S. HRG. 106–948

HOW SHOULD OUR FOOD SAFETY SYSTEM ADDRESS MICROBIAL CONTAMINATION?

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

ON

HOW SHOULD OUR FOOD SAFETY SYSTEM ADDRESS MICROBIAL CONTAMINATION?

SEPTEMBER 20, 2000

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HOW SHOULD OUR FOOD SAFETY SYSTEM ADDRESS MICROBIAL CONTAMINATION?

WEDNESDAY, SEPTEMBER 20, 2000

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The Committee met, pursuant to notice, at 9:00 a.m., in room SR–328A, Russell Senate Office Building, Hon. Richard G. Lugar, (Chairman of the Committee), presiding.

Present or submitting a statement: Senators Lugar, Smith, Harkin, Leahy, Daschle, Kerrey, and Miller.

OPENING STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA, CHAIRMAN, COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

The CHAIRMAN. This hearing of the Senate Agriculture Committee is called to order. Today, the Committee holds an important hearing to review our food safety system and how it addresses microbial contamination. We will hear from a number of scientific experts and representatives of the Federal Government and the consumer and public health community. We are hopeful today's hearing will help the Committee gather answers to these questions.

Microbial contamination is the most significant threat to our food safety system. What are the food safety responsibilities of the Federal Government and the private sector related to microbial contamination? What is the value of the Hazard Analysis and Critical Control Points [HACCP], HACCP, approach to food safety and addressing microbial contamination? And what are the barriers to the development and implementation of the new technologies and tools to detect, prevent, and reduce microbial contamination? Are changes needed in the food safety system to aid in that detection, prevention, and reduction?

Obviously, we know that all of the witnesses will not be able to address all of the questions, but we will be interested in hearing different perspectives from each of a number of distinguished witnesses today.

At this hearing, we now look forward to hearing the testimony from our Secretary of Agriculture and officials from the Food and Drug Administration and the Centers for Disease Control and Prevention about the responsibilities of the Federal Government. We will also hear findings from the General Accounting Office about a food safety resources project that Senators Harkin, Hagel, and myself requested last year. And finally, we will learn food safety perspectives from representatives of academia and scientific studies,

food processors, shippers and suppliers, growers and producers, consumers, and the public health organizations. I welcome all of our witnesses and look forward to receiving their testimony.

[The prepared statement of Chairman Lugar can be found in the appendix on page 50.]

I would like to note also the presence of the distinguished Democratic leader, Senator Daschle. Do you have an opening comment, Senator?

STATEMENT OF HON. THOMAS DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. I do, Mr. Chairman, and I thank you very much for your recognition and for convening this hearing today to consider the efficacy of our food safety system.

Food poisoning tragedies in recent years have underscored the importance of enforcing tough food safety standards, and I sincerely commend the Chairman for his continuing effort to make America's food supply the safest in the world. To respond to the challenge of making our food supply as safe as possible, USDA has made dramatic changes in the way it inspects meat products, including full implementation of HACCP. Since then, the Centers for Disease Control has found that foodborne illness has been cut in half.

At the same time, challenges remain. USDA is struggling to provide sufficient inspectors to meet the demands of new programs. It still lacks the full complement of tools to respond to all the food safety issues we confront today and should be given mandatory recall authority. Moreover, questions remain about USDA's authority to set and enforce microbial testing standards. In fact, the recent court decision in the *Supreme Beef v. USDA* highlighted the issue of microbial testing, and in July, Senator Harkin offered an amendment to the agriculture appropriations bill to clarify Congress' intent that USDA have the authority to set and enforce standards for pathogen testing.

The question of microbial testing encompasses a number of related issues. To understand how the system functions, we need to break it down into component parts. Considering these related issues separately helps clarify this debate. It becomes possible to assert that USDA should have the authority to set standards generally while challenging the standards currently in place. Or we can agree to support the need to provide USDA with sufficient enforcement authority while asserting that USDA should change or clarify its enforcement procedures.

I hope we hear this morning that microbial testing of meat is a beneficial tool independent of plant sanitation. In other words, it is possible to find pathogens on meat in a plant that has no detectable sanitation problems. Such a plant should not necessarily be penalized for meat that tests positive, but neither should excessive levels of pathogens be disregarded simply because their origin is not linked to plant sanitation.

The threat that foodborne pathogens pose to human health is not lessened by our inability to trace their origin. They are just as deadly. They are an invaluable indicator of a weak link in the system, and their detection should prompt USDA to work with the

packers or slaughterhouses to identify the cause or source and eliminate it. Pathogen testing is very useful and is absolutely necessary if we are to have confidence in our food supply.

The other issue I hope we can explore today is whether USDA should enforce standards. There are two questions embedded here, what a standard should be and how a standard should be enforced. The concerns I have heard are a blend of dissatisfaction with the current standards and a fear over how USDA might enforce standards in the future. The fact is, we need more data to determine whether it is most appropriate to set standards. While we have an abundant evidence showing that foodborne pathogens are a distinct threat to human health, it is my understanding that scientists and regulators do not have the data they need to precisely gauge the relationship between pathogen presence and the risk to human health.

With regard to fears related to enforcement, I urge my colleagues to consider USDA's record in enforcing the existing standard. The *Supreme Beef* case provides a good case study. It illustrates that USDA does not withdraw inspectors and effectively shuts down plants based on micro testing performance. In fact, in the *Supreme Beef* case, USDA tried to work with Supreme Beef for nearly a year before withdrawing inspectors, and it only resorted to that step when Supreme Beef became completely recalcitrant, effectively disregarding the risk they were posing to the public. If a packing plant supplying the public refuses even to try to reduce pathogens in their product, I question the good sense of anyone who wouldn't want USDA to withdraw inspectors at that point.

Moreover, I cannot understand how anyone can seriously argue that USDA intends to misuse the micro standard as an arbitrary litmus test. The agency has no record of doing so. It may be reasonable, however, for Congress to more clearly delineate the enforcement process so packers will know what to expect.

Last November, I introduced S. 1988 with Senator Hatch. We have 22 cosponsors, Republicans and Democrats. The reason I mention the legislation amid remarks on food safety is that for the first time in 30-years, this idea is supported by consumer and food safety groups. The bill also enjoys a number of first-time Senate cosponsors. Their support is due in large part to the fact that the uniform testing for pathogens in end products called for by the bill will increase the reliability of our overall food safety system.

It should be noted, however, that this uniformity is also a trade issue. Being able to assure that all of our exported project is subject to uniform inspection and that USDA is accountable for the performance of plants in that system protects our producers from potential trade barriers thrown up by other countries. If they can argue that our exports are inspected in systems that they have not specifically improved, then they would have grounds to reject not just some but all of our product. Therefore, while the uniformity requirement attracts the support of the consumer and food safety groups, it is necessary to protect access to foreign markets.

In conclusion, I want to reiterate my strong support for the HACCP system, my support for pathogen testing, and my support for the use of specific standards and enforcement authority employed similarly to the USDA's current practices. We should take

this opportunity to explore ways to do even better. In particular, I hope we can provide USDA with mandatory recall authority, improve standards with better data, to the extent possible, correlate micro testing results with the public health indicators, and ensure that we never use this inspection system punitively.

In the end, we need a food system that instills confidence in the public by achieving results. When a plant has a problem, USDA should work with the plant to fix the problem on an expedited basis and thereby protect the public health. But in the case of the rare bad actor, I hope we can agree that USDA should have the authority to withdraw inspectors as a last resort.

[The prepared statement of Senator Daschle can be found in the appendix on page 53.]

Again, Mr. Chairman, I thank you for holding this very important hearing.

The CHAIRMAN. Thank you very much, Senator Daschle, for a very important statement.

Senator Miller, do you have a comment this morning?

STATEMENT OF HON. ZELL MILLER, A U.S. SENATOR FROM GEORGIA

Senator MILLER. Thank you, Mr. Chairman. I will be very brief. First of all, I want to thank you for your willingness to hold this important hearing on an issue of great importance to this country. While I am the rookie on this committee, I have already determined that you keep this committee focused on issues that in some way or another affect each of us in our daily life and I thank you for that.

Food safety is obviously an issue that we all care about and that we all want to promote in this country. I would venture to say that everyone in this room is committed to doing all we can to protect our citizens and our domestic food supply. But we must approach this effort with a keen eye toward sound science and a commensurate regulatory system.

For the most part, I think that we have done a good job. It is often said that America produces the safest food in the world. I believe this. But it only takes one well-publicized incident to damage a reputation and signal that we must be diligent in the monitoring of our food safety systems. I also believe that USDA must be a critical partner in that effort and I look forward to Secretary Glickman's testimony shortly.

This issue is very, very important to my State of Georgia for two reasons. The first is obvious. Georgia regularly alternates with Arkansas as the top poultry-producing State in the Nation, and coming from the heart of the poultry country in north Georgia, I must add that I have a first-hand view of its importance to our agricultural economy.

The second factor is the tremendous dedication the University of Georgia's College of Agriculture has to food safety research. We have testifying before the Committee today one of the Nation's leading food safety authorities in Mike Doyle, who works at the University of Georgia. Mike has lent great expertise to Congress over the years with his work on *E. coli* research and he has helped establish the Center for Food Safety at the University of Georgia,

a tremendous resource for those working on these issues. We are fortunate to have Mike with us today and I look forward to reviewing his testimony, also.

In closing, Mr. Chairman, I believe we must do all we can to make sure that food production and food safety never become competing interests. We have to do all we can on this committee to promote both. I would like to thank you again for your interest in an issue that is important to my State and our country. I am anxious to learn more about these important issues today and to work with my fellow committee members in addressing them. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Miller.

It is a privilege to recognize again the presence today of our Secretary of Agriculture, Dan Glickman. He is accompanied by Catherine Woteki, who is Under Secretary for Food Safety, and Thomas J. Billy, the Food Safety and Inspection Service Administrator.

I know, Secretary Glickman, that you have a time commitment to another committee and will need to leave around 9:30 or thereabouts and will leave behind your cohorts who are here today. But let me take just a moment to thank you for the work you have done as Secretary of Agriculture. I do not know that this will necessarily be our last committee hearing or the last time we will have an opportunity to request your presence, but I thank you for your willingness to be so forthcoming and generous with your time and consultation, both here in the Committee room as well as at the Department. It has been a real pleasure to work with you. We recognize you for your testimony.

STATEMENT OF HON. DAN GLICKMAN, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC.; ACCOMPANIED BY CATHERINE E. WOTEKI, UNDER SECRETARY FOR FOOD SAFETY; AND THOMAS J. BILLY, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE

Secretary GLICKMAN. Thank you, Mr. Chairman. I remember those days going through vetting with your staff right here, those very pleasant days during the process of going through the confirmation proceedings. But there was never any unpleasantness from you or this committee, and I thank you for your friendship. I think you have been an excellent chairman and focusing on a lot of very interesting and controversial issues affecting American agriculture, and never one to run from controversy, either, so I appreciate that.

I appreciate my friend Tom Daschle and his statement and his dramatic interest in agricultural issues. In fact, I think about 80-percent of the calls into our Department are from the Daschle organization usually.

[Laughter.]

And I would welcome Senator Miller. I visited the governor's mansion, I remember at the Atlanta Olympics with the President. You talked about Dr. Doyle and the University of Georgia. Of course, USDA has a very fine food research/food safety laboratory by our Agricultural Research Service and the Food Safety and Inspection Service working with Dr. Doyle and the University of

Georgia and that is a place where a lot of research is currently being done on pathogens and so we appreciate their work.

Let me just first of all say that under the administration's leadership, we have made a wide range of improvements in our food safety system across the Government. Overall in the U.S., we have the safest food safety system in the world—I believe that very strongly—the FDA, CDC, USDA, and other agencies. It is not perfect, however. It is evolving and we are all working to make it better and nowhere is that more apparent than at USDA.

Our Food Safety and Inspection Service is probably the largest and most effective food safety inspection force in the entire world. Last year, our inspectors examined approximately 8.5-billion-carcasses and 3.4-billion-pounds-of-egg-products in over 6,000 plants. To ensure the safety of imported products, we also maintain a comprehensive system of import inspection and controls.

When the Department was reorganized in 1994, we created a separate food safety mission area to ensure an arm's length regulatory system that is independent of our market promotion activities. The theory was, in order to keep consumer confidence, they had to believe that the people who were doing the inspection were not subject to the same people who were doing the selling, and that separation, I think, has been most effective.

In 1996, we launched revolutionary improvements to our meat and poultry inspection system through our pathogen reduction and HACCP rulemaking. Our new system directly targets pathogens like *salmonella* and *E. coli* that cannot be detected with the naked eye. Microbiological contamination of food by pathogens is the most serious food-related public health threat, responsible for an estimated 76-million-illnesses a year, most mild, but some very serious and some causing death.

By no means have we abandoned traditional physical inspection, the sight, touch, and smell check performed by our USDA inspectors. But our focus now is on reducing pathogens. HACCP provides the framework for our pathogen reduction strategy. Each meat and poultry plant is responsible for setting up and following a plan to prevent, reduce, and control food safety hazards, and by and large, industry has done a good job in devising their own HACCP plans that comply with these rules. That is not to say that there are not some bad actors, but the vast majority of industry has successfully risen to the HACCP challenge.

It is important to recognize how significant of a step HACCP is. It represents nothing short of a revolutionary change in food safety policy, and like most revolutionary changes, it often causes people to perhaps want to go back to the way things were. But it has incorporated for the first time modern scientific knowledge and principles and it has replaced an antiquated system that I think, while it did an excellent job, did not keep up with nearly a century's worth of progress in the science area.

But HACCP is not enough. At USDA, we believe in addition to HACCP, setting up the critical control points, it is imperative to set clear, measurable, objective performance standards that industry must meet. Without some kind of benchmark, we have no way of measuring success and progress in reducing contamination and

foodborne illness. Without performance standards, we would be relying on little more than an industry honor code.

We began by setting a performance standard for salmonella. It is very simple. We collected data to establish the national rate of contamination in raw meat and poultry products. Some plants were above the average, some were below the average. Under the performance standard, all plants must now have a salmonella contamination rate that is at least no worse than this baseline.

Adolph Rupp, the legendary former basketball coach of the University of Kentucky, once said, "If it does not matter whether you win or lose, then why do we keep score?" Performance standards are simply our mechanism for keeping score, for making sure that plants are meeting their food safety responsibilities. And needless to say, when it comes to the safety of our food supply, it matters a great deal whether we win or lose.

This is something of a new paradigm in food safety and not one that everyone agrees with. Performance standards were a source of great controversy when the original HACCP rule was being debated and drafted, and more recently, they have been challenged in the courts, as was referred to in Senator Daschle's statement. I believe these attempts to undermine performance standards are dangerously misguided. The fact is that these standards are reasonable and reachable and I do agree that they must be applied fairly by USDA, as well. And most importantly, the standards are working.

Today, we are releasing new data that demonstrate dramatic salmonella reductions over the last year, that is, from July of 1999 to July of 2000. For example, in those plants that have completed HACCP implementation, salmonella has been cut by more than half on chicken carcasses and by one-third on ground beef. And for every product we regulate, at least 82-percent of plants have met or done better than the performance standard.

Given the success thus far, we hope in the future to be able to set the bar even higher, to establish even more stringent performance standards. We are also looking at the possibility of establishing performance standards for other pathogens beyond salmonella. Next month, we will complete a preliminary survey on the prevalence of another pathogen, Campylobacter in poultry, the first step towards possible performance standards there, as well.

It is important to recognize that pathogen reduction and other food safety imperatives do not begin and end at the slaughterhouse door. Pathogens and other food safety hazards can be introduced on the farm, in storage, during transportation, or in the home or restaurant. Producers, packers, shippers, wholesalers, retailers, and consumers all share food safety responsibility. That is why we have pursued a seamless farm-to-table food safety strategy.

For example, we have provided farmers with information on residue avoidance and helped them adopt quality assurance practices. We have also launched a public information campaign to educate consumers about safe food handling and preparation. Frankly, I would like to see us do more of this, perhaps by funding top-of-the-line public service announcements to keep emphasizing the food safety message. This is expensive to do. USDA does not have the dollars to do very much of this, but just for example, the mere

washing of hands on a periodic basis can reduce food safety illness dramatically. The mere cooking of meat and poultry to the appropriate temperatures can reduce food safety contamination dramatically. It would be nice if we could develop some clear-cut messages on television and radio to communicate those simple messages very clearly and I would hope that we could wok with the Congress in establishing some budgets in the future that would do that. Of course, all of this is not substitute for strong regulation and sound science-based inspection, but it is an important complement that we must continue to pursue.

USDA has devised a pathogen reduction system and an overall food safety system in which public health trumps all other interests and concerns. I think the system is working. But to ensure our continued success, we must constantly integrate new technologies, adopt new research techniques, and be on the lookout for emerging and evolving pathogens.

Our continued success also depends on help from the Congress. Congress has been very supportive of USDA's food safety efforts, but the Senate's fiscal year 2001 appropriations bill is currently several million dollars below our request. We also need $6 million on top of our budget request to cover costs associated with the delay in the implementation of the HACCP models project. And to ensure effective future use of resources to address egg safety, a restriction on the Secretary of Agriculture's ability to delegate shell egg surveillance activities, we would hope should be removed from the appropriations language.

I would like to just echo one point Senator Daschle made. I strongly believe that Congress should empower USDA with expanded authorities that will put more teeth in our food safety efforts. We must have mandatory recall and notification authority. The current system of voluntary industry recall is simply not reliable enough. And I have said this point many times before. The Consumer Product Safety Commission can order recalls of defective lamps and plugs and toys and other products, but we cannot do that with respect to defective food products. That is wrong, and that, I hope, is something that Congress will allow us to do in the future.

To ensure that there is some accountability and flexibility in the system, we also need the authority to impose civil penalties against firms that violate Federal food safety rules. Right now, we are limited to basically either removing the USDA mark, which effectively is shutting a plant down totally, or else referring a matter to the Justice Department for prosecution. But most regulatory agencies have a middle ground approach, which is civil sanctions.

Industry is worried about this because they worry how it would be applied and I understand that and I am working with Congress. I am sure we could come up on ways to make sure that those standards are fair. But it would give the enforcement folks at the Department more flexibility in dealing with food safety problems that often do not require what I call the atomic bomb, which is the removal of the mark and shutting a plant down. There has got to be some middle ground approach there to deal with.

Let me just conclude by saying this. The key here is, I think, beyond making sure that people do not get sick and eat safe food, is

consumer confidence. Safe food sells. If the public believes their food is safe, they will buy it. If they get hysterical about it, they will not. And we see a lot of hysteria around the world, not very much here in our country, because I think people have confidence that USDA, FDA, CDC, and the other food safety agencies are basically on the level, trying to work as hard as they can, call the shots as they see them and are willing to enforce the law in an independent way, a fair way, and an arm's length way from industry. But in other parts of the world, on any of these food-related issues, one small incident explodes into an opportunity for non-science-based hysteria to govern and it certainly affects people's habits in terms of what they buy and what they eat.

I have found that even the most outspoken skeptics of government activism agree that food safety regulation is necessary to keep our food supply safe and protect consumers from food-related illnesses. There are differences of opinion about what kind of powers and roles USDA has had, but I do not believe anybody wants to get rid of the mechanism that is there.

We are proud of the record we have built, but we also know that we can do and should do better. I hope that Congress can work with us to help USDA and help the entire Federal regulatory system become even more effective in terms of fighting for consumers and fighting for food safety in the future. Thank you very much, Mr. Chairman.

[The prepared statement of Secretary Glickman can be found in the appendix on page 62.]

The CHAIRMAN. Thank you very much, Secretary Glickman.

I am going to recognize Senator Harkin a moment for his opening comment, but while you are here, I just wanted to raise this question directly. The leaders in the meat industry who have met with many members of our committee state that the salmonella standard is scientifically flawed because it does not take into account the regional difficulties or seasonal differences in the prevalence of salmonella. Furthermore, they believe an advisory committee on microbiological criteria should have been consulted by USDA about the scientific validity of the performance standards.

So they believe both on the regional and seasonal business and the lack of consultation with this committee that the standard you have talked about is flawed and, therefore, the results that come from it are flawed. Do you have a response to that?

Secretary GLICKMAN. I would like for both Mr. Billy and Dr. Woteki to respond briefly and then I will take a stab at it, as well.

Ms. WOTEKI. I would like to respond first of all from a scientific standpoint. I am a scientist. I am a member also of the Institute of Medicine of the National Academy of Sciences, which recognizes scientists nationwide. So I think I can provide a scientific response to your question.

I feel that the salmonella performance standard does have a very sound scientific base and that base is one of reducing pathogens through an approach that has been used widely in the public health community but has not been applied previously to food safety areas and certainly not in the meat and poultry inspection area. But the basis of it is, first of all, to establish what is the prevalence of a pathogen in the food supply. That was done through the base-

line studies that FSIS performed while they were preparing the HACCP rule and prior to the implementation of the rule.

Based on those baseline studies, the performance standard was established at the midpoint of the prevalence and the scientific rationale, then, is to move the distribution of the pathogen in products below what that average was prior to the implementation of HACCP. And what we have demonstrated and through the data that are being released today and are following up on data that we have released on the first year as well as the second year of implementation of HACCP, we have demonstrated that, that approach can move downward the presence of salmonella in meat and poultry products.

So there is a very sound scientific rationale for it. There is also a history in other public health areas in using this approach to move downwards the distribution of, in this case, a pathogen in the food supply.

Mr. Billy?

Mr. BILLY. Just to supplement what Dr. Woteki has said, we believe that the date, the raw data that we used to establish the performance standard for ground beef, which I think is the one you are focusing in on, is representative geographically and seasonally in terms of what levels of salmonella are in products produced by industry.

I think what is probably the best measure of that is to look at the results across a large number of plants now where they have, in fact, been able to achieve the performance standard. As the Secretary said, this was established based on a national average in industry. We are holding all of industry to meet that national average, and clearly they are succeeding.

From a public health perspective, the notion that we should somehow make adjustments to allow industry to have higher levels of salmonella in certain parts of the country because it is higher at certain times of the year is contrary to our public health interest.

So I think we have got a good foundation. We have an opportunity with all of the data we have collected to look at revising the standard. We have got a strong database now to do that and would plan to forward and do that in the future, as the Secretary has indicated.

The CHAIRMAN. Thank you for those responses.

I would recognize now the distinguished Ranking Member, Senator Harkin, who has had, of course, a tremendous interest in this issue for many years.

Senator HARKIN. Thank you very much, Mr. Chairman. I apologize for being a little late and I thank the Secretary and Dr. Woteki and Mr. Billy for being here this morning. I just ask that my full statement be made a part of the record.

The CHAIRMAN. That will be included in the record in full.

STATEMENT OF HON. TOM HARKIN, A U.S. SENATOR FROM IOWA, RANKING MEMBER, COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Senator HARKIN. I will make a couple of comments. I do want to commend you, Mr. Chairman, for your interest in food safety and

for calling this hearing to examine how well our food safety system is addressing microbiological threats. As you said, I have had a long interest in this and I have introduced several bills that would help strengthen our food safety system.

S. 18, the Safer Meat and Poultry Act, would give USDA the enforcement authority they need other than the atomic bomb of inspection withdrawal that you spoke about, Mr. Secretary. S. 823, the Fruit and Vegetable Safety Act, would require that all fruit and vegetable processors meet existing good manufacturing practices, basically just have them do what they are supposed to be doing. S. 2760, the Microbiological Performance Standard Clarification Act, which would clarify USDA's authority to issue and enforce microbiological performance standards for reducing pathogens. I think all of these bills taken together would definitely strengthen our system.

HACCP has gone, as you said, Dr. Woteki, has gone a long way towards providing a stronger and more science-based food safety system, particularly in meat and poultry. However, in the last year, USDA's legal authority to enforce its microbiological performance standards has been seriously challenged. I am talking about the *Supreme Beef* case. This case directly undercuts USDA's attempt to create a standard based on the logic that reducing the level of pathogens on food nationwide will benefit the public's health.

We have to address this question directly. How do we ensure that companies nationwide are reducing pathogens? If we do not have some measure of a plant's performance, how do we verify that HACCP is really doing its job? There needs to be enforcement if consumers are to have confidence in this system. We need to find out how HACCP regulations and microbiological performance standards can best be enforced.

Generally we have done, a good job—the data shows that—in meat and poultry regulation. That does not mean we cannot do better. I believe there are ways that we can plug up some of the holes in enforcing these standards.

I am anticipating the testimony I read last night from the Center for Science in the Public Interest. I do not verify their data myself, But they say that nearly four times as many outbreaks were linked to Food and Drug Administration regulated foods as were linked to U.S. Department of Agriculture related foods. Their findings are that 682 outbreaks were linked to FDA regulated foods as compared to 179 outbreaks linked to USDA regulated foods. Lastly, they say our outbreak tracking shows that FDA regulated foods have been associated with many foodborne illness outbreaks-many more than USDA. However, FDA's budget for regulating foods is only about one-third of USDA's food inspection budget. In essence, FDA regulates more food with less money.

Mr. Chairman, the more that I have studied this, the more I am thinking that we have got these two separate agencies out there, both talking about food. It seems to me we need to bring them together somehow. I do not want to denigrate FDA. They are a great organization. But I must say for the record and openly and as frankly as I can that the Food and Drug Administration is really the Drug Administration. They have focused more on drugs, which

is fine. We need to have them focus on drugs and the safety of drugs and the application of drugs.

I think the Food and Drug Administration basically has given food a back seat to drugs. I do not think that is true at USDA. So I am hoping that out of this, somehow we find some way of putting all of food safety together under one umbrella. I think that is the path we have to go. How that is going to be done, I do not know, but I hope we can begin to examine that process. Thank you very much, Mr. Chairman.

[The prepared statement of Senator Harkin can be found in the appendix on page 51.]

Secretary GLICKMAN. Can I just make a comment on that?

The CHAIRMAN. Yes.

Secretary GLICKMAN. I think your point is a useful one. First of all, clearly, FDA has not had the resources to do these things. I mean, from the beginning, you look at the history of food safety activities, they occurred as a result of the progress era and the monies came into USDA and meat and poultry inspection was the prime function of USDA and other food safety inspections were basically not relegated to anybody, even though we had a Pure Food and Drug Act and there were some things there. But FDA was largely not given the authority nor the personnel to do that work.

We are working together. The President has, of course, created a food safety initiative that has resulted in attempting to get budget increases across the board and we are looking at what the structural role ought to be in the future to deal with the problems you talked about. It is probably going to be in the next Congress and the next administration before any of these decisions are going to be made, but I think you raise a very important point. We are going to have to modernize the way we handle the regulatory structure of our food safety system.

Senator HARKIN. We are approaching it today the same way we did 30-, 40-years ago, but the whole system of food production, distribution, consumption, has changed dramatically, and so we need a dramatic change in how we enhance and protect the public in that whole chain, from production to consumption.

