultimately be responsible for rectifying the lapse in safety.

If instead the government is responsible for investigating safety lapses and the government is

responsible for deciding how safety lapses should be rectified, then the economic logic of safety standards breaks down. They lose their ability to encourage or inspire efficiency and innovation and run the risk of HACCP.

Well, how should performance standards be set? We have a few guidelines. A few guidelines can be gleaned from the environmental literature, and we find as economists that often our discussion of safety, food safety seems to be paralleling a discussion that's taken place in the environmental literature maybe a few years ahead of our discussion.

Well, a few things that we've learned from environmental literature, one of the first things is that we should regulate as close to the end user as practical while encouraging upstream solutions, and we know that the food supply chain extends from this farm to the table and that a safety problem introduced anywhere along the chain can ultimately affect the safety of the final product, unless someone downstream of where the problem is introduced takes actions to mitigate the problem. We know that meat contaminated grinding will remain contaminated, unless someone downstream introduces a step, such as irradiation or thorough cooking.

The best way to regulate the whole supply chain is to put pressure at the end of the chain and then rely on the end user or the final processor to put pressure on upstream suppliers for safe input. Several studies have shown in fact that food producers adopt HACCP or other safety mechanisms, technologies, to satisfy their downstream customers.

Using Jack's example from yesterday, these performance standards applied to the end of the supply chain are analogous to making the final processor the chief of police. It's analogous to making that final processor responsible for reducing crime throughout his precinct, reducing food safety problems throughout the supply chain.

Now, of course, there will be a lot of wrangling among the different players in the supply chain as to who should have ultimate responsibility for meeting standards, and we've seen plenty of wrangling in the environmental literature. We've seen a lot of wrangling between the oil industry and auto makers. Should the oil industry be responsible for reducing emissions by producing cleaner gas or should the car manufacturers be responsible for reducing emissions by making cleaner running engines? Policymakers have had to deal with this type of problem constantly in the

environmental literature and it's very similar to the type of problem we're dealing with now in food safety.

A second guideline that we can see from the environmental literature is that strict standards are usually preferable to lax. Now, if risk analysts identify a standard that is challenging to meet, this is the standard that they set because of human safety concerns, regulators shouldn't necessarily shy away from these strict standards and choose instead the standard that is defined by feasibility. We often see regulators defining the standards as a means. They think that it's feasible because half the firms are meeting the standard already and half of them aren't. So, there must be some technology out there we can use to get everyone up to a standard. We define the standards as a means. It turns out that challenging standards are more likely to encourage efficiency and innovation, and we shouldn't necessarily shy away from them.

A third guideline is to regulate in sync or slightly before your competitors in order to minimize competitive disadvantage. Now, in the auto industry, we've failed to set aggressive emissions standards, and then we've played catch-up with the Japanese for quite a long time to get our cars up to Japanese levels as

far as emissions went.

Another perk to standards that are well set and well recognized early in the game is that those standards then become criteria for international standards, and if we go ahead and set firm standards up front, those standards may become the standards that are used for international trade and food safety.

A fourth criteria for verifying compliance is that standards should be informative, that is, they should be solidly linked to a policy objective. They should be reliably measured. This is one problem we're having with standards for non-biotech foods, is that one batch of food that tests as a non-biotech batch at one point in the supply chain and is tested later on in the supply chain and is actually tested as biotech. So, the testing has to be reliable.

Also, the criteria should be flexible. We know that policy objectives, production technologies, testing technologies, all of these are changeable, that a standard or a way to measure a standard that is set today could be irrelevant or in the worst case could be too binding in the future, and, of course, the prime example of this is the Delaney Clause, where testing methodologies became so fine and so precise, that a zero tolerance level for carcinogens became impossible

to meet with testing methodologies that were developed, and those standards were so rigid and set so inflexibly that it took an act of Congress to change them. It would be nice not to get ourselves in the same kind of situation.

Now, firms have a number of ways they can react to new regulation. The least desirable outcome is that a lot of firms in the industry would just simply drop out. So, sometimes this is not necessarily a bad thing. Sometimes regulation does flush out some fundamentally-inefficient firms.

Another undesirable outcome is that industry spends a lot of time and resources fighting or trying to influence regulations. That's also an undesirable outcome that policymakers are trying to avoid.

The best outcomes are, of course, full compliance and innovation. Now, how do regulators tilt the balance to compliance and innovation? Well, they have to try to minimize compliance costs. We know that standards, because they allow firms to adopt the most efficient compliance strategies, often are the best at minimizing compliance costs.

We also want to choose regulations that increase the benefits of compliance and innovation. One way is to increase the market benefits, and we know

that standards that are widely recognized help to increase the marketability of a product, both domestically and internationally, and to increase the benefits of complying, you want to increase the cost of non-compliance. You want to increase the probability of getting caught and the cost if you do get caught.

Quantifiable standards are usually easier for government officials to monitor and to regulate than qualitative standards and therefore are often better at increasing the cost of non-compliance.

This is the picture that I actually want to leave you with, economist's point of view, as we continue our discussion of performance standards or process standards, to think about the regulator trying to tip the balance towards compliance, tip the balance towards innovation, and the role that performance standards play in tipping the balance.

Thank you.

(Applause)

DR. ACUFF: Thank you, Dr. Golan. Man, I'm never going to get your name right, am I?

DR. GOLAN: Think Heights.

DR. ACUFF: Oh, yeah. Okay. Good.

All right. Our next speaker is Robert Buchanan. We all call him Bob. See his name tag is

Bob over there.

He has a Bachelor's, Master's and Ph.D. from Rutgers. He did a post-doc at the University of Georgia. His current position is with the Food and Drug Administration, Center for Food Science and Nutrition, and he is the Senior Science Advisor and Director of Office of Science.

He has previously worked for USDA at ARS and FSIS and has also worked with Drexler University. He has done lots of work with ICMSF. He's worked with Codex. He's done more than any of us, I think, in microbiological criteria.

So, welcome, Dr. Buchanan.

(Applause)

DR. BUCHANAN: Thank you, Gary.

When I was originally approached by Karen, she said, "Bob, we really would like you to talk a little bit about microbiological testing, its statistical basis and how you set standards, and, oh, by the way, you have 20 minutes to do it." So, I'm not going to spend a lot of time, other than the fact to say that what I hope to do is just give a quick overview of some of the principles of microbiological testing, a little bit about decisionmaking process, how it fits into a decisionmaking process, and then get

into it more in the panel discussion.

So, this is just sort of a primer, and I'd like to remind you that microbiological testing, at least I consider it one of the important tools we have for improving the safety of the food supply. It's important to keep in your mind as I go through this talk that this is a technologically-based statistically-based tool. It's dependent both on the statistics that underlie sampling and it is also based on the methods that you use. So, it's very hard to find hard and concrete things because a lot of it's based on probability and a lot of it's based on the methods that you employ.

It's also important to note that it is actually tools that we're talking about here, and it's incredibly important to pick the right tool for the right job, and much of the discussion that we have is interpreting which tool is used and what attributes you're looking at.

Microbiological testing is one of the most apparent things that we do in food microbiology, but it's also one of the most poorly-understood in terms of the rationale and the procedures that are actually being used, and I might note here that food microbiologists inherently understand this much better

than any other type of microbiologist. So, you can figure out what clinical microbiologists, you know, their baseline that they're starting with.

It's important to also note that when you ask about microbiological testing -- we'll make you an honorary food microbiologist, Anne Marie. When we're talking about microbiological testing, there are different types of microbiological testing, and so it's important to know which one you're using for what purpose. I'm going to be talking about two of the four general types of testing that we do; that is, the safety of batches and process control in my talk, and it's very difficult for me to talk about process control without talking about also the safety of batches.

To really understand, you really need to take the time to understand what are the goals of these different approaches to testing, what are the base assumptions that underlie the testing, and what are the characteristics of the testing programs, and really to simplify it, what we're looking at as we go through the difference between testing batches for safety versus a process is we're looking at the difference between within batch testing versus between batch testing, and they do have different goals, assumptions and

techniques that are used, and so I'd like to spend a couple of minutes talking about or comparing the two before I talk more about process control.

Within batch testing is primarily there to demonstrate the safety of a single lot of food. It is a very detailed snapshot of an operation. It assumes no prior knowledge of the process or the food product that you're looking at. It focuses on establishing the safety or if you're looking at a quality attribute quality of that batch, it provides only very limited capability of trend analysis of performance over time. However, it can be used to set up appropriately to acquire data on the state of the industry.

It is effective only within certain ranges of contamination, both in terms of frequency and/or levels of contamination. Below or above those ranges, it becomes increasingly ineffective. A general rule of thumb that we use is that if the acceptable defect rate that you're looking for is less than one percent, you should be thinking about other approaches in terms of measurement because below one percent defect rate, the number of samples that you have to take to demonstrate that a product is free or operating at a level below one percent becomes a true limiting factor.

This is in comparison to between batch

testing. The primary function of between batch testing is that a food safety system or process is continuing to function as intended, and it's important to keep that in mind, is that you have a system that you have set up and you're trying to determine whether or not it's operating as you expect it was. It is not designed to assure the safety of a batch. The safety of that batch is assumed if you're working with a validated process that you know is capable of delivering the safety you want and that that process is in control.

It assumes that you have an intimate knowledge of your process, that you know all the details, that you've done prior analysis in terms of that process's performance and variation, and that what you're determining is whether it continues to function. It does require that you do sampling over time. It also can be used to establish a national state of the industry database.

Now, this is a statement that I've used before, and I would like to reinforce this. It is much easier to demonstrate that a process is not functioning within a specification as compared to proving that something is not present. It is much easier to prove that you're functioning as you've designed your process

than to prove the safety of any particular batch, and hopefully the rest of my talk will demonstrate why I make this statement.

Now, I'd like to remind you of a couple things as we go along in regard to sampling and processes that we're looking at. One is, is that microbiological contamination typically flows with a process; that is, if you have a point of contamination, it will follow the process down until it is eliminated. It typically, unless there is a loop back, it does not go back up the process, unless you cross lines or some other means of reintroducing the end product into the beginning.

The best way to think of this is if you took a thousand ping pong balls and threw them into a stream, you would not walk upstream to find the ping pong balls, you would find them distributed downstream. So, a microbiological sample taken within a process provides a measure of the microbiological attributes of that process. It's anything that was above where you took the sample.

So, the way we can look at this is that the status of a multistep process or anywhere within that process is basically the summation of the initial levels of contamination and all the steps that increase

or decrease that level of contamination. That is, and I promise not to get into a whole bunch of math, but I couldn't resist just one formula, the microbiological status of any point in that process is equal to the initial level of contamination, plus the sum of the increases in the level of the microbiological concern, plus the sum of the reduction steps that took place.

So, sampling -- so, in putting this into perspective, what I just said in the two previous slides, basically sampling end products integrates the effect of the entire food safety system. So, if you could only take one sample and try to get an integrative look at what was happening, the sample that I would take would be at the end of the process. However, it is very beneficial, particularly if you're trying to be proactive and then eliminate problems, is actually to take steps or samples at several points in the location so you can go back and when you start having problems identify where those problems actually took place.

Now, the basis of control, process control statistics, which is what we used in evaluating process control in microbiology, and I might note that the statistics I'm talking about here are nothing magic. They're the same kinds of process control statistics

that were developed for making widgets in factories, for just about anything. It's looking at performance over time, and the basis of that control process evaluation is the collection of microbiological data over time, and typically we do this in a graphical means. We collect the data and then we array it graphically in the form of a controls chart, and so up on this top is just a hypothetical control chart that I've used in previous presentations on this subject.

So, the first step in coming up with a process control activity is to develop and then conduct a process control study. This is in microbiology. This is what we refer to as baseline studies, and it's basically using an under control process. We run the process for a period of time. We collect a lot of data just to see what the capabilities of that process are, and these typically involve collecting two pieces of data, the central tendency, the mean or the median, how the process normally works, and then we look at the variance, what kind of variation is normally associated with this.

We also use this data, assuming that it comes out relatively normally distributed, to set up, you know, potential at least initial critical limits that we would run, and typically in the statistical world,

we might use three sigma factors to establish the upper control and lower control values.

However, there is nothing magic about three sigma or six sigma. The decision on whether to take a value, be it three sigma out or would it be right on the mean, is a risk management decision that is dependent on the capabilities of the system, your likelihood for improvement, and decisionmaking process along those lines, similar to the ones that were discussed in the previous talk.

Then, once you have established these criteria and you continue to monitor the process, the loss of process control is just then assessed by determining if your defect rate, the number of defects that you detect when you take microbiological samples, is greater than what you would expect by chance alone.

Now, we can do this approach using either variables-type approaches or attribute. This is whether you're using quantitative data or whether you're using attribute data which is either plus presence/absence data or what we refer to as bend quantitative data, where you put it into different categories.

Now, probably the one that is most familiar to you is an approach called moving windows sum. This

is one of the simplest but most powerful of the process control statistics that are used, and what I wanted to do is just run a simple example through with you about moving window and basically a moving window is that you look at performance over time, but you have set windows of time that you look at, and I'm going to use for my example a very simple process, and I decided I didn't want to use food or food microbiology at all, but I do it to something that's a little bit more concrete.

So, my example, I'm going to have a three-step process that a manufacturer receives blue marbles. His primary process is that he then paints those marbles red and that he packages the marbles and that's his finished product. So, we have a really simple process and that his ability to paint these marbles is not flawless. In fact, he doesn't do such a great job. He has about a 10-percent defect rate, but as long as he meets that 10 percent, he's going to be able to sell his product and everyone will be happy.

And so, what happens is after you've gotten your central tendency and your variation here, you then base the probability of finding more than the expected number of defective responses within a specified window, and that is, if you start having -- say you're taking -- you're looking at marbles once every thousand

marbles, if you have too many blue ones, then you know that that was not by chance alone, that in fact you're not doing such a good job of painting them red.

So, let's look at a couple of examples, and believe it or not, most microbiologists intuitively understand this process, if you show them the data. So, let's look, and I'm going to ask the question: is this process under control? Just to put it into terms, we're sampling one out of every thousand marbles, and we're doing a really simple test. Are they red or are they blue?

So, if we run this process through, we get a red marble, a red, a red, a red, and we keep up sampling, and then all of a sudden we get a blue one, and we go back, and we continue to sample, and oh, lo and behold, another blue one came in, and we continue this process, and we just keep sampling, and I think I get to the end of it soon. Yeah. Actually, -- oops. So, the answer is most of you out there would intuitively look at that and you'd sort of in your mind say, well, the number of blue marbles over a certain amount of time was about the 10-percent defect rate, and yes, this process is under control, and in fact, it is. In fact, I set it up that way so there would be no question about it.

So, now I'll ask you the second question, again going through an intuitive example of how we process control. When is control of this process lost? Again, it'll be the same blue and red marbles, and we go through and we watch this process, and you can pretty much let you follow it, and we've got our first blue marble. That's our first defect. You wouldn't be able to tell whether it was in control or out of control, and you keep sampling and another blue shows up, and you say, hmm, that seemed to have come too fast, but it still could be chance alone, and then all of a sudden, another blue one came about, and you're getting pretty suspicious at this point because the odds of three coming up in that number of marbles is kind of unusual, and then another blue shows up, and yeah, you're out of control now, and so it gets even worse, I think.

But you can see intuitively that you would be able to say yes, that, you know, something's happening here. I've lost control of my process, and I think I just have it continue like that, yeah.

Now, the ideal situation is to have a sampling plan that would allow you to go and make really clearcut decisions. So, if that blue arrow that you see on there was our decision point, the ideal

operating curve would be that you would go along at the top and all of a sudden at that line, you would go all the way to the bottom and everything would fall nicely into yes or no.

In reality, we have distributions around that. We have to deal with Type 1 and Type 2 errors. However, we can get the steepness of those operating curves to take on the shapes we desire by manipulating both what percent of assurance we would have, by the size of the sampling window, and also by the number of positives within that sample window.

So, it's a very flexible tool that we have in terms of coming up with something that is practical in terms of being able to detect when your process goes out of control, but at the same time minimizing the number of samples that have to be taken.

Now, seeing that this was a science conference that was put on by FSIS, I think the best way of giving an example that would keep me out of trouble was to pick one that FDA is working on. So, what I'd like to do is just show you some practical ramifications of this using our newly-instituted juice HACCP talk about a couple practical attributes of microbiological sampling.

A key attribute within our new juice HACCP

regulation is the requirement that all juices receive a 5-D performance standard. In this case, since it is required, it is a standard, the more general term would be a criterion. It's restricted to juice that has been -- after the juice has been expressed. We have verification of that process. However, verification in this is based on process validation and review of process records. It is not based on microbiological testing, and again there was an underlying public health goal to establish a risk that was less than the possibility of disease of less than 10 to the minus 5th per year for the consumer.

Microbiological testing was not required for most people covered by the reg because it is ineffective. The ineffectiveness of testing at very low defect rates, and because the juice which was being treated, the treatments were affecting all parts of the juice, and the processes that were being employed were both validated and reliable, and just to give you an example why we made that decision, suppose that we had in juice a normal level of one enteric bacteria per milk and that's based pretty much on some baseline studies that we did.

A 5-D treatment would reduce this down to one viable organism per 10,000 mils, and therefore to

actually detect and evaluate the effectiveness of that process, we would either need to take and sample a one 10-liter sample, 10 one-liter samples, or 10,000 one-milliliter samples. To say the least, we're usually set up to run one mil samples in microbiology, and no one was volunteering to do 10,000 samples every time you wanted to validate your process.

However, and I put this into perspective, we did provide one key exemption for citrus juice processors, particularly the processors of fresh juices. In this case, the fresh juice processors may count surface treatments as part of their fulfilling either part of all of their 5-D process, and this is based on the underlying assumption in scientific data that we were provided, that for the most part, it doesn't appear that the inside of oranges become contaminated with enteric bacteria.

However, in putting the reg together, we did for those processors who opt to use surface treatments, we did put an additional HACCP verification requirement of periodic testing for E.coli, again E.coli as an indicator of fecal contamination, and in this case, they're required to either take two 10-mil juice samples per thousand gallons per day or at least once a week, if they produce less than a thousand gallons per

week.

The data is evaluated using process control statistics, using a seven-sample window, one positive sample requires a process review, two positive samples require diversion to a 5-D treatment after the juice is extracted, that is, you have to treat the juice by normal pasteurization or treatment processes, not just surface, until the cause of the deviation can be identified.

This is designed and the purpose of the testing is designed to verify that the original assumption that went into allowing for this exemption is still valid, i.e., that pathogens were restricted to the surface of fruits, because internalized pathogens, if you started getting pathogens within the orange or the grapefruit, etc., would not be affected by the treatment, that there is and we've demonstrated at least in the laboratory the potential growth of these pathogens within the fruit, the fact that this type of approach is both effective in terms of detection limits and is effective in terms of keeping the number of samples to a minimum.

So, in summary, what I've tried to do is give you some basic principles for microbiological testing, indicating that it is an integral part of any

integrative program for verifying the effectiveness of a food safety control system, but again you need the right tool for the right job and you need to understand why you're using that tool.

Thank you.

(Applause)

DR. ACUFF: Thank you, Bob.

Our next speaker is Dr. Frank Busta. He has been with the University of Minnesota. He's been at North Carolina State, University of Florida. He was chair of Food Science and Nutrition Departments at both the University of Florida and also the University of Minnesota.

He's published extensively, has at least a 125 refereed research papers, and something that's very important for today, he spent 15 years with ICMSF or the International Commission on Microbiological Specifications for Food.

He also was president of IFT, and see, he's coming to take me off the podium now, and he says he's Professor Emeritus, which means he's retired, and I don't believe that. So, maybe you can explain what retirement is.

DR. BUSTA: Retirement is doing only what's fun. You don't have to go to faculty meetings. You

don't deal with budgets.

Thank you, Gary. It's very unnerving to have someone start a session with history and find out that you remembered it all. Now, I'm not referring to Elsa's stuff. I don't remember Pasteur. The Swan flask was a little before my time.

This is a challenge I'm going to ask -- today, I'm setting a basis for our questions that follow in the discussion. I thought the perfect segue following Bob Buchanan was to cite him on definitions and you'll see that the classic definitions are an index organism is a microorganism group that is indicative of specific pathogens whereas an indicator organism is a microorganism of microorganisms that are indicative that a food has been exposed to conditions that pose an increased risk that the food may be contaminated with a pathogen or held in a condition conducive for pathogen growth.

Now, as we talk about today indicator organisms versus pathogens as possible performance standards, I would like you to keep this classic definition in mind because it is a little different thinking than we hope to fill out today.

What does it indicate? It indicates when there's a positive test for an indicator organism, it

doesn't necessarily mean that there's a pathogen there. If you detect an index organism, it points to the occurrence of a related pathogen. These are classic definitions that may not hold any longer.

Both of these are called microorganisms, and there are a number of other microorganisms. Sometimes we call them models, sometimes we call them sentinels, and sometimes we call them surrogates for specific kinds of process evaluations and validations, and if I have time at the very end, I'll mention a little bit more about surrogates.

What are some of the preferred qualities of ideal indicators? You'll hear this a couple-three times, and we'll reinforce it until we'll be able to all recite it together. The history and presence or absence of food is related to the pathogen or toxin. The microbial metabolites, if those are indicators being used, are present initially or after growth of a pathogen that might be present. If we use growth of indicators as an evaluation, it should be equivalent or greater than the target microorganism under all conditions, and there's some big generalities being stated here, and it's easily detected, quantifiable, distinguishable, and preferably very rapidly.

What are some of the indicators that we've

used? We've used specific microorganisms and it's a range from total colony counts, Richmond cultures, indirect county counts and a variety of other systems. We've used metabolites. We've used PCR, and we've used indirect methods for general assessment, such as ATP.