Secretary GLICKMAN. We just, I think, need to build on the strengths. There are certain strengths in the system and there are certain talents in the system. But I agree. I think that it is time to really look at this question in a very open way and I have not prejudged it myself. I think we have got to figure out in the modern world how we deal with the whole litany of food safety issues beyond just the historical way of doing it.

Senator HARKIN. Thank you very much, Mr. Secretary. Thank you, Mr. Chairman.

The CHAIRMAN. Just a quick question following up on this colloquy. How did we get the separation to begin with? In other words, why is FDA involved in this way and USDA, because obviously it begs the question of why we do not do something about it. I am grateful you are doing something, but it certainly highlights for this committee a very important agenda item, I would think, because this is totally unsatisfactory. If you are testifying that FDA regulated foods, people are three or four times more likely to get sick than the ones that you are doing——

Secretary GLICKMAN. Of course, Senator Harkin testified to that.
[Laughter.]

The CHAIRMAN. You are exempt. Give us a little bit of history, if you will.

Secretary GLICKMAN. I think Dr. Woteki——

Ms. WOTEKI. I can provide you a little bit of historical background. In 1906, Congress enacted the two laws that have led to our current food safety system that——

The CHAIRMAN. Nineteen-oh-six?

Ms. WOTEKI. Nineteen-oh-six, the Federal Meat Inspection Act and the Pure Food and Drug Act. The Department of Agriculture administered both of those laws until the, I believe it was in the late 1930s or early 1940s when the food and drug responsibilities were separated out, eventually finding a home in Health and Human Services. At that point, there was a lot of concern about something that the Secretary alluded to in his testimony of a potential conflict of interest within the Department for administering the Food and Drug Act and it was felt that it was appropriate that, that be separated out.

The CHAIRMAN. Senator Kerrey?

Senator KERREY. Mr. Chairman, that was before PAC contributions so that could not be the reason that the separation occurred.
[Laughter.]

STATEMENT OF HON. J. ROBERT KERREY, A U.S. SENATOR FROM NEBRASKA

Senator KERREY. I am sure it probably had something to do with Congressional oversight. I am not sure exactly what.

First of all, let me thank both you and Senator Harkin for holding these hearings. I think it is extremely important. We pay tribute to the United States Department of Agriculture insufficiently for making certain that we have the safest food supply in the world. Our consumer confidence is good as a consequence. We cannot be vigilant enough, in my view, given the new situation that we have in the marketplace, which is that it is a world market, not just world market in theory, it is a world market in practice, so that my consumers, no matter if I am manufacturing product in some little town in Ohio or some little town in Nebraska, they know worldwide. If there is a problem with my food product, they know it worldwide immediately and the market will put a substantial penalty.

This is the exchange, Mr. Secretary, you and I had before on the comparison with consumer products. It is a much different environment. If I put salmonella out to my customers, my customers will quit coming into my restaurant. I do not care what you do. FDA does not have to do anything. You do not have to do anything. The State Department of Health does not have to do anything. If there is a story in the Omaha World Herald that my customers have gotten sick from eating salmonella—and by the way, they are much more apt to get sick as a consequence of mishandling of dairy products than they are of meat products—if they get sick as a consequence of my serving them salmonella, I am out of business and I am going to have trouble in any other part of the country where I am operating as a consequence of that having occurred.

So everybody understands that in the food business that wants to stay in the food business and they are training their employees and working with their employees to make certain that does not happen. Now, occasionally you have got people, as in any economic environment, who do not care, and they are always running at the margin. They are always pressing the envelope and they are always trying to cut corners and they put everybody at risk as a consequence.

Therefore, it is very important that we give you the authority, in my view, to get the bad people out and keep the good people in the business, and that was really the underlying principle of HACCP. Not only are we going to use good science to go to the critical control points, and I was very much involved in trying to make HACCP a reality, but one of the things that I am also very much aware of is that there has been significant resistance inside of the meat inspectors' union to this new system and I would like to talk about that a bit.

One of the things I have privately talked about to my staff, and it is the first time I have said it out loud, perhaps because I am not running for reelection, but——

[Laughter.]

Senator KERREY.—that maybe in statute we should abolish this union and rewrite the law and create a real health-oriented organization, because they still are thinking like inspectors. They are still thinking in the old world, and a lot of them do not like this new system. They do not like it at all and they have oftentimes been reluctant to follow your instructions.

You are nodding. I wonder if you are willing to say, yes, that you have had some difficulty——

[Laughter.]

Secretary GLICKMAN. Well, I am not running for reelection, either, Senator.

[Laughter.]

But I am going to let Mr. Billy answer that.

Senator KERREY. Mr. Billy was nodding in the affirmative. Has there not been resistance inside the meat inspectors' union to making this change?

Mr. BILLY. Yes, there has been resistance and——

Senator KERREY. Why not at least change the name of it so they are not called meat inspectors anymore, so they are called food safety, even health specialists and require them to establish real liaisons with epidemiological people in the Departments of Health and so forth so that we can make these kinds of discoveries and track down where the problems are. Why not just change the name of the union, or the name of the job and just aggressively go in there and say, look, if you are willing to do a system which is health-based, which is basically saying there is a new sheriff in town—it is like "48 Hours," you know. It is Eddie Murphy walking in the bar and saying, "There is a new sheriff in town here."

[Laughter.]

If you are willing to help us figure out how to reduce pathogens at the levels that we have set, we will be your best friend. And if you are not, we are your worst enemy. We are your worst nightmare. I mean, why not that kind of an approach? Is it going to take

Congress to impose in the statute what it seems to me there has been great difficulty in doing administratively?

Mr. BILLY. I am intending to stay in my position——

[Laughter.]

and I do face certain requirements under labor-management law, so I am not going to comment on the union. But let me say this. We certainly agree that we need a different kind of person looking to the future that carries out our responsibilities in food safety and it is for that very reason that we have embarked upon the establishment of a new kind of position called the consumer safety officer that is college-educated, comes to us properly trained in the sciences, and then with additional training with respect to their job can play an entirely different role than the one we have looked to our inspectors to play traditionally.

Senator KERREY. Do not give the colleges more power than they need. They do not necessarily have to be college educated, do they, to understand the——

Mr. BILLY. I think in this day and age, they do. Otherwise, it will force us to do a great deal of additional training at our expense and it would shorten that process if we could acquire people that have the basic training in the sciences, math, and so forth to carry out the kind of thinking and decision making that is required under a HACCP-type approach.

We have asked for and forwarded to Congress proposals to implement this shift to consumer safety officers. Unfortunately, we have not gotten support from Congress in terms of moving forward and we are sort of wallowing——

Senator KERREY. You are talking about an add-on. You are talking about——

Mr. BILLY. No, we have——

Senator KERREY. Would you still have people in GS positions that would be called meat inspectors?

Mr. BILLY. We would through an interim period as we complete filling out what we consider to be our workforce of the future.

Senator KERREY. How long is the interim period?

Mr. BILLY. Probably several years, Sir.

Senator KERREY. What is several?

Mr. BILLY. Probably about 5-years it would take us to go through a transition like I have described, and that is with full support for it.

Senator KERREY. Just one person's opinion on this thing, I think this is one where you have just got to cut the cord. I think you start right now and say it is food safety specialist. Let us train them up. I mean, the market is demanding it. And, by the way, we are finding ourselves, those of us who supported HACCP, we are on the defensive. HACCP is not working. HACCP does not provide the intensity of regulation. It is a pro-industry champ. You are shaking your head no, but those of us who supported HACCP are answering press calls from people who are saying, this is not working, that HACCP is not a good system.

And I think my view is it is in part related to this old system of saying I am a meat inspector. I was trained as a meat inspector. I am a meat inspector and I am going to go out to that plant and act like a meat inspector. Fine. Give me your pathogen require-

ments and pathogen standards, but I am going to go out there as a meat inspector, and I think it creates a real problem in the field.

Senator HARKIN. I just might add, Bob, I think Senator Kerrey is absolutely right. HACCP works. If you have got a conscientious, good company that really wants to do it, HACCP works. But if you have got someone like you said that is—you know, there is always somebody cutting the edge, trying to be on the edge—then it does not work.

Senator KERREY. But I am skeptical about you needing additional authority. If you have got somebody out there who is a bad operator, shut them down. Just shut them down. I mean, you have got the authority to do that. Shut them down. Why do you need, what is it——

Secretary GLICKMAN. Mandatory recall, which I think we ought to have, and we also have asked for the same authorities that the FAA has, that the banking regulators have, and that is civil authority, civil fines. In some cases, it is more effective to levy a $100,000 fine a day than it is to shut them down. In some cases it is not. I am just saying that flexibility is there in most regulatory——

Senator KERREY. I see a discontinuity, I must say, Mr. Secretary. On the one hand, you talk about the consumer confidence they have in the food supply in the United States. I do not want to, because we have other panelists coming up here, I would love to explore the salmonella issue a bit because I do understand it fairly well from serving food product on a regular basis. But when you say we need more authority and you make the case for more authority, oftentimes when you make the case, you leave the impression that there are great gaps in our capacity to regulate and I do not see it.

Secretary GLICKMAN. I guess one parallel I would say was the airline industry. The FAA could always shut an airline down and remove its certification to fly, but they found that it was also useful when there were perhaps less serious things than massive safety problems, that civil fines, and that is a big deal now with the airlines and they publicize those fines and it has had an impact. I am just saying there are perhaps parallels.

Let me just mention one other thing. That is, there is a spectrum of viewpoints within the employees' sector on the HACCP program. There are a lot of our employees who think this is the right way to go. I want you to know that. Now, I think they——

Senator KERREY. I must say, that is not comforting. The word "lot" is not comforting.

Secretary GLICKMAN. No, no, no. In fact, in my judgment, it is the majority of employees feel that way.

Senator KERREY. That is not comforting.

[Laughter.]

Secretary GLICKMAN. When you have traditional labor-management relationships, this is always going to be a problem area. Now——

Senator KERREY. I think Mr. Billy's answer said it all. He cannot tell us what his opinion is. So I think we need to change the law. I think unless we change the law that gives you the authority to do what you have to do, you are not going to be able to it. Your

answer, which is I cannot answer your question, Senator, because of—what was it, labor something or other——

Mr. BILLY. Labor-management law.

Senator KERREY.—labor-management law. The labor-management law does not allow you to tell me whether or not you can do the job. I mean, I think you made the case by not being able to answer the question, even though I saw the head going this way [nodding] when I was asking.

[Laughter.]

Anyway, thank you, Mr. Chairman.

The CHAIRMAN. Thank you. I need to get Secretary Glickman out of the hearing as gracefully as possible because he has made a commitment really to be somewhere else at 9:30 and he has been most generous.

Secretary GLICKMAN. Thank you.

The CHAIRMAN. All right, one more.

Senator HARKIN. Just before he leaves, again, the salmonella performance standards have not been revised since they were issued in 1996, yet there have been plans to revise them. Do you know where you are in that process?

Secretary GLICKMAN. Mr. Billy?

Mr. BILLY. Yes. We made a commitment that after the very small plants had implemented HACCP and we had a measure of their ability to meet the initial performance standards, we would then review all them and move forward to make revisions. The very small plants implemented in January of this year. We are now collecting data from them. So about the end of this calendar year, we will be in a position to make decisions about revisions to the various performance standards. Obviously——

Senator HARKIN. So we could expect those early next year maybe?

Mr. BILLY. Early next year, yes, Sir.

Senator HARKIN. By March, April?

Mr. BILLY. Yes, we will be in a position to do it by March.

Senator HARKIN. Thank you.

The CHAIRMAN. Thank you very much. Thank you, Mr. Secretary. Will the other witnesses remain so that we can continue to visit with Mr. Billy and Dr. Woteki.

In the chart that is presented here, essentially, you have said or used the words "salmonella prevalence." What does that mean? What odes it mean, the prevalence of salmonella? Is this a standard all by itself or——

Ms. WOTEKI. It is a rate, the percentage of products that test positive for the pathogen.

The CHAIRMAN. Would some product not have any salmonella? I mean, is there a situation where there is none?

Ms. WOTEKI. Correct.

The CHAIRMAN. You move from zero to prevalence. What is that range?

Ms. WOTEKI. OK. In the testing that the Agency does, there are, for different products, a certain number of samples that are taken——

The CHAIRMAN. Yes.

Ms. WOTEKI.—and each one of those samples is tested for salmonella. So the percents that you see there are the percents out of that set of tests that were done that were positive.

The CHAIRMAN. By positive, you mean they had at least one unit of salmonella as opposed to zero?

Ms. WOTEKI. Well, there was a detectable level of the salmonella.

The CHAIRMAN. A detectable level of salmonella.

Ms. WOTEKI. Right.

The CHAIRMAN. So prevalence means detectable level as opposed to none at all?

Ms. WOTEKI. It is the percent of products tested that had a detectable level.

The CHAIRMAN. Let us try it again. Let us say that you have 15 different kinds of hot dogs and you get one kind of hot dog and a majority of the hot dogs in that category had salmonella.

Ms. WOTEKI. So that would be over 50-percent.

The CHAIRMAN. OK, of that particular item.

Ms. WOTEKI. Of that particular hot dog.

The CHAIRMAN. There could be many, many things this plant is doing, but that particular one had a majority of the pieces of hot dogs had salmonella. Now, in the chart that you have, for example, with broilers, prior to the HACCP baseline studies, you point out 25-percent of these lines had a prevalence of salmonella, and this is down ought of 9.9-percent——

Ms. WOTEKI. Correct.

The CHAIRMAN.—following the standard you have imposed. Will the standard be a floating standard? In other words, you talk about improvement. Is the improvement in the standard or the improvement in the number of times that you have a line that has prevalence?

Ms. WOTEKI. Well, the concept is that after HACCP implementation, after this last year when the very smallest of the plants came on line and we had experience from them from their performance with respect to the performance standard, that the Agency would then evaluate the overall performance of the industry and consider whether they would move downward the performance standard. And so far, the data are indicating for broilers, as you were pointing out, that the baseline studies that were conducted before HACCP implementation, 20-percent of broilers, that was kind of the mid-point of that distribution—tested positive for salmonella. Now it is just under 10-percent. So that whole distribution of product prevalence for salmonella has shifted downward. So it would make an argument, I think, for reexamining whether we should establish a new performance standard that will be lower than 20-percent for broilers.

The CHAIRMAN. Yes, Sir?

Mr. BILLY. And for the other performance standards for the various market or product categories. We would do this through notice and comment rulemaking. We have the data from all of our analyses, so we have a data set to use. We would pursue changing the existing performance standard and tighten them based on industry performance. In response to Senator Harkin's question, what I indicated was we would be prepared to move forward on that early next year.

The CHAIRMAN. Well, obviously, progress has been made, but getting back to the logic of Senator Kerrey's reasoning, is this comforting that 9.9-percent of broiler samples have a prevalence of salmonella? In other words, granted, you have gotten from 20 to roughly ten. Maybe next time you will try for five or so forth. But what does this mean in terms of the food supply of the country——

Ms. WOTEKI. It is comforting——

The CHAIRMAN.—that in this case, 9-percent of the poultry out there have a prevalence of salmonella?

Ms. WOTEKI. It is comforting from the perspective that the direction that it is going is downward. We are certainly not happy with that level of salmonella prevalence in the food supply and in this particular product class. But the direction that it is going is downward and that has a public health benefit.

The CHAIRMAN. Well, of course, but I am still trying to drive at what it is that we are finally about. Is it zero salmonella? Why should there be any salmonella? Or will somebody argue today, and we will find out, that we are being far too rigorous? In other words, if you have some evidence of salmonella, it does not make that much difference in terms of public health, a certain toleration level. In other words, we are talking about an impossible situation in which you knock out a good part of the food supply. What does any salmonella mean with regard to the safety of somebody ingesting food in America?

Ms. WOTEKI. Well, any salmonella poses a potential risk because it is an organism that can grow and multiply. So a raw food product with salmonella present within it, if it is not properly handled, not kept refrigerated, not cooked properly, has the potential for causing illnesses in people who consume that product.

The CHAIRMAN. When the meat industry, and you are correct, Mr. Billy, they were talking about the ground beef case essentially, say that an advisory committee was set up and it was going to look at this in a scientific way and they feel that has been ignored, that essentially over at USDA you sort of hit a standard and now you are going to lower it some more. As you find that people are complying, you may lower it some more, driving, from my question, it still not to zero, so now I am worrying about the public as a whole ingesting anything here.

How do you meet these arguments that people are actually producing this meat in the South in this particular case, the regional argument that was made, and you point out, well, after all, people in the South ought to be protected the same as people in the North. The fact that the weather changed should not make a difference, but it probably does make a difference if you are a producer, apparently, of ground beef.

So with all of these things floating around, how are we going to come to some equity that a court of law that heard all this case and sort of ruled USDA out of the picture for the moment is going to come to a reasonable conclusion?

Mr. BILLY. We knew from the outset that progress on reducing pathogens would come incrementally based on the availability of science, the understanding of where the pathogens are coming from and why, and the technology that is available. It is for that reason

that we set a course that we described as farm-to-table, that you cannot solve this in one location, one place.

If we can find better ways to produce the animals that minimize the presence of salmonella, we ought to figure that out and do it. If we can introduce new technology, which industry has done—steam pasteurization, steam vacuum, hot water washes, things like that, that can impact the presence of salmonella on a carcass, we should do that. There is a new technology, irradiation, available, that is available for products. Then we need to focus on the food service sector and the retail sector and training and the things that they need to do, and then finally the consumer in the home.

If we do all those things, our knowledge base and the technology that is available will allow us to minimize the risk of foodborne illness from salmonella. That is our goal. We do not know the answer of where the end point is. I think we need to be driven by our knowledge and by the technology that is available. As we see progress, ratchet down the standards and then that will force those that are marginal to do even better, and those that have resisted some of this new technology to put it in their plans or to follow different production practices.

So I think it is an incremental progress that we can expect here and we are seeing it and I expect it to continue. It is the beauty, I believe, of the performance standards, because it allows the calibration of HACCP, how effective it needs to be, and we are seeing that, in fact, the vast majority of industry can achieve the levels that we have set initially and I believe even if we tighten them up some.

The CHAIRMAN. Senator Kerrey?

Senator KERREY. I need to stipulate one more time at the beginning of my questions a couple things. One is that I want, whether it is USDA or FDA, I want you to shut down anybody that is putting the consumer at risk because they put me at risk, as well, and not just in my private businesses but also I have 100,000 people in Nebraska that work in the meat industry. They put them all at risk. Shut them down. So I am not going to shill for anybody out there that is putting somebody at risk.

Second, I think you guys are doing the best job that you can, so I am complimentary of you, but I am going to get into some stuff that may sound like it is not, because I challenge, along the lines that the Chairman is going, this idea of prevalence.

First of all, you say, Dr. Woteki, detectable. I presume you mean detectable with a given set of scientific tools, because if you want to, you can detect down to one. You could—no?

Ms. WOTEKI. Well, not necessarily.

Senator KERREY. You are saying that there are not scientific tools that could tell you whether or not there is salmonella in my coffee?

Ms. WOTEKI. We have at this point very good microbiological tests, but as with other types of scientific tests, as well, chemical as well as microbiological tests, there is a range as you get down to fewer and fewer organisms and fewer and fewer molecules, approaching zero, where you will come up with a negative test. You will have a non-detect. But there still might be an organism there——

Senator KERREY. All right. So you do not want to say to the consumer, when we say detectable, we do not mean that the product necessarily is completely free of salmonella. There still may be—you may have one organism.

Ms. WOTEKI. Yes.

Senator KERREY. You may have ten organisms on the product. You may still have some. On that basis, if you came in and let us say you tested 535 members of Congress to find out whether or not we had washed our hands. Is it possible there is salmonella on my fingers right now?

Ms. WOTEKI. Yes.

Senator KERREY. Then it is possible that you could come in and say that there is a 50-percent presence of salmonella in Congress as a consequence of us not understanding how to wash our hands properly, is that not true?

Ms. WOTEKI. Possible.

Senator KERREY. I could acquire salmonella poisoning, I could produce the gastroenterological, whatever the impact is. I forget why it makes you sick. Why does it make you sick, by the way? I have lots of organisms in me that are not making me sick. Why does that one make me sick?

Ms. WOTEKI. Well, some of these microorganisms, when they are in a food, produce a toxin, and so when you consume that toxin, it makes you sick. Others, when you eat the organism——

Senator KERREY. Or I might get used to the toxin. I mean, if I travel from one country to another or one region of the country to another——

Ms. WOTEKI. You may develop a resistance to the organism. But for those organisms like salmonella, when you ingest it, it can then produce a toxin inside your body that makes you sick.

Senator KERREY. I am just saying that the prevalence rate of salmonella on the hands of members of Congress could be higher than it is, let us say, in steers and heifers, could it not?

Ms. WOTEKI. A better comparison would be your GI tract with their GI tract.

[Laughter.]

Senator KERREY. Do we have to?

[Laughter.]

But it follows on what the Chairman is asking. I mean, what level of confidence do we acquire? Again, as I understand HACCP, not only do we do critical control points inside of the plant, we go after those things that produce the greatest chance of making consumers sick, and there you are talking about human beings with lower resistance. It will be children because of their lower body weight. It could be elderly people as a consequence of perhaps lower resistance, as well. Should we not be targeting in that fashion? It could come as a consequence of the consumers just simply not knowing what they used to know.

I mean, if I go to a picnic in the summertime, I do not eat deviled eggs. I think that is because my mom told me to be careful about eating deviled eggs. Well, I am not sure I told my kids that. And increasingly, consumers are not preparing their food as much. Somebody else is preparing it for them. You are talking about farm

to table. Should we not be targeting inside of that chain in aggressive fashions in an objective way to try to reduce illness?

Ms. WOTEKI. That is——

Senator KERREY. I mean, trying to reduce pathogens does not tell us anything. We should be trying to reduce the illnesses that are associated with the consumption.

Ms. WOTEKI. And the way that you do that is exactly right, Senator, in taking a farm-to-table approach.

Senator KERREY. But it could lead you back to washrooms in the Senate dining room. It could take you other places than just out to somebody that is processing steers and heifers.

Ms. WOTEKI. And that is why we have an active education program. That is why the Secretary was asking for some additional assistance to get out messages to consumers. And that is also why we have a very active research program.

Senator KERREY. But with great respect to the requests that are coming from the Secretary, the impression is being left, I believe, with the consumers that the number one problem is the bacteria, the pathogens—which is itself a rather provocative word—the prevalence of pathogens, in this case salmonella, that exists inside of processing plants. And in my view, in many ways, it is the least of our problems.

Ms. WOTEKI. Well, our overall message in our farm-to-table strategy to consumers has been that everybody has a responsibility for food safety, everybody who is involved——

Senator KERREY. If you get the prevalence down——

Ms. WOTEKI.—from production through to the final point where you do the preparation and serving to your family.

Senator KERREY. What is your——

Ms. WOTEKI. We have provided educational messages through a partnership with the industry and with consumer groups, the "Fight BAC" campaign that has gotten a lot of visibility but not as much as we would like to get those messages out about the things that consumers can do to help protect themselves. And the role of regulation and the role of HACCP in this is part of an overall strategy.

Mr. BILLY. Can I add something here?

Senator KERREY. Sure.

Mr. BILLY. You have a witness about to come up that is an expert in this area in terms of salmonella from CDC. I think their testimony is right on point in terms of your questions and I would suggest that you hear them out and then come back to your questions based on their views about this approach and what it is achieving and the overall problem——

Senator KERREY. Mr. Billy, what the Chairman is saying, and I will just say it directly, I do not have any confidence of going from 49-percent in ground turkey down to 30-percent is going to reduce the number of illnesses in America, and that is the objective.

Mr. BILLY. OK.

Senator KERREY. You can go from 30-percent down to five percent. One out of 20 is not great odds. If you go down to five percent, have you got the problem solved? The answer is no. We do not know that 30-percent is producing illnesses, that there is an epidemiological connection between that 30-percent and illnesses.

Ms. WOTEKI. We know that it is going in the right direction to reduce illnesses.

Senator KERREY. Tell me how you know that.

Ms. WOTEKI. Because if you have fewer people exposed, then you are reducing the likelihood that there will be illnesses.

Senator KERREY. Reducing the people that are exposed reduces the likelihood is not a scientific-based statement. I mean, that——

Ms. WOTEKI. Yes, it is, Sir.

Senator KERREY. No, ma'am, it is not. If I——

Ms. WOTEKI. We use statistics.

Senator KERREY. It lacks the precision necessary. You are establishing, it seems to me, a principle under HACCP that we are going to go at critical control points to reduce illnesses. So why not back this thing off and say, here is the number of illnesses that are occurring in America today. Here is where the illnesses are occurring and we are going to try to reduce the illnesses.

Ms. WOTEKI. That is——

Senator KERREY. That seems to me to be a scientific approach.

Ms. WOTEKI. And that——

Senator KERREY. But you start off by saying, we are going to just try to reduce the likelihood as a consequence of this effort. I do not necessarily think there is going to be a cause and effect relationship between the regulatory cost to the consumer and the benefits that the consumer receives.

Ms. WOTEKI. I think I would refer you to Mr. Billy's comment. You are going to hear from an expert that is monitoring the occurrence of illnesses in the U.S. population.

Senator KERREY. You underestimate both of your abilities. Both of you are experts, as well, and I am just saying I do not think you can give the consumers a great deal of confidence going from 50-percent down to 30-percent because you do not necessarily——

Ms. WOTEKI. I think it is a remarkable accomplishment, both by the industry as well as by the Food Safety and Inspection Service. It is moving us in the right direction. It is moving us towards lower levels of pathogens overall as well as reducing the occurrence of pathogens in products. That reduces exposure and that is going to lead to fewer illnesses.

Senator KERREY. It does not necessarily reduce exposure. It reduces——

Ms. WOTEKI. Yes, it does.

Senator KERREY. No, it does not necessarily reduce exposure based upon the statement that you made earlier, because you do not know what is happening in the rest of the food chain. You could have increased exposure in all the rest of the food chain and as a consequence you do not get reduced illnesses as a result of this reduction.

Ms. WOTEKI. Well, the data are showing that there are an overall reduction in foodborne illnesses. That reduction has occurred at the same point in time that——

Senator KERREY. Well, that is like saying I just had four sunspots in a row and George Bush dropped 20 points in the polls and that is why. You are establishing a cause and effect relationship because one thing happened right after another and it does not

necessarily—you know this—it does not necessarily mean that one thing caused the other.

Ms. WOTEKI. Epidemiologically, we also deal with associations. What I have described is an association in time. It has a biologically plausible base and it is, therefore, a scientifically sound inference to draw from our current program.

Senator KERREY. I sat for a long time on the floor of the Senate listening to arguments about asking for increased authority for USDA and the arguments that were used for asking for increased authority, I believe, set off unnecessary fears in consumers that they have got problems in processing plants in America and that there is great danger out there associated with consuming American food.

I have supported your programs. I like what you are trying to get done. I am just saying that I think there is a flaw in the thinking here. I do not necessarily disagree that it has been an accomplishment to go from 49- to 30-percent in ground turkey, but what does it tell us?