The traditional requirements for an indicator of food safety. Easily and rapidly detectable. That's very, very important because otherwise it can probably do the pathogen, and we'll talk about that a little more. Easily distinguishable from the normal flora. There's a history that is associated with the pathogen. It's present when the pathogen is present. The numbers correlate with the pathogen. The growth requirements are equal to the pathogen. It directly parallels the pathogen, and it's absent when the food is free of a pathogen. Ideal.

There's a variety of organisms that have been used through the years on a variety of foods as indicators or have been proposed as indicators and includes the entire family of the Enterobacteriaceae, which in turn includes coliforms, fecal coliforms, and E.coli. These have all been proposed or used in various situations as indicators of contamination. Enterococci, bacterium, coliphages, all have been

proposed or adopted as indicator organisms.

If we look at the whole family of enterobacteriaceae, these are anaerobes. This is taking you back to Introduction to Microbiology. Mesophiles, they produce acid and gas and glucose, at least acid from glucose, and some of them are psychotrophs that cover a whole series of genera, and it's been at least in Europe and by certain individuals recommended over any other type of individual genus in this family.

Coliforms have been used in a variety of places. Usually they're best used in something that's been processed. They're general. They may or may not be indicative of fecal pollution, and if you're dealing with fecal pollution, one maybe goes on to fecal coliforms, whatever those may be. That's a personal opinion. Fecal coliforms are defined as going at a 44.5 or 45.5. There are a variety of strains that are recovered. Some may or may not define fecal contamination. It's originally used in water and just for our own edification, 0157:H7 doesn't really grow very well at those temperatures.

E.coli, as you just heard Bob mention, is a very commonly used species to indicate fecal contamination. Its use is broad spread and obviously

it's in the performance standards. E.coli is really regarded as the most valuable indicator of fecal contamination. It's not necessarily a reliable contaminant to indicate post-processing contamination because it will grow in the environment, and it is -- but it is an indicator of inadequate processing.

Now, what indicator groups that I've just mentioned may be or are considered pathogens? Well, there are a lot of pathogens in the enterobacteriaceae. There are potential pathogens in coliforms, in fecal coliforms, in E.coli, and in enterococci. So, the concept of having non-pathogens as an indicator or as an index is really inappropriate in our current assessment.

What are some of the issues of using coliforms and fecal coliforms? Some may be non-enteric. They indicate inadequate sanitation but maybe not in the other situations. I put this up so that you look at what are some of the issues as we look at the limitations of pathogens as indicator organisms.

Some of the problems of using a pathogen as an indicator organism hopefully is the concentrations are very low and difficult to relate to other food safety situations. They may not compete well with the food flora, and as many of you know, isolating and

detecting pathogens in a system has always been the challenge in many of the microbiological methods.

The presence may not relate to another pathogen. E.coli may not be present when Salmonella is present or vice versa. The presence may be initiated regulatory action and therefore may be considered adulteration and is that an index or indicator or is it merely an action item? And that pathogens require special laboratory skills. We've always preferred a non-pathogen or indicator organism because of the easier laboratory activities.

So, let's look at that same list of advantages pathogens may have as indicator organisms. They may be easily and rapidly detectable. We're working on that more and more. The methodologies frequently focus much more on pathogens than they do on some other indicators. With this methodology, they may be more easily distinguishable from the food flora. They obviously are pathogens themselves, but the challenges, they may also be associated with other pathogens that could be present in the food.

That whole relationship to other pathogens is a major question, and it's the numbers, presence, growth requirements, die-off requirements, all of those may be appropriate for a pathogen to reflect other

pathogens or other safety or it may not.

When we look at performance standards, they're intended to effectuate decreases in pathogens with the goal of improving public health. Fecal contamination is a major source of enteric pathogens. We may use microorganisms classified as indicators or index organisms to evaluate this and a pathogen could be used if it meets criteria.

So, as we look at the performance standards, will or will not the pathogen serve as an index or indicator organism, and if you'll notice, I'm starting to change to index because that's apparently what we would like to show. An indicator in lieu of a specific pathogen, what are the basic criteria? Similar survival and growth rate, common source, direct relationship between a condition influencing the pathogen's presence and the indicator and practical methods.

So, if we look back at the performance standards, can we -- will the pathogen that could be used as an index or indicator meet those criteria? So, if we look at performance standards, is E.coli a good indicator or index? Are Salmonella an indicator or an index? Or is enterobacteriaceae an indicator, an index? Could those be used? Are those used? Could

they be really true indicators or indexes?

Again, one more repeat, what's ideal of an ideal index or indicator organism? Presence and rapidly-detectable, history of association with the pathogen of concern, the presence of the concentrations correlated with the pathogens, easy to detect, growth requirements are similar, not affected by other food components, resistant to injury from stress of processing, and non-hazardous to testing personnel. Those are ideal.

I'm going to skip over this one because I'd like to mention a little bit about surrogates. Surrogates are usually added to the food to evaluate a process. Surrogates -- I'm still all right on time, aren't I? Okay.

Surrogates are a special situation. Some people would like to use naturally-occurring microorganisms as surrogates to evaluate a process and to test a process and then to validate it. But as you all would be well aware, no one likes to bring a pathogen into a processing situation. So, we try to come up with a surrogate which would not necessarily be a pathogen, maybe similar, but is a microorganism or representative material, and I think that's important, that serves an alternative for a target pathogen when

we're evaluating or validating a controlled process.

Hopefully, it's very, very similar to the organism. The criteria are very similar to an index organism, but here non-pathogenic becomes very, very important, but its inactivation characteristics, its durability, its stability are similar to the target. You can prepare high concentrations. It's stable. It's easily enumerated, easily differentiated, generally stable, will not be established as a spoilage problem, and it's resistant to sublethal injury or reversibility. If we're going to validate processes, we also have to consider surrogates or indicators that are not pathogens, naturally-occurring.

So, in summary, indicators or index organisms have been used over a hundred years. So, this is not necessarily a new idea. We're back to history again. Effective with extensive validation and qualifications. There currently are no well-established relationships of indicators and the occurrence of emerging water and foodborne pathogens. There's some evidence of a relationship with well-established pathogens.

The direct sensitive and specific tests for detection and enumeration of target pathogens and metabolites are available and that may permit us to utilize them as index organisms themselves. The

indirect association of marker organisms where food safety and quality may not be reliable for due diligence, if you look at the indicator, it may not hold. If you don't look specifically for the pathogen, it may become increasingly useful, indicators may become increasingly useful with new analytical methods and the challenge is the selection and validation of the appropriate organism.

Thank you for your attention. I do have a handout. I put a bunch of research in it, and we'll talk about that later.

(Applause)

DR. ACUFF: Okay. I've been told that for people standing in the back, there are lots of seats up here in the front. Actually, there are. So, if you guys want seats up here? It's kind of like church, you know, nobody wants to sit up front.

Okay. My wife is a mathematician, and I watched her take classes like Real Analysis, and I thought as opposed to what, you know, Fake Analysis and Modern Algebra, and I thought, I guess I took Ancient Algebra. I don't know. And my kids have learned that they do not say why do we have to take this stupid math stuff, you know, because they're going to get this long lecture, you know, and I've sat through it several

times.

I say that because our next speaker is a mathematician. He has a Bachelor's degree in Mathematics from Iowa State in 1967, a Master's in Applied Mathematics from Johns Hopkins in 1969, and I have a lot of respect for anybody who can get multiple degrees in mathematics. So, it's a tough road to hoe.

He has worked for the Naval Research Laboratories and the Food and Drug Administration, Consumer Products Safety Commission. In 1979, he joined the Food Safety and Inspection Service, and he's currently an Assistant Deputy Administrator. He's going to speak to us about "Performance Standards and Statistical Sampling".

Please welcome our next speaker, Loren Lange.

(Applause)

DR. LANGE: Thank you.

This is a hard group of speakers to follow. I was quite impressed.

I did learn yesterday that I had one thing in common with our Secretary of Agriculture. Growing up, I was a member of 4-H and spent many years in 4-H, and I was thinking back. One or two years, my 4-H project was I was sort of a farm-to-table poultry processor. I raised chickens, and on Saturday, I would -- Friday

night actually because you collected them with a little hook and stuff from the trees, I had sort of -- and I would slaughter and process and clean and on Saturday, then I would deliver anywhere from 25 to 50 fully-processed cut-up or whole birds to neighbors and relatives and stuff like this.

I'm not sure. I made a little money, but my father gave me the chicken house free and the feed free. So, I'm never sure whether my economics was good, and I must say as I look back, my food safety was -- that was not a consideration in my process because one of the steps in my production process was I had a dog that would retrieve the birds after I had cut off the head. Anyway, enough of that.

This is "Performance Standards and Statistical Sampling". I could have talked about, I don't know, a lot of variety of things under that heading, but when our panel met, we did decide that I would sort of focus on sort of two areas to summarize, and one was a little bit our history of statistically-based studies or baseline studies, FSIS, and then how the data from those baseline studies was used to develop the existing performance standards.

One of, I guess, the first questions I thought about is what is a statistically-based study?

I guess there's a lot of things called surveys and statistically-based studies that, I guess, statisticians would certainly argue about, but I think in general, the important thing is that there's an up-front design consideration. The accuracy of estimates that are wanted. There's an up-front design of how many, you know, samples are collected, so that one can consider how accurate of an estimate they want, and certainly ability to sort of then put a confidence interval around the statistics. So, that is sort of what I think at least, is that there was some consideration of what you would be able to do with the data when you sort of were planning the study. So, I guess I considered that a statistically-based study.

As a little bit of background, we sort of looked in the files at FSIS, and I found a couple papers that talked about we had a Micro Division that was sort of first really a focus on microbiology in the mid-'60s. There was some history talking about how the microbiologists would do surveys. They would get in their car and they would drive to establishments. They would pick up samples and freeze them and take them back at that time to a lab in Beltsville and conduct the results and publish journal articles on surveys and stuff, but they were sort of restricted to sort of how

far they wanted to drive and sort of they would call up regional offices and at that time area offices and find out where they could go and get samples.

The first evidence of a sort of large statistical survey that we find was actually in '82 and '84 where the three field laboratories were all used, but it was -- at that time, it was a single organism, Salmonella, single product, young chickens, which sort of takes us to the sort of then the -- I would consider the modern era of national baselines.

The first national baseline was actually started in October of 1992, and on the FSIS website, I think the results of eight of the early, you know, baseline studies are published on the website right now. They were very different than some earlier studies. We also -- I forgot to mention. We found evidence in the early '70s there was a ground beef and trimmings study conducted that had over 1,400 samples, but it was again just Salmonella. There was a '90 and '91 study but again just -- I think that was again young chickens and Salmonella.

But with these baselines, it was a decision to look at a large number of organisms and to do a lot of laboratory analysis, and I'll get back to that later. So, there was one point here as we started

baselines in '92. Really, the development of the pathogen reduction HACCP rule began in the Fall of '94, after the first two baselines had actually been initiated, and, of course, you all know standards were published in 1996.

The objectives. The objectives of those early baselines. I mean, they were sort of pretty general. It was to collect data to provide a general microbiological profile of the product for selected microorganisms, and the second one to use that information and knowledge gained from those baseline studies as a reference for further investigations and evaluation of new prevention programs.

I do want to come back to that second objective a little later when I get into the talk because it sort of raised a question in my mind now.

We have some newer objectives from those original when the baseline studies started. They now are viewed as a support for risk assessments. The Reorganization Act of 1994 sort of required risk assessment for certain public health-oriented regulations that became effective in April 15th, 1995. Important to note that the proposal for the pathogen reduction HACCP rule was in, I think, February of '95. So, it sort of preceded the effective date of

requiring risk assessment.

Risk assessment just in general in the discussions we're having in OPHS, there's a lot of difference from thinking about process control and risk assessment needs, and I'll use young chickens as an example. We collect data at the end of the drip line carcass-by-carcass which, you know, is probably an indication of the process control, but the risk assessment people, I think, are far more interested in if we were testing the final sealed packages because in their view, you know, each package sort of is an opportunity to carry, you know, a pathogen into a restaurant or into a kitchen. So, we have new objectives, and, of course, we use the baselines to develop standards that were published in 1996.

I'm going to talk real briefly about three key design factors in baselines. We certainly have the number and the nature of the organisms that are going to be tested, the desired accuracy, and cost and laboratory resource considerations.

Excuse me for just a second.

(Pause)

DR. LANGE: In the eight baselines that are on the website, there were six different pathogens that were tested for. I don't need to read them. I'll

leave it up for just a second. These were selected either because they were associated with human illness, a large amount of human illness or a severity of illness. So, they were selected for the baseline studies, and there were three indicator organisms in all of those early baselines, and they were sort of selected because they were thought to be an indicator of either general hygiene conditions or process control.

The second factor that I mentioned certainly was, you know, the sort of desired accuracy. If you go to the baseline reports, you'll see that in the steer/heifer carcass baseline, the cow/bull baseline and market hog baseline, there were approximately 2,100 samples in those baselines. For poultry carcasses, they were in the range of 1,200 to 1,300.

I went back to one of the design documents and it was talking about, of course, the number of samples was going to vary with what you expect, the level of pathogen or the level of organism, but just sort of as an indicator, if one was looking for an organism that had a two-percent prevalence, if I took 3,000 samples, one's talking about, you know, the 95-percent confidence interval is really plus or minus .05. So, you would be between 1.5 and 2.5, and then if

you went up to 6,000 samples, you'd get plus or minus .035, 10,000 samples, .027. So, you see, as you move from 3,000 to 10,000 samples in a baseline, your range of confidence really narrows very slowly. You have to go up very rapidly to get that.

I would just point out what in our baseline, what the levels of precision that we did proceed with the samples we got. In market hogs, they estimated prevalence was 8.7 percent, the 95-percent confidence interval is plus or minus 1.8. So, you're really sort of 95-percent confident that the actual -- at the time the baseline was done, the real prevalence for Salmonella in market hogs was calculated at 7.5 to 9.9, I guess, would be the range, and for young chickens, it was 20 plus or minus 2.16, in cows and bulls 2.7 plus or minus .78, and those were all based on the samples that I talked about later.

I didn't put a slide up here actually on costs. Certainly cost was a consideration. Our laboratory resources was a consideration, but it isn't just numbers of samples. As I said, all those organisms, those nine organisms in those baselines were not only, you know, the samples are collected and shipped to the lab, but there was an attempt to quantify everything. Besides doing a positive-negative

test in those baselines, everything that was possible was quantified, and I think everything was quantified except for 0157:H7. Don't have figures on actually what they actually cost, but they were expensive when you take nine organisms, thousands of samples, and do quantitative levels of microorganisms, which, when I was putting this together, is something I think we and OPHS have to go back, and so the answer to that question is, what do those baselines cost, and thinking to the future, were we able to use that information and knowledge, you know, as a reference for further investigations and evaluation of new preventive programs?

Besides the Salmonella prevalence, which I'll talk about now, and the generic E.coli, we haven't been able to think about what the other -- what was the other data used for? Has it been used outside? Was it useful for academia, for industry, but it costs a lot of money to collect. It's on the website, and inside, we're not sure of how it was used.

Okay. With that, I'll move to my second topic a little bit. How were the performance standards derived from baseline results? Colleagues advised me that this is not the thing to do because I am going to have some equations and stuff, but I'm going to try to

simplify it as much as I can, and I think it's important because this isn't published in the preamble to the rule, and I don't think it's in any document that the agency has put out exactly how we took the baseline information and then sort of created the sampling plan which has been known as the sample set to sort of measure the performance in individual establishments.

What was used from the baseline for the Salmonella standards was those prevalence estimates from those baselines, and I'm sure everybody's pretty familiar with them. We have the seven different product prevalences listed here. This baseline prevalence, what is it? It's an estimate of the percentage of product that would test positive for Salmonella at the point in time when the baseline was conducted. It can also be viewed then as the probability that if you went out and took a sample of any of those commodities, there's a probability that that sample would be indeed positive.

FSIS sort of decided then that performance would be measured by a series of samples which we have referred to sort of as a set of size, N. Now, there could have been different sampling schemes. There could have been one of these continuous windows that

people have mentioned. That would have been another alternative, but the agency decided to work in discreet sets.

When one is sampling with two possible outcomes, positive or negative, could be heads and tails, flipping a coin, success or failure, anything that has two possible outcomes. The number of positives which we call X, you know, and N independent samples is said to possess a binomial distribution, where the probability of X positives equals this equation. I won't go through it.

Every time I see this, I remember I was tutoring what I thought was a would-be girlfriend at Ohio State, and she kept wanting to call those excited numbers, and, you know, I wouldn't let her call them excited numbers, and I said those are factorials, and she wanted to call them excited numbers. Anyway, that was the end of that. I guess I was too much into control.

But anyway, it's a probability distribution is sort of nothing but it's a mathematical expression where you can calculate the probability of any one outcome, if you want to, and, of course, then if you summed up overall the possible outcomes, it has to equal one. That is the simple definition of a

probability distribution.

It follows on the next slide that if one wanted to look at C or fewer positives in a set, one would calculate the probability of one positive, two positives, three positives, and up to C positives, sum that up, and I would have the probability of, you know, C or fewer positives.

The next decision that had to be made is that FSIS decided that an establishment that was operating actually at the baseline prevalence should have an 80-percent probability of passing. Dr. Buchanan referred to this and he had actually an OC curve which I'll get into next.

Now, where did that 80 percent come from? It was a judgment. It was a balance between the need to prevent the establishment from failing a set based on just pure chance and the need to identify establishments that are likely to be operating above the prevalence. So, 80 percent was -- it was a decision. It could have been 90, it could have been 70, but with the decision of 80 percent, then we had the equation. That summation of probability of 1-2-3-4-5, we set that equal to 80 percent. So, there was an 80 percent for each establishment. If they were operating right at the baseline prevalence, they would

have 80-percent probability of passing one sample.

So, this is just an equation that can be solved, and with a computer program, one can solve this with a whole bunch of Cs and Ns. One can start N equal 1, C equal 1, then just run it up. You can run the whole thing up so there's a whole range of Cs and Ns that actually answer that equation, and FSIS then finally decided that the N that we wanted would be greater than 50, so that our sampling would measure process control over time.

So, in the final sort of solution to those standards, the N and C that are in our regulations are the first combination where -- of N and C where N is greater than 50 and the probability of C or fewer positives is actually equal to .8 or 80 percent for an establishment operating at the baseline.

Finally, I'll just illustrate then an operating characteristic curve. A sampling plan like this obviously each of them have a curve that sort of illustrates the performance of that sampling plan and the risk of both types of errors you could get, calling a failure when it was indeed a pass, calling a pass when it was indeed a failure.

So, the OC curve will show the likelihood of passing at different levels of prevalence. This is

actually the operating characteristic curve for the market hog standard. On the bottom, it's pretty hard to read, so the bottom axis or the X axis is actually the establishment prevalence, and going up on the Y axis is the probability of passing, and the dotted line shows for that plant operating right at 8.7 percent, if you go up, there's an 80-percent probability of passing.

If one shifts to the right a little bit and look at, well, what if a plant was operating at 12 percent? Well, if you drew a line up from 12 percent, you would find out if the plant actually had a prevalence, a true prevalence of 12 percent, it would have a 50-percent probability of passing our set of 55 samples where they're allowed six or fewer.

On the other side, if you go down to a plant, a market hog plant that had a true prevalence of six percent, they would have about a 99 -- 95-percent probability of passing. Now, what would happen had we chosen .7 or .9 as opposed to 80 percent? Well, if you had 70 percent instead of 80 percent, you can just think of that whole curve with a shift to the left. If it was 90 percent, it would have shifted to the right, and as we shift to the right, you sort of increase the probability of passing regardless of where you're at.

If you shift to the left, you decrease the probability.

There's one final slide. As I said, there were a lot of combinations of C and N that could have been chosen, and this is again the market hog curve that if we would have had smaller set sizes. The colors show up here? Yeah. The black line is the current performance of, you know, six or fewer in 55 samples. The blue line in the middle would be if we had, you know, an N of 36 and a C of 4, and the red is N of 18, C of 2.

Now, all of those sampling plans would have measured the performance and they all would have had the same characteristics if operating at the standard. There would be an 80-percent probability of passing but with fewer samples, the curve tends to flatten out, and then the plants operating above the standard have a greater probability of passing, and if you went above the larger set size above 55, actually then the curve starts to steepen a little bit.

So, I hope, you know, that that at least gives people a little flavor of how we took that baseline prevalence, how that sort of was transformed into this thing of a set and how we sort of then put that into operation.

So, thank you.

(Applause)

DR. ACUFF: All right. Thank you.

Well, that concludes our presentations. We're going to have a panel discussion following a break, and I have to brag just a little bit. I got word that my daughter had been picked as outstanding student at her junior high, and they're going to give her an award tonight. So, I looked at the flight schedules. The only way I can get there is leave right now. So, I did a quick risk analysis, and you lost or won, depending on your perspective, you know.

But Dr. Busta is going to fill in in my place, and he's going to lead the panel discussion. So, I apologize for leaving early, but I know that he's going to do an excellent job.

So, we're breaking now until 10:50, and we'll start promptly back up again at 10 till 11.

Okay. Thank you.

(Whereupon, a recess was taken.)

Panel 3 - Discussion

DR. HULEBAK: Thank you all for returning reasonably promptly from break. The refreshments are really good. It's hard to tear oneself's away. But thanks for coming back.

We're now ready to open up a moderated

discussion period for Panel 3, and I will turn the mike over to Dr. Busta.

DR. BUSTA: Well, those of you that didn't want to rise to the microphone, we have cards, but first of all, I'd like to open this up for the first question from the microphone, if someone wants -- is anxious to do that. Otherwise, I can start from the cards. Does someone want to go to the microphone and ask the first question? I see somebody coming forward. I see two. I'll go with the individual in the red because she made the first move.

MS. NESTER: I'm Felicia Nester from Government Accountability Project. I have two questions actually for Loren Lange.

You were saying that the prevalence reflected in the baseline was indicative of the probability of finding Salmonella in the marketplace, is that correct?

DR. LANGE: No. It's indicative of finding Salmonella in an equivalent sample at the same sampling location, you know, where the baseline was conducted.

MS. NESTER: Right.

DR. LANGE: So, it's not marketplace necessarily.

MS. NESTER: Right. But it would reflect nationwide, right, and the combination of small plants,

large plants, very small plants?

DR. LANGE: True.

MS. NESTER: Right?

DR. LANGE: But --

MS. NESTER: Go ahead.

DR. LANGE: -- one qualification. When you do a nationwide baseline like this, you sample -- the sampling is done based on production volume, and it really is all the samples are from the establishment that produce, you know, 99 percent of the product. So, there really isn't in a nationwide baseline, there really isn't sampling of very small establishments, but behind it is the fact that no matter what very small establishments did, their proportion of production is so small, that it wouldn't affect the estimate of the national product prevalence.

MS. NESTER: So, you're saying that very small plants were not included in the baseline. So, you're saying large and small plants were included in the baseline collection?

DR. LANGE: Baseline -- when there's a nationwide baseline of carcasses, particularly what gets sampled is the large establishments and the larger of the small that really constitute --

MS. NESTER: 99 percent.

DR. LANGE: Yeah. 99 percent of the product.

MS. NESTER: Okay. Then, based on that, I'm looking at FSIS' most recent reports, and I'm looking at the ground beef numbers, and even before you aggregate for all years, the prevalence at small plants accounts for something like, well, not half of the samples that you then aggregate but a good bit of them, you know.

In other words, large plants account for something like 1/20th. They contributed about 1/20th of the samples for the aggregate figure, right?

DR. LANGE: Yes.

MS. NESTER: But you're saying that the large plants actually produce more than 1/20th of the ground beef on the market. So that, the higher prevalence at the large plants should be weighted, shouldn't it, in your aggregate figure if you want to talk about the actual prevalence of Salmonella?

DR. LANGE: Well, in the reports that the agency has published to date, it is just a report. These are the findings, and it is -- they have -- there are other ways to use that data and try to make a better estimate of prevalence, but there hasn't been an attempt to sort of take the data and sort of, you know, to do different things with it.

MS. NESTER: To weight it for volume?

DR. LANGE: Yeah.

MS. NESTER: Okay. So, this is FSIS' best estimate?

DR. LANGE: Well, it's FSIS' presentation of these are the samples that were collected in the enforcement testing of the HACCP verification testing and these are the results.

MS. NESTER: Okay. One last quick question. You exclude all but eight sets in these presentations, right? I mean, you exclude the results from sets that follow a failed set. So, I'm wondering, what is the percentage? Do you know what the percentage is of the sample sets that were excluded from calculation in this last report?

In other words, --

DR. LANGE: I don't know right offhand, but, yeah, the -- what's published on the website is the sort of sets from the initial eight sets, and the results from follow-up, what we call B&C sets are not included, but I don't right now, I haven't --

MS. NESTER: Okay. And that, unfortunately, is not on the web. I was looking for that. So, I'm not really sure whether you're excluding one percent of the sample sets from your calculation or whether it's

20 percent of the sample sets from your calculation. That's my last question.

DR. LANGE: Okay.

DR. BUSTA: I can't tell. Jim Lindsey, can you hear back there? I mean, can you hear the -- okay. All right.

I think because this is going to be recorded, if you'd identify yourself, please.

MS. MUCKLOW: Certainly. I'm Rosemary Mucklow with National Meat Association.

This is not the pick on Loren Lange session. The one thing I've learned, and I told Loren this at the break, that instead of writing letters to Tom Billey in 1999, I should have been in visiting with him and learning more about mathematics and statistics instead of focusing on microbiology and how much richer we might all have been.

I'd like to ask if the -- Loren gave us copies or copies were available on the desk. Maybe this just goes to all of the presentations. It really makes it much more helpful to have copies of that material, and I don't know if the other slide presentations will be made available because Dr. Buchanan shot through his very rapidly. Now, clearly, a paper copy with all of those marbles flowing around

would be quite difficult, but it would be useful.

DR. BUSTA: They don't come through in red and blue.

MS. MUCKLOW: Excuse me?

DR. BUSTA: They don't come through.

MS. MUCKLOW: Yeah. Especially in different colors and so on, but it would really be very useful to have those. I don't know if we can have them by the end of the day or not, but certainly it was very helpful, especially when Loren got into all that mathematical game planning and, you know, at least having -- I now know what that sum sign is and thanks to my computer, but it would really be useful.

I'd like to ask Dr. Golan, and I got in trouble on pronunciation yesterday. I don't know if I got her name right or not, but I found her presentation -- I got it right?

DR. BUSTA: Golan.

MS. MUCKLOW: Golan. Okay. Excuse me. Golan. I don't want to be fingered out again at the end of the day for getting the names wrong. I try to be a conformist to the extent that I can.

When Dr. Golan talked about the criteria for setting standards, I'd like her to maybe respond to a slightly different question. I think most of what she

talked about was where there was a normal or homogenous distribution when you're looking for the exceptions, and when we are looking -- and the product of my great choice is that which we eat 50 percent of, which is ground beef, we are looking at an abnormal or heterogeneous distribution of what we're looking for, and from an economic sense, I wondered if she could maybe talk to that unusual or heterogeneous distribution as distinct from the homogenous distribution that you would get in a pasteurized product or in juice or whatever. That would, I think, be interesting and helpful from an economic perspective.

DR. GOLAN: Are you speaking about heterogeneity within a product coming out of the plant or a heterogeneity across plants?

MS. MUCKLOW: Well, in terms of ground beef, the person that makes the ground beef will have bought the raw materials from several different plants, and I have a peculiar passion about ground beef which probably is understood better by this audience than maybe by you.

But that raw material comes from a variety of plants, even at a retail store where they may be grinding product still. So, a lot of product comes

from a variety of sources.

DR. GOLAN: It comes from a variety of sources, but I'm assuming that some of that product coming from some variety of sources is more contaminated than others, and so that then the person who is actually mixing the batch of product would/could place some restrictions on what type of product they'll buy. You could have a restriction saying I will not accept contaminated product into my processing plant, into my product.

MS. MUCKLOW: Okay. It's not considered contaminated product. It's all USDA-inspected product, and again I'm not here to -- what I'm looking for is the economic justifications for something that does not occur homogeneously in the product.

DR. GOLAN: You're right. If I took a lot of different bits of meat, thousands of different -- from thousands of different animals, I will get some that are -- have Salmonella or E.coli, and I will mix them into my great big vat of meat, and I will have a sprinkling of this Salmonella or E.coli throughout my mixture. Some clumps will be more laden than other clumps, and sampling will be a very difficult problem, and then that's a sampling issue. But from the economic point of view, this is getting back to

something that was mentioned yesterday about who has the ultimate responsibility for ensuring the quality of a product.

Economists would say you would put that responsibility on the end player. I am the person who is amassing all these great globs of meat. I'm the person who has a responsibility for putting safe product into my final product. You put the pressure at the end and that end player puts the pressure on the downstream players. That's what an economist would say.

MS. MUCKLOW: Therein lies a major, major problem under the present scheme of how product is produced because that end person has no ability, no clear ability and no testing ability or interventions to prevent or to do anything about that product that comes to them.

DR. GOLAN: That's very analogous to many of the problems that environmental economists have had to deal with. I gave the example of car manufacturers. Car manufacturers have the ultimate responsibility of making sure their emissions out of their cars are below a certain standard. Okay. Where do they put the pressure on? The pressure on the people to redesign that engine or is it on the input, the gasoline?

Gasoline is as easily as mixed up as ground beef. The pressure is on both parts of this chain actually there, but we can reduce levels of toxic material in gasoline, we can reduce levels of Salmonella and pathogens in meat and ground beef.

MS. MUCKLOW: But the big difference there is that gasoline is a homogenized product whereas the raw materials for ground beef are a heterogeneous collection of --

DR. GOLAN: I don't really see it that different, but there are many other examples. Incinerators who take in raw materials from across a whole dump have a responsibility for making sure that their emissions are below a certain standard, and the inputs that come into them can be all over the place as far as toxicity.

It is common practice in environment management to apply the pressure at the end of the chain. I really don't think that food safety needs to be so completely different. It is not more difficult to measure outcomes in food safety than it is for environmental policy.

MS. MUCKLOW: On that, we may have a fundamental difference, but you speak as an economist and I speak as a practical industry individual.

Thank you.

DR. BUSTA: Thank you.

Come up to the microphone, but I'm going to do a couple cards. One for Bob Buchanan.

Given that bad safety is so difficult to verify, is taking a two-ounce sample of ground beef and testing it for E.coli anything but futile? Pull the microphone close.

DR. BUCHANAN: I guess I would have to reflect on the person that posed that question, was what was the purpose for taking the two-ounce sample of ground beef and testing it? If you were taking a two-ounce sample and trying to make a decision about an entire, you know, batch of ground beef, depending on what your criteria were and what was the level of the likely contaminant in it, it could be/it could not be. It's really an issue here of you would need some more in terms of specifics.

If you were using it again as part of an on-going process of evaluating or verifying a process, again it might be, but it would have to be part of a larger sampling scheme. I would suggest that a single two-ounce sample of an unknown batch would probably be insufficient to make any kind of assessment of safety. Usually typically we would be dealing with a 375-gram

composite of 25 different analytical units, and I can go into the details and depending on the defect rate, you might need to have 60 subs or 30 subs or a variety of those, but it's dependent on your degree. So, it's really hard to provide any kind of response to that question without knowing more details.

DR. McNAMARA: Anne Marie McNamara from Sara Lee Corporation.

I think as food scientists, we can all agree that final product testing for pathogens plays a role in validating our HACCP plans in periodically assuring that our plans are attaining the food safety parameters that we set up and their designs.

But yesterday, a clinician made a statement that I'd like to get the food science perspective on, and that was Dr. Robert Tauxe from the CDC, who seemed to be implying that purchase specifications for pathogens was one way to reduce the incidence of disease, and as a food scientist, that disturbs me because one can never reasonably test enough to ensure safety, and it is against what I consider the principles of HACCP which is process control that we've striven since 1994 to attain.

And as a clinical microbiologist, I think it upsets me more because you're giving your consumers and

your customers a false set of expectations. So, I wondered if you could give me the food scientist perspective of the value of pathogen testing for purchase specifications when valid HACCP plans are in place.

DR. BUCHANAN: I'll take a shot at that, Frank, and attempt to put it in perspective at least of the talk that I presented here.

The establishment of criteria, be it standards, guidelines or specifications, depending on where they're applied, is a statement of the degree to which one expects that a hazard will be controlled, and we can either do this in rather vague terms, and most of our laws are actually in rather vague terms, you know, than interpret those laws in giving some more specifics to them.

I personally find that if you lay out a reasonable specification or criterion, let's use criterion as the more general term, it is helpful because then the people that are providing a good or service or whatever know what level to design their programs to meet.

However, we're mixing and matching two different things here. It's whether or not a criterion would be useful and whether or not you have to use

microbiological testing to verify that, that you're meeting that criterion, and I fall back to the discussion that I had earlier. It depends on whether or not you have any intimate knowledge of the product that you're dealing with.

If you have absolutely no knowledge of the product, then what you're doing is batch testing and that requires a great deal of sampling. It is quite burdensome, and I'm not sure that it can be used effectively in most instances.

However, if you have a process for which you have a great deal of knowledge and what you're doing is verifying that that process is under control, that is amenable to microbiological testing, and it is one of a number of useful tests that can be used, if appropriate. Again, it's dependent on the reliability of the process, your comfort zone with the people that are providing you their history of performance. It's a complex issue in managing a risk.

So, I'm not going to give you a definitive answer one way or another, other than to say it depends, and you should use the right tool for the right job, and batch testing normally, when you're getting down to low defect rates, is -- gets to be quickly burdensome in terms of the economics.

DR. GOLAN: Let me just add one point. I'm not really sure what Dr. Tauxe was referring to in his comments, but if he was referring to maybe the possibility that pathogens are introduced into the food from point of final sale to retail, well, if that was the case, then there are other ways to provide consumers with information about what has happened to the food.

One possibility would be having a label that records temperatures. You've probably heard of that proposal, that the label would record the temperature that the food has been kept at, and if it had dipped below a critical point or gotten too hot or gotten too cold, that the label would actually record that so the consumer at final point of purchase would be able to know if the food had been -- the quality or safety of the food had been compromised. So, there are other ways to get consumers information and all those ways are probably going to be very important in making sure that the final product is consumed safely.

DR. BUSTA: Here's one for me, and I'll get right to you. It says, are there currently reliable indicator index organisms for Salmonella and Listeria? No. A little bit of Letterman there. I hope I made the major point that we'd need a lot of data and a lot

of relationships and a lot more information to come up with good indicator organisms that would indicate a certain thing. We really are short on the data and information to make good conclusive directions at this point.

MS. CHEN: Lauren Chen from the National Food Processors Association. My question is also related to surrogate organisms.

I was wondering if genetically-modified organisms can be used as an appropriate surrogate. You've mentioned that one of the desirable characteristics of a surrogate would be if it's genetically stable. So, conceivable that we've identified a surrogate that has a similar, for example, heat-resistant characteristics to E.coli 0157:H7 and we can use it to validate process, now to facilitate identification of the surrogate, we transform the naturally-occurring surrogate to carry a genetic marker and now we would have to grow the organism in the presence of a selective agent, maybe an antibiotic, before actually using it.

So, my question is, would the transformed surrogate be considered generically stable, and would it be appropriate to use for -- as such?

DR. BUSTA: That has been proposed, to take

an avirulent strain, and if it has all the rest of the characteristics of the original, then it would be work as an excellent surrogate.

Some of the problems are that if you're looking for antibiotic resistance, your selection marker, if that organism got out into nature, there would be a concern about putting out antibiotic resistance into a population, and depending on the reversion rate, if it was even a natural mutant, there are some environmental questions about putting an organism like that out into the plant with the possibility of it getting into the normal system.

But I think with the appropriate safeguards, it would be an excellent surrogate, and some people feel that in thermal processing, PA3679 is in fact sort of a curative of Clostridium Botulinum that no longer was toxicogenic. That's sheer speculation.

Jill, I need to do a couple cards and then we'll get to you.

Loren, has FSIS sampled all the large and small plants so that all plants that produce 99 percent of the product have been tested at least twice, if not at least once?

DR. LANGE: I understand the question is that have we completed a sample set in every large and small

plant, and I think the answer is certainly in most. There is obvious characteristics -- you know, unique situations where, I'll use as an example, a ground beef plant sort of is in and out of production, and we start a sample set and they stop producing ground beef. We're working to improve sort of our tracking system in that area, but it's possible then that, you know, the inspector in charge in that plant asks what to do, and we probably said, you know, return the forms to the lab and stuff, and we stopped, and then until we get sort of information that yes, they're back up in production, we may have missed that.

So, I can find isolated cases, I think, where we haven't completed at least one set, but we certainly -- you know, our attempt is to sort of, you know, as we can keep track of the best information we can from who's producing which of the products, we try to get everybody scheduled.

MS. SNOWDEN: Thank you, Frank. Jill Snowden, SGA Associates, and thanks to all the panel members for their informative presentations.

I have a clarification to ask and perhaps a suggestion for Dr. Golan. I appreciated you coming up with guidelines, and I liked hearing the economics perspective on that, the guidelines for setting

performance standards, but I want clarification on understanding what you're trying to say when you say regulate as close to the end users as practical while encouraging upstream solutions.

As I think of the farm to table, I think of the end user as being the consumer, and I'm assuming that if that's what you're thinking, then the closest point to regulation there is going to be food service or retail. So, that's my clarification.

Are you saying that we regulate close to the food service and retail and push all the way back to production?

DR. GOLAN: I was actually thinking of the end of the production line.

MS. SNOWDEN: I'm not hearing you.

DR. GOLAN: Sorry. I was actually thinking at the end of the production line, but regulation well extends all the way to the consumer, and we do have a lot of regulation or actually policy, policy directed towards the consumer. We have a lot of education programs and labeling.

MS. SNOWDEN: Then I think my suggestion would be that as you do the oil analogy of the oil move in in terms of the impact on pollution, I think you need to -- maybe the economic models need to be

adjusted for the fact we're dealing with biological systems. Bacteria, in particular, I tend to think of as a web. I even challenge the farm to table approach as too many because of the different points of entry that the contamination can come in and because of the growth possibility or the reduction possibility.

So, I'll leave that as a suggestion, that as you continue to develop your models when applying this, that we think more weblike than we necessarily do linear to pull the biology into our models.

DR. GOLAN: Because the biology is more complicated than in an oil example, and because the pathogens can be introduced all along the line, maybe it makes it even more important to focus on that end player.

MS. SNOWDEN: Thank you.

DR. BUSTA: Dr. Buchanan, can you please define validation and compare validation between the food and drug industry, between the food and drug industry? Is there a document or guideline on validation?

DR. BUCHANAN: Interesting. As we have gone back and talked about terms, we've come to the realization that if you go to different documents, you'll find different definitions, and while they may

vary slightly, they do differ.

For me in terms of validation, I might note, also, in regard to the National Advisory Committee for Microbiological Criteria for Foods, for discussions that are taking place at the international level on Codex, validation is typically designed to establish whether your food safety system that you're using is capable of providing you with the level of assurance that you actually intended it to have; that is, if I have a system. For example, if I have a car, and I expect that that car can do 80 miles an hour and it can do it for a hundred hours, it's actually somebody getting out and testing that model to make sure that it's capable of doing that.

Typically, we would validate before we start a process up or, you know, in the early stages of it, and then it would only be revalidated periodically when the system changed so much as to require a reassurance that the system is capable of delivering what was intended.

The sampling during normal operations is typically referred to as verification and that's separated. If validation is determining if the system is capable of delivering what you expected it would be or what it was designed to do, verification would be is

it continuing to actually supply that, and so there is a difference between validation and verification.

Increasingly, validation is looked at, at least in FDA, as a necessary step before you start a food safety process.

MR. BAILEY: Stan Bailey from the Agricultural Research Service in Athens, Georgia.

My comment and question is, I guess, both to the panel and possibly even to people in the room. When we implemented the HACCP plan back in '94, it had the two components, one for Salmonella testing and one for the generic E.coli testing. The environment at that time was pushing very hard toward having all species, all animal species treated equally.

So, my question on the generic E.coli testing is (1) does the panel or anybody else think that there is real value coming out of that testing? It's pretty well established and Dr. Busta just referred to, it's not an indicator, it's not a good indicator of the presence of Salmonella or any other pathogen, and secondly, it's not really a measure of process control, at least in the poultry industry, which I work in mostly, and so I guess a two-part comment is (1) do we still consider it a valid thing to treat all animal species equal in terms of the E.coli testing, and what

value are we getting, other than a fairly large expense in doing the E.coli testing?

Thank you.

DR. BUSTA: Panel? Loren looks like he's about to address this.

DR. LANGE: Well, a lot of times, there's -- one can get themselves in trouble when their initial reaction is you don't know how to answer that question, and then you try to answer it. So, I should probably stick with I think the answer I would give is as a staff person in FSIS, we really haven't done the follow-up study to evaluate, you know, what we're getting from the requirement that the E.coli -- you know, the testing for generic E.coli.

I think the emphasis from the agency has been on trying to, you know, make sure that, you know, it is being done, that the results are being reported, but we haven't answered that question inside the agency of what we're getting from it. That's the best I can do.

There may be someone in the audience that would like to answer that.

MR. BAILEY: I appreciate the honesty of that answer. One of the preambles of the discussion at that time was the issue of measurement of fecal contamination and this would be a good way to know what

was going on. I realize there were a lot of other backdrops as to why it was done. I was aware of that discussion, but if one looks at the data within the industry, at least in the poultry industry, and even your own data where you're measuring fecal contamination, I think you'll find that there's very little correlation between the level of E.coli and the presence of fecal material.

As a matter of fact, the only time we really see blooms or outbursts of E.coli or high levels in the poultry industry is if there's an airsoculitis or some other disease problem, which is totally unrelated to the food safety aspect of this.

DR. BUSTA: Comments from the panel? Bob?

DR. BUCHANAN: I'm not going to address the specifics of the poultry industry, but I would like to talk a little bit about E.coli as an indicator and re-emphasize some of the points that Frank made in his presentation.

One, as an indicator, we're talking about a state or condition. So, in this instance, the state would be fecal contamination. What we need to keep in perspective is that as you get down to the low levels where you're exercising a high degree of control, you start to get in the situations where you are having to

deal with other sources of E.coli in the environment, and so when you're getting down to -- you're down to a percent frequency of about two percent, then you have to start asking the question, is the E.coli that's present in that environment down to the point where it's no longer indicating fecal contamination, it's indicating something else? That's just not to say that it's useful, and I think it would probably be better to ask the people that are actually in the industry what has been the usefulness of that indicator in terms of their ability to maintain good strong sanitation programs and pathogen reduction programs, and if it's not a useful indicator, what would be an alternative in terms of something that would help them monitor the microbiological status of their operation?

DR. BUSTA: Any industry comments on that?

(No response)

DR. BUSTA: How long do you wait? There's a question here for me that says, if all Salmonellae are not equally pathogenic for humans, isn't it futile to look for indicators in the indices or index organisms or surrogates?

Well, as an optimistic academic researcher, nothing is futile. There's always an opportunity, but I think as we develop greater and greater genetic

understanding and faster and better evaluations and measurements, that we may be able to sort out the appropriate hazardous Salmonella from the less hazardous Salmonella, the same with E.coli or the same with Listeria, and be able to do that sorting, and then it may be very appropriate to identify indicators of the presence or indices of the presence of the actual pathogens or the hazardous organisms and simultaneously have a real opportunity to pick surrogates for those specifically hazardous organisms.