Mr. Chairman, I will wait for the additional witnesses. I think the horse is dead and I am continuing to feed it.

[Laughter.]

Senator KERREY. I appreciate the exchange.

The CHAIRMAN. This is a characteristic of our Agriculture Committee hearings, that we have a spirited exchange and illumination, hopefully. I appreciate both of you coming and staying with the Secretary.

I want to make a comment that Senator Roberts has submitted a statement for the record, which we will include.

[The prepared statement of Senator Roberts can be found in the appendix on page 56.]

Senator Roberts has submitted, as well, a question that he would like an answer to and it has to do with the shortage in many of the packing plants in Western Kansas of inspectors. Of course, that is a problem all by itself in terms of the mechanics of making all this work, and if you would respond promptly to Senator Roberts' question, I would appreciate it.

We thank you both and you have heralded our next witnesses that we look forward to now with great anticipation. Thank you.

The next witnesses are Mr. Joseph A. Levitt, Director of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration, and Dr. Stephen Ostroff, Associate Director for Epidemiologic Science, National Center for Infectious Diseases, Centers for Disease Control and Prevention in Atlanta, Georgia.

Gentlemen, we welcome you. I will ask you to testify in the order that I have introduced you, which will be Mr. Levitt first. To the extent that you are able to summarize your full testimony, we would appreciate it. The full testimony will be made a part of the record for both of you, and for that matter for all of our witnesses today. Mr. Levitt, would you proceed.

STATEMENT OF JOSEPH A. LEVITT, ESQ. DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, WASHINGTON, DC.

Mr. LEVITT. Thank you very much. Mr. Chairman, it is a pleasure to be here today. My name is Joseph A. Levitt. I am the Director of FDA's Center for Food Safety and Applied Nutrition. As you know, Dr. Henney, the FDA Commissioner, is concurrently testifying at another hearing at the same time.

The CHAIRMAN. Dr. Henney called me—I will mention this for the record—and indicated that she would be in another hearing and very much missed being here today, and we miss her but we are delighted that you are here.

Mr. LEVITT. Thank you very much. Food safety is clearly a top priority at the FDA and I would summarize my testimony by making five main points with one small introduction, which I have here, in addition to the glass I am drinking from, a glass of water which is halfway down, and a lot of the questions I think that came up in the last panel that will continue to come up, is whether or not this glass is half empty or half full. What I think all of us in the Federal agencies believe is that it is halfway but moving in the right direction, and that as we continue to have these hearings into the future, we will continue to show clear progress.

Five points that I would like to make. Number one, food safety is clearly a compelling public health problem. The CDC estimates, and that everyone has repeated, 76-million-illnesses, 300,000 hospitalizations, 5,000 deaths annually, means that we must do all we possibly can to reduce the incidence of foodborne illness, and Senator Kerrey, you are right. We need to focus ultimately on reducing the illnesses, that is what our ultimate goal needs to be. The focus is clearly on microbial contamination, but we cannot let it be exclusively that. There are important issues of chemical contamination and physical hazards and these vary according to the different products that we regulate. So we cannot do one at the exclusion of the other, but microbial contamination is clearly of a paramount concern to all of us.

Point number two, again, a point that has been made already, we need science-based solutions to address this problem and address that all the way from the farm to the table. FDA has a strong tradition of being a science-based regulatory agency. The science enables us first to try and understand truly what the problem is and then to be able to devise solutions that could be scientifically shown to be effective. FDA has initiated a number of food safety programs, and I have a chart over here, that we have ongoing. While I list them there as accomplishments, the accomplishment is really at this point in the initiation and the approach in the issue. We have more work to do.

We have programs, you can see, through HACCP. Seafood HAACP was the first HACCP program put into place several years ago, about the same time as the meat and poultry program. We have a new program in good agricultural practices that we are addressing both domestically and internationally. We have a program on juice safety which started with warnings but is proceeding to preventive controls to be sure that all the juice is safe. We have

devised with the Department of Agriculture an egg safety action plan to reduce the risk from salmonella enteritidis in eggs.

We are working with the Customs Service on an imported foods action plan. We do have a world economy. Imports are skyrocketing in the foods area. We have to be able to address those both at the border but also with an increased overseas presence.

We are focusing our domestic inspections on those firms that produce foods at highest risk and have our goal with a budget that Congress is providing to get to those firms annually. We know that prevention is the key, but we cannot prevent everything, and so an effective outbreak response in conjunction with CDC, in conjunction with the State and local authorities, in conjunction with the Department of Agriculture is key and we have been putting in place systems that are more rapidly detecting and containing illnesses. Those are supported by research, risk assessment, and education.

Point number three, we have not done this alone and we could not do this alone. The Nation is focused this week on the Olympics. We are all familiar with the five Olympic rings linking the five continents of the world. So, too, in food safety. We have the Federal agencies. We have the State and local agencies. We have the industries, the consumers, and the health professionals. We are all interlinked and must remain so. The system is only as strong, as we know, as its weakest link.

Point number four, these programs are already showing what we believe are clear and undeniable results. The CDC data that you are about to see does show actual reductions in foodborne illness, not everywhere, but clearly in areas where we have applied attention and we are gratified on that. We believe the investment to date has been well spent.

But point number five, this is just a down payment. We must do more. These programs are working, but they are just starting. We must continue our resolve and go the distance to benefit American consumers, and the strategic plan to be unveiled by the administration this fall by the President's council that Secretary Glickman referenced, we believe will set a blueprint for the future.

In conclusion, in just 3-years, we that are involved believe that we have fundamentally improved the Nation's food safety system. There is no turning back, but there is much more work to be done.

I am very proud to be working here at the FDA at this critical time and I am especially proud of the hundreds of dedicated men and women at the FDA as well as the many more at all the other agencies who are working tirelessly to make our nation's food supply as safe as it can possibly be. Thank you very much.

[The prepared statement of Mr. Levitt can be found in the appendix on page 71.]

The CHAIRMAN. Thank you very much, Mr. Levitt.

Dr. Ostroff.

STATEMENT OF STEPHEN M. OSTROFF, MD, ASSOCIATE DIRECTOR FOR EPIDEMIOLOGIC SCIENCE, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. OSTROFF. Thank you, Mr. Chairman, members of the Committee, for the opportunity for us to be here today and to discuss

the CDC's role in addressing the challenges posed by foodborne diseases.

Much of this country's public health system was built around the control and prevention of food and waterborne illnesses, and I believe that all of us would agree that the century which just ended was largely one of success. Diseases which were common a century ago, like typhoid fever and botulism, have mostly faded from memory and our food supply is nutritious, varied, abundant, and among the safest in the world.

However, we also live in a time of rapid change and this has an impact on our ability to deal with foodborne illness. In an era of emerging infectious diseases, probably no area has seen more change than foodborne illness. Let me give some examples.

Twenty-five-years-ago, we did not recognize *Campylobacter* as a foodborne pathogen, yet now we know it is the most common of the major bacterial foodborne threats. Twenty-years-ago, *E. coli* O157:H7, which today strikes fear in parents throughout the country and is the most common cause of acute kidney failure in children, was unknown. Ten-year- ago, *Cyclospora,* the parasite which caused large outbreaks linked to Guatemalan raspberries, had not even been identified. And only 5-years-ago, no one knew that bovine spongiform encephalopathy, or "mad cow disease," posed a threat of fatal human illness.

Such a situation occurs because our food supply and production system is highly dynamic. Today's consumers have different preferences and demands than their predecessors and the food supply must keep pace. While today's diversified global food supply brings many benefits, it also brings with it an array of real and potential pathogens. Large-scale food production and distribution brings efficiency and economy of scale, but also creates opportunities for outbreaks of similar size and distribution. New prepared and prepackaged products make life easier in the kitchen, but they also produce new and different risks.

Last year, CDC published our first estimates of the burden of foodborne illness in the United States in a number of years. Our findings suggest that there are approximately 76-million-episodes of foodborne illness every year. While most of these episodes are mild and self-limited, others are more serious and result in 325,000 annual hospitalizations and 5,200 deaths.

Of these 76-million-illnesses, only 18-percent are caused by pathogens that we currently recognize. While some proportion of the remainder of the illnesses may not be due to infectious agents, many probably result from viruses, bacteria, and parasites still waiting to be discovered. With today's technologies, in the next 25-years we will probably find even more disease-causing agents than we did over the last 25-years.

Despite our 20th century successes, our estimates of foodborne disease demonstrate that we still have work to do. CDC's major role is to monitor trends in foodborne illness and the factors responsible for these trends. In response, we have worked with our partners at USDA and FDA and in State and local health departments to improve our ability to recognize, monitor, and respond to foodborne illnesses.

Among the more significant enhancements are the FoodNet and the PulseNet system. FoodNet is a network of nine sites around the country, as you see on the map, which actively and systematically monitors for the major bacterial, viral, and parasitic causes of foodborne illness, conducts surveys for unreported illnesses, and conduct risk factor studies. The combined population being monitored is 29-million-persons, or 11-percent of the U.S. population.

PulseNet is the Innovations in Government award-winning system of local, State, USDA, and FDA laboratories which does molecular fingerprinting of bacterial foodborne pathogens, allowing prompt recognition of large and small foodborne outbreaks so that interventions can occur earlier and disease prevented. Currently, 48 public health laboratories in 46 States take part.

FoodNet and PulseNet are powerful tools which harness 21st century technology to give us insights into patterns of foodborne disease not previously available. Because the FoodNet data are systematically collected, for the first time, we can actually evaluate trends over time and across sites, helping to prioritize interventions such as HACCP and then see their impact on disease occurrence.

Since FoodNet was started in 1997, we have seen some very positive trends. Among all the bacterial pathogens being monitored, we have seen approximately a 20-percent decline in the incidence of disease caused by these organisms, which translates into 855,000 fewer illnesses in 1999 compared with only 2-years earlier. Encompassed in these declines is a 22 percent drop in *E. coli* O157, a 26-percent decline in *Campylobacter*, a 44-percent decline in shigellosis, and a 48-percent decline in *Salmonella enteritidis*, the type of salmonella which is associated with eggs. Cases of *Cyclospora* have essentially dropped to zero since FDA took actions related to Guatemalan raspberries.

Since these trends are consistent across FoodNet sites, we believe they are real and strongly suggest that the food safety interventions taken over the last few years have had a positive, measurable impact.

One trend which is not improving is antibiotic resistance among foodborne bacterial pathogens. CDC and FDA monitor such resistance through the National Antibiotic Resistance Monitoring System. Between 1980 and 1999, the percentage of *Salmonella* strains resistant to at least one antibiotic has increased from 15-percent to 26-percent, while the proportion which were multi-drug resistant increased from 12- to 21-percent. Clearly, more needs to be done in this area, which has a direct impact on our ability to take care of patients with these diseases. Of note, as we meet, another hearing chaired by Senator Cochran is taking place in the Labor-HHS Subcommittee of the Senate Appropriations Committee to see what can be done to address this serious problem.

CDC is committed to work with our partners in government, industry, and the consuming public to continue to improve our ability to monitor, control, and prevent foodborne illness. We have defined core capacities at the State level to address foodborne illness and will soon make our outbreak data more readily available on the Internet to our partners and to the public. We will also periodically

update the foodborne illness burden estimates as we hopefully expand the scope and breadth of our monitoring systems.

The recent FoodNet data suggests efforts to improve food safety are bearing fruit even with the challenges of a changing food supply. We hope to be able to report continued improvement to you in the future as we work together to improve food safety. I thank you and will answer any questions that you may have.

[The prepared statement of Dr. Ostroff can be found in the appendix on page 94.]

The CHAIRMAN. Thank you both. The testimony you have presented, I think, is fascinating in implications for those of us who are semi-amateurs looking in at your work.

To begin with, the figure you have used, as did the previous panel, 76-million Americans having a problem here is a very significant number. It is one of every four of us in this room, on average, each year. But then beyond that, as you say, some of this is temporary, but 325,000 hospitalizations. So the health care costs associated with this situation is a profound figure. Have any of you come to that idea of what we are talking about in terms of the incidence of health care costs?

Dr. OSTROFF. We are in the process of doing economic analyses, both looking at the costs of the illnesses as well as the relative efficacy of interventions from an economic point of view.

The CHAIRMAN. If we were in a different committee at a different time, we would be talking about Medicaid and Medicare, health insurance. Obviously, this is not——

Dr. OSTROFF. But this is a substantial cost, there is no question about it.

The CHAIRMAN. I would think so. So one of the cost-benefit ratios of all this has to be what kinds of investments can be made in the kinds of work that you are doing and USDA and what kind of payoff there is going to be. Now, in addition to limiting human suffering, the incidence with regard to our medical costs and our health care costs could be significant.

Dr. OSTROFF. Right, and there is no question, if you look at these data, that suggests that there are probably close to a million fewer illnesses than there were 2-years ago, and especially since what we are monitoring here is among the more severe of the bacterial pathogens, that impact has also been significant in terms of cost saving.

The CHAIRMAN. Sobering in all of this, though, is the figure then that modifies the 76 in which you said that maybe only 18-million of these cases out of the 76, less than one out of four, actually can be traced to the pathogens that we know about now.

Dr. OSTROFF. That is correct. Actually, it is 14-million. It is 18-percent.

The CHAIRMAN. Oh, I see, 18-percent. So is daunting because out there somewhere, the other 50-some million people may have had something we do not know about. You sort of charted the times of discovery of the various things we do know about so that we have those on the radar screen at least, and we can argue as to how well we are proceeding with that, but the unknown, we do not know. How much time and money is being spent trying to discover the rest of it, how the other 50-some million Americans become ill?

Dr. OSTROFF. I think all of the agencies are looking to identify additional agents that may be responsible for foodborne illnesses. We see disease outbreaks very often, and some of it is due to technological limitations where we cannot identify what the causative agent is. We have a condition, one that comes to mind is something called Brainard diarrhea, which causes a chronic diarrheal illness, and we have had outbreaks caused by this over the years and we have looked and we have looked and we have looked and we cannot quite identify what the pathogen is.

It is a dynamic era. We see this all the time, not only in the foodborne disease arena but in all the other areas that we deal with, emerging infectious diseases, that there are lots of other agents out there yet waiting to be found and it is a challenge for anyone that deals with food safety, whether it is at the Federal level, at the State level, in the academic setting, etc., I think that over the coming years, we will clearly identify additional pathogens that we just simply have not had the technology to be able to find yet.

The CHAIRMAN. You have identified a network of people in your agency or allied with that are monitoring all the time the situation, but do they monitor situations—for instance, we had in the Committee a while back Senator Abraham of Michigan and he was here along with some parents who were aggrieved about strawberries.

Dr. OSTROFF. I remember that one well.

The CHAIRMAN. For instance, from things like that, do you see patterns or do you see an incident bobbing up and do you immediately go to the source, I suppose, to try to find is it something new, is it something different——

Dr. OSTROFF. Oh, absolutely. Absolutely.

The CHAIRMAN. Is that a way of discovery, then, of——

Dr. OSTROFF. Outbreaks are always unfortunate. I mean, I would love to be put out of business, to never see an outbreak of any disease. But in point of fact, they are very valuable to us. They very often are the sentinel event that tells us that something new and different is occurring. Whether that new and different thing may be a new pathogen that we have not seen before or may represent a new risk factor, because again, the food supply itself is dynamic and changing, so over time you recognize patterns of disease outbreaks that have different causes and different reasons for occurring.

So from our perspective, it is very important to investigate as thoroughly as possible every outbreak that we see because you just never know when you are going to recognize some new and different threat that——

The CHAIRMAN. But back there at central headquarters, when something bobs up at all in America, you go after it.

Dr. OSTROFF. Well, you know, the responsibility for doing so rests at the State level. We are a non-regulatory agency and we do not have authority to go out and actually investigate. We do so at the invitation of the appropriate State health department.

The CHAIRMAN. I see. So until a State health department calls you, you are sort of mute back there?

Dr. OSTROFF. Well, we can offer assistance even if they do not call us to come out into the field such as, accepting specimens to

do advanced diagnostics to find the causative agents, assisting them with their investigations, etc..

The CHAIRMAN. Are these State groups usually pretty quick in calling you, or——

Dr. OSTROFF. They are very cooperative and it has been very helpful to us. We have used many of the resources that we have gotten through the food safety initiative to channel them to the State health departments and even to the local health departments, so they can do their job better, and that creates a network, a network not only within our traditional partners in the State health departments, but also in the Department of Agriculture, etc., so that we can actually work better to respond to these problems.

The CHAIRMAN. Earlier, we were discussing the salmonella with regard to ground beef, but the salmonella you have here is with regard to eggs. There has been a 48-percent reduction in terms of illness over the course of this period of time you are graphing here. How important is the salmonella situation? Clearly, that has come to the fore because of the court case and one of the impetus of this hearing, but give us some perspective as to how important it is.

Dr. OSTROFF. It is important for several reasons. One is that it is among the most common of the bacterial foodborne causes of disease. It usually runs neck and neck with *Campylobacter*, being the more recent one. *Campylobacter*, generally, in most of the surveys, you find the incidences higher than *Salmonella*, but the severity of illness is significant. We do know that in terms of fatalities, that it is among the big three.

The CHAIRMAN. What are the other two?

Dr. OSTROFF. One is a parasite called toxoplasmosis, something that has not been discussed, and the third one is *Listeria*. Those, among the known pathogens, account for about 75-percent of all of the foodborne-related deaths. So it is a very significant pathogen. You are talking about millions of cases of illness every year and those are the ones that basically we know about. So ability to deal with and control the occurrence of *Salmonella* would have a significant impact on the burden of foodborne illness.

The CHAIRMAN. What would be your comment—as you recall in the court case last December, there was a separation between the idea of a sanitary plant and the idea of a specific standard for salmonella. These were two different things, at least the court apparently found that they were. What sort of comment would you have about that?

Dr. OSTROFF. Well, the only thing that I would say is that it is hard for us as a non-regulatory agency to comment on regulatory issues, but we are also an agency that likes to measure. That is what we do. We measure incidence and occurrence of many things and I think that the more we can define objective, measurable standards, the more likely we are to have something that we can hold ourselves against and seek to achieve.

The CHAIRMAN. Well, that is probably true. Now, looking at it from our standpoint in Congress, should we have written the law in a different way? In other words, is it possible that someone could say, well, the law as it is written says the plant must be sanitary.

It does not say the salmonella prevalence must be such or that you cannot have any.

Dr. OSTROFF. Right.

The CHAIRMAN. In other words, as legislators, should we sort of go down this chart and say, in essence, in your plant, our tolerance is zero for salmonella, that is the law, so it is unambiguous? Granted, I understand what you do, but I am asking you for advice as a witness on what the law of the land should be.

Dr. OSTROFF. My personal belief, and again, this is not an agency position, my personal belief is similar to what Senator Kerrey said. It is not that you can just focus on one particular thing. I do not think that it should be an either/or situation, to say that either it ought to be sanitary or you ought to have this standard. Quite frankly, I think that both are important. I think the more opportunities that we have to limit the burden of pathogens in the food supply, the more likely it is—and I hate to use that term "more likely," but Senator Kerrey is right, it is associations—the more likely it is that we will reduce the incidence of disease.

The CHAIRMAN. Mr. Levitt, you heard earlier some discussion by Senators as well as witnesses about the role of FDA and the role of USDA in all of this and whether we need to clarify who does what. What is your own view? You are here for the FDA and obviously proud of the work that you and your associates are doing, but it does appear that there is some confusion as to the history of this, starting with the laws in 1906 and progressing through the history we heard in the 1930s and 1940s that may have come from enthusiasm of the Agency, a President, the Congress, whoever initiated these situations. But what would be your own recommendation as to how we get this back under control where we have some unity of effort?

Mr. LEVITT. I think, number one, the FDA does regulate about 80-percent of the food supply.

The CHAIRMAN. Eighty percent?

Mr. LEVITT. Yes. I think the number in testimony is 78.

The CHAIRMAN. I see.

Mr. LEVITT. And so when somebody suggests that the majority of outbreaks are on products that are under our purview, well, most of the products are under our purview. To the extent that people thought originally because of some of the early episodes that the real problem on food safety was ground beef simply, that is wrong. We have found problems throughout, and to the extent that these organisms are in the environment, they get into different products. And so that is why we have this long litany of programs addressing the different kinds of product areas—a program for eggs, a program for fresh fruits and vegetables, a program for seafood. We need to look at each of these on their merits and I think we have tried to go in a risk-based way on how to apply and get that cup a little more full with each successive year. So I think point one is, we do have a lot of responsibility in this area.

Two is that we feel that a strong part of our history—I think each agency, we have our strengths. FDA's strength is strong science and know how and bang for your buck. One of the large food safety scares back in the 1970s was a concern about botulism. It was not a concern, it was a reality of botulism in canned food

and FDA very quickly—this is all clearly before my time—brought to the fore the science, what do you need to do, and came forward with the low-acid canned food regulations which are the predecessor to today's HACCP regulations. So it is an agency that has traditionally risen to the occasion.

What these kind of issues do is they raise the issue of coverage, of resources. We have over the last 3-years within the FDA under the food safety initiative, most of the increased funding has gone to the food part of the FDA, and I think we all feel that is needed and we all anticipate probably a lot more will be needed and GAO will have words to say, I am sure, on the resource front.

But I think the critical issue is, do we have, if you will, our eye on the ball? Are we addressing these problems in a way that is achieving real results? And if we are, then we need to, a combination of stay the course and accelerate the course. We have a program that is getting the job done. We are all impatient. Impatience here is good. We want it to go faster than maybe it does. There were some other discussions about how long things take. Change takes time. We wish it would take less time.

We have a conundrum of one of the safest food supplies in the world, and yet looking at these numbers, we want to make it even safer. And so I think we need to continue to approach it in a way that is getting us somewhere, that is cost effective, that is receiving real results, and that we have to also realize we have to change a little with time.

I see Senator Harkin has rejoined us. I had the opportunity, Senator, earlier this week at a conference of—not a food safety conference but a different conference where you were not able to come in person but you were able to send a video and you talked there about the difference between the torch bearers that are moving into the future and the pallbearers that are trying to return to the past. I think in this setting we feel very much that we are the torch bearers. All of us are the torch bearers moving ahead on food safety.

We have a system that has been in place for a long period of time. We have changes that are going on all around us—the global economy, the changes in the demographics of the population with a greater number of elderly and immune-compromised in the population, more people eating outside the home.

We have not talked much about retail. One thing FDA has is while the States have the primary responsibility for retail, the FDA has put out and established what we call the food code, which is a set of model recommendations to States and States are adopting it more and more. We wish it were faster, but we are proceeding.

So we have in place a system that while imperfect is filling up that glass, and we have very much benefitted by Congress' support in the area of funding, and as I said, in the administration's plan, we are trying to lay out what we think we need over the long haul.

The CHAIRMAN. Let me, while Senator Harkin is getting his breath, ask Senator Kerrey to continue the questioning.

Senator KERREY. Thank you very much, Mr. Chairman.

First of all, I appreciate both the witnesses' testimony and obviously successful efforts in making our food supply safer. What con-

cerns me still is that we talk about regulating using science but we oftentimes do not.

For example, Dr. Ostroff, I do not think there is really any scientific basis for this chart that you put up here. I mean, there is no question there has been declines in foodborne illnesses of a million. I do not question that. But as to whether that was caused by CDC's program, which was at least inferred in the testimony, that CDC's program produced that reduction. My guess is you do not have a scientific basis for that evaluation. It may have occurred as a consequence of parents and other consumers watching television and learning in the process of the 0157:H7 debate that they have got to cook at 180 degrees and you could see the reduction occurring just because people are not ordering rare hamburger anymore, medium-rare product as a consequence of acquiring some understanding that came as a result of now being more afraid of eating the product than they were before.

I presume that you have not done a scientific evaluation in order to produce that chart, although I would say it is likely that the chart will be reused in arguments, that there have been a million fewer illnesses, etc.. That there is a cause and effect relationship may not be quite as obvious as the chart at least implies that there is.

Dr. OSTROFF. Well, first of all, it is not CDC's program. We again are not taking the regulatory actions. We obviously have participated in trying to get the prevention messages out, to conducting the investigations to identify the risk factors, etc..

Senator KERREY. I was less under the impression that you were making the case that FoodNet had produced substantial successes and that——

Dr. OSTROFF. No. Before we had such a system which systematically and methodically uses the same exact technique year after year after year to accumulate the data, when we saw changes, either up or down, we were never confident that those were true changes, that they could simply be artifact. The State of Nebraska may have changed the way that they do monitoring of foodborne illnesses, and so from 1-year to the next they all of a sudden see more disease.

We have had many instances where we have had what we refer to as pseudo outbreaks, where all of a sudden we have laboratories that start testing for a pathogen and you see a tremendous upsurge in the number of cases of *E. coli* or something like that and it is not real. It is simply because there was a change in the practices of the monitoring.

But because we have the FoodNet and we have the sites doing the same thing exactly the same way from 1-year to the next, we are in a position now to say that these trends do actually represent reductions. But what I cannot say, and you are absolutely correct, is that it may be true, but unrelated. I mean, it could be both.

Senator KERREY. You say there are 5,200, approximately, deaths a year——

Dr. OSTROFF. Correct.

Senator KERREY.—that occur as a consequence of food illnesses——

Dr. OSTROFF. Correct.

Senator KERREY.—and 360,000 hospitalizations that occur as a consequence of food——

Dr. OSTROFF. Correct.

Senator KERREY. Do you have data that allows us as policy makers to try to figure out how much money to put in education, how much and how to regulate? Do you have data that allows us to know what it is that is killing American people, what is producing the deaths?

Dr. OSTROFF. Well, again, as was pointed out before, for a substantial proportion of those deaths, the pathogen is not identified. However——

Senator KERREY. Does that mean you are not certain that it was a foodborne illness?

Dr. OSTROFF. No, we are not certain. We know that it was food associated, but we do not exactly know what the causative pathogenic agent was. In other words, the microbe has not been identified.

Senator KERREY. Does that mean you are not certain—I mean, you have 5,200 deaths a year. Do you have data for each one of those deaths or is that an extrapolation from a smaller set?

Dr. OSTROFF. No, it is an extrapolation.

Senator KERREY. An extrapolation from a smaller sample?

Dr. OSTROFF. Right.

Senator KERREY. You have deaths that are occurring, and are you able then to break that down to guide us? I mean, I take Mr. Levitt, and I presume you agree with Mr. Levitt's five things, that the first order of business has got to be scientific based, and we should have both our regulation and an education effort be scientific based. And part of our purpose on this committee is trying to decide what the regulation ought to be. We heard USDA earlier making an appeal for increased authority to regulate.

Mr. LEVITT. Right.

Senator KERREY. And we are trying to figure out, should we give increased authority. Will that increased authority reduce the number of deaths, reduce the number of hospitalizations, reduce the number of foodborne illnesses? So it seems to me that from you, we need to be able to track this in a more precise fashion.