So, I think the opposite of futile. As we learn more and more about these organisms, we'd be able to do a better job with improved data than we've done in the past.

Sir?

MR. MARLER: William Marler. I'm the attorney that represented the young boy who developed HUS that Secretary Murano mentioned that she testified with her mother.

My question is for Dr. Golan. Given how FSIS and USDA presently regulate the industry and given that most people who develop a foodborne illness never know what product they got it from and never know where it came from, can you explain to me where the economic force is to have the industry make any changes

whatsoever in their food safety practices?

DR. GOLAN: Well, the economic force, the force is not market-driven, because of the failure that you've identified. We have a market failure that the information is not available to consumers. They're not always clear about the quality or the safety of the food that they're consuming.

So, many of the market incentives for firms to produce foods, safe foods, dissolves, which is why government regulators say we have a reason to step in and regulate this industry. So, exactly what you're saying is why we step in, why regulation is necessary.

DR. BUCHANAN: I'm sitting in for Gary on this. There was a question directed to him. It says, historically in the U.S., pork and poultry have been thoroughly cooked while undercooked beef continues to be generally accepted. While each has pathogens associated that can be heat-killed, why the disparity between the species?

I'm going to focus on pork and beef in answering this response because it's an interesting history. Pork has traditionally in the United States been cooked to a well-done state. In fact, if you go back to the early part of the last century, there was a tremendous effort on the part of the U.S. Government to

convince consumers not to eat pork in less than a well-done state.

It's one of the few examples we have in the country where food safety education programs have been effective to the point where it actually could be relied on to assure the safety of the product. This reflects the fact that pork in the early part of the 20th Century had a fairly high contamination rate with Trichinosis, and as opposed to beef, and for any of you that are not familiar with Trichinosis, it's a parasite. It's incorporated right into the muscle tissue. So, you had the -- even if you -- you couldn't have the assumption that the inside part of the muscle was sterile, as opposed to beef. The working assumption that if you take an intact cut of meat, the contamination is restricted to the outside.

The reason why that's interesting is that it demonstrates how there are different approaches to solving the same problem. In Europe, where pork continued to be consumed despite the fact that there was Trichinella, and they consumed it in the raw state, they relied on an entirely different approach. They relied on carcass-by-carcass inspection of the animals, taking a piece of the diaphragm and actually testing and holding those animals to make sure that they were

Trichinosis-free.

Got to the same point. Both were equally effective in terms of controlling that disease, and we can see beginning in the early part of the 20th Century the rate of Trichinosis associated with disease in this country dropped dramatically as a result of this impact that we had on the safety of that product.

Again, beef was not affected by these parasites. There has been a working assumption that the inside of that muscle tissue is free of pathogens, though, of course, we do get into instances where lymph nodes may be contaminated. So, a little history.

DR. BUSTA: Bob mentioned earlier that this panel was a demonstration of true graybeards. Gary's gone already, but the three of us.

Here's a question for any of the panel, but Bob, probably you're the best on this. From the audience, the individual was surprised at the level of Salmonella in ground turkey and chicken considering there is a "zero" tolerance for Salmonella in shrimp and fish that is imported into the U.S.

What is the reason or are the reasons for this discrepancy?

DR. BUCHANAN: Let me again give you a historical example and where technology and changes in

agriculture have generated a controversy or a need to go back and relook at it.

Typically, shrimp were harvested from deep sea waters. They were in an environment where Salmonella was a rare and transitory occurrence and that Salmonella associated with this product was typically acquired as a result of post-harvest contamination; that is, it was contaminated on the boat or it was contaminated at the dock or it was contaminated in the processing plant because Salmonella was just not a normal part of the marine environment and that was the basis upon which a zero tolerance for Salmonella was originally derived by FDA for that product.

The reason why it has now become an issue of controversy is that during the last 20 years, there has been a shift from marine sources for shrimp to fresh water shrimp, and we also now see a great deal of shrimp being produced by aquaculture, and in such an instance, in fresh water ponds and in aquaculture setting, the presence of Salmonella when you have ponds that, you know, ducks swim in and, you know, animals come down and run-off from agricultural lands, Salmonella now becomes a part of the normal flora and there's been an on-going debate internationally whether

the zero tolerance for Salmonella is any longer justifiable, and this is an issue that has been in front of Codex, for example, and continues to be debated and discussed.

So, I can't give you an answer definitively, but it's an example of how as the world changes, how we need to go back and relook at the justifications because it may no longer be the same rationale that was used originally.

DR. BUSTA: Loren, is it true, if a company were at the mean rate of contamination, its probability of failing one test is 20 percent, the probability of failing two tests is .2 or .04 percent, the probability of failing three tests is .2 times or 22 or .008 percent, and therefore the probability of passing three tests -- passing with those three tests is .992?

DR. LANGE: That's correct.

DR. BUSTA: He wasn't very close to the microphone but that was correct.

For the panel, how has test sensitivity changed over the last decade, and what are the implications for performance standards? Test sensitivity being that -- I mean, we're going to have to define test sensitivity. This would be -- is that --

DR. LANGE: The only thing I can think of, if the question is related to -- there was some discussion yesterday that there's been a different laboratory method for 0157. There's been a -- for FSIS laboratory, as I understand, there's been a constant method for analyzing for Salmonella through the baseline period and the post-HACCP period.

DR. BUCHANAN: The limiting factor right now in terms of testing sensitivity since the tests are -- the one for Salmonella and E.coli are -- have been around forever, and they haven't really changed much, they're highly sensitive, detectable at levels practically down to about one per 10 grams.

Basically, it's dependent on the size of the sample you take, and those, as far as I know, have been kept constant.

DR. BUSTA: What about PCR? Has that improved the level at all?

DR. BUCHANAN: Typically, PCR, the level of detection at PCR is when you take into account the sample size, which is actually quite small, and you're taking smaller and smaller samples as you go to that, you really -- the limiting level of sensitivity for a straight PCR method is actually down around one -- you have to get up around 10 to the 4th actually where

you're detectable, and basically anything below 10 to the 4th requires enrichment and still the most sensitive means of detecting the organism is culturally, including all the classic enrichment steps, and certainly you may be able to speed it up or confirm it.

DR. BUSTA: My question was merely rhetorical.

DR. BUCHANAN: Right.

DR. BUSTA: But people expect that the PCR's going to give you instant fast and wonderful results, and it's got limitations.

Mike?

MR. ROBACK: Mike Roback, Wayne Farms.

My question is related to performance standards. Again, we've talked a lot about performance standards, talked a little bit about indicator organisms, index organisms, and I think we have a difference between whether we're looking at a raw agricultural commodity versus a ready-to-eat food on one hand that I think a distinction needs to be drawn, and as we talk about the Salmonella performance standard in particular, with raw meat and poultry, what is the true value of having a qualitative performance standard versus a quantitative performance standard

when one cell is as damning as 10,000 cells?

I wonder as we're looking at measuring public health outcomes, if a qualitative performance standard is really providing us with the information and the standard that we truly need to improve food safety, and I'd just like to hear your comments on that.

DR. BUCHANAN: It's -- Mike, it's not quite as clearcut as you think because really whenever you go to a qualitative determination, as you would in any attribute sampling, in reality, you can make a quantitative estimate of what is actually occurring within that animal. If you're down at a low level where only one out of every so many carcasses are showing up as positive, you can -- assuming a normal distribution of that or even a log normal or others, you can actually make an estimate of what the level was in order to have that positive.

That's the whole basis of an NPN, is that kind of approach. It's a statistically-based approach, and it would not be hard to take any of the results that are there for plus/minus and actually come up with a best estimate of the mean concentration on that organism at -- on -- in that product, including confidence intervals around it.

So, this artificial designation or separation

between qualitative and quantitative really doesn't exist when you start dealing with statistics. In order for you to get down that low on this kind of a process control, you have to be down where there's just a few organisms on the carcasses anyway or everything would be a hundred percent.

MR. ROBACH: Well, I don't know if that's necessarily the case, Bob. I think it would be very interesting to run a validation on that theory, and I think one of the points that was made earlier is that this performance standard was really established prior to a risk assessment being done, and I think the other point that needs to be made is that if we're after improving public health, then it behooves us all to perform the proper risk assessments to determine, you know, what is an appropriate standard?

Just because you can easily measure an organism or it can be found in a regular basis does not necessarily equate to an improvement in public health if you indeed reduce that organism. So, I think as you point out, it is a very complicated situation, and I think in meat and poultry, we're in a situation where we have a HACCP system in a raw process, where we do not have a terminal step, and we're doing what we can to reduce or at least control contamination of product

going through a process, and we have to take into account (a) the initial contamination coming into the plant and then do the best we can to reduce that or at least control the numbers of organisms through the process, and I still believe that a qualitative performance standard does not really give us the proper measuring tool to accomplish that.

DR. LANGE: I would just add that in my presentation, I mentioned that certainly the risk assessment people in OPHS, you know, are, as we make decisions about allocating our laboratory resources, are certainly interested in testing to find the quantitative levels, at least at some point in the production process, whether even if it's at where we currently test for poultry at the end of the drip line or consumer packages. So, they are -- for the development of the risk assessment models, they do want quantitative levels.

DR. BUSTA: I'm going to limit this now to two cards, and then we will have a lunch break.

The last one for Dr. Golan. Golan. No one's ever going to forget that except me. Golan.

If improving the safety of food costs money, how can we prove, I think it's provide, safe food for everyone and just not the rich?

DR. GOLAN: Well, I'm really not sure where to go with that. I mean, policymakers for a lot of different social objectives decide that everybody needs to have the same level of production or everybody in the whole society needs to be -- well, have the same safety, and in other cases, policymakers decide that's not really important, that people can decide how much risk they want to assume and how unsafe lives they want to lead.

We make people wear motorcycle helmets in most states. We let people ski without helmets in all states. So, sometimes we as a society decide that certain risks are acceptable and certain risks are unacceptable, and it is just a complete cost-benefit analysis and that's what economists in the Federal Government end up doing a lot, particularly now. Probably we're going to end up doing more and more with changes at OMB.

But these are -- there's a careful calculation of how much safety the society wants and how much safety a society is willing to pay for. That's a difficulty.

DR. BUSTA: Funny you should mention motorcycle helmets. It was ruled that that was an individual choice in the state of Minnesota, that they

don't have to wear motorcycle helmets. That was before we had a bald governor.

Okay. I have -- this is -- this seems very appropriate for the last question before lunch. If 100 sandwiches were set out, 25 with white bread, 25 wheat, 25 rye, and 25 raisin, from a consumer safety or performance standard view, which type of bread should be allowed to test positive for Salmonella 49 percent of the time? Which one of the 82 samples? I didn't make it up, honest.

DR. BUCHANAN: That sounds like a mathematician is needed.

DR. LANGE: Now, we all hear different things. I heard that as a question that was raised yesterday, as how did we justify allowing a different level or prevalence of Salmonella in one product versus another, and the answer is sort of -- actually has a preamble to the '96 rule in my briefcase. I could read it, if it's -- you know, a decision that there was a sense of, you know, quality in requiring each segment of the industry to operate at least at a level that had been shown as baseline prevalence in a study, and it was determined that without a public health outcome, that that would in fact generate reductions in pathogens and therefore lead to reductions in the

foodborne illness. If that's how -- that's what I heard. Now, maybe someone else heard a different question.

DR. BUSTA: Well, I think it requires a research activity at lunch. Lunch is on your own. Please be back sharply at 12:50, 12-5-0, 10 minutes to 1, and we'll reconvene with the afternoon panel and Jim Dickson.

(Whereupon, at 12:01 p.m., the meeting was recessed, to reconvene this same day, Tuesday, May 7th, 2002, at 12:50 p.m.)

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

12:58 p.m.

DR. HULEBAK: Good afternoon, everybody.

Welcome back from lunch and the beginning of our last session, Panel 4, focused on Animal Product Intervention Strategies.

The chair of this afternoon's panel, my pleasure to introduce, Dr. James Dickson, Associate Professor and Chair of Microbiology at Iowa State University.

Dr. Dickson received his Bachelor's of Science in Microbiology from Clemson University, from where he went to get his Master's of Science in Dairy Science at the University of Georgia, and then on to the University of Nebraska at Lincoln for his Ph.D. in Food Science and Technology.

Dr. Dickson has had many and varied successful research strategies in his career. He's developed a predictive model to estimate growth of Salmonellae during cooling of carcasses which have had some singular practical applications actually at USDA. He has conducted studies of bacterial attachment, carcass washing and sanitizing that have seen a number

of practical applications.

He currently serves on the National Academy of Sciences Committee that's looking at scientific criteria and performance standards, and he chairs the Meat and Poultry Subcommittee of that committee.

So, it's with great pleasure I introduce Dr. Dickson and Panel 4.

Thank you.

(Applause)

Panel 4: Intervention Strategies, Including Verification of Effectiveness

DR. DICKSON: Well, thank you, Dr. Hulebak.

I would like to say at the outset that for those of you who have ever had the pleasure of assembling a meeting, especially a meeting of this scale, you appreciate the challenges, if you will, of getting everybody in order and everybody in the same place at the same time, and I have to say that Dr. Hulebak and her staff have been very professional and have done an excellent job of doing this in the relatively short time frame that they had to work in.

Well, this afternoon's panel is on Intervention Strategies, and we have a number of speakers this afternoon which I think you'll find interesting, beginning with discussions on intervention

strategies in live animal production, intervention strategies at slaughter, intervention strategies during processing, and then finally a discussion of the benefits and costs of intervention strategies which may ultimately determine the actual use of some of these interventions. The reality is the best intervention strategy in the world is not useful if it is too costly or too expensive to use.

I've been asked today to give a few introductory comments on the subject of intervention strategies and just to reiterate when we talk about intervention strategies, we're talking about the entire food system and that includes production, transportation, processing, distribution, whatever the ultimate end point is, whether it is commercial preparation in a restaurant or food service or retail sale, and ultimately the consumer.

So, when we talk about interventions, bear in mind that there is no one point along the way that we're speaking of interventions. We're talking about interventions all the way through the chain.

I thought I'd start out by saying what is an intervention, and for lack of a better definition, I made one up, which is simply a procedure or process or technology which reduces or eliminates a potential

foodborne hazard, and although our focus has been primarily microbiological, I'd, of course, like to remind everyone that it also includes chemical and physical hazards as well.

Okay. To begin with, first intervention is prevention, and it doesn't really matter how you approach this, whether you are a food service employee or an animal production employee, however you approach this, the first intervention is prevention of contamination and just to give you a very brief example of this, if you apply an intervention, and I don't care what intervention it is, that has a two log reduction, the resulting product is much better off if you start out with 10 to the 4th as opposed to 10 to the 6th bacteria of whatever bacteria you choose to talk about.

So, when we talk about interventions, bearing mind that interventions are part of the strategy of reducing hazards in the foods and that definitely the first hazard by far and away is one of prevention. I don't think there's an individual again that would say that they would rather be in the business of solving a problem rather than preventing a problem, and so let's bear in mind that intervention or prevention is in fact our first line of interventions.

There are a couple of categories of

interventions, whether we're talking about on-farm or processing, slaughter or even at the retail consumer level. Those are things like procedural interventions, and I guess for lack of a better term, I'll call it procedural. These are things, such as good agricultural practices, if you're talking about production of crops or production of livestock, sanitation practices, safe food-handling practices. Again, these fall into a procedural type of category. These are things that tend to be, for lack of a better term, again procedures that simply allow us to either prevent, reduce or eliminate a potential foodborne hazard.

I'm going to go through an example of how all these sort of fit together here in a minute. But bear in mind, procedural is just that, simply things like good sanitation practices at any point in the process.

Process interventions. These could be things like trimming and washing processes on animal carcasses, cooking processes, even canning processes. Canning process might be the ultimate process intervention, if you will, simply because the product ultimately is sterile as it comes out, but again that's a physical process or some type of process that's applied to intervene, to reduce or eliminate some

potential foodborne hazard.

And the final group, I'll call it technology interventions, and these fall under the general category of things like equipment design. Steam pasteurization is a good example, just to pick one, of a technology intervention. I think if 10 years ago, someone had said, well, why don't we steam beef carcasses to kill E.coli, most people in the industry would have said yeah, that's a nice idea, why don't you go work on it?

But steam pasteurization is in fact a technology that has been developed in the last several years which again does a very good job of reducing potential foodborne hazards. Irradiation again is an example of a technology intervention. Again, something that's out there, a technology that exists that can simply be applied in a different format.

Now, when we talk about interventions, bear in mind, as I said, we're talking about interventions across the entire food distribution chain. We're talking about multiple interventions and for a couple of reasons. First off, there is no magic bullet. There is no silver bullet. If there were, none of us would be here today, okay, because we would have all figured out what that magic bullet was and that's what

we'd be using and there would be no problem.

So, there is no single answer that addresses all the issues, but the second issue is opportunities for recontamination. As an extreme example, let's talk about food service. You can take canned foods which we will for the purposes of this discussion, we'll consider to be sterile, open the can in a food service establishment, warm it up to serve to a customer and have it handled by a food service worker carrying hepatitis A, and your customer still will become ill with hepatitis.

So, when we talk about opportunities for contamination or points in the chain where contamination can occur, bear in mind that that goes all the way through the system. We're not talking about cattle on a feedlot or we couldn't talk about cattle on a feedlot, but we could just as easily talk about food service workers in a commissary or a food service establishment, for example, the one here in the Georgetown Conference Center, that also needs to bear in mind that they have a role in interventions.

I do have one example of this and how all these multiple interventions come together and for the sake of discussion, we'll talk about pasteurized milk and the Grade A pasteurized milk ordinance.

As many of you are aware, the Grade A pasteurized milk ordinance includes interventions at several points, and it begins on the farm with specific requirements for milking of dairy cattle, and those include things such as equipment design, sanitation within the milking parlor, temperature control of the product, in this case it's a raw product, but there are temperature standards or guidelines for controlling the product. So, there's actually a production intervention or several production interventions.

At processing, we have pasteurization which, if you will, is the food safety intervention. The time/temperature process used to destroy foodborne pathogens which should at that point render the milk free from pathogenic microorganisms and should render it safe for human consumption, and ultimately during distribution in retail that we keep the product at refrigeration temperatures in part to prevent spoilage but also in part to limit the growth of anything that may have accidentally come through the pasteurization system. So, we have a system where multiple interventions work together.

No single step in that process could be eliminated. Okay. For example, you would not want to remove the production controls on farm, the sanitation,

equipment design and things of that nature, at the source of milking and simply say, well, we can fix all the problems with pasteurization. Even though that may technically be true, the point is that you don't want to remove it.

Likewise, you wouldn't want to say we're going to do all of our interventions on the farm and therefore we don't need pasteurization. I think history has proved to us that pasteurization of milk is probably one of the best public health success stories we've had. So, again what we're saying is that we'll use multiple interventions at different points in the process and not rely solely on one specific aspect or one specific intervention to solve the issue.

I think we'll see that this afternoon as we go through the various talks that we have on animal productions, slaughter processing and then ultimately on cost-benefits.

We have a couple of discussion issues. I'd like you to think about these as you listen to the presentations. First off, what research needs to be done to develop new technologies? How can USDA/FSIS provide incentives to conduct the research? Again, think about these things as we go through. How can you measure and verify the food safety impact of

interventions? These are questions to ask as you hear the presentations. What new technologies have been developed that are ready for implementation? How can USDA provide incentives to implement these technologies? Ultimately, what can be said about likely benefits and costs of interventions?

As I started out by saying, the best intervention in the world is useless if nobody can afford to implement the technology. So, as I said, think about those things as we go through the presentations, and with that, I'd like to introduce our first speaker, Martin Firth. If you'll bear with me one second here, I promised that I would do -- Martin Firth.

Martin Firth is the Manager of the Policy and Strategies Division, Canadian Food Inspection Agency. Martin is leading the development and implementation of an agency-led recognition protocol for on-farm food safety systems.

So, for those of us interested in on-farm food safety controls, it will be quite interesting to hear what the Canadians are doing in that level.

Martin?

MR. FIRTH: I'd like to take the opportunity to thank the organizers for inviting me. It's not only

a pleasure but an honor to be here and be part of this discussion. It's been very informative from my focus, I guess, in terms of HACCP and where we're going.

I guess there was some regional references to hellos and greetings and so from my native tongue, I'll say good day to you all.

What I'm going to try and make some sense into providing you with a bit of a process that we're working with where the agency's leading the recognition process, and I would like to try and describe that to you, going through the participants' roles and very briefly rules and responsibilities and then end up with some of the intervention strategies and programs that are involved in some of the individual on-the-farm programs.

So, press page down. Just to give a quick background, we had -- the agency was created in 1997 out of four separate government bodies, but more importantly for HACCP, before and after the creation of the agency, there was certainly a strong support towards the industry adoption of the principles, and we've been working on a number of -- basically two programs for processing sectors.

The Food Safety Enhancement Program, which covers the agrifood and meat and poultry sectors, and

then for the Fish Programs, we have a mandatory quality management program and just to get you right up to speed, we're in the works of going down the road of mandatory HACCP implementation for our meat and poultry sectors.

Broadly, I guess we've been working with our industry and with the processing sectors since about 1991, and then interest began about 1994, and we formally engaged with on-farm commodity groups in 1995, and through all this, our minister has provided some assistance, and I put this bullet in for some of the food for thought you had up earlier. There has been some assistance programs in helping industry adopt the HACCP.

Some of the pressures facing the on-farm in general, these are pretty broad. There's certainly consumer awareness and that's been well presented earlier. What I will -- what we've been calling HACCP pushback, and this relates to the discussion that's been presented earlier regarding upstream. Liability, and this is an interesting one. What's really come to the foreground on this one is that it's the liability of not doing anything and that is becoming of greater concern with the industry groups and the processors themselves.

The early-on discussions in liabilities was for the producer. If I put something in place, then wow, I'm going to be singled out. Through their development of the programs, they soon realized that there's actually more liability for doing nothing, and then buyer specifications, and from this point, we're seeing a lot more pressure for the producer groups to be on some form of HACCP-based program. We have a large number of retailers that are starting to push back now, and with the mandatory approach for our meat and poultry sectors, there's a lot of development going on and pressures being put on the livestock sectors to develop their programs.

Some of the principles that we've been working with is that the programs have to be HACCP-based, and I'll define that a little later on, but the strongest point here is that these programs have to use sound science in their development. They have to link with other stakeholders, and probably it's more accurate to say that they have to be linked with other sectors of that industry. So, therefore, there has to be a clear linkage with the beef program towards the up to the slaughter and then up to the processing.

In Canada, there's a shared jurisdiction between the Federal Governments and the Provincial

Governments. So, that has to be respected at all times, and that it has been made clear that industry wants to take the lead in the development and implementation of these programs. So, we've respected that, and the most important part is that these programs are dynamic, that although they may be implemented at time max, they certainly will change down the road and they will be expected to change to keep current with science and regulatory requirements.

Not to bore you, but talking about making up definitions, we made this one up at the federal process. So, it wasn't just me. So, I'll share the blame. It's basically what we're looking at is a systematic approach based on HACCP principles that represents a set of good production practices or referenced earlier good agricultural practices, including control measures, on-farm food safety program background, including the HACCP generic model and its analysis, a producer manual, and the management manual, and I'll try and describe those pieces a little later, and it's developed to promote the production of safe food at the farm level.

We are not trying to develop these programs and state that they will definitely guarantee levels of safety because, as has been discussed earlier, it's

extremely difficult to take those measurements at the consumer level, the impact of what's going on at the farm. So, we feel pretty safe to say that these programs, if implemented, will provide promotion of safe food.

I mentioned earlier I would try and define HACCP-based. The first piece that we realized very early on, especially after talking to some producers, that HACCP would be very difficult to implement in its pure sense or the sense that we use it at the processing level, mainly because of the management styles at the farm level and the environment that they live in, and I use environment here loosely.

So, what we mean by HACCP-based is these programs at a commodity level are developed through a technical committee. The committee membership must include some members from academia, technical experts, as well as producers and some government personnel as well.

The process that they work through is that they develop a generic model for that commodity. They then go through the hazard analysis based on that generic model and go through, using the seven principles, they work through the process. They identify any critical control points, and they also use

that hazard analysis to give them direction in the development of their good production practices, and the CCPs that are derived from the analysis are also incorporated into those good production practices.

At the end of the day, what they have then is they have a generic process that's allowed them to develop their producer manual, but they also have a very clear record of decision as to where they went with their decisionmaking.

Some of the background participants and kind of globally to the system is we have our sister organization, Agrifood Canada, and they're providing a lot of the developmental pieces in terms of financial assistance, etc. We have Health Canada with us as they have primacy in terms of standard-setting for food safety. We have ourselves. We have the Canadian Federation of Agriculture, an industry organization that has been administering the funds that the minister has allocated, and then we also have the individual producer associations.

Just for a bit of a background, we've identified, it may seem small numbers to you folks, but nationally, we've identified 22 significant national commodity associations. Out of those 22, we have 21 represented involved in this program. So, it's not

only just livestock sectors, it's the full spectrum of the input, including service groups, bean sprouts, the whole bit. So, it's -- we've been pretty fortunate.

Just generally then, the program that we're talking about, the on-farm food safety programs in general, then we can say that they're commodity-specific. We are not excluding any commodity. So, we have aquaculture at the table as well working on things.

We try -- it's intended to identify all hazards in the program, that they must be HACCP-based, that they're industry-driven, that the producers develop the national -- the programs are developed by the national organizations, and they're delivered by networks of organizations at the provincial or local levels, and that government will provide support through recognition.

I'll try and give a graphical of this as we move a little bit through. I'm not going to bore you with reading every point on this slide, but hopefully you'll get copies of this. I apologize for the organizers for not making this earlier.

Anyway, there's three or four key points that I'll go through on this slide. Notice on the first bullet, what we're saying is that the Canadian Food

Inspection Agency in support of these programs will provide a technical review of the documented programs. So, what we mean by that is with the provinces, we'll sit down, we'll take a look at their hazard analysis, we'll take a look at their producer manuals, the pieces that are getting down to the farmers, and we'll evaluate them against their technical soundness, against common science and regulatory requirements.

Once that's successful, the industry association then can go ahead and implement their program. We're requiring them to have a third party audit of their full system as it's implemented against their documented program, and then once that's successful, we'll come back again with the provinces and take a look at how the program is administered nationally, and through the evidence of the third party audit and our assessment, we'll provide recognition in support of that program.

So, how does this all shape up? So, the whole on-farm food safety system, we'll call it, the whole structure, is very generically set up in this manner. We have the National Association that develops the program. What we mean by develop the program, they have, of course, the background or the HACCP process. We have the producer manuals, but we also have a

documented management structure. So, they have clearly spelled-out roles and responsibilities as the different participants. Training materials for both the national structure and the on-farm participants.

They then work out a form of delivery agent. That could be a provincial government or a provincial body that works on their behalf in terms of implementing the program at the field level, and from that point, we have the producers themselves that get on to the program by the implementation, and then they are audited by on-farm validators or auditors that will come in and certify that these programs -- that these producers are on the program against the criteria, and they'll make recommendations back to the National Association to recommend that this producer is on or off the program.

Working with that, then we have the third party services which will provide an impartial audit on a regular basis of the full implementation right down to the field level of that program, and then providing a level of oversight to that, then we have the agency, along with the provinces, going in on a regular basis after the recognition process, going on on a regular basis to verify that the audits are being carried out and that the program is administered nationally against

the written program. Then behind all that, we have Health Canada providing the regulatory standards that these programs will have to meet.

So, just some examples here. I'm just going to quickly go through some of the interventions and try and respect time of the various programs, and this is kind of a real quick walk through the park. In the bovine species, both beef and dairy, we have certainly interventions with the use of veterinarian medicines. This is considered a must-do, and it's derived from the CCP and through the hazard analysis. So, there are a number of steps that the producer must have in place to properly administer the medications. They also have a full set of records, etc., that they have to keep on the farm.

We also have -- we're dovetailing with the animal ID program that has been recently put in place in Canada for beef and dairy cattle, so that the two mesh together.

In the poultry sector, we certainly have biosecurity up in front. We have -- there was some discussion earlier about the programs have caused the producers to work with buyer specifications with their supplier, and again it goes back with the upstream philosophy, and another dovetail for poultry is the

flock information sheets. These will be a requirement through the Poultry Inspection Programs, but they're based on the on-farm programs and the derived records from that.

For the layer flocks, we have some sanitation and buyer programs, as in the poultry and biosecurity, and they also have some specifications for feed and suppliers, etc.

In the pork, we certainly have veterinary medicines as well, biosecurity, and they are taking -- they do have a program right now where they're going out and actually sampling barns for Salmonella prevalence, and in the horticulture, we have the use of agricultural chemicals is their processes for that, and the use of organic fertilizers and ground water testing, and there is a point that -- the common point between all these is water testing, and it'll be interesting to see over the long run, to see producers regularly taking water samples.

Some of the things that are coming down the road, certainly we have medicated feeds regulations that we're working on, and they will have to be dovetailed into the producer programs. We're looking at other points of information transfer, such as where we have the poultry flock information sheets, we'll be

seeing that moved into the other livestock sectors. Animal ID, we'll be seeing that moving beyond just the beef and into the pork and other livestock sectors.

We have a number of vaccination trials going on, and hopefully with some success, we'll see those moved into the process, and on information, each one of the programs will be running baseline studies at the point of implementation as a starting point for validation of their programs.

So, I guess in conclusion, we're not trying to set the world on fire with this, but I think if we achieve one major point and that is having the producers not worry about affecting the things they do as more importantly we affect the way they think about the things they do, and if we can achieve that and get them remembering that they're producing food in the final outcome, we'll achieve a lot.

Thank you very much.

(Applause)

DR. DICKSON: Thank you, Martin.

Our next speaker is Dr. John Sofos. Bear with me one second while I get Dr. Sofos' presentation up. There we go.

Dr. Sofos is a Professor in the Department of Animal Science at Colorado State University. He has

both a Ph.D. and a Master's from the University of Minnesota and also a Bachelor's from the Aristotle University of Thessalonika in Greece.

Dr. Sofos is internationally recognized for his work on meat microbiology and especially in his efforts with decontamination or microbiology of fresh red meat products.

I know Dr. Sofos as both a professional colleague and as a friend and many of you may not realize but you may know him a little closer than you think. For all of you who read Journal of Food Protection, Dr. Sofos is one of the scientific editors for that journal.

So, John?

DR. SOFOS: Due to time constraints, I'm going to skip the joke and go directly to the presentation, and I'm going to talk firstly, my presentation is focused on the reduction of contamination during slaughter of beef, although much of what I'm going to say applies to other species, also.

As Dr. Dickson said, one of the interventions is prevention, and by doing things before they move out of the hide, we can prevent or not prevent but reduce the initial contamination that goes from the carcass

that we need to reduce by other interventions later.

So, before hide removal, there may be interventions associated with animal cleaning and hair removal or the chemical dehairing process, and after hide removal, there are knife trimming or steam vacuuming operations, washing or spraying or rinsing of the carcasses either with water or chemical, and they're usually cold or warm or hot, pressurized steam process, and then that's followed by chilling, and often we use multiple interventions, either combined or in sequence.

Of course, we have the question as to whether how do we deal with additional contamination that is introduced after slaughter, during fabrication, and how we control that contamination during distribution, processing and retail of the product.

This is basically an outline of what I'm going to talk about in a little more detail, and we'll start with animal cleaning and hair removal, and there are situations or countries or states where there is an effort to remove fecal tag and associated hair from heavily-contaminated animals or to apply washing of the animals before slaughter, either complete or partial, especially in some countries. These operations have been found to give variable results in terms of how

much they reduce contamination of the carcass, and they are, of course, limited in their application by climate and the need for facilities.

So, alternatives to be used when there are heavily-contaminated or soiled animals are to segregate those soiled animals and slaughter them separately and reduce the slaughter speed as well as increase the number of people working on the line so they can be more careful and take care of the carcasses to minimize contamination.

The chemical dehairing process is installed in at least one plant at this point. It is an effective procedure because it keeps the hide contamination outside of the plant. It uses sodium sulfide to hydrolyze the hair and hydrogen peroxide to neutralize the sodium sulfide. It is applied by spraying in sequence or in two or three cycles, and, of course, it requires capital investment and the issue of waste handling because you generate all this waste, chemical as well as hair waste, and how they deal with that is to regenerate sodium sulfide for the use and to make fertilizer out of the hydrolyzed hair.

Knife trimming and steam vacuuming. Knife trimming, of course, is required by the zero tolerance directive to remove visible contamination from

carcasses during the slaughtering process. The published results indicate that may be variable in its effectiveness in reducing contamination, and sometimes there may be a potential for spreading or redistributing the contamination during knife trimming, but at least it is important and necessary to apply, if nothing else, for aesthetics.

Steam vacuuming has been approved and is used in almost every plant as an alternative to knife trimming to remove visible contamination that is less than one inch in diameter. It also may have variable results and that will depend on the equipment maintenance and especially the diligence of the employees in applying the process, how well they apply it.

Carcass washing and decontamination processes can be applied to whole carcasses before evisceration or to half of carcass sides after evisceration and before chilling of the carcasses. They may be applied through immersion or flooding or dilution or cascading, depending on the system and the type of animal. For example, some of these apply more to poultry than beef or other species, or they're applied by spraying or rinsing, depending on how much pressure is used. Rinsing is the situation where the pressure is very

low, and they are done with water or chemical solutions.

Important variables that affect their effectiveness include, of course, the method that is used and the stage and time of their application during the slaughtering operation, the design and the maintenance of the equipment, the pressure during spraying operations, and the type of nozzle, for example, that they use, the temperature of application, whether they use chemicals, which ones and what concentration, as well as the duration of exposure of each carcass to these processes.

When spray or rinsing of decontamination is applied before carcass evisceration, the objective is to apply this treatment as soon as possible after removal of the hide and initial contamination to reduce as much of that contamination as possible before it gets attached on the surface of the carcass.

They may use organic acid solutions in evisceration spraying, but there are limitations on how much pressure you're allowed to use because of potential weight gain concerns because the carcasses have not been weighed at this stage, and also in many plants, you need to limit the temperature of the solution you apply because at this stage of the

operation, you may generate condensation and create problems.

After evisceration comes a final carcass washing treatment with water and after that comes the more effective decontamination treatments, including thermal decontamination, either with hot water or with pressurized steam, the steam pasteurization process, and chemical decontamination by spraying or rinsing with organic acid solution mostly for beef at concentrations of 1.5 to 2.5 percent. The acids used are mostly acetic and lactic. Lactic replaces acetic in most situations now, and the acids are found to be more effective when they are applied warm temperatures of about 55 degrees Celsius.

Chemical decontamination also may involve using a variety of other chemicals, including chlorine dioxide solutions, which apply mostly for poultry as well as trisodium phosphate or acidified sodium chloride and some feroxyacidic acid-based products, which are used to lesser or higher extent. They are approved. Also, there are some other chemicals that either are approved, proposed or being investigated for use or are in the process of being approved, including activated lactoferin, acidified calcium sulphate, hydrogen peroxide, and many others that are being

researched, as well as a number of physical processes, as we know, are effective in reducing contamination and may be applied to different situations, not necessarily to carcasses all the time.

Very often in most situations, the industry relies on the application of multiple interventions in reducing contamination, and those multiple processes are applied either as combined processes or as processes in a sequence, one following the other. Combinations of treatments could be, for example, using warm acetic or lactic acid or acetic acid solutions because the temperature of the acid together make it more effective or using steam vacuuming together and steam vacuuming to remove contamination, and, of course, the complete sequential application of decontamination sequence would start with animal cleaning and/or chemical dehairing of the animal before slaughter, followed by knife trimming of visible contamination or steam vacuuming of visible contamination of small size, followed by washing at pre-evisceration, followed by final washing, chemical and/or thermal decontamination, before carcass chilling. So, that would be a complete sequential order of decontamination. The rinsing is to produce a carcass that's as clean as possible.

And to prove that I'm not just talking but I'm basing off of some data, I have a few data slides out of the many that I started with, and this is a set of data that we collected some time ago before E.coli 0157:H7 was an adulterant, in six commercial plants where we had soiled practices and were analyzed for these pathogens, and we proved the point here that trimming with a knife reduced contamination, washing with water reduced contamination, but when carcasses were both trimmed and washed, the contamination with Listeria and Salmonella was reduced much more, showing the effectiveness of combinations of treatments.

Another point we can make here is related to a lot of the talk that took place this morning and yesterday about indicators and what do we measure and how it can be dangerous to rely on measuring the pathogen that is not frequent or at very high levels because, as we see when we tested for E.coli 0157:H7, we found the opposite of what might be expected. Of course, everything is so low, that you cannot draw any conclusions, but it is very clear that you have some -- you have to have something to measure before you can use it as an indicator of your process effectiveness in this case.

Are there any concerns associated with

washing and decontamination prevention practices? Yes, there are, and one concern that I always think about is the great variability we find. We tend to look at averages, but if we check the data that are published, we'll see that there is what seems to be plant variation, and we don't know if that's true plant variation. There is animal lot variation, method of decontamination variation, variation in different animal type, season of the year, anatomical site of the carcass, of course, plant site, and method of sampling may have a major influence on what results we get when we're evaluating the decontamination processes.

Other concerns are, is there a potential for spreading or redistribution of bacteria, if the process is not applied correctly or is the equipment is not operating correctly? Could there be penetration of bacteria in the tissue where we use high pressures? Could we allow formation of attachment of bacteria and potential formation of biofilms on the meat later? And the issue of do we get mostly removal in activation, and do we get any injury of microorganisms by these treatments as well as the potential for selecting resistant or adopted pathogens after application of such decontamination interventions?

And again, a couple of data slides to show

some variation between animal types and seasonal variation. Here again, we had commercial samples from different plants, and we see variation between steer and heifer carcasses or steer/heifer and cow/bull carcasses, Salmonella prevalence before decontamination as well as seasonal variation, and this slide also makes the point how these decontamination interventions reduce the prevalence of the pathogens after carcass washing and chilling.

Speaking about variation, these are data from the data published by Elder, et al., in 2000, and they evaluated beef animals for E.coli 0157:H7 contamination in the feces, the hide at pre-evisceration, post-evisceration, and after washing and decontamination of the carcasses, and as you can see with all these high numbers here, they have -- they found -- they proved the effectiveness of decontamination interventions in reducing prevalence of this pathogen, but what I find interesting is that there were situations of lots of animals where 77 percent of the samples of feces were positive and 11 percent of the hide samples, 56 percent of the carcasses were contaminated after hide removal, and eventually zero percent after decontamination.

What is more puzzling is that here, there were no fecal or hide positive samples but 75 percent

of the carcasses were contaminated, and there were situations where there was no contamination anywhere. So, you can find all kinds of combinations and all that variation, and we need to find out why it's there. Is it due to plant operations? Is it due to animal lot variation? Is it due to sampling limitations or could it be due to something else?

Other concerns associated with application of process to reduce contamination during slaughter are related to the safety of the application, such as the toxicological properties of what we use, the health of the workers, the safety of the product in terms of chemical residues or other changes, the quality of the products in terms of appearance, taste, shelf life and functionality, as well as environmental concerns, such as dealing with waste generated and damage to the equipment, and, of course, after carcass decontamination during slaughter, there's always the concern of recontamination and whether there is a need for additional decontamination later on.

During carcass chilling, we don't really know exactly what's going on there. There is a lot of research here. We could get contamination reduction by chilling or we could get microbial growth or we could get additional contamination. It all depends on

chilling rates and chilling uniformity and sanitary and hygienic practices applied.

Some contamination concerns during fabrication of the carcasses. We could get new or additional contamination. We could get spreading and redistribution of the existing contamination. We could get microbial growth, and all that depends on proper hygienic practices, low room temperature, and shortness of duration of this process.

As far as applying decontamination interventions at this stage, it's an area that should be investigated and a potential place for additional reduction of contamination, but we need to figure out technological issues and labeling issues because this product now goes into the package.

A couple of data slides from fabrication. In the commercial plant, in a three-hour period, we found that carcasses coming out of the chiller, as they were coming out, they pretty much stayed in the same level of contamination, but very quickly the belts of the fabrication tables reach high levels of contamination and that was transferred on the subprimals generated from those carcasses in a very short period of time, and they were high during the rest of the period.

If we applied decontamination after or during

fabrication before product packaging, we need to do more work on that because we have done some preliminary work and found that when we took pieces of beef and we inoculated with Listeria monocytogenes and then we exposed to water or hot water or lactic acid at 55, acetic acid at 55, and then vacuum packaged and stored at 10 degrees for 28 days, we see that we got the initial expected reduction of contamination by these treatments, but then we found that the control in the control product, Listeria grew very nicely and very fast, but it also grew in the water-treated products, especially in the hot water-treated products.

If we think about it, there are reasons for that to happen. So, someone could say it's better to treat with acids because we didn't find any growth during that period of time, but the question there is, could those survivors become stress adaptive and more difficult to control later on during preparation and consumption of the product? We need to find out about those issues.

So, what are some questions, concerns and issues here? The issue of potential spreading of contamination or cross-contamination, any contamination that may survive or remain in the product, what happens to it? We don't know how much of that ends up in

trimmings or ends up in rendering or if it is a problem or not.

We need to figure out if there's actually animal lot variation in terms of how much contamination is brought in the plant and why and do things pre-harvest, and also if there is variation due to plant operations, so they can be improved.

We don't know anything about how much of the carcass surface area is contaminated. We only have qualitative results from certain areas of the standardized. So, if someone wanted to really estimate exact levels of contamination and whether that part of the carcass goes in ground beef or not, we don't know that, and we only have prevalence data, as I said. We don't have any idea about actual populations and changes in populations during decontamination. We don't know how much of the contamination from the carcass is transferred to the meat. There are fabrication contamination concerns and potential need for intervention.

We should keep in mind that these decontamination treatments are instantaneous or of short intensity, and their intensity is inadequate for complete inactivation. The product is not sterile, and there is a potential that they may alter the metabolic

activity of surviving microorganisms, that they may change their microbial association in the plant and the meat and that may select adaptive and cross-protective microorganisms, and we don't know if that makes any difference in the virulence.

So, in summary, I want to acknowledge the importance of decontamination during slaughter because it reduces carcass contamination by one to three logs. It has a major effect in reducing pathogen prevalence and those things assist plants to meet the regulatory and industry criteria.

However, we should think about evaluating these decontamination processes for potential and predictable risks, and we need to optimize them for matching benefits with no risks. We need to consider that potential long-term effects on interactions of different interventions, most of them sublethal, on the microbial ecology of plants and raw and additive products, and then we can select and apply proper interventions of the right intensity and the correct sequence and the sequence may make a big difference, it does, we have evidence for that, in order to maximize the microbial effects and minimize the resistance development.

We need to evaluate further processing

concerns in terms of contamination and reduction of contamination. We need to research new technologies that apply beyond slaughter. We need to validate these technologies in commercial situations. We need to find out why we have variation in decontamination and to avoid that, and we need to remember that the product after slaughter is not ready to eat until it's further processed or cooked.

However, decontamination during slaughter is useful because it reduces the probability of illness when product is intentionally or unintentionally undercooked.