Dr. OSTROFF. Right. You know, there are many thins that are occurring at the same time—consumer education, the HACCP regulation, changes on the farm, changes in handling after product leaves the plant. It is difficult for us to say what the relative contribution of each of those changes is to the reductions that we see. All we can say to you is that based on the monitoring systems that we have in place, we do see reductions in the number of illnesses. We have to believe that the reasons behind those reductions——

Senator KERREY. Let me give you an example, Dr. Ostroff. Let us say Congress passes a law and says that the United States of America will not accept any food imports whatsoever. We will guard our borders. No more food from outside the United States is going to come in. Consumers of America are going to have to eat only those things that are grown and processed here. Will that reduce the number of deaths in America as a consequence of foodborne illnesses?

Dr. OSTROFF. We have always maintained that we do not have data that suggests that food that comes into the country from overseas is any riskier than food which is produced domestically. All we know is that the patterns of the——

Senator KERREY. Does that apply to all countries, Dr. Ostroff, or just to——

Dr. OSTROFF. All I know is that we have no data right now that shows we see more foodborne disease associated with imported products on a relative basis than we——

Senator KERREY. Do you have sufficient data to reach that conclusion, do you think, or——

Dr. OSTROFF. We do not have data that tells us that one is riskier than the other. All we do know is that the patterns of pathogens that we see in foods that come into the country versus foods that are produced domestically are different.

Senator KERREY. My own view is that we would be on sounder ground, especially on the regulation side, to track these deaths from foodborne illnesses back into regulatory responses. Whatever the regulatory response is, let the science and let whatever is happening out there with consumers guide our decisions both on regulation and on education, because I think what is happening is not that, and I acknowledge that in politics it is rare that we use science to evaluate what it is that we are doing.

Dr. OSTROFF. Right.

Senator KERREY. But it seems to me that when you are dealing with something like the food supply of this country, that it should, and it seems to me the most important indicator is the ones that you provided. Even though you have extrapolated it from smaller samples and you are not 100-percent certain, it seems to me that the beginning point ought to be people that you think that have died as a consequence of consuming food in the United States or who were ill as a consequence of consuming food and we ought to track that back and produce a regulatory response that tries to reduce those numbers.

Dr. OSTROFF. What I can say is that at the same time that we have noticed these reductions in the incidence of foodborne disease caused by these pathogens, we have also seen reductions in, and I hate to use the term "prevalence" again, in the prevalence of organisms in the various products that are being assessed. While it is possible that those are completely unrelated to each other, that it is a chance coincidence, you have to believe that since it is biologically plausible that there is a cause and effect there.

Senator KERREY. What I am suggesting is that our response, our regulatory response needs to begin with the thing that provokes the most concern. The most concern amongst consumers is, and indeed, I drink this water comfortably as a consequence of presuming that the Washington, D.C., water supply is safe. You are drinking a glass of water there. Have you checked out our ice machine?

Dr. OSTROFF. Not today.

Senator KERREY. Perhaps you should before you drink it. I do not know. So I am consuming based upon believing that I can drink this glass of water without either getting sick or dying, because I prefer not to have either one of those two things happen. So it seems to me that our regulatory response should begin with that

concern, and I am not sure it does. I am not sure it does at all. We have a HACCP system that is supposed to be paying attention to critical control points, but I see less science than I would like when it comes to trying to evaluate what our regulatory response ought to be in our food industries, and I thank you.

The CHAIRMAN. Thank you very much, Senator Kerrey.

Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman. Again, I am sorry I had to leave. We had to report some bills out of another committee, so I had to leave for a little bit.

Mr. Levitt, first, I just want to say that I am happy to see that FDA is making progress in picking up review of new food safety technologies, especially in the area of—we had to deal with packaging materials for electron beam irradiation.

Mr. LEVITT. I remember that.

Senator HARKIN. I am glad we got that through. I often wonder, why did it take so long? I mean, we had packaging materials that were safe for gamma ray radiation which any scientist will tell you, if it is safe for that, it has got to be perfectly safe for electron beam irradiation, yet it just took months and months. It just drug on and on, and finally we got it, but I wonder why it just took so long to do that. I am happy we finally got it done.

I am also concerned about FDA's labeling on electron beam irradiation. Processors and manufacturers still have to put that symbol on there and I am wondering why. Why do you have to put that symbol on there? Why don't you allow alternatives? Why do we have to continue with this, what do they call it—I forget the name of it, that symbol you put——

Mr. LEVITT. The radura symbol.

Senator HARKIN. Yes, the radura symbol, that is right. Why?

Mr. LEVITT. The background on the labeling for food irradiation is that FDA's labeling regulations and laws are based on has something changed about the food that we would consider a material fact for consumers to know. And in the case of food irradiation, when the safety determinations were made, with which we have very high confidence, there was also a conclusion made that the irradiation process can make some changes, if you will, in kind of the texture or the quality of the food in terms of how it feels, not how safe it is. And so the conclusion was made that we needed to put that on the label as a material fact.

Now, we have received a lot of comment on that point from opposing sides. We have consumers that are saying we must know. It is very important for us to know if this is used. We have others from the industry that have argued forcefully it is scaring people. It is, if irradiation is going to help, we have to be able to use it in a way that is consumer friendly, if you will.

Senator HARKIN. Well, I like to call it electron beam pasteurization because it is closer to a pasteurization process than it is to a radiation process. We are not using any kind of nuclear materials or anything like that for gamma rays. This is only electron beams. It is similar to the electron beams in a microwave, not quite the same, but similar. So to use that terminology is a holdover from the past when, in fact, it was a gamma ray radiation.

Mr. LEVITT. We did issue an advanced notice of proposed rulemaking and we will be proceeding ahead to kind of relook at the issue.

Senator HARKIN. Well, I hope so, because I think you——

Mr. LEVITT. I cannot say how that relook will come out, but I know there is a lot of interest, certainly from you, from a number of other members of the Congress. In our appropriations, I believe we are being directed to pursue vigorously ahead on that, and so we will be relooking at that issue.

Senator HARKIN. Do you not agree that, that is a significant step that can be used to significantly reduce pathogens in food and food products?

Mr. LEVITT. I would certainly agree. We have——

Senator HARKIN. That does not absolutely ensure it. Obviously, when it gets into consumers' hands, if they mishandle it, obviously, you cannot prevent that.

Mr. LEVITT. But again, you look at the numbers of and the scope of the problem. If we have a tool, whether it is food irradiation or other technologies, we need to be able to use those tools effectively to make the food supply as safe as possible—we are in 100-percent agreement on that.

Senator HARKIN. Well, this is just in the beginning and obviously there are storage, transportation, consumer information, "Fight BAC," all the other things you and USDA are doing, which are good.

Mr. LEVITT. Right.

Senator HARKIN. But I am glad to hear you are moving ahead on that.

On another topic, seafood—I am told that a large part of the seafood industry still fails to comply with the seafood HACCP rule that you have had for a couple of years now. In addition FDA still has not addressed concerns with mercury in seafood that Senator Leahy and I have repeatedly asked you to address.

Two questions. Why is it taking so long to get seafood processors compliant with HACCP and what are your plans for addressing mercury in seafood?

Mr. LEVITT. Let me begin with seafood HACCP. Again, it is a little bit of a half empty, half full story. We believe that we are and the industry is making truly significant progress. We are dealing with an industry that prior to this regulation in December of 1997 was very much, if you will, in the old school of how to produce food, and we have worked through what we call a seafood HACCP alliance with training with the industry. We have produced something called the Fish and Fishery Products Hazards and Control Guide, which is an over 200-page manual addressing how to do seafood HACCP right.

Now, we are dealing with over 150 species of fish and we are dealing with, for the most part, an industry with small businesses throughout. We recognize that and try to put into place, if you will, a progressive program, where year one we went out and inspected and the good news was out of the 4,000 domestic processors, 1,000 got it right the first time, and we have a very rigorous rating system. We grade these plants on 11 different types of hazards that could apply there, and if the company passes on ten and does not

pass on the eleventh, they do not get an overall passing grade. So the overall grade is designed to encourage comprehensiveness in approach.

The second year, we have got a lot of progress. The third year, we are seeing more. We are also losing patience. We also took our first enforcement action just a short time ago and we have entered into a consent decree of injunction with one company that simply was not getting it at all. And so there is a limit, that we feel if it is raising a public health issue, the company has had time, then we need to take the next step.

But we feel that if you look at it as a whole, each year we are making clear progression. The industry is seeing it. There was an interesting survey done or study done—we did not even know anything about it—by a sea grant college up in Stonybrook, New York, which did their own survey of the industry. And what they found and documented was that, that industry is going through an entire thought change on what it means for food safety. They are looking and identifying their hazards. They are putting in, what are the control points that are critical? What are the limits that I have to meet? What is the verification? What is the monitoring? What is my built-in corrective action? This is an entirely new way of doing business.

Based on what limited baseline data we had, we are progressing ahead. The reality is, we are probably on a 5-year plan to get to where everybody would like to be. But I think that we feel so long as we are seeing progress and that we should continue in this direction.

At the same time, we have to realize maybe we need to make some mid-course corrections. We are doing that in two ways. Number one, we are looking and evaluating to say where are most of the problems we are seeing and really channel the next degree of training and inspections focusing on where the biggest problems are.

Second, our program, seafood HACCP, has been cited for an inadequate amount of testing that is done, and beginning in this coming fiscal year—we actually started last year partway through the year to increase the testing, but we will be increasing our verification testing that FDA will be doing when we go out and inspect in the 2001 cycle. So we are trying to be responsive but also realize that if we are moving ahead, again, let us continue to press. We do not mind being tough graders. We think that is important. So again, we think the cup is half full and getting fuller, but we know it is a work in progress. We know we are not all the way there.

Senator HARKIN. I appreciate that. I think in your testimony you said that your HACCP requirement requires all 4,100 seafood processors and 150 species of fish to complete HACCP systems.

Mr. LEVITT. Right.

Senator HARKIN. Beginning in 1998, your goal has been to inspect domestic seafood processors annually. Is that still your goal, just once a year?

Mr. LEVITT. Yes, and within our, if you will, world, that is——

Senator HARKIN. How would you feel if we just had meat and poultry inspections once a year, that someone came by a plant once a year?

Mr. LEVITT. That is really not my area.

Senator HARKIN. Well, I know it is not your area, but people eat seafood like they eat meat and poultry. Again, I am not taking you to task. What I am trying to do is to make a point. In your testimony, you said you cover 78-percent of all domestic and imported food. That means Agriculture does the other 22-percent.

Mr. LEVITT. Right.

Senator HARKIN. Yet their budget for food safety and inspection is, what, three times yours? So you are covering three times as much food with one-third as much money.

Mr. LEVITT. That is correct.

Senator HARKIN. Well, I am saying there is a problem there.

Mr. LEVITT. Right, and that is why we have been requesting increases, and I know you are a member of the Appropriations Committee and you have been supporting those.

Senator HARKIN. I sure have.

Mr. LEVITT. And as I said, I think that the investment is paying off.

Senator HARKIN. Let me ask you another pointed question, Mr. Levitt. How good is your tracing ability? If there is an outbreak of illness due to seafood, how good do you think your tracing ability is to trace it back to the source and to find out where other elements of that seafood may have been distributed?

Mr. LEVITT. I think in terms of ability—I will get to authority, but let us start with ability.

Senator HARKIN. Ability, yes.

Mr. LEVITT. Ability to do it is improving. We all think we need to continue to get better at it. That is both FDA in conjunction with CDC and the——

Senator HARKIN. Well, CDC obviously has a part of this, too.

Mr. LEVITT. Right, and the State and local health officials do, also. We are working hard at it and getting better at it, but it is difficult.

Senator HARKIN. It is my information—again, I could be corrected, and I ask Dr. Ostroff if he wants to chime in on this—that when it comes to meat and poultry, that the tracing ability, both of FSIS and CDC in conjunction with them, is pretty darn good. They can trace an outbreak back pretty well. But in terms of seafood, it is not that good. That is just my information and that is why I asked you the question.

Mr. LEVITT. Yes. Well, I mean, it kind of goes back to one of the initial perceptions——

Senator HARKIN. OK.

Mr. LEVITT.—which was probably true at the beginning of the century when the laws were set up, which is that the meat by its nature poses a greater hazard than the other products which are now regulated by FDA. And so different statutory systems were set up that were felt to be appropriate with each.

What we are seeing today is that the hazards have changed, the foods implicated have changed, and we are needing to keep up and being sure all our programs are modernized, and I think you are speaking directly to the need for that.

Senator HARKIN. Exactly.

Mr. LEVITT. So I think we would agree.

Senator HARKIN. Thank you. I appreciate that. Thank you very much, Mr. Chairman. I know you have to move on. We could go on with this panel for a long time.

The CHAIRMAN. Well, thank you. We could, indeed, and we really appreciate your working with us, really, throughout what has been an hour or more of testimony.

Mr. LEVITT. It was our pleasure. Thank you very much.

The CHAIRMAN. Thank you for coming and for your achievements.

Dr. OSTROFF. And thank you for your attention to this matter. We appreciate it very much, Mr. Chairman.

Mr. LEVITT. Thank you.

The CHAIRMAN. The Chair would like to call now a panel that will include Mr. Lawrence Dyckman, Director of the Food and Agriculture Issues at the U.S. General Accounting Office; Dr. Michael Doyle, Director of the Center for Food Safety and Quality Enhancement, University of Georgia, Griffin, Georgia, on behalf of the Council for Agricultural Science and Technology; Mr. Dane Bernard, Vice President, Food Safety Programs, National Food Processors Association, Washington, DC.; Dr. Donna Garren, Vice President of Scientific and Technical Affairs, United Fresh Fruit and Vegetable Association, Alexandria, Virginia; Dr. Gary Weber, Executive Director, Regulatory Affairs, National Cattlemen's Beef Association, Washington, DC.; Dr. Ann Hollingsworth, President of the American Meat Science Association, Carrollton, Georgia, on behalf of the American Meat Science Association and the American Meat Institute; Ms. Caroline Smith DeWaal, Director of Food Safety, Center for Science in the Public Interest, Washington, DC.; and Mohammad Akhter, MD, Executive Director of the American Public Health Association in Washington, DC.

Senator HARKIN. While these witnesses are taking their seats, I wonder if I might just ask Mr. Billy a question here. I am sorry I had to leave early. Mr. Billy, I am going to put this in the record but there is a report, and let me just read it to you. "Using fluorescent spectroscopy, the ARS researchers and Iowa State University chemist Jacob W. Petrich built a detector that illuminates unseen fecal contamination on meat. Petrich says the device is adaptable to any size packing plant. As a hand-held unit, similar to a metal detectors used in airports, the instrument could alert meat packers to fecal contamination within seconds. The contaminated carcass could then be sanitized before the contamination spreads." Do you know about that and do you know if that technology is being utilized or what is being done with it?

Mr. BILLY. I am aware of the research that is going on and I think it is very promising, and I think it offers the potential to see changes in how we examine carcasses using that kind of technology. We are planning to hold another technology conference and feature that kind of new development. We think it is a terrific new development.

Senator HARKIN. Would you work with my staff on this? I want to see, if this technology really works, why are we not implementing this? This seems to me another device or another way we could use to really cut down on fecal contamination.

Mr. BILLY. Oh, I agree——

Senator HARKIN. I just wondered if you were aware of it.

Mr. BILLY.—and that is the source of a lot of pathogens, so it is a real—very vital area to what we are trying to do.

Senator HARKIN. Thank you, Mr. Billy. Thank you, Mr. Chairman, for indulging me.

The CHAIRMAN. Thank you, Senator Harkin. Thank you again, Mr. Billy.

I will ask you to testify in the order that I introduced you, and let me mention that, in fact, testifying on behalf of the American Public Health Association will be Dr. Richard Levinson.

First of all, let me state that all of your testimony will be placed in the record in full and you need not ask or request that. It will be done. second, we will ask that you confine your initial comments to 5-minutes so that all can be heard and we can then get into a free-flowing comment here, as you witnessed with the previous panel.

First of all, Dr. Doyle.

STATEMENT OF MICHAEL P. DOYLE, DIRECTOR, CENTER FOR FOOD SAFETY AND QUALITY ENHANCEMENT, UNIVERSITY OF GEORGIA, GRIFFIN, GEORGIA; ON BEHALF OF THE COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

Mr. DOYLE. Good morning and thank you, Mr. Chairman and members of the Committee. I appreciate the invitation to present testimony before the Senate Committee, especially as related to approaches to increase the microbiological safety of foods. I hope my testimony will be helpful in understanding the value of the HACCP approach to increasing the safety of foods and in identifying changes needed in the food safety system to aid in the reduction of microbial contamination.

I am Michael Doyle, the Director of the Center for Food Safety and Quality Enhancement at the University of Georgia and my primary professional experience has been focused on research and developing methods to detect and control foodborne pathogens at all levels of the food continuum, from farm to table.

My primary involvement in the topics of interest to this committee include membership on the Institute of Medicine Committee to ensure safe food from production to consumption and on the Council of Agriculture, Science, and Technology, task force on foodborne pathogens, risk, and consequences.

I am testifying on behalf of CAST, which is a nonprofit consortium of 38 scientific societies representing more than 180,000 scientists and many individual student, company, nonprofit, and associate society members. The mission of CAST is to identify food and fiber, environmental and other environmental issues, and to interpret related scientific research information for legislators, regulators, and the media for use in public policy decision making.

Now the information I shall provide you largely has been extracted from three sources, and these include a CAST report on foodborne pathogens entitled "A Review of Recommendations;" a second CAST report which addresses foodborne pathogens, risks, and consequences; and a third report which deals with an Institute of Medicine report addressing ensuring safe food from production to consumption.

A large variety of microorganisms having varied growth characteristics, unique niches in animals and processing facilities, and differing tolerances or sensitivities to food preservatives and processing treatments are responsible for an estimated 76-million-cases of foodborne illness annually in the United States. Considering the wide diversity of sources, tolerances, and growth properties of foodborne pathogens, there is no single process that can assure absolute safety of all foods and still retain desirable eating characteristics.

For this reason, a science-based systematic approach that identifies and assesses the microbiological hazards and risks associated with food and incorporates effective treatments for their control was needed to effectively reduce the risk of foodborne illness. Hence, the HACCP system subsequently was developed to meet this need, largely through the efforts of the International Commission on Microbiological Specifications for Foods and through the USDA and FDA National Advisory Committee on Microbiological Criteria for Food.

Many refinements and improvements of HACCP have been made since the HACCP concept was first introduced. However, the HACCP system is believed by the food safety community to be the best approach available both nationally and internationally for reducing the risk of foodborne illness. CAST recommends that HACCP principles be applied from farm or other production sources all the way through consumption.

It should be recognized that HACCP is not a panacea. For example, not detect emerging hazards and no minimum level of safety is guaranteed. Furthermore, the HACCP approach is a dynamic process and refinements and adjustments will continually need to be made as new foodborne hazards are detected and processes are modified. A major limitation to the adoption of HACCP by food processors is that small firms have minimal resources to develop, implement, and maintain effective HACCP programs. Progress is being made at this level, but more resources may be needed to assist small processors in adopting the HACCP system.

Under the current statutory and budgetary constraints, the benefits of HACCP systems cannot be fully realized. For example, current resources are inadequate to continue traditional inspection and to implement HACCP systems fully. A glaring defect in the present USDA meat and poultry inspection is that substantial resources are directed to problems that do not have the greatest health impact, for example, carcass-by-carcass organoleptic visual or water detection, which is involved in the inspection of meat and poultry.

The elimination of continuing inspection of meat and poultry would not necessarily end all anti-and postmortem inspections of carcasses if HACCP programs were appropriately developed and implemented. Such programs would have to include appropriate methods to identify diseased animals which might require some level of carcass inspection as identified by hazard analysis.

An additional impediment to the application of HACCP to reduce the risk of foodborne illness is the failure of many segments of food production to adopt effective intervention strategies that can be used on the farm. When practical and effective intervention strate-

gies on the farm and on-site preharvest levels are made available, food producers should be provided resources where needed and should be required to use such strategies in the interest of enhancing public health.

An overarching impediment to improving efficient and effective regulatory attention to microbiological food safety issues is the major statutory shortfall that exists for our current system. Specifically, they are inconsistent, uneven, and at times archaic food statutes that inhibit the use of science-based decision making in activities related to food safety.

Also, these statutes can be inconsistently interpreted and enforced among agencies. For example, the current directive embedded in statute requires that each meat and poultry carcass be subjected to physical inspection. Although physical inspection may have been appropriate for hazards present 70-years-ago, the process impedes the FSIS efforts to allocate its substantial regulatory resources in ways that correspond to the health hazards presented by contemporary sources of food or modern means of food production and processing, specifically the implementation of HACCP-based inspection.

In short, the hazards of greatest concern today are microbiological contamination and they are not readily detectable with the traditional inspection methods of sight, sound, odor, and touch. This regulatory statute impedes coherent risk-based regulation to enable implementation of a more science-based inspection system now available to regulatory agencies.

Again, I thank you, Mr. Chairman, for this opportunity to comment on this very important issue and I would be happy to answer any questions.

[The prepared statement of Mr. Doyle can be found in the appendix on page 124.]

The CHAIRMAN. Thank you very much, Dr. Doyle.

Let me mention that in introducing all of the witnesses, I neglected to mention that the Director of Food and Agriculture Issues at the U.S. General Accounting Office, Mr. Dyckman, is here, and he has two helpers with him, Mr. Oleson and Mr. Dobbins. I would like to hear now from you, Mr. Dyckman, and then we will proceed with the remainder of the panel of which Dr. Doyle was the first in line. Would you proceed with your testimony?

STATEMENT OF LAWRENCE J. DYCKMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, DC.; ACCOMPANIED BY KEITH OLESON, ASSISTANT DIRECTOR; AND BRAD DOBBINS, SENIOR ANALYST

Mr. DYCKMAN. I am with distinguished company, so I am not at all offended, Senator.

Mr. Oleson, to my left, is the Assistant Director who has done much of the food safety work over the last several years, and Mr. Dobbins from San Francisco also heads the effort that we are doing for you today.

Mr. Chairman, we are pleased to be here today to provide an overview of the food safety expenditures by the Department of Ag-

riculture's Food Safety and Inspection Service and the Food and Drug Administration. FSIS is responsible for ensuring the safety of meat, poultry, and processed egg products moving in interstate and foreign commerce and FDA oversees all other foods and animal drugs and feeds.

As this committee and Senator Hagel requested, we are conducting a review to determine for fiscal years 1998 and 1999 the amount of resources available to both of these agencies, how these resources were spent, and how much States are spending on food safety themselves.

My testimony today presents an overview of our work to date on Federal agencies' expenditures. We have not finished our surveys of the States and will be reporting that to you in our final report.

You have heard a lot of background about foodborne illnesses, so I will not bore you with the details or Senator Harkin. But I just want to repeat that the CDC estimates that there are 76-million illnesses. We took those estimates and we, from a much smaller number of illnesses reported to CDC for which the source of the illness was confirmed, we computed that 85-percent, were associated with food products that FDA regulates and 15-percent with products under FSIS jurisdiction, and I think this has some relevance to the budgets that we will be talking about right now.

FSIS spent about $678 million in 1998 and $712 million in 1999 on food safety activities. Figure 1 in my full statement, and it is on page five, shows that about 84-percent of FSIS's 1999 expenditures were for field activities. Inspections at slaughter, processing, and import establishments accounted for $486 million, or 68-percent of the total agency's expenditures. Field office administration, supervision, and compliance activities accounted for another $34 million. Also, the Office of Field Operations in Washington, DC., the office that manages field activities, spent another $80 million, of which $44 million was in support of State inspections.

FSIS headquarters-based activities accounted for $112 million in 1999 or 16-percent of that agency's dollars. Four offices conduct these activities. There is the Office of Management, which spent about $62 million. Next comes the Office of Public Health and Science, spent about $25 million. The Office of Policy Program Development and Evaluation, about $19 million. And finally, the Office of the Administrator, and they spent about $6 million.

Moving on to FDA's food expenditures, in 1998 and 1999, they spent about $231 and $260 million, respectively, obviously much less than FSIS. As shown in Figure 2, which is on page eight of my full statement, about $146 million, or 56-percent of fiscal year 1999 money, went to field activities. About 44-percent went to headquarters activities involving three centers.

The Office of Regulatory Affairs conducted field activities for FDA centers. Its staff conducts inspections and enforcement activities as well as criminal investigations, education, and outreach activities. For 1999, the office's work for the Center for Food Safety and Applied Nutrition totaled $134 million and work for the Center for Veterinary Medicine totalled about $12 million.

In aggregate, FDA's headquarters' based activities totaled $114 million and the vast majority went to the two centers I just mentioned.

Now, Mr. Chairman, I would like to end with a perspective on some of the reasons for the relative size of FSIS and FDA's food safety budgets. Prior witnesses have touched upon this, but by legislation, FSIS must preapprove products under its jurisdiction before they can be marketed. It operates under a mandated inspection frequency that marks all inspected and approved meat, poultry, and egg products with a USDA inspection stamp so that they can be legally sold.

In contrast, by law, FDA generally allows the food products it regulates to enter the market without preapproval. It has no mandated inspection frequency. As such, FDA inspects food establishments under its jurisdiction about once every 5-years and inspects only 1-percent of the almost 4-million annual imported food entries.

Mr. Chairman, we plan to issue you and Senator Hagel a report in early 2001. We will include information on States and more analysis of these figures.

This completes my prepared statement. My colleagues and I will be happy to answer any questions you or Senator Harkin have.

[The prepared statement of Mr. Dyckman can be found in the appendix on page 109.]

The CHAIRMAN. Thank you very much for your oral testimony, likewise for your very full statement. This is made a part of the record.

Let me mention a procedural problem at this point. I am told, due to objections from Senator Murray and other Democrats on the Senate floor, there has been an objection to committees continuing past the hour of 11:30, which gives us 1-minute. Let me consult with my colleague, Senator Harkin. My idea would be, Tom, to proceed in this way, that we have already put into the record the full statement of all of our witnesses and at 11:30 we will ask the stenographer and court reporter to cease operations, but the two of us might then continue to hear the witnesses and engage in colloquy with them because we appreciate your coming, taking time to come here. Your statements are going to be a part of our record and made available to everybody in a public manner. But at the same time, there may be some benefit to Senator Harkin and to myself from visiting with you informally, as we would be doing. Is that a satisfactory procedure?

Senator HARKIN. As long as we do not get hauled into court someplace.

[Laughter.]

The CHAIRMAN. I think this will suffice. The Committee has faced this problem before and we have usually overcome in about this manner.

We will at this point bring the official hearing to a conclusion. The official hearing is adjourned.

Senator SMITH. Mr. Chairman?

The CHAIRMAN. Yes?

Senator SMITH. Before we adjourn, may I include in the record my opening statement and perhaps a few questions I had for earlier witnesses?

The CHAIRMAN. Yes, we will include that in the official record, Senator Smith's statement and his questions and ask witnesses to respond as rapidly as possible.

[The prepared statement of Mr. Bernard can be found in the appendix on page 128.]

[The prepared statement of Dr. Garren can be found in the appendix on page 134.]

[The prepared statement of Dr. Weber can be found in the appendix on page 139.]

[The prepared statement of Dr. Hollingsworth can be found in the appendix on page 147.]

[The prepared statement of Ms. DeWaal can be found in the appendix on page 153.]

[The prepared statement of Dr. Levinson can be found in the appendix on page 175.]

The CHAIRMAN. Having said that, now we are officially adjourned and we move into an informal session.

[Whereupon, at 11:30 a.m., the Committee was adjourned.]

APPENDIX

SEPTEMBER 20, 2000

Chairman Richard G. Lugar

U.S. Senator for Indiana

Opening Statement - Food Safety Hearing

Today this Committee holds an important hearing to review our food safety system and how it addresses microbial contamination. We will hear from a number of scientific experts and representatives of the federal government and the consumer and public health community.

We are hopeful that today's hearing will help the Committee gather answers to the following questions:

Is microbial contamination the most significant threat to our food safety system?

What are the food safety responsibilities of the federal government and the private sector related to microbial contamination?

What is the value of the Hazard Analysis and Critical Control Points (HACCP) approach to food safety in addressing microbial contamination?

What are the barriers to the development and implementation of new technologies and tools to detect, prevent and reduce microbial contamination?

Are changes needed in the food safety system to aid in the detection, prevention and reduction of microbial contamination?

Obviously not all witnesses will be able to address all of these questions, but we will be interested in hearing different perspectives from each of our witnesses today.

At this hearing today, we look forward to receiving testimony from the Secretary of Agriculture and officials from the Food and Drug Administration and the Centers for Disease Control and Prevention about the responsibilities of the federal government. We will also hear preliminary findings from the General Accounting Office about a food safety resources project that Senators Harkin, Hagel and I requested last year. Finally, we will learn food safety perspectives from representatives of academia and scientific societies, food processors, shippers and suppliers, growers and producers, consumers, and public health organizations.

I welcome our witnesses and look forward to receiving their testimony.

Opening Statement of Senator Tom Harkin
Hearing on How Should our Food Safety System Address Microbial Contamination?
9/20/2000

Thank you Mr. Chairman. Everyone in the food chain – from the farm on through to the table – has a vital stake in our country's food safety and inspection system. The linchpin is consumer confidence. Our food safety system must adequately protect consumers, and it must assure them that their food is safe. If consumers lack confidence in the safety of the food in restaurants and store shelves, they will not be good customers. And that means less demand and lower prices and income for livestock and poultry producers, as well as for packers and processors.

I commend the Chairman for his interest in food safety and for calling this hearing to examine how well our food safety system is addressing microbiological threats. I, too, have had a long-standing interest in food safety. I have introduced several pieces of legislation this Congress to strengthen our food safety system. S.18, the Safer Meat and Poultry Act, would give USDA enforcement options other than its "atomic bomb" authority of withdrawing inspection. S. 823, the Fruit and Vegetable Safety Act, would require all fruit and vegetable processors to meet existing Good Manufacture Practices. And, S. 2760, the Microbiological Performance Standard Clarification Act, would clarify USDA's authority to issue and enforce microbiological performance standards for reducing pathogens. These bills, together, represent solid steps towards a stronger system.

During the past few years with the leadership of the current Administration, we have made good headway in reducing the unacceptable toll of illness and death from foodborne disease. In fact, from 1996 to 1999 the incidence of foodborne disease has fallen 20%. Congress, too, has done its part by working to substantially increase funding for food safety programs.

This success by no stretch means we are finished. Foodborne illness continues to be a major public health threat. We need to continue to make sure our food safety system is up to the challenges before it. We need to continue to make sure we are investing in education and new food safety technologies. And we need to make sure we have a regulatory system in place that is as effective and efficient as possible.

HACCP has gotten us a long way towards a stronger and science-based food safety system, particularly in the meat and poultry industry. This success has been based on the twin goals of enlisting industry to help find the best ways to address food safety risks, and ensuring that food is safer over all by trying to reducing the risks from pathogens on meat and poultry products nationwide.

In the past year, USDA's legal authority to enforce its microbiological performance standards has been seriously challenged. This development directly undercuts USDA's attempt to create a standard based on the logic that reducing the level of pathogens on food nationwide will benefit the public's health.

We need to address this question directly. If we are going to give companies more and more responsibility and authority to run their own food safety programs in a plant, how do we ensure that companies nationwide are reducing pathogens? If we don't have some measure of plant's performance, how do we verify that HACCP is really doing its job? There needs to be enforcement at some point if consumers are to have any confidence in the system. There needs to be some guarantee that plants are being held to some minimum level of performance in reducing pathogens.

There are clearly questions that must be answered. We need to find out how HACCP regulations and Microbiological Performance Standards can best be enforced. How we can best allocate food safety resources to address the food safety risks of greatest public health concern. How USDA and FDA inspectors can best be utilized to ensure the safety and wholesomeness of the products they are responsible for. I don't think any of these questions have easy answers, but we have a responsibility to the public to come up with the best solutions we can.

This hearing should shed light on where we have had successes, and where we need to improve. I am committed to seeking that improvement–to ensuring that we have a food safety system that ensures a safe and abundant supply of food. A system that works for everyone in the food chain, from farm to table.

Remarks by Senator Tom Daschle
Senate Committee on Agriculture, Nutrition, and Forestry
Hearing on Microbial Contamination of Meat
September 20, 2000

Thank you, Chairman Lugar, for convening this hearing to consider the efficacy of our federal food safety system. Food poisoning tragedies in recent years have underscored the importance of enforcing tough food safety standards, and I commend the chairman for his continuing efforts to make America's food supply the safest in the world.

I have been interested in the performance of our food safety system for a long time. As chair of the Agriculture Subcommittee on Agriculture Research in 1993 and 1994, I held a number of hearings on meat and poultry inspection, including a 1993 hearing on the E. coli outbreak in the Pacific Northwest. Recently, I have become very interested in the relationship between improving food safety and S. 1988, a bill to allow interstate shipment of state-inspected meat.

To respond to the challenge of making our food supply as safe as possible, USDA has made dramatic changes in the past decade in the way it inspects meat products and enforces federal food safety standards, including full implementation of HACCP (the Hazard Analysis and Critical Control Point system). Since then, the Center for Disease and Control (CDC) has found that food-borne illness has been cut in half. That is a tremendous success story.

At the same time, challenges remain. USDA is struggling to provide sufficient inspectors to meet the demands of the program. It still lacks the full complement of tools to effectively address all the food safety issues we confront today, and should be given mandatory recall authority. Moreover, questions remain about USDA's authority to set and enforce microbial testing standards. In fact, the recent court decision in Supreme Beef vs. USDA highlighted the issue of micro-testing. And, in July, Senator Harkin offered an amendment to the agriculture appropriations bill to clarify Congress' intent that USDA have the authority to set and enforce standards for pathogen testing of meat and poultry in slaughter and processing plants.
The question of microbial testing encompasses a number of related issues. To understand how the system functions, we need first to break it down into its component parts.

What has struck me about this debate is the considerable confusion that seems to characterize discussions of this topic. For example, the question of <u>whether</u> USDA has the authority to set performance standards can become confused with what the standards <u>are</u>. This, in turn can become confused with the <u>process</u> by which standards have been set. And, <u>whether</u> USDA has the authority to enforce standards can become confused with the question of <u>how</u> it enforces them. Considering these related issues separately helps clarify this debate. It becomes possible to assert that USDA should have the authority to <u>set</u> standards <u>generally</u>, while challenging the standards <u>currently in place</u>. Or, we can agree to support the need to provide USDA with sufficient enforcement <u>authority</u>, while asserting that USDA should change or clarify its enforcement <u>procedures</u>.
I hope to hear this morning that microbial testing of meat, as part of the HACCP system, is a beneficial tool, independent of plant sanitation.

In other words, it is possible to find pathogens on meat in a plant that has no detectable sanitation problems. Such a plant should not necessarily be penalized for meat that tests positive for pathogens. *But neither should excessive levels of pathogens be disregarded simply because their origin is not linked to plant sanitation.* The threat that food-borne pathogens pose to human health is not lessened by our inability to trace their origin -- they are just as deadly, they are an invaluable indicator of a weak link in the system, and their detection should prompt USDA to work with the packers or slaughterhouses to identify the cause or source, and eliminate it. Pathogen testing is *very* useful, and is absolutely necessary if we are to have confidence in our food supply.

The other issue I hope we can explore today is whether USDA should enforce standards. There are two questions embedded here: 1) what a standard should be, and 2) how a standard should be enforced. The concerns I have heard are a blend of dissatisfaction with the current standards, and fear over how USDA *might* enforce standards in the future.

The fact is that we need more data to determine where it is most appropriate to set standards. While we have abundant evidence showing that food-borne pathogens are a distinct threat to human health, is my understanding that scientists and regulators do not have the data they need to precisely gauge the relationship between pathogen presence and risk to human health. We need that data – it will both improve our ability to protect public health, and minimize the regulatory burden we impose on packing plants. I hope that we all can agree that we should encourage much more research on this topic in the future. Until then, we have no choice but to continue to do the best we can with what we have, which is a standard keyed to average performance by species.

With regard to fears related to enforcement, I urge my colleagues to consider USDA's record in enforcing the existing standard. The Supreme Beef case provides a good case study. It illustrates that USDA does not withdraw inspectors -- and effectively shut plants down -- based on micro-testing performance. In fact, in the Supreme Beef case, USDA tried to work with Supreme Beef for nearly a year before withdrawing inspectors. It only resorted to that step when Supreme Beef became completely recalcitrant, effectively disregarding the risk they were posing to the public. Over nearly a year, Supreme Beef failed three sets of *Salmonella* tests, and eventually tested positive for the fatal E. coli 0157:H7. One might say the public would be justified in asking what took USDA *so long*.

If a packing plant supplying the public refuses even to try to reduce pathogens in their product, I question the good sense of anyone who wouldn't want USDA to withdraw inspectors at that point. Moreover, I can't understand how anyone can seriously argue that USDA intends to misuse the micro-standard as a arbitrary litmus test. The agency has no record of doing so. It may be reasonable however, for Congress to more clearly delineate the enforcement process, so packers will know what to expect.

Last November, I introduced S. 1988 with Senator Hatch. We have 22 cosponsors, Republicans and Democrats. The bill is supported by a wide range of groups, including the National Farmers Union, the American Farm Bureau Federation, National Cattlemen's Beef Association, National Pork

Producers Council, American Sheep Institute, American Association of Meat Processors, and National Association of State Departments of Agriculture, among others. It is opposed by the bigger packers, the processors, and the Chicken Council. The reason I mention the legislation amid remarks on food safety is that for the first time in thirty years this idea is supported by consumer and food safety groups. The bill also enjoys a number of first-time Senate cosponsors. Their support is due in large part to the fact that the uniform testing for pathogens in end-products called for by the bill, will increase the reliability of our overall food safety system.

It should be noted, however, that this uniformity is also a trade issue. Being able to assure that all of our exported product is subject to uniform inspection, and that USDA is accountable for the performance of plants in that system protects our producers from potential trade barriers thrown up by other countries. If they can argue that our exports are inspected in systems that they have not specifically approved, then they could have grounds to reject not just some, but all of our product. Therefore, while the uniformity requirement attracts the support of the consumer and food safety groups, it is necessary to protect access to foreign markets.

In conclusion, I want to reiterate my support for the HACCP system, my support for pathogen testing in slaughter and packing plants, and my support for the use of specific standards and enforcement authority employed similarly to USDA's current practices. We should take this opportunity to explore ways to do even better.

In particular, I hope that we can:

- Provide USDA with mandatory recall authority;
- Improve upon current standards with better data;
- To the extent possible, correlate micro-testing results with public health indicators; and
- Ensure that we never use this inspection system punitively.

In the end, we need a food safety system that instills confidence in the public by achieving results. When a plant has a problem, USDA should work with the plant to fix the problem on an expedited basis and thereby protect the public health. But in the case of the rare "bad actor," I hope we can agree that USDA should have the authority to withdraw inspectors as a last resort.

Again, I thank the chairman for holding this hearing and I look forward to hearing the testimony.

Statement by Senator Pat Roberts
Food Safety Oversight Hearing
Senate Committee on Agriculture
September 20, 2000

Pat Roberts

Mr. Chairman, thank you for having this oversight hearing today on the food safety programs of the United States government.

There is no doubt that our consumers demand and expect a safe food supply. And while it is inevitable that we will at times face concerns over food safety and experience a recall, it is important to remember what we have here in the United States. We have the safest and most dependable food supply in the world. That does not mean we cannot and should not do more. Any food borne illness is one too many. But as a whole, I believe those of us living in the U.S. are very lucky.

I appreciate the insight being provided today by the strong panel of witnesses you have put together. Mr. Chairman, as always, you have gone out of your way to make sure all sides of the issue are represented. It is important that we receive the testimony and comments of these witnesses. Our constituents demand strong oversight over our food safety programs, and they expect us to take steps to strengthen those programs when needed. At the same time, in our zest to guarantee a safe food supply, we need to be sure we do not make knee jerk reactions and pass legislation that may be punitive in nature but which does little to actually improve the safety of our food.

Mr. Chairman, I believe that we will be asked to look at many food safety issues during the next Congress. Today's hearing gives us the opportunity to get a head start on those activities. I thank you for holding this hearing.

When I became the chairman of this Committee back in 1987, I introduced a major food safety bill called the "Safe Foods Standards Act." This introduction was met by thundering silence.

It contained provisions on pathogen reduction, microbiological monitoring, safe food handling labels, research on rapid tests for pathogens, traceback rules, consumer education, and much more.

I ended up with a total – after two years – of NO cosponsors.

There is a famous line from Carl Sandburg:

Sometime they'll give a war
And nobody will come.

It reminds me of that bill.

A lot has changed since then. Now there is broad bipartisan – and bicameral – support for food safety initiatives and most of the Members of this Committee have taken a very active part in these matters.

So has the Administration. Two days before Secretary Espy took office there was a major food poisoning outbreak in Washington State – and children ended up dying from eating undercooked hamburgers. Secretary Espy called for pathogen reduction programs, safe food handling labels, rapid tests for pathogens, consumer education, and lots more.

Secretary Glickman continued this approach and has done a great job – against some significant obstacles – in making America's food supply the safest in the world.

We all agree, whether the victims are kids eating undercooked, tainted meats, or the elderly eating contaminated fruits and vegetables - the government has to keep a constant vigil for new and better techniques to inspect the food that gets to market--and to our kitchen tables.

Every Vermonter, every American, has the right to be secure in knowing the food they put on the table for their families is nutritious and safe for their families.

When USDA was created, over half the U.S. population lived and worked on farms. President Lincoln called USDA the "people's Department" for just that reason.

Today, less than two percent live on farms - but now USDA has major responsibilities to 270 million consumers.

All consumers demand a safe food supply and it's in part our responsibility to ensure that the government is doing all it can in this area.

America has to be ever vigilant for new contamination threats. While biotechnology offers hope for new medicines and a promise for agriculture it also presents new risks such as allergic reactions – which could be fatal – to consumers.

For example, this week's newspapers were filled with stories about a genetically modified version of corn which was not intended for human consumption that found its way onto supermarket shelves.

While you can sometimes smell tainted fish, or sour milk, American families have no way to know if improperly controlled genetic modification has put potentially harmful

allergens in their evening meal.

I would like to know what the agencies are doing to address this immediate situation with Taco Bell taco shells and to prevent these types of risks in the future.

UNITED STATES DEPARTMENT OF AGRICULTURE

STATEMENT OF DAN GLICKMAN, SECRETARY

BEFORE THE SENATE COMMITTEE ON AGRICULTURE,
NUTRITION AND FORESTRY
SEPTEMBER 20, 2000

Introduction

Mr. Chairman and Members of the Committee, I am pleased to have the opportunity to discuss the measures that the Department of Agriculture and the Food Safety and Inspection Service (FSIS), are taking to improve food safety, modernize our regulations, wisely utilize our resources, and maintain consumer confidence. Several years ago, we began a journey of change, modernization, and improvement regarding meat and poultry safety and inspection. While the journey continues, considerable progress has been made.

Under the leadership and commitment of President Clinton and Vice President Gore, this Administration has made great strides in improving food safety. In five and a half years, I have presided over many food safety accomplishments. First, when we reorganized the Department in 1994, we created a separate food safety mission area to ensure an arms-length regulatory system that is independent of our market promotion activities. As you know, since 1996, we have been in the process of replacing antiquated food safety regulations with the Pathogen Reduction and HACCP rule. This new science-based meat and poultry inspection system is the first modernization of the meat and poultry regulations since 1906 and it is helping to reduce outbreaks of foodborne illnesses. We have also overseen the creation of FORC-G and I am proud to serve as a Co-Chair on the President's Council on Food Safety, along with Health and Human Services Secretary Shalala and Neal Lane, Director of the White House Office of Science and Technology Policy. We have also played an important role in the formation and support of FoodNet and are key supporters of the Partnership for Food Safety Education.

Our food safety goal is to achieve the greatest possible reduction in the risk of foodborne illness associated with the consumption of meat, poultry, and egg products, consistent with available science and technology. Toward that end, we are applying resources in a prudent manner to make fundamental changes in industry responsibilities and FSIS inspection. We also want to build on our partnerships with other Federal agencies, the States, industry, consumer groups, academia, our employee organizations, and other interested segments of the public.

USDA Responsibilities

USDA's Food Safety and Inspection Service has a long, proud history of protecting the public health. Our mission is to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and accurately labeled, as required by the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).

FSIS provides inspection at approximately 6,000 plants that slaughter cattle, swine, sheep, goats, horses, chickens and turkeys, or that process a wide range of products including hams, sausage, stews, eggs and frozen dinners. In FY 1999, our domestic inspectors examined approximately 155 million carcasses in livestock slaughter plants, 8.4 billion carcasses in poultry slaughter plants, and 3.4 billion pounds of egg products for public consumption. To ensure the safety of imported products, FSIS maintains a comprehensive system of import inspection and controls. Annually, we review the equivalence of all foreign inspection systems in countries eligible to export meat and poultry to the U.S. Last year, during in-country reviews, we visited 265 foreign establishments and 33 foreign laboratories.

Reducing Threats to Public Health

Our food safety programs are designed to reduce all types of hazards in the food supply, whether they are chemical, physical, or microbiological. In recent years, we have emphasized the reduction of and control of pathogens that contribute to an estimated 76 million cases of foodborne illness reported by the Centers for Disease Control and Prevention. Pathogens cause foodborne illness and can have high fatality rates with illnesses such as listeriosis. This does not mean that we have ignored other hazards. FSIS continues to operate a strong residue control program to address chemical contamination, and continues to conduct inspection to remove diseased and unwholesome animals. These programs have been very successful and are recognized worldwide. And they need to continue, as scientists worldwide recognize that many of the newly emerging foodborne illnesses will be zoonotic – passed from one species to another – including from animals to humans. But experts agree that pathogens are the most serious threat to public health associated with food, and certainly with respect to meat and poultry products.

That is why, over the past six years, we have redesigned our food safety programs to target microbial pathogens. Organoleptic inspection – inspection by sight, touch or smell – is not sufficient in reducing these threats. Requiring plants to implement science-based preventive control systems targeted to meet performance standards set by FSIS, and conducting microbial testing to ensure those standards are met, has proven to be the best strategy. This approach, accompanied by a farm-to-table strategy that strives to reduce and control pathogens before animals reach FSIS-inspected establishments and after products leave the plant and enter consumer channels, has given us the best chance to reduce foodborne illness and strengthen consumer confidence.

We are not by any means ready to claim victory. The greatest possible reduction of microbiological contamination remains a challenging goal for a number of reasons. First, efforts to reduce microbial pathogens must constantly adapt to new technology, new research and emerging and evolving pathogens. In other words, addressing microbial pathogens is a continual, evolving process. Second, they can multiply or be introduced after a meat or poultry product leaves the federally inspected plant, particularly if a product is mishandled during transportation, storage, or in the home. That is why we are taking a farm-to-table approach.

Pathogen Reduction Strategy

Our pathogen reduction strategy is not a "one size fits all" strategy. We have developed different approaches based on a number of factors, including the individual pathogen and the risk it poses, the

type of the product relative to how much processing it has received and what degree of additional preparation it will receive that will affect pathogen loads. Our strategy is also highly dependent on the degree of technological development that exists relative to pathogen reduction. As research provides better and faster testing methodologies and effective risk assessment and risk management strategies, we can adjust our pathogen reduction strategies accordingly. With additional research and testing, for example, much more may be possible on the farm or ranch, earlier in the farm-to-table continuum.

Raw Products

For raw products, our goal has been to reduce levels of contamination of key pathogens to the greatest extent possible. Thus far, we have chosen to establish pathogen reduction performance standards for *Salmonella* because it is a major pathogen of concern, is present on virtually all classes of raw meat and poultry products in numbers large enough to detect, and effective methods are available to test for the pathogen. Studies show that technologies that reduce the prevalence of *Salmonella* on carcasses would lead to a reduction in other pathogens as well. Repetitive failures to meet the performance standard is an indicator that the plant's HACCP plan is not adequate.

The *Salmonella* performance standards provides an incentive for producers of raw meat and poultry products to establish and maintain HACCP plans that reduce and control the prevalence of *Salmonella* on their products. The pathogen reduction performance standards are based on FSIS baseline surveys on the prevalence of *Salmonella* in raw products. FSIS conducted a number of baseline surveys in order to determine the prevalence of various pathogens in various products. In addition, over time, baseline profiles for meat and poultry provide a basis for measuring the effectiveness of changes in slaughtering and processing procedures on microbial contamination of raw products. Establishments must achieve the applicable performance standard consistently through appropriate and well-executed controls. The *Salmonella* pathogen reduction performance standards in the HACCP regulation apply a uniform policy principle: all slaughter and ground product plants must achieve at least the industry baseline level of performance with respect to *Salmonella* for the product classes they produce. This approach encourages progress on pathogen reduction across all species.

The data we have collected since HACCP implementation has proven our strategy effective and fair. It is significant that if we were setting the performance standards today, they would be substantially lower than those originally established. Plants have made significant progress in reducing the prevalence of *Salmonella* in raw products. I want to commend the industry for its efforts. I will discuss our data in greater detail shortly to show our pathogen reduction efforts are working.

We intend to reassess whether these standards should be tightened, and whether there are additional pathogens for which pathogen reduction performance standards should be set. In fact, in October, we will complete a baseline survey on *Campylobacter* in poultry, and will begin the process of deciding whether to develop performance standards for that pathogen.

Ready-to-Eat Products

Our strategy for ready-to-eat products differs considerably from our strategy for raw products, because consumers may not apply additional cooking steps to kill pathogens. The performance standards we have established for ready-to-eat products are not pathogen reduction performance standards, but are designed to remove unsafe, adulterated products from the marketplace. In this case, the presence of a pathogen means the process to render the product ready-to-eat has failed or the product has been recontaminated.

FSIS began testing ready-to-eat products for *Salmonella* in 1983 and *Listeria monocytogenes* in 1987. The following product categories are included in the *Listeria monocytogenes* and *Salmonella* monitoring programs: (1) sliced ham and luncheon meat, (2) roast beef, cooked beef, and cooked corned beef, (3) small-diameter cooked sausage, (4) large-diameter cooked sausage, (5) cooked, uncured poultry, (6) salads and spreads, (7) dry and semi-dry fermented sausage, and (8) beef jerky.

Plants are encouraged to hold products targeted for *L. monocytogenes* and *Salmonella* testing by FSIS until results are available so that potentially contaminated products do not reach consumers. However, in the event that FSIS discovers a positive sample and the product was not held by the plant, FSIS requests that the plant voluntarily initiates a product recall. In addition, when a positive sample is found, FSIS conducts follow-up testing of products produced by the plant. Monitoring samples is one method FSIS uses to verify compliance with our regulations.

Special Requirements for *E. coli* O157:H7

There are exceptions to our basic strategy to address pathogens in raw and ready-to-eat products. *E. coli* O157:H7 in ground beef and other non-intact beef products are examples. This pathogen presents unique public health concerns with the consumption of certain beef products. Thus, FSIS declared it an adulterant in raw ground beef in 1994. FSIS expanded this designation to other non-intact beef products in January of 1999 based upon new scientific data. This is the first and only time that a pathogen has been declared an adulterant in raw meat and poultry products. This action was taken because of the nature of the pathogen and the manner in which the product is prepared by consumers. Studies by the Agricultural Research Service and industry demonstrate that the organism is far more prevalent than previously understood and HACCP-based processing technologies can significantly reduce contamination. To further prevent *E. coli* O157:H7 related illnesses, we advise consumers to use a thermometer and cook ground beef to an internal temperature of 160 degrees F, consistent with our farm-to-table strategy.

Our experience with *E. coli* O157:H7 is a good example of why a "one size fits all" policy does not work for pathogen reduction.

Role of HACCP

HACCP is the centerpiece of our pathogen reduction strategy because it provides a framework in which industry can develop and implement controls to eliminate or reduce and control hazards. Under this system, each meat and poultry plant is responsible to identify all food safety hazards reasonably likely to occur in its operation, taking into account all hazards—microbiological, chemical, and physical. The plants then establish critical control points, at which steps are taken to

prevent, reduce or control hazards. HACCP and performance standards go hand-in-hand—HACCP provides a system for preventing and controlling foodborne hazards, and the performance standards provide a benchmark that the HACCP system must achieve.

Industry began HACCP implementation in 1998 based on plant size. The completion of very small plant implementation in January 2000 brought 100 percent of U.S.-inspected meat and poultry products under the HACCP system. We are seeing significant reductions in *Salmonella* prevalence for large and small plants. We expect to see similar results from HACCP at the very small plants. HACCP is clearly working to achieve our food safety goals.

***Salmonella* Data**

With the PR and HACCP rule, the prevalence of *Salmonella* on raw products has been substantially reduced. All categories tested showed a marked decrease. For example, *Salmonella* has been reduced on chicken carcasses by more than 50 percent and by one-third on ground beef. The prevalence on ground turkey is also very impressive - a nearly 40 percent reduction. These products account for the majority of domestic production. Industry has clearly risen to meet the challenge, with the result being safer food for Americans. One of the strongest aspects of HACCP is that it provides for constant improvement. As hazards change and new hazards become known, plants must adjust their plans accordingly.

Prevalence of *Salmonella* in meat and poultry products: Post-HACCP implementation results from large and small plants from July 1, 1999, through June 30, 2000

Class of Product	Pre-HACCP Baseline Studies	Post-HACCP implementation *Salmonella* Prevalence (%) n=number of samples
Broilers	20%	9.9% (n=9,231)
Hogs	8.7%	7.7% (n=3,685)
Cows and Bulls	2.7%	1.6% (n=1,450)
Steers and Heifers	1.0%	0.2% (n=902)
Ground Beef	7.5%	5.0% (n=9,010)
Ground Turkey	49.9%	30% (n=901)

HACCP - The Next Steps

Now that initial HACCP implementation is complete, FSIS is developing a strategy to improve the quality and effectiveness of HACCP. We are exploring ways to improve the quality of industry's HACCP programs. In addition, we must improve the effectiveness of FSIS under HACCP.