Thank you.

(Applause)

DR. DICKSON: Thank you, Dr. Sofos.

Our next speaker is Dr. John Luchansky. Dr. Luchansky is the Research Leader of the Food Safety Research, Microbial Food Safety Research Unit at the Eastern Regional Research Center, USDA, ARS.

Dr. Luchansky has a Ph.D. and Master's from Iowa State University and a Bachelor's from Penn State University.

John?

DR. LUCHANSKY: Thank you, Jim.

Good afternoon, everyone. I'm very pleased

as the other panelists to have this opportunity to talk to you, and I want to thank the organizers for allowing me to do so.

I'm going to take a little bit different approach. I knew John would do a real great job introducing various interventions on the animal side of things, and many of those same interventions and the efficacy applies to the product side. So, I thought I'd spend just a little bit more time talking about input, questions that one needs to ask as you develop interventions and how you go about collecting some of that data.

So, I'm going to share with you some studies that were done by ARS investigators that have recently been published and hopefully, Jim, there's some studies that have recently been published, some studies that were just completed, and --

DR. DICKSON: Dr. Luchansky just broke my computer.

DR. LUCHANSKY: I didn't even push a button.

(Pause to fix PowerPoint)

DR. LUCHANSKY: Thanks for the intervention, Jim. Well, sorry for the delay.

But what I thought I'd try to do is more or less talk about the type of questions one needs to ask

as you develop interventions and then share with you a little bit of the research that we've been doing to collect information that goes into that.

Studies that have just been published, studies that we are just about ready to present at some meetings this summer, and some on-going studies that I think you'll find of interest.

So, I put together this list. It's not meant to be exhaustive by any means and feel free to add to it during the discussion, but this would be useful input for developing interventions. What is the targeted pathogen or indicator, and Dr. Busta this morning or this afternoon made some nice comments about that. So, we've already had some good discussions there.

Where does it reside, and how long does it persist or predominate? We can be talking about on the animal at slaughter or for that matter, we can be talking within a package of hot dogs, and I'll come back to that in a minute, but is it on the hot dog? Is it in the purge? Is it within the pack? So, where does it reside is an important question.

How many types are present, and at what levels? So, are all strains that you find of, for example, Salmonella equally virulent, and if so, what

levels are they at, and what does that mean to the targeted population that might be ingesting that particular product? How well does your favorite pathogen or indicator respond to environmental cues? Things like acid, refrigeration, hot, salt, and what can you do knowing that to develop interventions? Where did it come from, and where might it end up?

All too often, this is overlooked. We mind find it in one source, but we really don't know how it got there. A perfect example are livestock. Are they indigenous to the livestock or did they come in the feed? Did birds drop it on the farm and the animals ate it? So, we really do need to have a lot of on-farm microbial ecology and in-plant microbial ecology.

I think perhaps the most important question, although this is also arguable, is, what levels and types of the targeted microbe are tolerable? We talk about zero tolerance for Listeria monocytogenes in cooked ready-to-eat food. So, for example, what levels are tolerable, and under what situations for the entire population or for those most at risk? And knowing that, we can then say, well, geez, how much of a reduction should our intervention deliver?

So, I just, you know, made an attempt to put this down for talking points, but it's those types of

questions that we've developed our research strategies around to answer as we develop interventions, and so just very briefly here, we kind of pick it up from where the animal leaves the farm and arrives at slaughter. We take it through slaughter, fabrication and processing, all the way to the finished product.

This is some of the work we've been doing. We feel predictive microbiology -- excuse me. Predictive microbiology plays a big role in our interventions, and I'll tell you why in a minute. We then feel there needs to be a known of the magnitude of the problem. So, you have to be able to detect your favorite pathogen, and we use standard cultural methods, but we also rely on antibody-based methods and on nucleic acid-based methods.

An area that I know you're going to hear a lot more of in the next two to five years is the area of genomics and proteomics. Very sophisticated but it's going to be very impactive, and this is really studying the microorganism right down to the nucleotide level in case of genomics and/or at the amino acid level in case of proteomics. So, I'll share a little information with you about that.

Then once you know a little bit about how the bug might behave, a little bit about where it has come

from and the genetic mechanisms it uses to survive in those environments, you can then select your interventions, be they physical, biological, chemical or mechanical, and again John Sofos did a nice job of highlighting those that are available.

What I thought I'd do is spend a little bit now in the predictive microbiology component. For those of you who are familiar with the pathogen modeling program, an effort started by Dr. Buchanan and Dick Whiting a few years back up at Eastern and one which we really picked up on lately and have taken it to the next level, I feel, we're at Version 6.0. This is a copy of our CD-ROM. I'd be more than happy to get you a copy of it, if you give me your cards. I'll also point you towards our website where it can be downloaded.

Dr. Mark Tamplen up at Eastern Regional Research Center is our lead scientist on this program. He'd be happy to help you out as well.

For those who are not really that familiar with the PMP, it's a group of models that estimate the behavior of pathogens in specific environments. You can set the temperature. You can select the pathogen. You can select the salt concentration, and you can see whether or not that bacterium is likely to grow, merely

survive or in some cases actually decline.

It's important to note that there is a user-friendly interface to access these models. Why did I bring it up for this particular audience? Because I wanted to give you an idea of how often it is used, to give you an idea of the impact that it can have. There's about 5,000 downloads per year, in addition to the several thousand CDs that we have distributed. It's used by about 30 percent of the food industry to design HACCP systems, a very useful tool in terms of deciding critical control points and how much effort needs to go in to verifying and validating that with the information in the predictive microprogram.

We're coming out with Version 6.1 in a couple of weeks. Growth, Survival and Inactivation Models will be included in that. For those of you who are interested, there are also dynamic cool-down models for Clostridium Perfringens that I think you'll find very useful. We also have added a reference database. We can go right from the PMP into the literature, if you'd like to get to the original data, and there are enhanced help functions.

Something you might not be aware of is another effort, a companion to the PMP that we started within the last, I guess, about 18 months. This is a

collaborative effort with colleagues over at the Institute for Food Research in Norwich in the U.K., and it's a program that we're calling Combase. This is a relational database of predictive micro information, and what I want to emphasize is whereas the PMP is very user-friendly and meant to be used by people out in the field, Combase is a very useful tool for academicians and risk assessors because it actually contains the raw data. You can get right in there and access the raw data for which models might not be available.

I think at present, there are over -- I think there's over about 15,000 records/growth curves in this database and we continue to expand upon that. So, I'd be more than happy to share some more information with that after the meeting.

Now, to help us better enhance both the PMP and Combase, up at Eastern, we've created the Center of Excellence in Microbial Modeling and Informatics, and if you can read this slide, it says that this brings together researchers with diverse and complementary talents to advance the science of predictive microbiology in essence. So, it's a collection of scientists that are looking to add more data to both PMP and Combase, to find out better ways to analyze these data and better ways to use that in very

practical ways to predict growth and enhance the safety and quality of foods.

I think this is about six months old, and we'd be more than happy to take on any new members or address any problems or concerns you would have.

So, that's a little bit about the predictive microbiology advances we've been making and how you can maybe use that for HACCP program or intervention development. It allows you to actually predict the growth, survival or decline of a microorganism based on statistical estimates that were done largely in microbiological medium and using that information, you can then narrow down your choices for what you actually might validate in a plant or in a product.

I'd like to move on then and talk a little bit about some studies that we've done for microbial detection. Three studies in particular which I think you'll find interesting. The ARS/National Alliance of Food Safety, Downer Dairy Cattle Survey, the NAHMS 2000 Swine Survey. I'll be picking up on comments Dave Dargatz made yesterday, and the Microbial Surveillance Project. All of these have to do with our efforts to go out there and look for E.coli 0157:H7.

Beginning with NARMS 2000 or NAHMS 2000, I should say, 17 states, a 160 farms, about 60 samples

from each of those farms. It represents 93 percent of the hogs and 92 percent of the producers who have at least a hundred hogs on that farm.

I'll share the results that we've had thus far. Our group was responsible up at Eastern for looking for E.coli 0157:H7, Shigitoxin-producing E.coli, Yersinia Enterocolitica and Listeria monocytogenes, and in addition to prevalence, I want to mention that we're also looking at clonality by ribotyping and pulse field electrophoresis, and we're sharing those isolates with our colleagues down in Athens who are doing antimicrobial susceptibility testing.

Again, this is a very, very collaborative study, one component of which was done at Eastern, the other component with the 0157:H7 was done at Athens, and Jeff Gray is in the audience from Athens who can also help me address any questions.

Relative to the data, there were about -- maybe I'll try this side now. There were about 2,500 samples that were tested, and I want to point out that about a hundred of those or four percent were 0157-positive, but none of those 2,500 samples were 0157:H7-positive, and the other thing I want to emphasize here, this is feces from the pen floor, not from an

individual animal. This is feces from the pen floor, and we were unable to find 0157:H7 without a prevalence or a recovery rate of four percent. We were able to recover 0157.

I want to show you the next slide which looks very, very similar to this, but there's one difference. We actually took fecal samples from intact colons from a swine slaughter facility. The difference again being now this is fecal material from the inside of the animal at slaughter.

Again, now, we have 305 samples, but again about four percent of them were positive for 0157, and this time, two percent were positive for 0157:H7. We found that quite interesting.

Some of the conclusions. Within the time frame and geographic scope of this study, the prevalence of 0157 isolates was similar in colon samples from slaughter and fecal samples obtained on farms and Serotype 0157:H7 isolates were recovered from the colon but not from the feces.

So, because I thought it might be useful in our discussion, I put up some talking points. What is the impact of collection, storage, shipment and/or methodology on recovery relative to finding 0157:H7 in the colon samples but not in the fecal samples? What

is the impact of transport and holding on the shedding and/or viability of this bacterium? Then lastly, should studies -- should further studies be initiated to determine the prevalence of the pathogen in matched animal and fecal samples from the farm all the way through to slaughter? So, those are some talking points that perhaps we can visit again in just a little bit.

I want to switch from pigs to cows and share with you a study we just recently completed on Downer versus healthy dairy cattle from the Upper Midwest. This study will in fact be presented in July in San Diego at the International Association of Food Protection Meeting, and it's a study that was funded by or through the National Alliance of Food Safety with collaborators at the University of Wisconsin and the University of Nebraska.

I guess just for definition purposes, we defined Downer cattle as non-ambulatory. In this sense, the culled dairy cattle or the Downer animals might contribute to about 17 percent of the meat supply and almost all of the meat from those animals goes into producing ground beef. So, you can see that they could have quite a significant impact in terms of contribution to the meat supply.

We looked at about 200 samples from healthy and about 200 samples from Downer animals at two slaughter facilities, four visits to a facility that exclusively handled healthy animals and seven visits to a plant almost exclusively dealing with Downer animals, from April through October of 2001.

Now to the results. About six percent of the Downer animals compared to two percent of the healthy animals harbored E.coli 0157:H7. We retained several isolates, multiple isolates from a positive sample from both Downer and healthy, and I'm not going to show the data because I don't have enough time, but what we were surprised to find was that more of the isolates from the healthy animals, almost twofold more, were resistant to antibiotics than those recovered from the Downer animals. So, again, some interesting points for discussion.

Conclusions within the time frame and geographic scope of this particular study. There was a threefold higher prevalence of 0157:H7 in Downer than in healthy, about 1.7-fold higher prevalence of antibiotic-resistant isolates in the healthy animals compared to the Downer animals, and via PFGE, we saw pretty much an eclectic group of isolates.

However, isolates recovered, multiple

isolates recovered from a given animal typically displayed the same profile type. So, we'll have a little bit more information on this in our presentations this summer and in the ensuing publications.

Talking points from this exclude Downer-suspect animals and those receiving antimicrobials from the meat supply and/or channel those animals into cooking operations, conduct additional sampling to address the impact of methodology, geography and seasonality on the prevalence, develop further interventions at a variety of points along the line and/or practice and police more prudent use of antimicrobials. Again, just for discussion purposes.

We're going to switch from the animal to the product and talk a little bit about hot dogs because we've done a lot of that kind of work up at Eastern lately. The ultimate handheld food. For those of you who really don't know how many hot dogs we as Americans eat, we eat a lot. 20 billion consumed annually and about seven billion between Memorial and Labor Day. So, we do ingest a lot of hot dogs.

What I want to share with you are three studies that we've been involved with over the past year, based on recovery methodologies, prevalence and

optimization of formulation, by beginning with a brief update on the ARS/FSIS frankfurter shelf life study. This was a very daunting and challenging project at the outset but one that has run very well because of our partners in FSIS. I know Karen had a lot to do with that and Walt Hill, Loren Lange, Jerry Ransom and our industry partners, largely coordinated through AMI, and I see Jim Hodges here and Randy Huffman, and many of you in the audience, including those from the NFPA, Dane Bernard, really brought this thing together in terms of design and implementation.

It's going to be a very impactive study and one that I think will have a lot of merit academically and for the industry. Very briefly, the study is designed to determine the prevalence levels and types of LM in commercially-prepared frankfurters. Each of 12 volunteer manufacturers are going to contribute 3,000 packages/pounds of product. Those will then go anonymously to Winmore, Pennsylvania, our facility. We will sample those within five days of their manufacture and at various time points over a two-to-three-month period during refrigerated storage.

As I said, the study is basically in the home stretch. We'll complete the prevalence component by July of '02 and be able to share the data with you

shortly thereafter. I think this will have a lot of utility for risk assessment and for designing interventions, and I look forward to sharing that with you at a future opportunity.

One of the outcomes of this was how do you go ahead and sample 36,000 pounds of hot dogs, and so we simply tried to sit down and figure out a very easy yet sensitive way to do that, compared to the standard FSIS product enrichment. The standard method would be to open a few packs and take a five-gram sample from about five franks, combine those five-gram samples into a 25-gram composite, enrich that, and look for the presence or the absence of the bacterium.

We thought, boy, that's good, but it would be a lot of work dealing with the volume we need to deal with. So, we said, why don't we just cut open the package, pour in a little diluent, since we expect it to be surface contamination anyhow. We would then shake the package, pour out the diluent, and actually sample that rather than the product.

It was a great idea. It has led to a very good publication that came out about a month ago and made our lives a heck of a lot easier, but was it effective? Here's the conclusion. The package rinse method was about sixfold more sensitive than the

approved FSIS product composite method, and we feel that is so because the package, the purge and the product all are tested.

Essentially, we're sampling the entire inside of that hot dog package. The package rinse method requires less hands-on manipulation and this is good because it minimizes the likelihood of contamination and decreases the time required for us to sample the product. So, I think this was a nice outcome of the ARS/FSIS shelf life study.

Just very briefly, I guess this is my one intervention slide. Another outcome of that was when we were trying to look at the effect of formulation on recovery, we were comparing the commercially-prepared franks that did have potassium lactate with those that did not, and here are the data. If you don't have any potassium lactate in the product, in about two to three months, you get about a four-to-five log increase in counts of the bacterium during storage in the refrigerator. You put in either two or three percent and counts of the bacterium do not increase.

I want to stress the fact that this is the addition of potassium lactate to the batter as an ingredient. This would be a very effective and, I think, reasonably-cost effective way, particularly for

small manufacturers, to deal with the problem of LM if indeed it found its way on to the product or into the package post-process.

Very briefly in the time that I have, I wanted to update you on one other project, one other large collaborative project that we've been involved with the past year. It's a collaborative effort between or among a variety of laboratories within the Agricultural Research Service and through a specific cooperative agreement with TIGR, the Institute of Genomics Research down in Rockville, Maryland.

Again, at the outset, a very daunting task but one in which that we've completed quite well. We simply wanted to know what makes Listeria monocytogenes tick at the molecular level. So, we decided to send the Jalisco cheese strain to TIGR and have them elucidate the entire base pair sequence of that bacterium.

We completed that task a couple of weeks ago on April 16th. We now know every base pair on the circular chromosome of the Serotype 4-B strain of Listeria monocytogenes responsible for the 1985 outbreak. It's about 2,874,000 base pairs. I'm not going to show a slide listing those base pairs. You'll have to take my word for it. We are now confirming

some single coverage areas, and we're assigning the genes to their proper location on that circular arrangement, and in fact, I'm pleased to say that we are now going on to do some comparative genomics.

We're going to look at three or four more strains of this bacterium at the DNA level to try to get some insight on what makes this thing better able to survive in people and their foods. We have a manuscript in preparation for the biotechnology buffs in the audience. You can also access the sequence on the TIGR website, tigr.org.

What are we going to do with this information now that we have it? Just a few suggestions here. We're going to study the regulation of phenotypes of interest. For example, how the bacterium is tolerant to salt, pH, increased water activity, refrigerated temperatures and modified atmospheres. We really want to look particularly at the comparative genomics to see what allows this bacterium to persist in foods and/or food processing plants and what allows it to survive in animal and human hosts, and for the purposes of this, once we get insight on that, we're going to be able to use that information to develop more effective management strategies, both biological, chemical and thermal interventions.

So, we really are now down to the nucleotype level of understanding a bacterium like LM. We're going on. The Western Group is doing campylobacter. We've got a little bit of work going on with E.coli 0157:H7, and I really think this will pay big dividends in the genomics and proteomics approach to food safety, and we're pleased to be a part of that.

So, I hope I've given you a little bit of an idea of some of the work we have on-going and how that can fit into the development of interventions. Although it's our intention to get rid of the bacterium, I think we have to look at it from the bacterium's perspective. The goal of every bacterium is to become bacteria, and we as scientists have to do our very best to outwit it.

Thank you very much.

(Applause)

DR. DICKSON: Thank you, John.

I'd like to introduce our final speaker for this afternoon in the formal presentation of the panel, Michael Ollinger.

Michael is an economist with USDA, ERS, Economic Research Service, and has been with them for the past 11 years. He's worked with food safety issues for the last five years. I think of particular

interest to this group is that Michael is working with the costs of HACCP and the use of food safety methods and technology, and he hopes to publish or at least have that information available on the website some time this summer, I believe, Michael.

MR. OLLINGER: This summer, I believe.

DR. DICKSON: Excellent. Thank you.

Michael?

MR. OLLINGER: Thanks a lot, Jim, and thanks to John and Martin, and I have a lot to talk about because they set me up for, you know, what I'm about to present.

I also want to thank Karen Hulebak for inviting me to the conference. I feel honored to be here, and thanks to all of you for sticking around. I know it's about 2:30, and a lot of people left and you were going to listen to one more. So, thanks for staying, and there's really one other guy I want to thank, and he's not here and his name is Lalow. Lalow was a friend of mine when I was a Peace Corps volunteer in the Philippines, and Lalow used to come over to my house every day and he'd drink coffee, and he was addicted to coffee.

So, I knew he'd come every morning, and I had a sick chicken one day, and I said to Lalow, "Lalow,

that chicken looks sick. I think I better kill it and throw it down the outhouse hole." And Lalow said, "No, no, don't do that. I'll take it. I'll get rid of it for you. I'll save you the trouble." So, the next day, Lalow didn't come back at the normal time. He was a little late, and it happened to be market day that day, and I saw him coming back from the market. He had a big smile on his face, and I said to Lalow, "Lalow, what did you do with that chicken?" He said, "I got rid of it for you." And I said, "Lalow, what did you do?" He said, "I sold it." I said, "You were supposed to throw it away, Lalow." Then he says, "Well, I got 12 pesos for it."

And the market rate for chickens at that point was about 18 or 19 pesos. So, what the market did, it discounted that chicken because it looked sick, and it discounted it by about seven pesos. So, the market worked, but the problem is the market didn't work well enough because that chicken shouldn't have been sold. It was sick. So, that was my introduction to economics and the food safety of economics.

As far as firms go, they're going to invest in food safety technologies up to the point where it's profitable. As soon as it becomes unprofitable, they're not going to invest. So, if quality sends a

clear signal to the consumer or to the ultimate buyer, then the market is going to work, but if there's no clear signal of quality, then there's going to be some kind of a market failure and perhaps a need for government intervention.

So, what does private industry do or what do they use? What kind of tools does private industry use, and what kind of tools do government regulators use to determine what a profitable investment is or what a good investment is? And what the private market or what a firm will use is a net present value calculation, and what the government's going to use is something very similar, a cost-benefit analysis.

And the purpose of each type is the same really. They're both going to serve as gatekeepers to keep out unwanted projects and they're also going to allow you to select from a collection of alternative investments or alternative approaches.

And the calculations are also very similar. A lot goes into each, but basically the amount you invest has to be less than the amount of return you're going to get and that return is going to be the non-food safety profit. There may be some kind of a labor reduction or a material savings or something like that out of an investment, and then there's also maybe some

kind of a market value of food safety, and what about in cost-benefit analysis?

Well, then there's a government intervention and that's the G. There's some kind of investment and some kind of maybe an industry investment motivated by government, and on the other side, there's going to be certain public health benefits that are going to be -- that are going to include society as a whole. Those are the calculations that each party makes, and you can see that they're quite similar.

Okay. I broke market mechanisms. What I'm going to do is I'm going to outline some market mechanisms, some market approaches that work, that are going to generate profits to firms, and then I'm going to really go over some of the things that people have discussed here for the last two days on why these may not always work. Then we'll talk about three ways that FSIS has regulated, and then we'll summarize then.

Okay. So, the first market mechanism or market approach to controlling food safety is some sort of an unintended consequence investment. Maybe a chicken poultry plant'll invest into some kind of a poultry transfer mechanism. It reduces the amount of labor on the production lines. So, they have a savings in labor. That may be why they make the investment,

but they also get a savings in, say, bacterial contamination because there's less employee handling of the chickens or the turkeys. So, that's sort of an unintended consequence of a normal investment decision.

Now, there's another way in which a seller can recover all of the or a lot of the profit from a food safety intervention and that is something like irradiation where you can communicate directly to the consumer that the product is free of some harmful pathogens or at least there's a pretty strong evidence or support for your claim.

So, there's a market premium on that. I think a newspaper in Minneapolis quotes a price of about 10 to 15 cents a pound on beef, irradiated beef. So, there's a market premium that goes to various players in the market, and it's profitable to provide food safety.

Now, the final way that the private markets are going to work is through contractual mechanisms, and one type of sort of -- well, it's a quasi-contractual relationship in which there may be a single supplier of, say, beef products to a major retailer, and suppose that products from that retailer happen to be implicated in a food safety outbreak or a food safety problem. The consumers go back to the retailer,

the retailer goes back to the meat provider. They know who the meat provider is. It's only one source. So, they know who caused the problem.

So, here you can have a linkage in liability and because of that linkage, this single source supplier is probably going to make a greater investment in food safety-type technologies. They may use the multiple intervention approach that John Sofos was talking about, okay, or some other proven way to provide food safety.

Another way is through branded product. If a consumer gets sick, and they see somebody's name on the package, they know who to blame, and so these producers of branded products have a lot to lose by providing an unsafe product. So, they're going to make maybe a little bit more investment in food safety to ensure they don't lose their market.

And then, a final way is through explicit buyer contracts. McDonald's makes contracts with its suppliers to provide greater quality, and it does, I think, with all of its food providers, and on top of that, McDonald's is going to ensure that it heats its hamburgers up to, I think, a 160 degrees through an automated cooking process. So, McDonald's is going to ensure that nobody's going to get sick on their account

in their restaurants because as soon as an outbreak occurs, their brand name is lost and their sales drop considerably. This is not just true for McDonald's, by the way. All the major fast food restaurants and the major restaurant chains are -- have these type of contracts.

I'll just show you how -- an example of one or the way one might look. Say, suppose with no contract, a supplier contracts to sell product to McDonald's for a dollar a pound, and say it costs them 80 cents a pound to produce that pound. Okay. They can make about 20-cent margin on that and say they sell 10 million pounds a year to McDonald's. They're going to make a profit of about two million pounds. Okay. Now, McDonald's comes back to the supplier and says, well, if you increase your -- if you do this, this and this and this for me, that's going to add some costs maybe to your production process, but we're also going to increase how much volume we're going to buy from you, and we're going to guarantee you that market.

So, now they're going to sell 12 million pounds and they're still going to make a profit. These are all cooked numbers. So, it's all going to work out, but the point is that it's profitable to do this. Otherwise, they're not going to enter into a contract.

Okay. So, those are some ways that private markets are going to accommodate food safety concerns.

There are some problems, though, and those are the problems that were outlined earlier today. Well, first of all, in the case of a retailer, there can be and there often is more than one provider of meat products to that retailer. So, then you don't know who produced the product that made a person sick. Okay. The source of the foodborne illness may not be identified, and a consumer illness may not be even recognized as a foodborne illness.

So, there's lots of problems and probably you guys can think of a bunch of other ones. Okay. So, that's why there's a call or at least a reason for FSIS intervention, and I'm going to outline three ways in which, you know, they've sort of intervened. Okay. First of all, they're going -- one approach they've used is shift responsibility for quality to industry, and they do this by -- well, their incentive or their interest is to increase food safety investment, private investment.

Back in the '80s, they tried a voluntary approach which had at least on paper some similarities to a HACCP plan and that was called a total quality control plan or whatever and those were completely

voluntary and there was about five percent adoption on that. There were a few benefits given to producers for adopting this quality control program, but it really wasn't that popular. So, then in the 1990s, they came up with HACCP. That was mandatory, and it did require a lot of investment.

Okay. Now, another way that FSIS has tried to increase food safety investment is better investment of its own resources, meaning its allocated budget, and if it can shift some of its responsibilities to private industry, then it has more of a budget that it can devote to public health concerns.

Okay. So, back in the '80s, they introduced the new line speed inspection system which allowed poultry producers to increase the line speeds as they took over some of the more mundane tasks that their inspectors used. So, what would happen in a situation like this is that some plants may be producing at the FSIS-mandated level of, say, 70 birds a minute and you'll have some producers that may just be able to produce 70 birds per minute, others that may be able to produce a 120 birds per minute.

So, what I did here is I thought of an example and again these cooked numbers, but say that you have a plant with a capacity of, say, 70 birds per

minute, and you have 10 workers on that line. The productivity of that plant or that line is going to be about seven birds per worker per minute. Okay. If they can't increase their speed and FSIS comes back and tells them that, okay, you can increase your speed -- okay. If you can increase your line speeds if you add two workers to remove some of the birds off our inspectors, well, their productivity dropped, but if it happens to be that a plant can increase its line speed to what FSIS is now going to permit, then they're going to use their own workers.

So, they're going to voluntarily inspect some of their own products, and they're going to do it because it's profitable to do it. Productivity is increased. So, they're going to make that shift but not everybody's going to make the shift. They're going to have some that just aren't going to find it profitable to do it. So, any kind of a voluntary program, you're going to have some plants adopting the technology or making the switch and some not, and it could be based on their own technical reasons, like the plant size or the line speed. It might be based on a market relationship they have with providers. So, those are going to be the two key things that are going to encourage a plant to make a switch voluntarily.

Okay. Now, another way FSIS has tried to encourage investment is by -- you know, I think it was in '97 or '98 or so, they started taking, I think, a bigger sample size for their E.coli 0157:H7 tests, their Listeria monocytogenes tests. So, what they did is they sort of increased the sensitivity of that test, at least that's my understanding from talking to the few people, and so when they do that, the number of recalls should go up if that's what happens, if I used that term correctly.

But what they also do or what inherently happens when you test for a certain type of pathogen, like E.coli 0157:H7, which was mainly, what, prevalent in beef is you favor certain industries over other ones. So, that's going to favor poultry and hog producers over beef producers because those are the ones that are least affected. Poultry and hogs are less affected than beef producers.

In the same sense, Listeria monocytogenes is going to favor slaughter plants over processing plants because that's where it's going to be more commonly found, is the processes. So, that's a second way, and the final way is just a new regulation, and it seems like we've heard a lot about performance standards, and I just really want to present an example. I don't want

to, you know, enter into the argument on performance standards, but the reason that economists like them is that it grants a lot of flexibility.

Suppose that we have four plants that are affected by a regulation with a target pathogen. Two meet the standard. They don't do anything. Plants A and B, they have to change, and one plant, Plant A, maybe produces 500,000 carcasses or animals a year, Plant B produces about 5,000. There's two ways to reach their goals. One is through steam pasteurization and I outlined some of the costs there. It's going to be a lot more expensive for a small plant to use this steam pasteurizer.

Option 2 is better dehiding methods. Maybe you have to invest in training, and I just made up some numbers to make it work out right, but there's greater worker turnover at the larger plants, so they lose their investment every time the dehider leaves. So, their dehiding costs are actually going to be higher than for the small plants.

I made it work out so that the net result was about 40 cents a head for Plants A and B, but one chooses a steam pasteurizer and the other one chooses the dehiding approach. So, the technologies can work. It may be that different size plants just choose

different types of technologies to reach a certain point.

So, let me go through an example of a process standard. It's just a mandated technology and an example of one using a time process standard is outlined below. A lot of it gets cut off there. Okay. So, suppose that plants are expected to clean hand tools once per hour. Okay. Plants A and B process a 105 animals -- one produces a hundred animals, the other produces five animals per hour. So, you can see that at least for the mandated process standard, the number of cleanings per -- the number of animals per cleaning is a lot greater in one plant, meaning that the cost is going to be a lot lower for that plant. In this case, it's the higher volume plant.

That was the kind of approach that FSIS took in the preliminary HACCP study. They used some process standards along that line, I think, for generic E.coli testing. Now, how does it change if you use per unit of volume standards? Well, if you use a per unit of volume standard, and you say one cleaning every five animals, then productivity or at least the costs are the same, whether you have a small plant or a large plant. So, the volume standards are going to have less distortion than the time standards.

The problem with process standards is you don't know whether you're getting the results that you really want. So, we'd prefer a performance standard if we can have one and that you guys' job.

Okay. So, I just want to summarize some things and leave a little bit of food for thought. Okay. Four ways in which markets work were mentioned earlier. One is through irradiation. Another one is contracting directly for improved food safety quality. Three is food brand names, and four is inadvertent contract. That's where you have a single source supplier.

Okay. And the incentives offered by FSIS is (1) to try to shift responsibility for quality to industry. Second is to raise food safety costs by increasing regulatory stringency, and third is impose new regulations, either performance standards or process standards. They've used both.

Now, just an assessment. Markets need our information to function properly. FSIS has -- most of its regulations have been cost impositions or, you know, maybe changes in regulations to encourage adoption of the technology. Yet FSIS does have a lot of information. It has information on performance of HACCP. It has information on Salmonella standards. It

has information on generic E.coli tests, and one possibility is to somehow permit a label or somehow to rate plants on their performance and let the market decide which one of those plants is a good plant. Anyhow, I want to leave that thought with you and maybe we can talk about it a little later.

Thanks for listening to me.

(Applause)

DR. DICKSON: Thank you, Michael.

We're scheduled for a break, and Dr. Hulebak has asked us to all be back by 3:00. I currently have 2:45. So, if we can take about a 15-minute break, and on break, why don't you think about some discussion issues and questions to bring up for us?

Thank you.

(Whereupon, a recess was taken.)

Panel 4 - Discussion

DR. DICKSON: Here it comes. First question. I would invite anyone who would like to ask questions to come up to the microphone and again identify yourself and your organization.

MS. ROBERTS: Tanya Roberts from the Economic Research Service in USDA.

Actually this was for Martin Firth. I wanted to hear a little bit more about two things that seemed

kind of unusual and different from the U.S. and Canada. One was that the requirement that you had to include academics in your HACCP plan, if you're a company, if I understood you correctly, on farm. You don't have it?

MR. FIRTH: What I was referring to -- is this on? What I was referring to is the process that we're going down the road with on farm is that the hazard analysis, etc., is done through a technical committee.

MS. ROBERTS: Hm-hmm.

MR. FIRTH: So, on that technical committee, which represents a National Association, on that technical committee, we're asking for a number of specialists through academia, through in terms of livestock, veterinary specialists, etc., that comprises or make up this technical committee. So, it's for the development of this program.

MS. ROBERTS: Okay. So, this is to identify the HACCP across the whole industry?

MR. FIRTH: For that commodity.

MS. ROBERTS: Is that what you're saying? For that commodity.

MR. FIRTH: Yes.

MS. ROBERTS: Okay. And so, then each company then would say okay, you've already done the

hazard identification part for me, and --

MR. FIRTH: Each producer would -- what happens is this hazard analysis takes place. They come up with this generic hazard model.

MS. ROBERTS: Hm-hmm.

MR. FIRTH: From that analysis, etc., they develop what we call producer manuals. So, the control measures and the CCPs that were identified through the hazard analysis get translated into these producer manuals which are then implemented by individual producers.

MS. ROBERTS: Okay. And who pays for the consulting of the academics? The industry or --

MR. FIRTH: The association, yes.

MS. ROBERTS: -- the association? Well, the other thing that seemed different, the second thing, was about the third party audit, and was this each individual on-farm thing that the HACCP plan is working as planned or is this at the association level? Maybe I misunderstood that.

MR. FIRTH: No. There's two different levels.

MS. ROBERTS: Hm-hmm.

MR. FIRTH: For the delivery of that national program, they are -- the association is required to

contract an independent third party to come in and carry the full systems audit of that program as it's delivered.

The second level of auditing is at the farm level.

MS. ROBERTS: Oh, okay.

MR. FIRTH: Now, that on-farm level of auditing takes place like inside the structure of that program. So, you have described in the program that there will be a person come on to the farm on a stated frequency. They'll evaluate the producer against given criteria in an audit manner. So, you have two different levels of audit there.

MS. ROBERTS: Hm-hmm. And what happens to people if they don't make the audit?

MR. FIRTH: They get to take the sign off their mailbox in the laneway. They're off the program. That's basically it. Now, there's some significance to that, too, though. We're seeing -- the perfect example is in the pork sector, where we have a large number of -- well, a couple of large in Canada is a couple.

A couple of large processors that are now requiring farmers to be on the national program in order to sell their product to the processors.

MS. ROBERTS: And that's what you hope for, right?

MR. FIRTH: Exactly. I guess for the economists, the marketplace is taking care of itself.

DR. DICKSON: Thank you.

For those of you who do have questions that you'd like to write down, we do have cards over here.

Rosemary?

MS. MUCKLOW: I can't write, so I have to use the microphone.

I would like to say thank you to Dr. Ollinger for his exquisite example of discounted diseased chickens and to explain to him very clearly that that's why the industry is very strongly supportive of ante- and post-mortem inspection. Something that has been decried by politicians but is one of the fundamental assurances of the Federal Meat Inspection Act and is probably as important today as it was restated in the 1967 law and is extremely important. So, thank you for the story. It had a wonderful moral to it.

A couple of other minor things, if I may, while I'm here. Dr. Sofos did a great job on all of the various interventions, and once again lactoferin was mentioned, and somebody mentioned that yesterday. I'd just like to tell you all that lactoferin was first

identified in February 1998 at our convention in San Francisco, and it's now four years and three months later, and it's still in the trial stages and not actually implemented.

It takes a long, long time, even by those who work very hard to move interventions forward, and we had this discussion yesterday about the other interventions that came along and overcoming very longstanding inhibitions about anything other than a knife to remove contamination. There are some really great opportunities, and if we could only find some way to speed up the process, it would really be wonderful.

The final thing, Dr. Ollinger talked about TQC programs and how they didn't achieve a great deal. I don't know if he is aware how many PQC programs, partial quality control programs, there really were practicing in the industry, and they had an enormous impact, probably much, much greater than the originally-intended TQC programs and were very effective, and they've kind of fallen by the way now, but they were a major, major preemptive effort towards where we are today. So, it wasn't all lost. It wasn't just five percent on the TQC. Lots and lots of PQC programs that were enormously beneficial.

Thank you.

DR. DICKSON: Thank you, Rosemary.

Dr. Wagstrom?

DR. WAGSTROM: I'm Liz Wagstrom with the National Pork Board.

I just wanted to kind of give an update on what we're doing with pork quality assurance after the questions about the Canadian Assurance Program. Canadian Quality Assurance is doing a wonderful job, and in the United States, we do have a voluntary pork quality assurance plan. However, we do have a committee that has planned that pork quality assurance plan that has academics, veterinarians, producers, processors and several experts. It's about, I believe, over 20 members on that committee.

The program that has come out of that committee is a program that is a HACCP-based program. We just have a new book that was published. The second edition was published this Spring, and it takes the producer through all the HACCP principles and how to identify critical control points on their farm, and while it's a voluntary program, virtually all of the federally-inspected plants in the United States as part of their HACCP program require that their producers are certified in pork quality assurance.

So, even though we don't have as much

government input into the program and we don't have a government overseeing the program, we do definitely have a program that I'm not sure we could actually call voluntary anymore if you want to sell your animals to an inspected plant.

Then the other statement I was going to make is this, I wanted to let you know that we also have a trichinae intervention program. We're not sure it's really required because our last NAHMS sample, we had one weekly positive sample out of all of the market hogs that were sampled under NAHMS which was about 1,600, but again that is an auditable program with third party verification. So, there are some auditable-verified programs that are happening at the farm level in the United States.

DR. DICKSON: Thank you.

MR. ROACH: Hello. I'm Steve Roach with FACT.

Again, my question is going back again to on-farm intervention programs, but also I want to kind of link it to some what happens at slaughter as well.

So, my question is just what is the role of microbial testing in on-farm control programs? Because control programs that I'm aware of that are most effective, probably the one in the U.S. would be the

PCAP Program, really is strongly based on having on-farm microbial testing, and the other one, I know, I am aware of that seems to have worked is the Danish Salmonella and some of the other European control programs.

So, what is the role of on-farm microbial testing in terms of controlling pathogens on farm level, and then the second level question is, is there any way you can link microbial testing at slaughter with farms? So, when doing microbial testing at slaughter, it seems to me that it would be a good idea to know which farm and kind of linking it back to what happened on farm and what lot it came from. So, I just had some questions about does that seem to work with what you all understand about on-farm interventions and also kind of understanding what's happening at slaughter and afterwards?

MR. FIRTH: It's basically -- to answer that question, you almost have to go commodity-by-commodity, but I guess where all the sampling right now that's taking place is in the chalet or the layer barns, and they're starting to introduce the idea of environmental sampling in some of the other poultry sectors.

As a control measure, it's more of an indicator. What these programs are -- for control

measures, what they're looking at is enhanced biosecurity, proper cleaning of the barns, farm sanitation between flocks or between, you know, as they move the animals out. So, they aren't looking at, you know, testing as a control measure per se. It's more of an infrequent indicator of how effective their other measures are happening.

In terms of linkages between, you know, prevalence at the farm and at the processors, that's wonderful research. Those things have been identified. It's just a matter of getting -- that's -- it sounds great, but when you sit down and work out the mechanics of the sampling regime to effectively look at that, it's pretty difficult. So, it's going to -- you know, there will be some work towards that, but it's going to -- it won't be happening tomorrow.

DR. DICKSON: I will also ask John and John to make any comments, since both of you have some research that might possibly relate to that question.

DR. SOFOS: Microbial testing can be very useful in identifying sources of contamination, developing interventions, validating the interventions, to reduce contamination, but microbial testing is as good as sampling, and with pathogens that are not present at very high levels, and even if they are

present at very high levels, why test? We know they are there.

Those that are present at very low levels, we need extensive sampling to find them. So, I don't recommend it as a control procedure. I would spend that money instead of testing in interventions that would reduce contamination.

DR. DICKSON: John, I guess I was thinking more about your Downer cow study. If you guys had any thoughts about linking slaughter house data with production sites, animal production sites.

DR. LUCHANSKY: Couple of points. Yeah. I think that that's useful and something that can begin to be introduced into the experimental design of any kind of survey that anybody might want to do. The real challenge is to have some groups serve as a repository for that information, so the database can continually be added to, maintained and that way, everybody can make use of it.

So, specifically to the Downer cattle, we'd like to go back and initiate those types of studies, both for antimicrobial susceptibility and DNA fingerprinting profiles. I think John and Martin already did a nice job of addressing the utility of on-farm testing, and I was talking to somebody over the

break and mentioned a slide that I often use, too, from Phil Olsen and that's why should you test, and it was pathogens are a lot like babies. Until you know where they come from, they just keep coming.

DR. DICKSON: I'll have to remember that one, John. Thank you.

Yes, ma'am? Question?

MS. DONLEY: Nancy Donley from STOP.

Just actually a couple observations, and I do have a final question. But I found it very interesting, the five percent compliance number that was mentioned as far as for voluntary types of programs, and I think it points out the very real necessity to have very strong governmental regulatory programs in place when we're talking about something as basic as food safety, that we cannot rely just on voluntary actions on the part of plants. Some plants are excellent in being very progressive, but we should expect the same level of protection in our food from all plants, not just the good players because we frankly don't know. We can't identify necessarily where our food does come from.

And with the motorcycle helmet that was mentioned earlier today, the fact that, you know, do you wear a motorcycle helmet or not? Is it something

that's mandated or not? Riding a motorcycle is totally -- is a discretionary act. You don't have to ride a motorcycle, period. We all do have to eat.

Also, another cost-benefit analysis, Dr. Tauxe yesterday mentioned that -- I don't have the exact figure, but it's upwards in the neighborhood of $7 billion expense per year in the cost of foodborne illness, treating it, lost productivity. I think that we could -- $7 billion a year goes a long way into strengthening food safety programs, that plants -- if we had $7 billion to spend every single year on food safety, I think we would probably not have a problem any longer.

And then last is that this conference was titled, you know, "Pathogen Reduction", and my question is, we've been talking about the successes that we've had to date and they're wonderful. I think some of the successes that industry and FSIS and consumers can be very happy about is the -- some of these new numbers that have come down as far as Salmonella prevalence.

My question is, what's next? This is -- it's pathogen reduction. We've shown that it can be done. We have reduced levels of pathogens. So, what's our next step? I don't think we should stop here. I think, I'd like to hear, and I'm hoping that maybe Dr.

Pierson will be mentioning this in his comments, where do we go from here? What do we do next? How do we make it even better?

DR. DICKSON: Thank you. And I think I speak for all of our panelists in saying we hope that this is a beginning and not an ending of pathogen reduction.

Any comments from the panel?

(No response)

DR. DICKSON: Thank you.

I do have a number of questions that have been submitted in writing. Some of these are fairly straightforward. So, I hope anyway. I'll take a couple at random.

For Martin. Does the Canadian Food Inspection Agency require HACCP plans for farm-raised game, such as elk and deer?

MR. FIRTH: I actually discussed this with the individual and he had to leave. So, I'll fill the rest of you in on our discussion.

The first point is we're not requiring HACCP to any farm. There's no regulatory requirement in this program. But to answer the wild game, there are a number of smaller national associations that are coming to the table, such as, as I mentioned, the Cervic Council, the National Wild Boar Association. So,

there's a number of these smaller groups that are actually taking interest in them.

But once again, this is -- it's an industry-led program. So, it'll be voluntary in terms of the uptake, but again the marketplace will certainly assist, I'm sure, in the long run.

DR. DICKSON: Thank you.

For Michael Ollinger. Mike, it's your panel. So, I'm not letting the panel off the hook here.

If one way to make markets function properly would be to publish performance ratings, why hasn't the USDA used its own data in selecting suppliers from whom to purchase for its school lunch and commodities programs?

MR. OLLINGER: That's a good question, and I'm probably not the person to ask because I have no control over the school commodities purchasing program. So, I can't answer that question.

DR. DICKSON: Is there someone here from Ag Marketing Service? I suppose I should have asked that first before I read the question. But I think the point's well taken. I personally don't have an answer to that.