For example, we are seeing a large range in the quality of HACCP plans, ranging from excellent to poor. We are exploring options to address this problem and have asked industry organizations for

assistance. Another problem we are seeing involves our own inspection force. Some of our inspectors need more training to better understand and evaluate the hazard analysis process, for example. Also, we must address how inspectors evaluate the various data generated through HACCP and how FSIS uses the data to determine whether a plant's systems are working as intended.

We also must refine what is addressed under HACCP versus other plant process control and quality assurance systems. As I mentioned, HACCP can be adapted to new food safety concerns. As part of these next steps, we are exploring how plants can best prevent *Listeria monocytogenes* in ready-to-eat products. FSIS is also looking at the broad subject of residue monitoring and control by slaughter plants in a HACCP environment. A public process will be used to explore and develop our strategy.

We are developing a HACCP-based Inspection Models Project (HIMP), that tests whether alternative models of inspection can do a better job than our traditional inspection system. The results to date are encouraging and show that we can develop a model of inspection that will significantly improve public health and other consumer protections. I want to emphasize that the models project will only proceed if there continues to be objective data that shows it works at least as effectively than the traditional inspection system. HIMP is not about lowering standards or cutting back on inspectors. It's about finding better ways to protect the public, and having the data to ensure continued consumer confidence.

Risk Assessments

In addition to improving the effectiveness of HACCP, another way we are improving our ability to address pathogens is by relying more heavily on microbial risk assessments. Regulatory agencies seldom have all the information needed to make policy decisions and often are forced to make decisions based on the best scientific information available at the time. Risk assessment helps to organize scientific information in order to characterize the nature and likelihood of harm to the public. Such assessments also are tools to help target risk management strategies.

Over the past several years, Federal agencies have made great strides in the science of microbial risk assessment. It has taken some time because there are many challenges in applying risk assessment methods to microbial pathogens. One challenge relates to the fact that unlike chemical contaminants, bacteria can multiply and produce toxins as conditions change. In addition, we have many data gaps currently that limit the precision we can achieve through risk assessments.

Despite these challenges, we are making good progress. In 1998, we completed a risk assessment on *Salmonella Enteritidis* in eggs and egg products. We are close to completing a risk assessment for *E. coli* O157:H7 in ground beef, and FDA has taken the lead on a joint agency risk ranking of *Listeria monocytogenes* in ready-to-eat products.

With the information contained in these risk assessments, Federal agencies that set food safety policy can establish better performance standards and better determine where to apply their resources to get the best return in terms of public health improvement.

Farm-to-Table Strategy

I would like to turn from in-plant improvements to what we are doing farm-to-table. Food safety experts, including the National Academy of Sciences and the National Advisory Committee on Microbiological Criteria for Foods, agree that pathogen reduction requires a farm-to-table approach. While HACCP is designed to address and achieve improvements at the plant level, additional initiatives at other points in the food production chain are also needed. FSIS has already begun a number of projects to address these other points, including encouraging industry to develop on-farm pathogen prevention models, working with the Food and Drug Administration (FDA) on the retail Food Code, which is a model code for all retail and food service operators, and requiring safe handling instructions on products for consumers. Now that initial HACCP implementation has been completed in U.S. slaughter and processing facilities, FSIS has the opportunity to make further progress in implementing other aspects of its farm-to-table strategy.

USDA supports research and educational activities that promote the adoption of voluntary, industry-implemented food safety and quality assurance programs that improve food safety at the farm, and we recently co-sponsored a very successful conference in St. Louis, Missouri, on animal production food safety.

With HACCP clarifying industry responsibilities for food safety, slaughter plants are focusing more on the potential hazards in incoming animals while developing and executing their HACCP plans. This is already affecting the relationships between producers and their customers, the packers, by providing producers with an incentive to address food safety.

Our intent at FSIS has been to provide information to all producers about HACCP and how its implementation might affect their ability to market their animals for slaughter. For example, we have provided information on residue avoidance through adoption of quality assurance practices and programs. As small producers have fewer resources, FSIS is providing more attention to assisting them with applying HACCP concepts to their operations, as well as working closely with State agencies and local extension offices.

We have a steep learning curve when it comes to finding ways to reduce pathogens. We recognize that reducing pathogens in animals is a significant challenge. Scientific information is lacking to demonstrate what is routinely effective and economically feasible at the production stages to reliably eliminate or at least substantially reduce pathogens on carcasses. We must develop plans based on the best information we have today and update them as new scientific information becomes available.

New Technology

FSIS encourages research that will lead to new technologies to better enable plants to meet FSIS-established performance standards, as well as to help both industry and government to rapidly, accurately, and inexpensively detect pathogens. Examples of technologies that help to reduce or eliminate pathogens are steam vacuuming, steam pasteurization, and TSP washes. Aseptic packing systems are another example of technologies that help prevent the introduction of pathogens.

The Agency recognizes that in order to foster innovation, it cannot be an obstacle, so FSIS reviewed its policies and procedures governing new equipment and in-plant technologies and eliminated many burdensome requirements. As a result, we approved many new technologies this year. For instance, FSIS approved the use of irradiation for meat products and also provided for the use of certain food additives (Sodium Acetate, Sodium Lactate, and Potassium Lactate) to inhibit the growth of pathogens, like *Listeria monocytogenes*. Neither food additives nor irradiation alone are the answer – no one tool or technology is – but, used properly, they provide additional opportunities for an increasingly safe food supply.

FSIS also recognizes that for technology to be most beneficial, it must be accessible to all. Although new technology is almost always designed for large plants, FSIS is placing special emphasis on seeing new technologies adapted so they can be used economically in small and very small plants.

Future Technology Needs for FSIS

FSIS has held three scientific and technical conferences and one public meeting to discuss the need for new technology that can assist the Agency meet its goal for reducing foodborne illness and protecting the public health.

Because microbial performance standards are taking on heightened importance, the Agency and industry need new microbial detection technology for use in our laboratories. Quantitative detection methods are needed that are practical, inexpensive, sensitive, and that provide rapid results, as are methods that can detect more than one pathogen. In addition, the potential for on-line detection in slaughter and process plants needs to be developed. Similar new technologies are needed for chemical residues.

Partnerships for Increased Food Safety

In striving for a seamless farm-to-table food safety system, we are forging ties between animal producers and slaughterhouses and are looking more closely at our role once product leaves federally inspected establishments. Hand-in-hand with this, we are strengthening ties with our state and local counterparts. USDA also is interested in ensuring that its policies and procedures are as consistent as possible with the other Federal bodies regulating food safety.

We are working closely with FDA on a number of issues including streamlining the approval process for food ingredients, such as food and color additives, and sources of radiation, by ending the requirement that they be approved separately by both the FDA and FSIS. Previously, once FDA approved a food ingredient, FSIS had to conduct separate rulemaking in order for it to be approved for use in meat or poultry. This is the latest in a series of regulatory reform initiatives published by the Agency to: (1) improve food safety, (2) make regulations less burdensome and easier to use, (3) make regulations more consistent with Hazard Analysis and Critical Control Point (HACCP) Systems, and (4) eliminate outdated regulations.

Another joint effort with FDA was last year's Memorandum of Understanding to facilitate the exchange of information at the field level about food establishments and operations that are subject to the jurisdiction of both agencies. District offices of each Agency will notify their counterparts of food safety recalls, instances of product contamination and mislabeling, and conditions at facilities that could result in unsafe or unwholesome food.

In an effort to facilitate information exchanges with the Centers for Disease Control (CDC), we placed an FSIS employee in CDC's Atlanta office. In return, CDC placed one of its employees at FSIS' headquarters.

To educate consumers about cooking foods to the correct temperature and promote the use of food thermometers in the home, I announced the kick-off of the ongoing "Thermy" national campaign in May. The campaign features a cartoon thermometer called "Thermy" that proclaims, "It's Safe to Bite When the Temperature is Right."

Conclusion

Though we have made tremendous gains over the last several years, we are not content to sit back and congratulate ourselves. As long as anyone is getting sick from the products we regulate, there is room for improvement. We will continue to take whatever steps are necessary to improve the safety of meat, poultry, and egg products and look forward to working with Congress, other government agencies at the Federal, State and local levels, industry, and consumers, to do so.

STATEMENT OF

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DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

UNITED STATES SENATE

SEPTEMBER 20, 2000

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Mr. Chairman and Members of the Committee. I am Joseph A. Levitt, Director of the Center for Food Safety and Applied Nutrition in the Food and Drug Administration (FDA or Agency). Thank you for this opportunity to discuss how our food safety system should address microbial contamination. As you know, food safety has been a top priority for this Administration. I am pleased to be here today representing my FDA colleagues at our Office of Regulatory Affairs, Center for Veterinary Medicine (CVM), and National Center for Toxicological Research, and to be here with my colleagues from the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA).

It is especially appropriate that you are holding this hearing now as September is National Food Safety Education Month. This year's theme is as follows: Be Smart. Keep Foods Apart. Don't Cross Contaminate. The goals of the Month are to reduce microbial contamination and prevent foodborne illness by reinforcing food safety education and training among restaurant and foodservice workers and by educating the public on how to handle and prepare food safely at home. This year's theme reinforces the simple messages of washing hands, cutting boards, utensils, and dishes with hot soapy water and of keeping raw meats, poultry, seafood, and eggs separate from

prepared or ready-to-eat foods.

The key methods for addressing microbial contamination and preventing foodborne illness are through surveillance, education, research, risk assessment, outbreak containment, and improved inspections and compliance. The Federal food agencies, in cooperation with our State and local government partners and with private partners, have been working vigorously and successfully on all these fronts. I will describe some of FDA's activities in these areas below.

THE PROBLEM

CDC has estimated that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States (U.S.) each year. There are many reasons for this. People are eating a greater variety of foods, particularly seafood and fresh fruits and vegetables. As many of these foods are becoming available all year round, safety concerns associated with transportation and refrigeration arise. The rising amount of imported foods increases dramatically the number of potential sources of food contamination. People are eating more of their meals away from home. In fact, fifty cents of every food dollar is spent on food prepared outside the home. As more food workers become involved in preparing our meals, the opportunity for disease-causing errors also increases. This problem is especially

important for persons at greatest risk who eat foods prepared in hospitals, nursing homes, and daycare centers. Indeed, persons at highest risk for foodborne illness -- children, the elderly, pregnant women, and immuno-compromised persons -- now comprise nearly a quarter of the population.

Other important changes, however, are the emergence of new foodborne pathogens and the ability of existing pathogens to overcome traditional food safety barriers such as temperature and acidity. We are aware of more than five times the number of foodborne pathogens now than we were in 1942. Many of these pathogens can be deadly, especially to those at highest risk. A strong scientific foundation is critical to meeting these challenges and continuing to ensure the safety of the food supply.

THE FOOD SAFETY INITIATIVE

While there are many challenges, there are also many successes. The American food supply continues to be among the safest in the world. To reduce the incidence of foodborne illness due to microbial contamination to the greatest extent possible, President Clinton launched the Food Safety Initiative (FSI) three years ago. Thanks to the budgetary support provided by Congress, this multi-agency effort has successfully built a strong foundation for a state-of-the-art, science-based food

safety system and has promoted partnering among the key Federal agencies, States, academia, industry, and consumers. This foundation constitutes the main building blocks of an effective food safety system that will drive future progress for years to come. These building blocks are the surveillance systems that have been put in place -- FoodNet and PulseNet through CDC and the National Antimicrobial Resistance Monitoring System (NARMS)-- and preventive controls such as Hazard Analysis and Critical Control Point (HACCP) systems.

In just three years, FSI has resulted in tremendous achievements. The risk of foodborne illness and death related to microbial contamination of both domestic and imported foods has decreased dramatically for a number of pathogens. CDC published data this March that reflect a 20 percent decrease from 1997 to 1999 in illness due to the most common bacterial foodborne pathogens. Foodborne outbreaks have been contained more quickly, thus preventing illness. Research conducted with FSI funding has led to significant advances in our ability to detect or eliminate pathogens. As noted, numerous interagency and Federal/State partnerships have been formed to more efficiently utilize our collective resources. I have provided information about some of these partnerships in an appendix to this statement. These partnerships include: the Joint Institute for Food Safety Research (JIFSR), the Foodborne Outbreak Response Coordinating Group (FORC-G), the Risk Assessment Consortium (RAC), the National Food Safety System,

and the Partnership for Food Safety Education.

FDA'S FOOD SAFETY PROGRAM

I would like to highlight actions FDA has taken to address microbial contamination. FDA has jurisdiction over 78 percent of domestic and imported foods that are marketed in interstate commerce. As you know, the Agency regulates all food products except for meat, poultry, and egg products, which are regulated by USDA. We seek to ensure that these products are safe, nutritious, wholesome, and adequately labeled. Our jurisdiction is extensive and includes places where food is produced, processed, packaged, stored, or sold.

Prevention

If we are to make significant progress in reducing foodborne illness, prevention is the key. Prevention is a combination of better understanding of the risk and potential sources of contamination, increased training, education, and development of systematic preventive controls, including HACCP.

HACCP

An important method for reducing the risk of microbial contamination is the HACCP approach. HACCP is a systematic approach to the identification and control of the biological,

chemical, and physical hazards associated with a particular food production process. There are a vast array of microbiological and chemical contaminants that have the potential to affect the safety of foods. However, for any particular food, there are only a few specific hazards that must be controlled to ensure a safe product. HACCP is a risk-based, food safety management system that helps food manufacturers determine which hazards are reasonably likely to affect their products and then to develop safety assurance programs targeted to the specific steps that must be controlled to safeguard consumers.

Over the course of the past 30 years, HACCP has been adopted by numerous industry and regulatory agencies worldwide as it is a focused, flexible, verifiable, and cost effective approach. As HACCP systems place an emphasis on prevention, they significantly reduce the possibility that the end product will contain illness-causing hazards.

FDA has been applying HACCP principles for many years, beginning with the 1979 low-acid canned food regulations. FDA implemented seafood HACCP in 1997. In 1998, FDA proposed HACCP for fruit and vegetable juices. FDA has incorporated HACCP into its Food Code, a guidance document that serves as model legislation for state and territorial agencies that license and inspect food service establishments, retail food stores, and food vending operations in the U.S.

FDA's HACCP requirement for seafood went into effect in December 1997. It requires all 4,100 seafood processors, covering 150 species of fish, to implement complete HACCP systems. Beginning in 1998, our goal has been to inspect domestic seafood processors annually. Now in its third year, we are seeing across-the-board progress by the seafood industry. But not everywhere, as we have just completed our first enforcement action, and additional actions will be considered as inspectional findings are reported. We are also in the final stages of completing an evaluation of our seafood HACCP program and would be happy to share the results with the Committee upon completion.

To help ensure effective implementation of the HACCP system, FDA continues to train and assist the seafood industry. For example, FDA published the "Fish and Fishery Products Hazards and Controls Guide." The guide is being used worldwide, both by industry and by foreign regulatory authorities, and is becoming an international standard. The training requirements in our regulations were the catalyst for the creation of the Seafood HACCP Alliance to provide low-cost, uniform training to industry on seafood hazards and controls and the application of HACCP.

Fresh Fruits And Vegetables

In 1998, FDA issued a guide for growers, packers, and shippers of fresh fruits and vegetables. The "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" provides science-based guidance to help reduce microbiological hazards common to the growing, harvesting, washing, sorting, packing, and transporting of fruits and vegetables. This guide was produced in consultation with USDA and has been published in four languages. We have conducted numerous training sessions on the guidance for domestic and foreign government and industry officials. We also produced and distributed a video that provides an overview of the practices outlined in the guidance.

In 1998, due to increasing numbers of foodborne illness outbreaks associated with unprocessed juices, FDA published a proposed rule that would require processors and importers to apply HACCP principles to ensure the safe and sanitary processing of fruit and vegetable juices. FDA believes the most effective way to ensure the safety of juice products is to implement a system of preventive controls based on HACCP principles. The Agency is currently in the process of finalizing this regulation.

Pending finalization of the HACCP requirement, FDA implemented

a warning statement requirement on unprocessed juices as an interim measure. The purpose of the warning statement is to advise vulnerable persons that the unprocessed juice may cause serious illness. The warning statement allows at-risk persons to avoid potentially dangerous products.

Last year, in response to several foodborne illness outbreaks associated with sprouts, FDA issued a warning to consumers of the potential hazards associated with eating raw sprouts and issued guidance documents for the sprouts industry. These documents, "Reducing Microbial Food Safety Hazards for Sprouted Seeds" and "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" advise sprout growers and seed suppliers of the steps they should take to reduce microbial contamination.

In addition to issuing the guidance documents, FDA and the California Department of Health Services produced and are distributing an educational video on good agricultural and manufacturing practices for sprout producers. To assess the extent to which the sprout industry is following the recommended practices, we issued a special assignment this year to inspect 150 sprout producers. FDA is also working with academia and the sprout industry on research to identify techniques to prevent contamination.

Egg Safety

In coordination with USDA, FDA is implementing an Egg Safety Action Plan to reduce the incidence of *Salmonella enteritidis* (SE) illnesses. While eggs are an important source of protein in the diet, an estimated one in 20,000 eggs in the U.S. contains the SE bacteria and can cause illness if eaten raw or not thoroughly cooked. The Egg Safety Action Plan is a comprehensive nationwide strategy to address this important food safety and public health concern.

The President has set a goal of reducing SE illnesses associated with eggs by 50 percent by the year 2005. We have been working closely with our Federal partners, with Congress, the industry, and consumer organizations to develop a workable plan to achieve this goal. In addition, FDA will establish final regulatory standards on temperature storage and egg safety labeling this year.

Domestic Inspections

Domestically, we are expanding inspections of establishments that produce food that is at high risk of microbiological contamination or high risk of causing severe disease. High-risk foods include infant formula, ready-to-eat foods, heat-and-serve products, seafood, low-acid canned foods and acidified foods. Our goal is to conduct annual inspections of

the approximately 6,250 high-risk facilities by 2001. We are also re-evaluating our establishment inventory to be sure we have identified all the firms that appropriately fit within the definition of high risk.

Imports

To carry out the President's initiative to improve the safety of imported food, we have been working closely with our colleagues at the U.S. Customs Service. To prevent problem importers who have evaded our laws in the past from moving unsafe food into U.S. markets, we are developing guidance for field personnel to ensure that food offered for import by problem importers will be held in secure storage until FDA has reviewed and released the shipment. We are also developing guidance for field personnel on procedures for requiring the destruction of food that poses a significant health risk. FDA plans to issue a proposed rule this year to require the marking of refused food shipments to prevent attempts at re-importation.

In addition, FDA is completing a 1,000 sample survey of imported fresh produce that was initiated last year. The purpose of the survey is to determine the incidence of microbial contamination of these commodities. This type of surveillance activity will help the Agency protect consumers from foodborne illness and will provide baseline information

that will help us focus our research and regulatory efforts on the foods that pose the greatest risk. We are conducting a similar survey of domestic produce.

In addition to increased surveillance and tighter controls at the border, we have concluded we need to expand our foreign presence to address food safety at its source. For example, we have begun a project with Mexico to start a monitoring system for antimicrobial resistance in *Salmonella*. To start, Mexico will collect isolates from children in daycare settings to characterize the carriage rates of *Salmonella* in children and identify the antimicrobial resistance patterns of the isolates. This collaboration between the U.S. and Mexico represents the first international human and animal monitoring system for foodborne antimicrobial drug susceptibility surveillance of the Americas. Also, we are assessing foreign controls over food products exported to the U.S. and are providing technical assistance to foreign countries. We are increasing our number of foreign inspections and are focusing our inspections on food establishments that produce food products that are at high risk for microbial contamination.

Research and Risk Assessment

Research and risk assessment are critical to ensuring the strong scientific basis necessary for our regulatory programs to be effective. I would like to mention just a few examples

of some recent advances in research regarding microbial contamination. For example, we developed a new technique to detect harmful *Escherichia coli* O157:H7 in food within thirty minutes, compared to the 24 to 48 hours required by conventional techniques. FDA has developed a rapid and reliable method to detect low levels of Norwalk virus in shellfish. We developed an improved polymerase chain reaction method for the detection of *Cyclospora* in produce. Use of this method provided the first isolation of this pathogen from a food product associated with human illness.

FDA has also established an extramural grant program to support research in the areas of produce safety, egg safety, antimicrobial resistance, methods to detect foodborne viruses in foods, and for research on food service, transportation, and consumer practices. So far, FDA's CFSAN has funded eight new research and risk assessment grants totalling two million dollars. CFSAN is currently reviewing proposals and anticipates awarding six to seven new grants totalling approximately one million dollars this year. FDA's CVM has awarded approximately one million dollars in grants per year over the last three years for antimicrobial resistance research.

FDA's involvement with two academia/industry/government research consortia, the National Center for Food Safety and Technology (NCFST or the Moffett Center) and the Joint

Institute for Food Safety and Applied Nutrition, have been instrumental in developing solutions to new food safety problems. For example, collaborative research projects have led to new techniques to help small businesses improve the safety of sprouts and apple cider.

One of the partnering efforts that has played a critical role in FDA's food safety efforts is the NCFST. The NCFST, which is located at the Illinois Institute of Technology in Chicago, is a consortium of FDA, academic members, and 70 industry members. The core of the NCFST mission is the identification of emerging food safety problems and the development of techniques to prevent the problems from becoming public health crises. Collaborative research spans the breadth of technologies from sophisticated new processing and packaging methods to the development of effective techniques for use by small processors.

Most recently, FDA scientists worked with representatives of the sprout industry and academia to develop techniques to improve the safety of sprouts and to monitor these products for the presence of pathogens. The results of these studies were incorporated in FDA's guidance to the sprout industry. NCFST scientists worked with the State of California, University of California, and USDA in a small cider mill to evaluate preventive technologies such as washing and sanitizing fruit and using ultraviolet (UV) light to destroy pathogens. This

research was used in the proposed juice HACCP regulation and in the evaluation of UV processing.

Another important collaborative effort is the NARMS. This is a surveillance program by FDA, CDC, and USDA that monitors when foodborne bacteria that can cause disease in humans begin to develop resistance to antimicrobials used in food animals. State and local health departments also participate by providing samples for analysis. Increasing antibiotic resistance and loss of the effectiveness of antimicrobials is an emerging public health threat worldwide. NARMS is proving to be a valuable tool in helping to identify the emergence of resistant pathogens and to develop effective intervention strategies.

One of the payoffs from both government and industry research is the development of new technologies to reduce microbial contamination. To ensure new technologies are available and to provide an incentive, FDA implemented an expedited review mechanism to give priority to the review of petitions for additives intended to reduce foodborne pathogens. As of September 2000, FDA has reviewed and issued final rules for seven such agents, which range from chemical agents to sources of irradiation. There are 12 additional expedited review food additive petitions in process.

Microbiological food safety risk assessment is one of the

powerful new tools that is becoming available for evaluating the public health impact of microbial contamination of food and the potential impact of control programs. The Food Safety Initiative has been instrumental in allowing FDA and our Federal partners to become world leaders in the application of these new techniques to food safety concerns. FDA is in the process of finalizing risk assessments of *Listeria monocytogenes* and *Vibrio parahaemolyticus*. We are also conducting a risk assessment of the emergence of antimicrobial resistance in *Campylobacter*. Integral to these rapid advances in microbial risk assessment has been the high degree of cooperation and mutual support among Federal agencies. Through the RAC initially established by FDA, 14 Federal food safety agencies have been working together to advance our capabilities to conduct risk assessments.

Education

The issuance of guidance documents is an important way to assist industry in preventing microbial contamination. Of equal importance are education programs for consumers and foodservice workers on safe methods for storing and preparing foods. FDA is a member of the Partnership for Food Safety Education, which includes representatives from several government agencies as well as from industry and consumer organizations. The Partnership was formed to develop and disseminate effective educational messages for a variety of

audiences: consumers, food producers, food preparers, food transportation workers, and public health professionals.

The "Fight Bac" campaign created through the Partnership educates consumers on four simple principles (clean, chill, separate, and cook to proper temperatures) to prevent contamination during preparation of food in the home. Now in its third year, the "Fight Bac" campaign has greatly increased its range and its impact. Last year, major corporations began to include the "Bac" character and the food safety messages in their national consumer education initiatives. For example, McDonald's distributed some 12 million family safety brochures which opened with the "Fight Bac" message. Pfizer incorporated the "Fight Bac" video and brochure in their traveling teaching exhibit, "Microbes: Invisible Enemies. . . Amazing Allies." This exhibit opened at the Smithsonian last spring and will be shown at museums around the country over the next two years.

These education programs are making a difference in consumers' food safety behavior. Consumer research data show a significant reduction in the consumption of raw protein foods such as oysters and eggs. The data show nearly a 40 percent increase in safe practices such as washing their hands, utensils, and cutting boards when handling raw fish or eggs. And, perhaps more importantly, the data indicate an increase of 50 percent in consumer knowledge about how microbial pathogens

contaminate food products and about how to prevent that from happening.

Outbreak Response

Responsibility for responding to foodborne disease outbreaks is shared among local, State, and Federal governments. Local and State governments are often the first to detect the occurrence of an outbreak and initiate an investigation if appropriate. It is important to note that many episodes of foodborne illness are addressed exclusively at the local level. The States play a major role in outbreak surveillance and investigation. The role of the Federal agencies in large or complex multi-state outbreaks is to assist the State and local agencies in preventing additional cases of illness from occurring. FDA's objectives in outbreak investigation and response are verification of the association with a regulated product, identification of the source of the product and the extent of distribution, prevention of any further exposure to the contaminated product, and initiation of regulatory action if indicated. In addition, a critical role of outbreak investigation is to identify contributing factors so similar problems can be avoided in the future.

To improve outbreak detection and response by the Agency and our State and local partners, FDA has developed several training courses. FDA's satellite courses on food

microbiology, foodborne disease epidemiology, and traceback in outbreak investigations, have been attended by thousands of government and industry representatives from around the country. FDA has also conducted presentations on how to conduct tracebacks to determine the source of an outbreak at numerous conferences in the U.S., Mexico, and Latin America.

CONCLUSION

Mr. Chairman, through the efforts of the government and private partners, much progress has been made in the effort to reduce microbial contamination of foods. I have briefly described some of the achievements and partnerships that have resulted under the Food Safety Initiative. The work done so far has created a strong foundation but is just the beginning.

In 1998, the President created the Council on Food Safety to strengthen and focus our efforts to coordinate food safety policy and resources. FDA, CDC, Environmental Protection Agency, and USDA have been working together and with state and local governments, academia, industry, and consumer organizations to develop a strategic plan to address actions necessary to ensure the safety of the food and water Americans consume. The plan, which will be released soon, provides a long-range method to set priorities, improve coordination and efficiency, identify gaps in the current system and ways to fill the gaps, enhance and strengthen prevention and

intervention strategies, and identify measures to demonstrate progress.

Within that broader context, we at FDA stand ready to continue our science-based regulatory program to systematically reduce the incidence of foodborne illness for American consumers.

Thank you again for this opportunity to discuss this important public health issue. I would be happy to answer any questions.

Appendix

USDA, FDA, and the EPA joined together to create RAC. RAC has established an intramural research program to provide data for use in microbial risk assessment modeling. Risk assessment is a valuable tool for evaluating the public health impact of microbial contamination of food.

The FORC-G is a partnership of Federal, State, and local agencies that was formed to provide a more efficient response to foodborne illness outbreaks and to prepare for emerging threats to the food supply. FORC-G partners have drafted a document, "Foodborne Outbreak Response and Coordination," that is intended to guide Federal agencies and State or local officials on procedures for coordinating multi-state outbreaks.

At the President's direction, USDA and the Department of Health and Human Services (DHHS) have created Joint Institute for Food Safety Research (JIFSR). This institute coordinates planning and priority setting for food safety research among the two Departments, other government agencies, and the private sector. This coordination optimizes food safety research investments, channels Federal resources to research priorities, and avoids research redundancies. JIFSR also fosters the effective translation of research results into practice along the farm-to-table continuum.

FDA is leading an effort with Federal, State, and local officials from health, agricultural, and environmental agencies, to improve coordination and communication at all levels of government, particularly for foodborne illness outbreaks. Known as the National Food Safety System, this project will lead to more effective implementation of existing food safety programs. One of the joint projects currently underway is one to develop standards for testing methods and for the exchange of data regarding *Escherichia coli* O157:H7. A contract has been awarded for a pilot project to demonstrate the feasibility of food safety laboratories securely sharing data using internet technology.

STATEMENT OF

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CENTERS FOR DISEASE CONTROL AND PREVENTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

AGRICULTURE, NUTRITION AND FORESTRY COMMITTEE

U.S. SENATE

September 20, 2000

I am Dr. Stephen Ostroff, Associate Director for Epidemiologic Science, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I would like to thank the Committee for the opportunity to be here today with my colleagues from the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA)

Today, I will discuss CDC's role in the area of foodborne diseases and food safety, including how CDC has worked with other federal partners and used resources obtained through the National Food Safety Initiative to strengthen the Nation's ability to detect and respond to emerging foodborne disease threats. I will also discuss the public health burden of foodborne illnesses in the United States, highlight our progress in reducing foodborne illnesses, and provide examples from surveillance reports and recent outbreak investigations to demonstrate how National Food Safety Initiative resources are being applied to today's public health practice.

Today, more than 200 known diseases are transmitted through food. The causes of foodborne illness include viruses, bacteria, parasites, toxins, metals, and prions. The symptoms of foodborne illness range from mild gastroenteritis to life-threatening neurologic, hepatic, and renal syndromes. We estimate that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. Of these, known pathogens account for an estimated 14 million illnesses, 60,000 hospitalizations, and 1,800 deaths. Three pathogens, *Salmonella, Listeria, and Toxoplasma*, are responsible for 75 percent

of these deaths each year. Unknown agents account for the remaining 62 million illnesses, 265,000 hospitalizations, and 3,200 deaths.

In the wake of this public health burden on our Nation's health, I can report significant progress in reducing foodborne illness. CDC data show that from 1997 to 1999, illness from the most common foodborne pathogens declined by 20 percent. This decline represents nearly a million fewer Americans suffering illness each year from foodborne illness since the launch of the President's Food Safety Initiative. I am happy to summarize these data for you this morning.

Many factors may have contributed to these impressive two-year declines in foodborne illness -- the fact that they were seen across all of our active surveillance (FoodNet) sites suggests they are not surveillance artifacts. This further suggests that preventive measures, including those being implemented by the FDA and USDA, are working. Let me offer a few examples:

- *Campylobacter* (the most common foodborne bacterial pathogen) down 26%: Changes in poultry processing plants encouraged by USDA's Food Safety Inspection Service (FSIS) HACCP rule likely contributed here.

- *E. coli* O157:H7 infections down 22%: Improved sanitation in slaughter and processing plants and attention to hamburger cooking temperature likely contributed here. *E. coli* causes a serious disease which often leads to diarrhea and kidney failure, particularly in young children.

- *Salmonella enteritidis* down 48%: FDA, FSIS, state and industry efforts to decrease contamination of eggs likely contributed here. The implementation of the Egg Safety Action Plan and FDA's pending final rule on egg refrigeration and labeling are expected to contribute to further decline.

- *Shigella* down 44%: This decline follows a large outbreak in 1998 traced to imported parsley. The outbreak showed the need to improve sanitation on produce farms throughout the continent. Recent FDA/FSIS Good Agricultural Practices Guidelines focus on this need. FDA also has increased sampling and detection of imported produce, and supported education outreach programs in foreign countries.

- *Cyclospora down 70%:* This decline follows rapid FDA action and subsequent production controls on imported raspberries.

- *Salmonella* up 2% overall: This trend is partly due to large outbreaks in 1999 due to raw sprouts, unpasturized orange juice, and imported mangoes. New FDA guidance on raw sprouts, pending juice regulations, and import sampling/detection strategies would be expected to contribute to future declines in illness.

These few examples show the importance of public health surveillance data and how such data can be used. Surveillance data document the incidence and prevalence of foodborne illness, and

suggest where preventive measures, including regulatory action, may be needed. Over time, surveillance data also help to document the effectiveness of these preventive measures.

Despite these impressive gains in reducing the burden of bacterial foodborne illnesses, we need to point out that many challenges remain. New foodborne pathogens are emerging, old foodborne pathogens are showing up in new foods, and antimicrobial resistance in foodborne pathogens is increasing. As we are here, another hearing is being conducted on the worsening trends in antimicriobial resistance, which will be a serious threat in future years.

CDC's Role in Foodborne Diseases and Food Safety

At its most fundamental level, CDC is the agency that keeps its finger on the pulse of the Nation's health. CDC is the cornerstone Federal agency responsible for identifying and monitoring foodborne and other illness and for documenting the effectiveness of prevention and control efforts, including both voluntary and regulatory measures. Using this information, we then work with partners to develop ways to improve disease control and prevention actions. CDC collaborates with State and local health departments, clinicians, academic centers, industry, other countries, and international organizations. In food safety, CDC works in very close coordination with the other agencies represented in today's hearing.

Foodborne and waterborne diseases is a target area in CDC's plan, Preventing Emerging Infectious Diseases: A Strategy for the 21st Century. Public health priorities in the plan are organized under four broad, interdependent goals, each of which can be applied specifically to

the prevention of foodborne illness: improving surveillance and response capacity, addressing applied research priorities, repairing the Nation's public health infrastructure and training programs, and strengthening prevention and control programs required to control emerging, reemerging, and drug-resistant infectious diseases.

CDC plays a critical and unique role as a monitoring, investigative, and advisory agency that is separate from regulatory agencies, but that works closely with them. CDC monitors the occurrence of human foodborne disease in the United States. This includes not only traditional public health concerns, such as illness caused by pathogens such as *Salmonella*, but also newer foodborne threats such as the bacteria *E. coli* O157:H7 and the parasite *Cyclospora*. We also monitor levels of antibiotic resistance in bacteria that cause foodborne illness. CDC works with State and local health departments to conduct ongoing surveillance of cases of foodborne illness and to investigate disease outbreaks, which often provide the first warning of new or different threats to the food supply. CDC uses both surveillance data and results of outbreak investigations to identify the factors responsible for illness so that immediate control measures can be taken and longer term prevention strategies can be developed. While other agencies measure success of interventions via reductions in food contamination, CDC's role in measuring the success of interventions is to see whether they translate into reductions in the number of human cases of foodborne illness. The ultimate test of all prevention efforts is whether they prevent human illness.

Once an outbreak is detected, the first response is usually from the State or local health department. CDC will often be invited by the State health departments to participate in the investigation if an outbreak is very large or complex, is thought to involve an unusual pathogen or unexpected food vehicle, affects multiple states or countries, or when preliminary investigations do not reveal a source. When investigating an outbreak of a foodborne illness, public health officials must combine laboratory diagnostic techniques and epidemiologic investigative methods to determine the causative agent of the illness, the food vehicle responsible for transmission, and the environmental factors that contributed to the outbreak. If a food is identified as the source of illness, CDC collaborates with FDA or FSIS on the investigation and control of the outbreak, based upon which agency regulates the suspected food.

In addition to our surveillance and response activities, CDC also conducts applied foodborne illness research. Some examples include developing laboratory diagnostic tests where none currently exist, such as detection of hepatitis A virus in food and detection of Norwalk-like viruses or *Cyclospora* in clinical specimens and foods; developing methods to subtype, or "fingerprint", bacteria, viruses, and parasites causing foodborne illness; conducting risk factor studies for foodborne illness in special populations, such as the immunocompromised; and performing cost-effectiveness analyses of potential prevention measures such as routine use of hepatitis A vaccine in food workers.

The public health infrastructure is the underlying foundation that supports the planning, delivery, and evaluation of public health activities and practices. CDC's ongoing effort to rebuild the U.S.

public health infrastructure that addresses infectious diseases is critical to improve the capacity of health departments, health care delivery organizations, and clinical and public health laboratories to detect and report cases of foodborne and other illness and to implement prevention and control strategies. Part of this effort includes enhancing capacity to respond to disease outbreaks and training public health professionals to be able to respond to emerging threats now and in the future. With respect to the prevention and control of foodborne diseases, these efforts are directed at enhancing the states' ability to investigate, control, and report all outbreaks of foodborne diseases.

CDC also engages in educational activities targeted to health care professionals and the public. Examples of assistance to health professionals include producing videos on laboratory methods to diagnose foodborne pathogens and materials on how to avoid foodborne illness among immunocompromised, high-risk persons. To educate the public, CDC actively participates with FDA, FSIS, and other Federal agencies, industry, and consumer organizations in the Partnership for Food Safety Education, an ambitious public private partnership created to reduce the incidence of foodborne illness by educating Americans about safe food-handling practices through many activities, including the national Fight BAC!™ Campaign. The purpose of the Fight BAC!™ Campaign is to help educate consumers about the problem of foodborne illness and motivate them to take basic sanitation and food-handling steps that will reduce the risk of foodborne illness.

The Challenges of Food Safety

Although the United States has one of the safest food supplies in the world, the public health burden of foodborne diseases is still substantial, and we continue to face challenges to the safety of our foods. New foodborne pathogens are emerging, old foodborne pathogens are showing up in new foods, and antimicrobial resistance in foodborne pathogens is increasing. The eating habits of Americans have changed. We now consume more fresh produce and seafood and demand a constant supply throughout the year. Changing food habits can result in a changing pattern of foodborne illness. To meet the demand, an ever increasing proportion of our food is imported, especially from developing parts of the world. As a result, we are being exposed to pathogens not commonly found in the United States, as demonstrated by the *Cyclospora* outbreaks associated with imported raspberries. The array of new products and processing methods, such as pre-packaged salad mixes, presents another challenge, as does mass production and distribution of foods, which has the potential to produce diffuse, nationwide illness outbreaks of unprecedented scale.

New challenges require new, creative ways to do our job more effectively and efficiently. The President's National Food Safety Initiative, launched in 1997, recognizes this need and is moving our food safety system forward. CDC has been an active partner in the development and implementation of the Food Safety Initiative. Our resources under this initiative have primarily been targeted to harnessing the information and laboratory technology revolution to propel our Nation's foodborne disease surveillance system into the 21st century.

FoodNet

I will provide two examples of CDC's progress in this area. First is the Foodborne Diseases Active Surveillance Network (FoodNet). The FoodNet system is a joint effort by CDC, FDA, USDA, and State health departments to capture a more accurate and complete picture of trends in the occurrence of illness caused by priority foodborne pathogens. It is built on the foundation of CDC's emerging infectious disease activities, which provides the basic infrastructure to conduct active disease surveillance. Before 1996, the Nation's foodborne disease surveillance system was based on passive reports of illness from clinicians and laboratories which were submitted to local health departments and then onward to the State health department and from the State to CDC. Such information lacks timeliness, is often incomplete, and is highly variable from one place to the next depending on the resources invested at the state and local level.

FoodNet is part of CDC's Emerging Infections Program (EIP). CDC funds EIP cooperative agreements with State and local health departments to conduct population-based surveillance and research that goes beyond the routine functions of health departments. In these sites, the program, which usually involves a partnership between the State health department and an academic center, canvasses laboratories and other data sources for illnesses caused by nine different pathogens on an active, ongoing basis using standardized data collection methods, standard definitions, and standard techniques. Special case-control studies are conducted across FoodNet sites in order to identify the major risk factors for sporadic illness. Community surveys are conducted to help determine the overall burden of foodborne illness. These can include mild cases of illnesses which do not come to medical attention or cases where there is no diagnostic

test performed. Data are electronically submitted to CDC for timely analysis. FoodNet gives high quality data never before available and also allows us to make determinations that differences across sites are real and not due to differing surveillance intensities or methodologies.

PulseNet

A second system to highlight is PulseNet, a system developed in partnership with State health departments and the Association of Public Health Laboratories and a winner of the Ford Foundation's "Innovations in American Government Award." PulseNet is a network of molecular subtyping (fingerprinting) laboratories at State health departments, FDA, USDA, and CDC, which enhances the ability of laboratory-based surveillance to rapidly identify clusters of related foodborne infections of certain pathogens, sometimes scattered over large geographic areas. This system uses a methodology known as pulsed field gel electrophoresis (PFGE) to digest bacterial DNA and produce unique patterns. Like human fingerprints, each bacteria and its offspring have a unique PFGE pattern. If two bacteria are found with an indistinguishable pattern, it is likely that they have a common source, meaning they may be part of an outbreak of many similar cases. CDC initially standardized PFGE methodology for *E. coli* O157:H7 and for *Salmonella*. In 1998, CDC also standardized PFGE methodology for *Listeria*, not long before there was a multi-state outbreak of listeriosis associated with contaminated hot dogs. Using funds obtained through CDC's Epidemiology and Laboratory Capacity (ELC) cooperative agreements and from the Food Safety Initiative, state health laboratories have obtained PFGE equipment, and CDC has provided training and standardized methodology to them to test for

foodborne pathogens. USDA and FDA laboratories also participate in the network to allow comparison between animal, food, and human isolates. Currently, 48 state public health laboratories in 46 states are linked into this network. Eventually, CDC hopes to include all state laboratories.

To enhance the power of the PulseNet system, in 1998, CDC created a national computer database of PFGE patterns that is housed at CDC. Now states can submit PFGE patterns to the database over the Internet. The computer then automatically scans previously submitted patterns searching for matches. If a match is found, a signal is given to the submitter that duplicate patterns are present and where they came from, so that an investigation can begin to look for a common source. When the system is fully implemented, all of this will happen in real time, allowing the early warning system for nascent outbreaks that we all desire.

The impact of PulseNet has been enormous, both in identifying outbreaks that would otherwise have gone unnoticed, and in allowing us to focus our investigations to determine the true source and extent of an outbreak. For example in late 1998, an increased number of cases of listeriosis were noticed. Using PulseNet technology, CDC tested the strains from several states and determined that many had the same PFGE pattern. Epidemiologic investigations found a strong association with hot dog consumption in patients with the outbreak strain, leading to recalls which occurred just before Christmas. CDC then continued to work with states to test all available *Listeria* isolates from patients from the previous summer in order to determine how many cases and deaths occurred as part of the outbreak and to confirm that the outbreak is over.

Some of the strains, which were tested, were different from the outbreak strain. Among these strains, a second cluster with a common PFGE pattern was found. Investigation of these cases found they were linked to consumption of a specific imported cheese. Other small clusters of cases have been identified and are under investigation. If not for the ability to do the subtyping, it is unlikely that these outbreaks would have been discovered and investigated, and prevention measures would not have been undertaken.

Another PulseNet example involves *Shigella*, a bacterial pathogen that can be foodborne but most often is not. The Minnesota Department of Health, a FoodNet site, routinely fingerprints *Shigella* isolates, and, in 1998 they identified a cluster of strains with a similar pattern. Epidemiologic investigations found that illness was linked to eating chopped parsley at two different restaurants. By informing other states and searching databases for places with an increased number of cases, similar outbreaks were identified in five other states and Canada. The *Shigella* from these outbreaks also had the same PFGE fingerprint. All of the outbreaks were parsley associated. Working with FDA, the implicated parsley was traced to a specific farm. Again, if not for routine utilization of PFGE, the links between the outbreaks would have been missed, the source would not have been identified, and the outbreak would have spread much further.

PFGE is a powerful surveillance tool. It allows us to detect widely dispersed outbreaks and small clusters that would have previously been missed. This illustrates a central tenet of epidemiology: better surveillance leads to better and more accurate disease detection, which in

turn leads to more field investigations. This causes increased burdens, not only on CDC and other Federal agencies, but also on State and local partners.

Therefore, as surveillance improves, more outbreaks, not fewer, will be detected. However, this should not be interpreted as a failure. Rather, it represents success, because only by finding and investigating the outbreaks can we define risks, develop and implement interventions, and over the long term, identify and limit the risk.

National Food Safety Initiative at CDC

CDC will continue to direct its resources to developing the needed public health infrastructure throughout the Nation to detect, control, and prevent foodborne illness and to strengthen prevention and control programs required to control emerging, reemerging and drug-resistant infectious diseases. In short, CDC, in collaboration with others, will continue to build State and local health department capacity to conduct appropriate epidemiologic, laboratory and environmental investigations; and continue ongoing efforts to inform health professionals and the public about foodborne illness and prevention.

For example, we will continue to develop a national network of laboratories capable of using state-of-the-art laboratory methods and technologies. This includes increasing the number of States participating in PulseNet, and increasing the number of pathogens monitored by the system in order to detect additional outbreaks.

We intend not only to expand our development of state-of-the-art gene-based diagnostic and subtyping tools for bacteria, but also to develop a comparable system for identifying viral contaminants. We also will continue to support a system known as DPDx, which harnesses telemedicine technology to transmit images of parasites under the microscope to our experts at CDC for appropriate diagnosis. In addition to our efforts to improve epidemiology and laboratory capacity, we intend to work with the States to strengthen their environmental health capacity. For example, we plan to work with the States to assess the training needs of food protection specialists (environmental sanitarians) and develop food safety guidance for local food protection programs. We also intend to continue development of school-based prevention and control efforts, including development of a model coordinated school health and food safety program. We also will continue to update analyses and estimates of the public health burden of foodborne disease.

Conclusions

In conclusion, these activities represent a small sample of how CDC supports its State and local partners and other Federal agencies in monitoring, controlling, and preventing foodborne illness. Foodborne diseases remain a challenge for public health. To address this challenge will require continued investments in our public health infrastructure and strong partnerships among State and local health departments and Federal agencies.

Thank you for the opportunity to discuss the surveillance of foodborne disease. We will be happy to answer questions you or other members of the Committee may have.

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United States General Accounting Office

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Testimony

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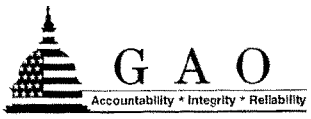
FOOD SAFETY

Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures

Statement of Lawrence J. Dyckman,
Director, Food and Agriculture Issues
Resources, Community, and Economic
Development Division



GAO/T-RCED-00-300

Mr. Chairman and Members of the Committee:

We are pleased to be here today to provide an overview of food safety expenditures by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's Food and Drug Administration (FDA).[1] As you know, FSIS and FDA are the two agencies with primary responsibility for food safety in the United States. FSIS is responsible for ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, labeled and packaged. FDA is responsible for ensuring that (1) all foods moving in interstate and foreign commerce, except those under FSIS' jurisdiction, are safe, wholesome and properly labeled; and (2) all animal drugs and feeds are safe, properly labeled, and produce no human health hazards when used in food-producing animals.

As this Committee and Senator Hagel requested, we are conducting a review to determine, for fiscal years 1998 and 1999, the amount of resources available to FSIS and FDA for food safety activities, how these resources were expended by the agencies, and how much the states, territories, and District of Columbia expended on food safety activities. My testimony today presents an overview of the results of work to date on the federal agencies' expenditures. We cannot yet report on nonfederal expenditures because our surveys of the states, territories, and the District of Columbia are still ongoing.

In summary, FSIS and FDA in aggregate expended almost $1 billion in fiscal year 1998 and again in fiscal year 1999 on food safety activities. In fiscal year 1999, FSIS expended about $712 million, of which 16 percent was for headquarters activities and 84 percent for field activities associated with overseeing more than 6,000 meat, poultry, egg product and import establishments. FDA expended about $260 million on food safety activities in

[1] GAO has previously reported on food safety resources. See *Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness* (GAO/RCED-98-224, August 6, 1998).

fiscal year 1999, of which 44 percent was for headquarters activities and 56 percent for field activities associated with overseeing an estimated 57,000 food establishments and over 9,000 animal drug and feed establishments, and ensuring the safety of FDA-regulated imported foods. We found similar expenditures for FSIS and FDA in fiscal year 1998.

Background

Foodborne illness in the United States is an extensive and expensive problem. The Centers for Disease Control and Prevention estimates that unsafe foods cause as many as 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually.[2] In terms of medical costs and productivity losses, foodborne illnesses cost the nation between $7 billion and $37 billion annually, according to USDA's estimates.

According to the Centers for Disease Control and Prevention, almost 12,000 cases of foodborne illness were reported in 1997, the latest year for which data are available. Of the approximately 7,000 cases in which the food source for the illness was known, about 85 percent were associated with food products that are regulated by FDA, such as fish, shellfish, fruits, vegetables, and salads. The remaining 15 percent of illnesses were associated with food products, such as meat and poultry, which fall under FSIS' jurisdiction.

While 12 different federal agencies located within six federal departments conduct food safety activities, FSIS and FDA have primary regulatory responsibility for ensuring the safety of the food supply.[3] FSIS has responsibility for ensuring the safety of meat,

[2] Reported data on foodborne illnesses and related deaths are incomplete and may understate the extent of the problem. The Centers for Disease Control uses reported illnesses, among other sources, to estimate the extent of foodborne illnesses each year.

[3] The 12 agencies are USDA's Animal and Plant Health Inspection Service, Grain Inspection, Packers and Stockyards Administration, Agricultural Marketing Service, Agricultural Research Service, and FSIS; HHS' Centers for Disease Control and Prevention and FDA; the Department of the Treasury's U.S. Customs Service and the Bureau of Tobacco, Alcohol and Firearms; the Department of Commerce's National Marine Fisheries Service; the Environmental Protection Agency, and the Federal Trade Commission. See *Food Safety: U.S. Needs a Single Agency to Administer a Unified, Risk-Based, Inspection System* (GAO/T-RCED-99-256) for information on food safety agency roles and responsibilities.

poultry, and processed egg products.[4] Under the governing meat, poultry, and egg products inspection acts, FSIS, in effect, preapproves products under its jurisdiction before they are marketed. As such, FSIS operates under a mandated continuous inspection frequency for meat and poultry slaughter plants and egg processing plants, and inspects meat and poultry processing plants, such as those that run deboning and canning operations, daily. FSIS marks all inspected and approved meat, poultry, and egg products with a USDA inspection stamp. Without this marking the products cannot be legally marketed.

FDA is responsible for ensuring the safety of a broad range of products, including foods, animal drugs and feeds, human medicines and vaccines, radiation-emitting devices, medical devices, blood and blood products, and cosmetics. With regard to food safety, FDA is responsible under the Federal Food, Drug, and Cosmetic Act for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. In administering the act, which generally follows the regulatory approach of allowing food products to enter the market without preapproval, FDA inspects domestic establishments that manufacture, process, pack or hold food, and inspects and tests imported food products. However, the act does not mandate or specify inspection frequencies. As such, FDA inspects the more than 57,000 food establishments under its jurisdiction about once every 5 years, on average, and according to FDA officials, inspected less than 1 percent of the 3.7 million imported food entries in fiscal year 1999. Products under FDA's jurisdiction do not require, and FDA does not place, any inspection mark on the products before they can be legally marketed. FDA is also responsible for maintaining surveillance of all animal drugs and feeds to ensure that they are safe and properly labeled, and produce no human health hazards when used in food-producing animals.[5]

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[4] The meat act regulates meat from cattle, swine, goats, sheep, and equines (horses); the poultry act defines poultry as domesticated fowl, which FSIS regulations define as chickens, turkeys, ducks, geese, and guineas. Egg products are eggs removed from their shells for processing.

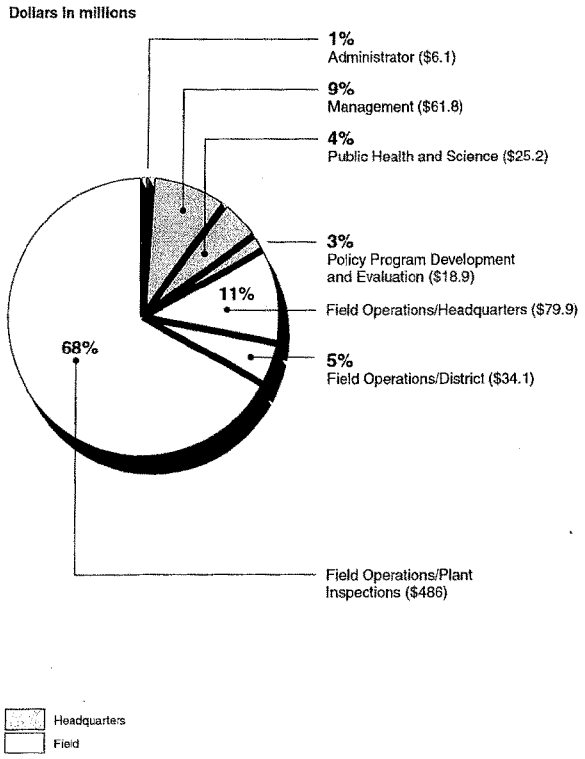
[5] Both FDA and FSIS have implemented Hazard Analysis and Critical Control Point (HACCP) systems that are designed to identify and control foodborne hazards that are likely to occur. In December 1997 FDA required seafood establishments to implement HACCP and in January 1998 FSIS began requiring that meat and poultry establishments implement HACCP.

States, territories, and the District of Columbia also have food safety responsibilities and operate agencies that regulate and enforce their own food safety laws to ensure the safety of foods produced, processed, and/or sold within their borders. These responsibilities generally lie within the departments of agriculture and health, and may involve others, such as state environmental protection agencies or county health departments. States and territories may also perform inspections for FSIS or FDA under contract or partnership agreements and report their inspection results to the federal agencies.

FSIS' Food Safety Expenditures

FSIS expended about $678 million and $712 million in fiscal years 1998 and 1999, respectively, on food safety activities. FSIS' food safety activities can be separated into two major components; operations conducted in the field by district offices or in direct support of those district offices, and operations conducted primarily in headquarters offices. As shown in figure 1, about 84 percent of FSIS' fiscal year 1999 expenditures were for field activities, and 16 percent were for headquarters office activities. Each activity's proportion of the total expenditures did not vary by more than 1 percent from fiscal year 1998 through fiscal year 1999. (See app. I for detailed information on expenditures, staff years, and activities for fiscal years 1998 and 1999.)