If anybody does have any knowledge, I would invite you to take advantage of one of the microphones

here in the room. I personally don't have any knowledge of it, but I think the point is well taken. That is, if the driving force is in fact performance, then, you know, what is the rationale, if you will, for selecting suppliers for school lunch programs?

MS. MUCKLOW: AMS has very prescriptive specifications on which they buy product. Those are published in their specifications and are slightly different from FSIS specifications, and in order to know that, all you've got to do is go to their website and see them.

DR. DICKSON: Thank you, Rosemary.

Okay. John Luchansky. Here we go. USDA says a product is "fully cooked" at a 148 degrees Fahrenheit. At this temperature, can we be assured that Listeria monocytogenes will be destroyed? If not, is there a temperature to destroy Listeria without destroying the product? Sounds like a prelim question, but John?

DR. LUCHANSKY: I think I'll answer the way Bob Buchanan answered one this morning and say it depends. It does sound -- it sounds like you'd need a little bit more information about strain-to-strain variation. I don't think all strains would be similarly in -- under those conditions. You'd need a

little bit of information about the uniformity of the cook and the starting levels of the bacterium.

So, I guess without additional information, I only would know if they were totally eliminated or there could be spurious survivors.

DR. DICKSON: Okay. Thank you. Any other comments from the panel?

DR. SOFOS: Also, the product, what type of product we're talking about. Is it on the surface or is it throughout the product?

DR. DICKSON: Thank you.

I have a question here for Martin. A two-part question. What are the risk factors for E.coli 0157:H7 on farms in Canada, and the second part of the question, what kind of regulations or standards does Canada have to control E.coli 0157:H7?

MR. FIRTH: That's a really good question. That's why we have scientific and academia on these technical committees. I am not the person to answer that kind of question. Sorry.

DR. DICKSON: John Sofos. Oh, Lord. I hate getting old. Most studies in intervention methods are done in the lab using -- oh, I'm sorry. An exterior square area of the carcass.

Can you give some guide to processors as to

how they can adapt these methods to whole or half carcasses so it will have the same reduction efficiency?

DR. SOFOS: Obviously, they are done in the lab because that's where we can use pathogens to inoculate the product. In the plant, you have to use an indicator type of contamination or a surrogate type of microorganism, and you have to rely on that, I guess, in terms of validating the process, and then the product can also be tested for pathogens over time to see if there is a problem there, but you cannot rely on testing, for example, for E.coli 0157:H7. First of all, you cannot introduce it in the product, and second, you're not going to find it enough to see an effect of the process.

You have to use indicators to validate the intervention and then pathogen testing the finished product over the period of time to see if you have high levels.

DR. DICKSON: Thank you.

John Luchansky. Your group does some process validation as well. Do you have any comments you'd like to add on that?

DR. LUCHANSKY: I would just concur with John. I mean, I think having better control over it in

a laboratory situation, working out things of the experimental design in terms of physiological state, levels, concentration and even more the sort of the engineering aspects, you know, of heat transfer or so forth before you go out and pilot scale up.

DR. DICKSON: All right. Thank you.

I have one more question here, and again I'm at the end of my cards, so that if you do have further questions, please take advantage of the microphone.

Last question for Mike Ollinger. USDA refers to farm-to-table. However, controls seem to stop at processing establishments. Are there any steps the USDA plans to take to assure food safety from the time products leave USDA plants until those products reach the table?

MR. OLLINGER: That's a good question, also. I don't believe that FSIS has jurisdiction over what goes on after the processing plant. So, you know, I wouldn't be aware of any plans, and if somebody out there knows, perhaps they can step to the mike on the floor there and respond to this question. But I don't know.

DR. DICKSON: I believe that's correct. I believe FSIS' jurisdiction ends at the processing plant, and if there's anyone here from FSIS that would

like to address that question in more detail, I think I saw Dan Engeljohn here a little earlier. There he is.

DR. ENGELJOHN: This is Dan Engeljohn with USDA. I would say it's true, we don't have jurisdiction in the individual's home. The way the Federal Meat Inspection Act laws work is that product as labeled still cannot be adulterated throughout its life.

So, if in fact we were to find 0157 in product at any point in time for which that product was labeled, then that puts us into a situation where we can make some determinations about adulteration, but with regard to intentions for where we're going in the future, I would say that the agency, along with FDA, has had considerable concern about the transportation of products once it leaves the federal establishments and goes into distribution channels, particularly to retail, and that we had advanced notice of proposed rulemaking back in 1994-95 for which we sought input as to what the agencies could and should be doing to control the environmental handling of product once it leaves the federal-inspected facilities as well as the handling from the temperature standpoint because we know that organisms grow in conditions where the temperatures are elevated.

I would say that's still high on the agenda for both agencies to be looking at. FSIS isn't particularly interested in transportation. It's not something that we're going to be working on in the near term, but I think as the science develops with regard to handling and transportation and predictive microbiology, that we will in fact be looking at performance standards that may be put in place to control the growth of organisms once they leave the federal establishments, but that would be a long-term effort.

DR. DICKSON: Thank you.

I believe we have some questions back here. Yes, sir?

MR. CORRIGAN: I'm Philip Corrigan. I'm from the Embassy of Australia, and I represent the Australian Federal Department of Agriculture, and I also represent Australia, which is a major livestock-producing and processing and exporting country.

Last year, Australia exported meat to a 132 different individual countries, and it's the second-largest exporter of meat after Canada into the United States.

I just want to take this opportunity to compliment and congratulate FSIS and USDA and the U.S.

industry for putting on a symposium such as this. I want to commend you on your transparency in this country. This debate is going on in Australia as well, and it's well down the track, and we're following very closely the debate here, but really you are to be complimented on your transparency and openness that allows representatives, I'm not the only one here from the diplomatic community here in Washington, that can come and participate and listen and report back, and we will be watching the further evolution of this issue very closely, and we wish you very well.

Can I commend and congratulate the quality of the presentations throughout the whole symposium and now I get specific, particularly this panel? I thought the information provided this afternoon has been excellent really.

I'd just say over the whole symposium, we've had a lot of researchers and a lot of economists here. Just a personal observation of mine is that researchers and economists provide you with tremendously good accurate information, but then they all come to the depend factor. You're always told, well, then the next stage depends on what, and also the final conclusion is always more research is required. That seems to be a lot of reports.

Could I ask a specific question maybe of Professor Sofos? You gave detailed intervention strategies. I presume it was a beef slaughtering plant. I wasn't a hundred percent clear on that, but -- and then, in the end, you outlined a lot of research that needs to be done in the future and a lot of sort of limitations on the knowledge of distribution of microbes, etc.

But the real world is comprised of risk managers really and risk managers, both in industry or in the government, have to make management decisions today and whether their management decisions are on a plant or regulatory decisions, and my question to you is, could you outline -- could you give us your advice what to risk managers today for, say, an average beef plant with your average livestock coming in for intervention strategies and for government verification and validation of a system in place to ensure that safe food is being produced in that system?

DR. SOFOS: My presentation was centered mostly towards beef, and based on what we know today, I think we're doing the right things in applying these interventions in the sequence. In some places, you can have more in the sequence than in others. I know in Australia, the washing of the animals overnight before

slaughter is very common and that helps. In other places, they use chemical dehairing and so on.

As far as helping with risk assessments, we do really need the research that I indicated should be done. For example, it's not easy to estimate how many cells of the pathogen will be in how many ground beef patties when we only know that we have one percent of the carcasses contaminated. So, that kind of information is really missing, and we are not going to have the best ways of assessing risk without that information.

DR. DICKSON: Other comments? Yes, sir?

MR. SHIRE: I'm Bernie Shire with the American Association of Meat Processors, and I have a question, I don't know if one of you can answer it or maybe somebody else here, concerning the agency's testing for -- that it carries out for E.coli 0157:H7 in ground beef.

Earlier this year, a plant underwent that test and the E.coli sample turned up positive, and anyway, the situation ended up in a recall, and after that situation happened, about a period of 30 days went by, and in this 30-day period, the plant went back to processing and processing thousands of pounds of ground beef as it turned out.

As you know, under that procedure, the plant has to undergo a 15-day period, 15 times in a row, where it's tested for E.coli 0157:H7. There was a one-month period that went by where the plant was allowed to go back to its normal ground beef processing and then it started its 15-day testing in a row procedure.

Could you or somebody from the agency explain the logic and the thinking behind the way this process is carried out?

DR. DICKSON: Well, if you're specifically asking me to explain it, no, sir, I can't. However, I'm hoping that someone from the agency would take the opportunity to address this issue. Thank you, Dan. You're going to quit coming to these meetings if we keep calling on you to answer questions.

DR. ENGELJOHN: I'll try to address the issue. I'm not familiar with the situation that you raised, Bernie, in particular, but the agency's policy has been for many years that once a positive result is found in an FSIS sample, as an example, for E.coli 0157:H7 in ground beef, the agency would in fact take follow-up samples, 15 of them, after that action.

We also had in place a policy that if a positive was found at any time in the six months prior to a sample collection coming forward into that

facility, that FSIS would take the sample. That particular policy was put together prior to the implementation of HACCP, and the controls that we believe are in place with HACCP with regard to process control and the preventive system, and through a series of public meetings over the last couple years, the agency has identified the 15-sample follow-up and the six-month trigger as being potentially outdated types of policies that may in fact provide disincentives for the industry to actually do more testing of their product with regard to process control, so that there could be greater preventative systems in place.

So, with regard to where the agency's going on that particular issue, we have raised the concern in public meetings that we are looking into the potential for removing those provisions and relying upon the HACCP plan, corrective action provisions, that would be in place if in fact a plant were to find a positive sample.

So, my assumption would be in this particular case that, in this particular situation, the plant itself was undergoing corrective action to put in place procedures that would limit the potential for 0157 being present in the product that it was producing, and then after a period of time, the agency would schedule

that sampling. But that happens to be the existing policy that we have in place and that policy is under review.

MR. SHIRE: Thank you, sir.

I'd like to make a comment just to follow up on that, Dan. Thank you.

That very well may be, and the plant was in fact undergoing -- making some changes in the way it did things, but to -- the question was raised because it seemed a little strange that the plant would be able to go -- in view of this 15-test requirement that follows up, that the plant would be able to go back to business somewhat as usual and to go through and to make thousands of pounds of ground beef while it was making some changes in its HACCP plan, to go back to that and in fact the inspector was asked by the plant manager about this, why they were, you know, -- the fact they could go back and put out one month's production and then the inspector would come back in and start taking the 15 samples, and the inspector kind of just shrugged his shoulders as if to say that's life.

Thank you.

DR. DICKSON: Thank you.

I do have one more -- one final question, and

we do have a final speaker for the day. This is for Martin. Again, two-part question. What makes the program you described attractive to on-farm producers, and the second part is, do you have a goal for participation that you would call success? In other words, what percentage of producers do you need before you consider your program to be a success?

MR. FIRTH: What was the first part again?

DR. DICKSON: The first part? What makes the program you described attractive to the producers? Why would the producers do it?

MR. FIRTH: A lot of it is present market conditions. We're seeing -- I mentioned the pork, but we're looking at the hort sector and other areas that the demands are increasing for them to be on these programs. That's probably the primary one, plus I think there's a higher level of conscience on behalf of the producers to be part of this process.

The second half of the question is the targets for success. Again, there's 17 different commodities, and there's a lot -- well, you know, Canada as about 214,000 farms that we're talking about, a population base. If we could get 50 percent of those in five years, we'd be doing really well and again that's going to vary according to commodity.

DR. DICKSON: Thank you.

And with that, I will close the discussion section of Panel 4 and turn the program back over to Karen Hulebak.

I would like to say again from my own perspective and certainly the perspective of my panel members that we appreciate the outstanding job that Karen and her staff have done on organizing this meeting and, one word, professional at least as far as our dealings with them in all the technical details of bringing us in and getting us here.

Thank you.

(Applause)

DR. HULEBAK: Thank you very much.

Administrative Matters

DR. HULEBAK: My final duty to close this symposium is to introduce to you our final speaker, Dr. Merle Pierson, Deputy Under Secretary for Food Safety at USDA, sworn in by Secretary Ann Veneman in February of 2002.

In his position, Dr. Pierson will work with the Under Secretary for Food Safety, Dr. Murano, to oversee the policies and programs of FSIS, and he also has as a big part of his portfolio the direction and high-level substantive involvement in U.S.

international activities which is Codex Alimentarius.

Dr. Pierson brings extensive experience to USDA. He's internationally recognized for his work in HACCP and his research on reduction and control of foodborne pathogens. He's authored or co-authored more than a hundred journal articles and given numerous workshops on HACCP and food safety. He's also authored or co-authored at least five books, and I won't read you all their titles.

Before his appointment as Deputy Under Secretary, he was Professor of Food Microbiology and Safety at Virginia Polytechnic Institute and State University, where he served as head of the Department of Food Science and Technology, at one point acting superintendent of the Center for Seafood Extension and Research, and he has also been actively involved in various capacities throughout his career with Codex Alimentarius Commission.

Dr. Pierson got his Bachelor's of Science in Biochemistry from Iowa State University and his Master's of Science and Ph.D. in Food Science from the University of Illinois, and I have to say that one of the things I've -- one of the important discoveries I've made through this symposium is that there is an Iowa State University Mafia in our midst. I didn't

fully appreciate that before hearing all these bios but it's remarkable.

So, Dr. Pierson?

Closing Remarks

MR. PIERSON: Thank you, Karen.

I have my remarks on the computer because I know that our speech people will say you better turn it in. The other thing, I can't do this with my computer. Frank, I can't do like you did with my computer. They get pretty upset with me when I do that with my presentation, okay, because you see the university stuff that I haven't gotten all out of me, you know. A university person will stand up here with a bunch of slides, and they'll just start talking and whatever comes next, they'll say something. So, I'm used to that mode, and I have to stick more to script now, see.

Talking about being off a script, Bernie, I can tell you one thing that'll happen, and you're going to make the people in our policy area nervous because they know as soon as I get back, I'll call Andrew and I'll say, "Andrew, I want to see some people, and I need to have an explanation relative to this E.coli testing", and so we'll have a briefing and all those sorts of things. That happens, doesn't it, Warren? Yeah.

Okay. That's all right. Let's get this thing over with. Get into all those big equations and everything. Man alive, you can see who took statistics at Iowa State University. You know, they're known for statistics. I never did take much statistics there. Anyway, okay, back to the script.

This "Symposium on Pathogen Reduction: A Scientific Dialogue" is the second of eight that are being sponsored by USDA/FSIS over the next few months, and I would like to thank the organizing committee headed by Karen Hulebak for their excellent job in developing this program and execution of the conference. I don't mean execution in the sense of, you know, whack, it's a dead dog, but, you know, in the sense that it happened, it all happened.

Our thanks to the speakers for developing their excellent presentations and thoughtful comments. I'd like to thank all of you for your interest, for being here, for participating in the dialogue, and in addition to all this, yesterday, there was inaugurated a very special recognition and that is to a pioneer in the area of food safety and HACCP, Howard Bauman.

Now, why is USDA/FSIS sponsoring these conferences? I might say something. You see, being the Deputy Under Secretary or Under Secretary's Office,

you can write all these comments out and then we have to live with those things, but you see, when Loren writes a speech and then turns it in, then we get to change it and all those sorts of things, right? So, the changing, I guess, ends in our office. So, I guess I'm held accountable for all this stuff.

Well, Elsa's not here, is she? No, she couldn't be here right now. So, if we keep all this secret, we're going to be okay. Just between us, because I found out in Washington, D.C., that happens all the time, you know, just keep it between us. You know, nothing gets out, does it, Dane? Absolutely nothing. You know, actually, a lot of stuff, I know it before I know it. Okay. You know, well, I won't get into all these speculation things. Anyway, when you have two science types -- I know it before Dane tells me about it. That's it. Okay. No, Dane, you're not the source.

When you have two science types in the Office of Food Safety, as you can expect, you know, collectively with several decades of professor experience behind them, you can expect that we're going to be talking science and, you know, that was the basic premise of this meeting, was the science.

We're committed to science in our policies

and our policymaking process, and it's dialogue such as we had today and yesterday that are very, very important to providing that scientific information and having that scientific interchange to help develop policy.

Now, what we need to do is to assure that we have the best available scientific information, that it's used correctly, it's used accurately, you know, it's used effectively. It has to all be used in the right way. There can be very, very serious misuse of science.

You know, Scott, I remember, you know, some of Deming's precepts. One is, what is the most dangerous type of information? It's that which you think you know, you think you know correctly but actually it is incorrect. You can dig a pretty big hole by doing that sort of thing.

Now, this conference has provided an excellent forum to discuss our current understanding of four important areas of pathogen reduction in foods. Well, meat and poultry products in particular. We talked about hazards from farm to table, impacts of HACCP systems and approaches, including prerequisites and good manufacturing practices, talked about performance standards and microbial testing and

intervention strategies, including verification effectiveness, and being a HACCP person, I was really tempted to start answering these questions, you know, about validation and all those things, but I'm going to leave that alone.

You know, I won't attempt, and you're going to say whoo, man, I'm glad of that, I won't attempt to summarize all the presentations, but I'd just like to give you just a few brief observations. You know, I, too, recall early attempts to introduce microbial criteria for foods. I don't go back quite as far as Frank Busta in that regard. Well, we got what, an eight-year difference in that, didn't we, Frank? Something like that. Exactly. Let's put it this way. You can date me back to the Oregon standards. Okay. That's kind of my starting in the food safety area.

Now, there's been much progress over the years with the advent of new surveillance methodologies. You know, we know all the things that have been happening through these surveillance sites and the like. Microbial identification techniques, the development of those over the years, the license systems, etc. We have new processing technologies, intervention strategies, new approaches to food safety management, and the industry-wide adoption of HACCP.

You had no choice in that, though. You know, it gave a good opportunity for implementation of HACCP.

Also, we see the recent CDC reports on foodborne illness and trends indicating significant declines in foodborne illness.

Nancy, you know, you'll enjoy this. Nancy wrote this part of my script. That's not good enough, is it, though? It's not good enough. We need to be doing more. We have to move forward. You know, we can't just say oh, wonderful, things are fine. You know, we've gone this far. We really have to move forward and find out where those areas of importance exist and how to effectively address them.

You know, it's clear that adoption of HACCP as a food safety management system has been important in improving our food safety supply, and it needs to be recognized that HACCP is only a food safety management tool. You know, it's no better than what you use to apply that tool and how you function within that tool.

It has to be supported by essential scientific information and ideally other frameworks for addressing food safety, such as risk analysis. Off-script thing here. For example, we have to take a much stronger look at raw meat and poultry and how we can provide more effective interventions to do a better job

in that regard. You know, we need to do a better job in truly applying HACCP to fresh meat and poultry, and as an example for pushing that in that direction, Dan, when is that directive coming out? Where are we at on the directive on ground beef? Soon. Okay. No, I'm not going to have another meeting with you tomorrow. Okay. Yeah.

But we're coming out with a directive on ground beef that will talk about interventions, you know, and recognizing that there is a stimulus that is needed in that area, and we're looking towards interventions for ground beef to take things the step further and to do better.

It's clear that there's still many critical scientific questions that need to be answered. We need to have a clear understanding of the relationship of food safety policy and hazard management to public health outcomes. Our performance standards, and, you know, you said it, Loren, is that, they're based upon, you know, a hope of a positive public health outcome by reducing the level of incidence, but those performance standards were not based upon, you know, knowing public health outcomes. Okay. We need to better know that relationship.

You know, what is the relationship of

specific levels and incidence of pathogens, such as Salmonella, on raw meats to foodborne illness? To what level can these pathogens be reduced in raw meat and poultry, and what is the associated impact on public health? Are there certain serotypes or biotypes and associated ecological niches that have the most significant contribution to foodborne illness? How should performance standards be used, and how do they relate to public health outcomes? What are the most effective intervention points and strategies for pathogen reduction and associated impact on public health?

The occurrence of foodborne illness is also impacted by factors, such as handling practices, at all stages of the food system, not just consumers, all stages of the food system. What are the practices that have the greatest impact on food safety, and how can they be improved?

It is clear that we need multiple strategies or approaches to addressing food safety and to reducing foodborne threats. These strategies must be appropriately targeted. We must clearly know their impact. Of course, there's many more questions that I could ask, and this is just a sample of the questions, and I need to give a disclaimer and for those people

that I did not encompass within the questions or my questions and comments, I -- my apologies. Pass me a note next time and maybe I can turn it in or, you know, go to the speaker just before I'm ready to say something and I'll say it maybe. I won't promise it, though.

You have to remember food safety is a responsibility of every person involved in the food system. All the way from primary production to the final end user, there's a responsibility. We all then share a common goal and we have a common goal of food safety, safe food. The difficult question is how do we get there? How is it accomplished? That's accomplished, quite frankly, not just by government regulation. It's not accomplished by just cooking your hamburger correctly. It's not accomplished just by some intervention at production. It's accomplished through a multiplicity of efforts and a cooperative effort to produce safe food products. Okay. You know, it's not a pointing the finger at a specific segment, but it takes a vast cooperative effort.

You know, for example, HACCP offers a commonly-understood approach to food safety, food safety management in particular. Risk analysis now offers a commonly-understood set of principles relative

to food safety policy, and it's through conferences such as this that we can exchange the essential information that is needed to identify areas where we need to make progress, and we should then take this and move forward towards producing safer food products, and I hope that you're able to attend the future conferences and be a part of the dialogue at those meetings, and again thank you very much for being here. It's been great having you. I look forward to seeing you in the future.

Thank you.

(Applause)

DR. HULEBAK: Thank you, Dr. Pierson, again and thank all of you who came and stayed. Appreciate it.

Good night and safe travels.

(Whereupon, at 4:05 p.m., the meeting was concluded.)