Figure 1: FSIS' Expenditures for Field and Headquarters Activities, Fiscal Year 1999



Note: Percentages do not add to 100 because of rounding.

In aggregate, FSIS' field activities accounted for $600 million in fiscal year 1999, or 84 percent of total agency expenditures. Inspections at slaughter, processing, and import establishments accounted for $486 million, or 68 percent, of total expenditures; and field office administration, supervision and compliance activities accounted for

$34.1 million, or 5 percent of total expenditures. In addition, the Office of Field Operations, the Washington D.C. headquarters office that manages field activities, accounted for $79.9 million, or 11 percent of total expenditures. The largest expenditure of the field operations office was for grants to states for inspection activities, accounting for $44.4 million, or about 57 percent of its total expenditures in fiscal year 1999. This office also funds the Technical Service Center, located in Omaha, Nebraska, which serves as the agency's center for technical assistance and guidance for field operations personnel and industry and conducts reviews of domestic and foreign inspection programs.

In aggregate, FSIS' headquarters-based activities accounted for $112 million in fiscal year 1999, or 16 percent of total agency expenditures. FSIS' headquarters food safety activities are conducted by four offices—management; public health and science; policy, program development, and evaluation; and the office of the administrator. Specifically:

- The Office of Management accounted for about $61.8 million, or 9 percent, of total expenditures. The management office is responsible for providing centralized administrative and support services to all other FSIS program offices, including functions such as human resource management, strategic planning, procurement, and financial management.

- The Office of Public Health and Science accounted for about $25.2 million, or 4 percent, of total expenditures. The office is responsible for conducting scientific analysis, providing scientific advice and data, and making recommendations involving all public health and science concerns relating to products under FSIS' jurisdiction. This includes mission activities such as epidemiology and risk assessment, surveillance and response to food safety emergencies. Almost half or $16.6 million of its expenditures were for laboratory analyses by the agency's three field laboratories.

- The Office of Policy, Program Development, and Evaluation accounted for about $18.9 million, or 3 percent, of total expenditures. The policy and program office is

responsible for, among other things, coordinating activities, such as developing and recommending domestic and international policies for FSIS; reviewing product process standards; labeling; and developing and evaluating inspection programs.

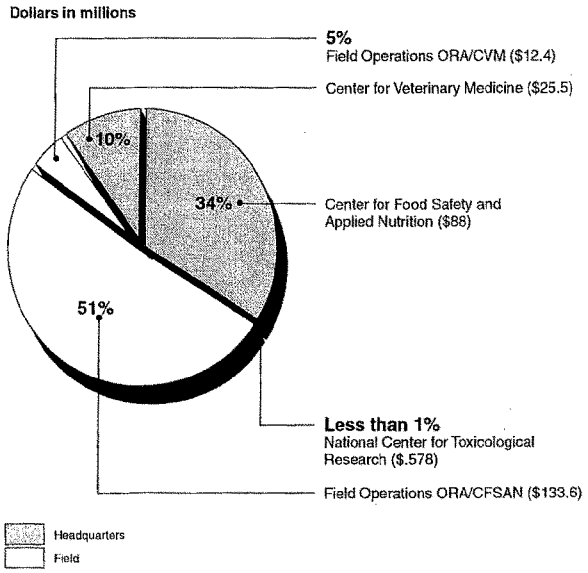
- The Office of the Administrator accounted for about $6.1 million, or 1 percent, of total expenditures. The office is responsible for management of agency activities such as public affairs, food safety education, coordination of U.S. involvement in international standard-setting for food safety, and maintaining liaison with trade organizations.

FDA's Food Safety Expenditures

FDA expended about $231 million and $260 million in fiscal years 1998 and 1999, respectively, on food safety activities.[6] These expenditures represent the combined activities of the three FDA Centers with food safety responsibilities: the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and, the National Center for Toxicological Research, as well as the field activities conducted for these centers by the Office of Regulatory Affairs. As with FSIS, FDA's food safety activities can be separated into two major components: operations conducted in the field by district offices or in direct support of those district offices, and operations conducted primarily in headquarters offices. As shown in figure 2, about 56 percent of FDA's fiscal year 1999 expenditures were for field activities, and about 44 percent were for headquarters office activities. Each activity's proportion of total expenditures did not vary by more than 1 percent from fiscal year 1998 to 1999. (See app. II for detailed information on fiscal year 1998 and 1999 expenditures, staff years, and activities.)

[6] These figures exclude central agency support costs, which FDA is in the process of determining.

Figure 2: FDA's Expenditures for Field and Headquarters Activities, Fiscal Year 1999



Legend:

ORA Office of Regulatory Affairs

CVM Center for Veterinary Medicine

CFSAN Center for Food Safety and Applied Nutrition

In aggregate, FDA's field activities accounted for $146 million in fiscal year 1999, or 56 percent of total agency expenditures. FDA's Office of Regulatory Affairs (ORA) is responsible for conducting field activities designated by the centers. ORA's compliance, inspection, and laboratory field staff manage, supervise, and conduct enforcement, compliance, inspection, sample collection and analysis activities, as well as criminal investigation, education and outreach activities. For fiscal year 1999, the ORA-conducted field component of the Center for Food Safety and Applied Nutrition's food

safety activities accounted for $133.6 million in expenditures and the ORA-conducted field component of the Center for Veterinary Medicine's food safety activities accounted for $12.4 million in expenditures.

In aggregate, headquarters-based activities accounted for $114 million in fiscal year 1999, or 44 percent, of the agency's total food safety expenditures. Specifically:

- The Center for Food Safety and Applied Nutrition's headquarters component accounted for $88 million in fiscal year 1999, or 34 percent of total expenditures. The center operates FDA's Foods Program, which is responsible for ensuring that FDA-regulated food is safe, sanitary, wholesome, and honestly labeled. To achieve this goal, the center implements programs that address specific food safety concerns, such as food and color additives, infant formula, medical foods, and seafood. The center also engages in regulatory policy development and education and outreach activities, and manages federal/state cooperative programs. Food safety research and risk assessment accounted for the center's largest expenditures, about $32 million each year.

- The Center for Veterinary Medicine's headquarters component accounted for $25.5 million in fiscal year 1999, or 10 percent of total expenditures. The center operates FDA's Animal Drugs and Feeds Program, which has primary goals of ensuring that only safe and effective animal drugs, feeds and feed additives are marketed, and that foods from animals that are administered drugs and food additives are safe for human consumption. The Center maintains surveillance over all animal drugs and feeds to minimize threats to human health. Premarket application review for new animal drugs accounted for the Center's largest headquarters expenditures, about $12.8 million.

- The National Center for Toxicological Research, located in Jefferson, Arkansas, accounted for $578,000 in fiscal year 1999, or less than 1 percent of total expenditures. The center's mission is to conduct peer-reviewed scientific research

that provides the basis for FDA to make sound science-based regulatory decisions and to protect the public health through pre- and post-market surveillance. During fiscal years 1998 and 1999, the center conducted research projects that contributed to FDA's food safety mission. It did not engage in field activities related to food safety.

Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions you or Members of the Committee may have.

Contact and Acknowledgement

For future contacts regarding this testimony, please contact Lawrence J. Dyckman at (202) 512-5138. Individuals making key contributions to this testimony were Keith Oleson, Brad Dobbins, Kathy Colgrove-Stone, and John Nicholson.

Appendix I

Food Safety and Inspection Service's Food Safety Expenditures and Staff Years, Fiscal Years 1998 and 1999

For fiscal years 1998 and 1999, the Food Safety and Inspection Service (FSIS) expended about $677.8 and $712 million, respectively, for its food safety activities. As shown in table 1, 84 percent of the expenditures were for field office operation, compliance, and inspection activities, while the remainder were expended for FSIS headquarters office activities. Each activity's proportion of the total expenditures did not vary by more than 1 percent between the 2 fiscal years.

Table 1: FSIS' Expenditures and Staff Years for Food Safety Activities by Office, Fiscal Years 1998 and 1999

Dollars in millions

Office	Expenditures (percent of total)		Staff Years (percent of total)	
	1998	1999	1998	1999
Field Operations—Plant Inspections	$463.4 (68)	$486 (68)	9,441 (85)	9,330 (85)
Field Operations—District Compliance, Supervision and Administration	35.4 (5)	34.1 (5)	521 (5)	517 (5)
Field Operations—Headquarters	69.1 (10)	79.9 (11)	222 (2)	211 (2)
Field Operations—subtotal	**$567.9 (83)**	**$600 (84)**	**10,184 (92)**	**10,058 (92)**
Headquarters—Management	62.7 (9)	61.8 (9)	406 (4)	382 (3)
Headquarters—Public Health and Science	23.9 (4)	25.2 (4)	254 (2)	281 (3)
Headquarters—Policy, Program Development and Evaluation	18 (3)	18.9 (3)	149 (1)	162 (1)
Headquarters—Administrator	5.3 (1)	6.1 (1)	64 (1)	68 (1)
Headquarters Operations—Subtotal	**$109.9 (17)**	**$112 (16)**	**873 (8)**	**893 (8)**
Total[a]	**$677.8 (100)**	**$712 (100)**	**11,057 (100)**	**10,951 (100)**

[a]Totals may not add because of rounding.

FSIS' field activities include inspections of establishments under the agency's jurisdiction and compliance work to ensure that the establishments are following applicable regulations. Table 2 presents selected results from FSIS' inspection and compliance field work.

Table 2: Number of Establishments Inspected by FSIS and Selected Compliance Activities, Fiscal Years 1998 and 1999

Activity	1998	1999
Inspections		
Slaughter establishments	254	262
Processing establishments	4,297	4,343
Combination slaughter and processing establishments	985	968
State agreements[a]	256	254
Import establishments	135	129
Egg product establishments	78	75
Total establishments inspected	**6,005**	**6,031**
Compliance activities		
Compliance reviews	26,176	43,976
Warnings issued	1,520	2,778
Suspensions for Hazard Analysis and Critical Control Point violations	77	118

[a]Funded through FSIS' headquarters Office of Field Operations at a cost of $40.6 million and $44.4 million in fiscal years 1998 and 1999, respectively.

Appendix II

Food and Drug Administration's Food Safety Expenditures and Staff Years, Fiscal Years 1998 and 1999

For fiscal years 1998 and 1999, the Food and Drug Administration (FDA) expended about $231.3 and $260 million, respectively, for its food safety activities. As shown in table 3, about 56 percent of the expenditures were for field office operation, compliance and inspection activities, while the remainder were expended for FDA headquarters office activities. Each activity's proportion of the total expenditures did not vary by more than 1 percent between the 2 fiscal years 1998 to 1999.

Table 3: FDA's Fiscal Year 1998 and 1999 Expenditures and Staff Years for Food Safety Activities by Center, Fiscal Years 1998 and 1999

Dollars in millions

Center	Expenditures (percent of total)		Staff Years (percent of total)	
	1998	1999	1998	1999
Field Operations—Office of Regulatory Affairs/ Center for Food Safety and Applied Nutrition	$116.2 (50)	$133.6 (51)	1,426 (57)	1,535 (59)
Field Operations—Office of Regulatory Affairs/Center for Veterinary Medicine	12.5(5)	12.4 (5)	138 (5)	137 (5)
Field Operations—Subtotal	**128.7 (56)**	**146 (56)**	**1,564 (62)**	**1,672 (64)**
Headquarters Operations—Center for Food Safety and Applied Nutrition	78.3 (34)	88 (34)	733 (29)	721 (28)
Headquarters Operations - Center for Veterinary Medicine	23.7 (10)	25.5 (10)	203 (8)	206 (8)
Headquarters Operations—National Center for Toxicological Research	.6 (<1)	.6 (<1)	4 (<1)	4 (<1)
Headquarters Operations—Subtotal	**$102.6 (44)**	**$114 (44)**	**940 (38)**	**931 (36)**
Total*	$231.3 (100)	$260 (100)	2,503 (100)	2,603 (100)

*Totals may not add because of rounding.

FDA's field activities include inspections of establishments under the agency's jurisdiction and analysis of product samples to ensure that the products are in compliance with applicable regulations. Table 4 presents selected results from FDA's inspection and sample analysis field work.

Table 4: Selected FDA Food Safety Inspection and Sample Analysis Activity, Fiscal Years 1998 and 1999

Activity	1998	1999
Inspections		
Food importers	940	765
Domestic food establishments[a]	11,922	14,680
Feed establishments[b]	4,182	3,128
Total inspections[c]	**17,044**	**18,573**
Sample Analysis		
Domestic food samples	10,894	9,335
Import food samples	16,802	15,439
Feed samples	1,580	1,784
Total samples analyzed	**29,276**	**26,558**

[a]Includes state contract inspections that are funded by the Center for Food Safety and Applied Nutrition at a cost of a little over $2 million each year.

[b]Includes state contract feed mill inspections that are funded by the Center for Veterinary Medicine at a cost of $833,000 and $614,000 in fiscal years 1998 and 1999, respectively.

[c]An individual importer, food or feed establishment may be inspected more than once in a year.

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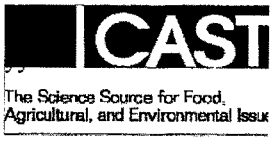

TESTIMONY OF MICHAEL P. DOYLE, PH.D.
DIRECTOR, CENTER for FOOD SAFETY and QUALITY ENHANCEMENT
UNIVERSITY OF GEORGIA

On behalf of
THE COUNCIL for AGRICULTURAL SCIENCE and TECHNOLOGY (CAST)

Before the
U.S. SENATE
AGRICULTURE, NUTRITION and FORESTRY COMMITTEE

FULL COMMITTEE HEARING on FOOD SAFETY
WASHINGTON, D.C.

SEPTEMBER 20, 2000

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Thank you Mr. Chairman and members of the Committee. I appreciate the invitation to present testimony for the Senate Committee on Agriculture, Nutrition and Forestry, especially as related to approaches to increase the microbiological safety of foods. I hope my testimony will be helpful in understanding the value of the Hazard Analysis and Critical Control Points (HACCP) approach to increasing the safety of foods, and in identifying changes needed in the food safety system to aid in the reduction of microbial contamination.

I am Michael P. Doyle, Director of the Center for Food Safety and Quality Enhancement at the University of Georgia. My primary professional experience has been focused on research for developing methods to detect and control foodborne bacterial pathogens at all levels of the food continuum, from farm to table. My primary involvement in the topics of interest to this committee include membership on the National Academy of Sciences, Institute of Medicine Committee to Ensure Safe Food from Production to Consumption; on the Council for Agricultural Science and Technology (CAST) Task Force on *Food Pathogens: Risks and Consequences*; on the National Advisory Committee on Microbiological Criteria for Foods; and on the International Commission on Microbiological Specifications for Foods. All of these groups have issued reports addressing approaches to improve the microbiological safety of foods.

I am testifying on behalf of CAST, which is a nonprofit consortium of 38 scientific societies representing more than 180,000 scientists and many individual, student, company, nonprofit, and associate society members. The mission of CAST is to identify food and fiber, environmental, and other agricultural issues and to interpret related scientific research information for legislators, regulators and the media for use in public policy decision making.

The information I shall provide largely has been extracted from three sources. These include: (1) the CAST report *Foodborne Pathogens: Review of Recommendations*, Special Publication No. 22, October 1998; (2) the CAST report *Foodborne Pathogens: Risks and Consequences*, Task Force Report No. 122, September 1994; and (3) the Institute of Medicine report *Ensuring Safe Food from Production to Consumption*, National Academy Press, 1998.

A large variety of microorganisms, having varied growth characteristics, unique niches in animals and processing facilities, and differing tolerances or sensitivities to food preservatives and processing treatments, are responsible for an estimated 76 million cases of foodborne illness annually in the United States. Considering the wide diversity in sources, tolerances, and growth properties of foodborne pathogens, there is no single process that can assure absolute safety of all foods and retain desirable eating characteristics. For this reason, a science-based systematic approach that identifies and assesses the microbiological hazards and risks associated with a food and incorporates effective treatments for their control was needed to effectively reduce the risk of foodborne illness. The HACCP system subsequently was developed to meet this need, largely through the efforts of the International Association of Microbiological Societies (IAMS) International Commission on Microbiological Specifications for Foods (ICMSF), and the U.S. Department of Agriculture (USDA) and U.S. Food and Drug Administration (FDA) National Advisory Committee on Microbiological Criteria for Food. The ICMSF is linked to the World Health Organization (WHO) and hence is a body of the United Nations. Many refinements and improvements of HACCP have been made since the HACCP concept was first introduced;

however, the HACCP system is believed by the food safety community to be the best approach available, both nationally and internationally, for reducing the risk of foodborne illness. CAST recommends that HACCP principles be applied from farm or other production sources through consumption.

It should be recognized that HACCP is not a panacea. For example, it will not detect emerging hazards and no minimal level of safety is guaranteed. Furthermore, the HACCP approach is a dynamic process, and refinements and adjustments will continually need to be made as new foodborne hazards are detected and processes are modified. A major limitation to the adoption of HACCP by food processors is that small firms have minimal resources to develop, implement, and maintain effective HACCP plans. Progress is being made at this level but more resources may be needed to assist small processors in adopting the HACCP system.

Under current statutory and budgetary constraints, however, the benefits of HACCP systems cannot be fully realized. For example, current resources are inadequate to continue traditional inspection and to implement HACCP systems fully. A glaring defect in the present USDA meat and poultry inspection system is that substantial resources are directed to problems that do not have the greatest human health impact (for example, carcass-by-carcass organoleptic [primarily visual and odor detection] inspection of meat and poultry). The elimination of continuing inspection for meat and poultry would not necessarily end all ante- and postmortem inspections of carcasses if HACCP programs were appropriately developed and implemented. Such programs would have to include appropriate methods to identify diseased animals, which might require some level of carcass inspection as identified by hazard analysis.

An additional impediment to the application of HACCP to reduce the risk of foodborne illness is the failure of many segments of food production to adopt effective intervention strategies that could be used on the farm in a HACCP program. When practical and effective intervention strategies at the farm and on-site preharvest levels are made available, food producers should be provided resources where needed and should be required to use such strategies in the interest of enhancing public health. The importance of preharvest practices has been highlighted by several recent developments such as the increasing identification of fruits and vegetables causing U.S. outbreaks of foodborne illness, the specter of bovine spongiform encephalopathy in United Kingdom cattle and *E. coli* O157:H7 in U.S. cattle, and worldwide increases in bacterial resistance to antibiotics. Produce and animal preharvest practices are important opportunities for controlling or minimizing spread of foodborne pathogens. Attention should be given to development and implementation of practical and effective control strategies at the production level.

An overarching impediment to providing efficient and effective regulatory attention to microbiological food safety issues is the major statutory shortfall that exists for our current system. Specifically, there are inconsistent, uneven, and at times archaic food statutes that inhibit use of science-based decision-making in activities related to food safety. Also these statutes can be inconsistently interpreted and enforced among agencies. For example, the current directive embedded in statute (Meat Inspection Act, 1909; Poultry Products Inspection Act, 1957) requires each meat and poultry carcass to be subject to physical inspection. Although physical inspection may have been appropriate for the hazards present 70 years ago, the process

impedes the Food Safety Inspection Service's (FSIS) efforts to allocate its substantial regulatory resources in ways that correspond to the health risks presented by contemporary sources of food or modern means of food production and processing; specifically, the implementation of HACCP-based inspection. In short, the hazards of greatest concern today are microbiological contamination and they are not readily detectable with the traditional inspection methods of sight, sound, odor, and touch. This regulatory statute impedes coherent, risk-based regulation to enable implementation of a more science-based inspection system now available to regulatory agencies.

Again, thank you Mr. Chairman for the opportunity to comment on this very important issue. I will be happy to answer any questions that you or members of the committee may have.

The mission of the Council for Agricultural Science and Technology (CAST) is to identify food and fiber, environmental, and other agricultural issues and to interpret related scientific research information for legislators, regulators, and the media for use in public policy decision making.

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Statement of Dane Bernard
on behalf of
The National Food Processors Association
Before the Committee on Agriculture, Nutrition and Forestry
United States Senate
"How Should Our Food Safety System Address Microbial Contamination?"
September 20, 2000

Mr. Chairman and Members of the Committee: My name is Dane Bernard, and I serve as Vice President of Food Safety Programs for the National Food Processors Association (NFPA). I am pleased to join the Committee today to discuss the important issue of food safety and how our nation's food safety system addresses those threats posed by microbial contamination. I am a microbiologist by training, and, in my position at NFPA, I oversee the Association's food safety-related technical and regulatory affairs activities.

NFPA serves as the scientific and technical trade association for the $460 billion U.S. food processing industry. We operate three laboratory centers and employ approximately 75 scientific and regulatory experts. NFPA's primary mission focuses on food science and food safety. Our strong scientific and technical base gives us unique expertise on food safety issues, and we are pleased to have the opportunity to participate in today's hearing.

The Food Supply is Safe

American consumers continue to enjoy a safe and abundant food supply. Actual data of food-related illnesses compiled by the Centers for Disease Control and Prevention (CDC) indicate that the greatest risk to consumers appears to be that presented by microbial pathogens that may occasionally contaminate food products

Food Safety is a Shared Responsibility

In this day of farm-to-table food safety, it has become increasingly obvious that food safety is a responsibility shared by all stakeholders. It is the responsibility of the food industry to provide foods that meet the safety expectations of our consumers. Toward meeting this goal, the

food industry implements hazard control programs; conducts testing of ingredients, products during processing, and finished food products; provides assistance to foreign producers who provide ingredients and raw materials; conducts audits of suppliers; and carries out many other activities on a voluntary basis to help assure that foods are safe and wholesome.

The total efforts of the food industry in assuring the safety of food through self-inspection and testing amount to significantly more than those of the collective government agencies who claim responsibility for food safety. At the same time, however, the industry mission is most successfully fulfilled within an environment of fair, science-based laws and regulations that facilitate the production of safe foods. In order to ensure that the regulatory inspection system is fair and science-based, NFPA feels there are issues that deserve attention. These will be discussed later.

HACCP Is an Integral Component of Food Safety Management Systems

The current paradigm for addressing food safety issues is the implementation by industry of the Hazard Analysis and Critical Control Points (HACCP) concept. While it is widely accepted that HACCP is the best system for assuring safety of foods, it is not a magic wand that will fix all food safety problems. HACCP can successfully allow the government and industry to address food safety issues, as long as it is understood what HACCP is and what its limitations are.

HACCP is a management tool that facilitates the focusing of resources and control measures on those hazards that pose a risk to consumers. HACCP can only be effective in controlling those risks if adequate and appropriate control measures are applied. In certain situations, few control measures are available that can eliminate microbial hazards that may be associated with some foods or ingredients. Unfortunately this is the situation with most raw products. Thus, without application of some globally effective process like irradiation to raw products, the best that can be achieved is a reduction in the level of the hazard.

HACCP has been adopted by the Food and Drug Administration (FDA) for the regulation of the seafood industry and by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) for the regulation of the meat and poultry industry. While recent information indicates these programs are enjoying success in reducing levels of hazards associated with raw and processed products, HACCP, as a regulatory tool, is still a work in progress. Some have begun to criticize these efforts, but NFPA continues to believe that HACCP offers the best approach to assure the safety of our food supply.

In our view, successful implementation of HACCP involves basic changes in the nature of the industry-regulatory agency relationship. After 90+ years of regulation in one mode, certain habits are difficult to change, but change is necessary for any contemporary food safety system to be able to address new challenges. Toward this end, the agencies involved have recognized a need for ongoing flexibility. In late 1999, many organizations from the food industry collectively petitioned the FSIS to consider certain changes to the Pathogen Reduction HACCP Rule. This "friendly" petition was aimed at sharpening the focus of application of HACCP in the

meat and poultry industry and at reducing some of the factors observed in the field to have been confusing. In our estimation, addressing these issues will promote a more complete understanding of HACCP and will help to achieve its full potential as a food safety assurance tool.

The Appropriate Role of Microbiological Testing in a Regulated HACCP System Must be Determined

One controversial item related to the responsibilities of government and industry within a HACCP framework is the role and utility of microbiological testing. This topic has been the subject of debate for both FDA- and FSIS-regulated products. In particular, several questions have arisen about the application of microbiological standards in a regulated HACCP system.

To the heart of the matter, FSIS, in its combined Pathogen Reduction HACCP Rule, established mandatory microbiological standards for *Salmonella.* Microbiological standards are not a new concept, as they have been applied for decades in the processed food area. For example, canned goods and products that are cooked and ready-to-eat are expected to be free of pathogenic microorganisms capable of causing illness when the foods are properly handled by the consumer. These criteria have been a regular part of our food safety system and they work. Further, microbiological criteria focused mainly on indicator organisms have been used routinely by the food industry on a voluntary basis for both raw and processed products as a guidepost to indicate that there may be operational or production problems deserving further investigation.

What is unique about the *Salmonella* standards contained in the FSIS Pathogen Reduction HACCP Rule is that for the first time bright-line, pass/fail standards based on frequency of finding *Salmonella* were broadly applied to products that are not ready-to-eat. While NFPA believes that the goal of providing more focus on microbiological quality is laudable, such standards are simply not appropriate when used as a pass/fail regulatory tool. These standards do not measure whether a product is safe or whether the operation that produced the product is sanitary. Such microbiological measurements are a very useful tool as an operational or production quality control indicator, but are not reliable as a definitive regulatory measure.

Quite simply, a tool that works well as a guidepost to indicate that there may be operational or production problems deserving further investigation is not

necessarily appropriate as a bright-line, pass/fail microbiological standard for raw commodities

Application of such microbiological criteria as bright line standards will, sometimes arbitrarily and unfairly, discriminate against and result in closure of some establishments. This is the nature of mandatory microbiological standards, especially those that are not strictly tied to achieving a specific public health goal, where the pass/fail level is somewhat arbitrary. In addition, smaller firms will have a more difficult time in meeting these criteria, as they may lack the technical and financial resources needed to consistently meet the criteria, resulting in more and more plant closures and consolidation.

NFPA feels that there are opportunities to utilize results of microbiological testing of raw products to achieve the desired result of improvement in the food supply within a HACCP system, but without arbitrarily and unfairly discriminating against certain facilities. The approach we suggest is one where results of microbiological testing are used to indicate that an in-depth investigation is warranted rather than a determination that product or an establishment is non-conforming solely on the basis of the test results. We also note here that FDA has taken a somewhat different, and we feel a more scientific approach from FSIS on certain raw foods by issuing growing and production guidelines that will lead to better controls rather than an over reliance on microbial testing with its inherent variability.

Support Is Needed for The Development and Implementation of New Food Safety Technologies

NFPA feels that, eventually, there must be other questions addressed by all stakeholders: What is a fair criterion, (or standard) for raw products, and what is our ultimate goal in terms of hazards associated with raw foods? As we continually strive for "zero," we must either make quantum leaps in technology or submit to eating only foods that are canned, irradiated, or treated in some other way to sterilize them

New and innovative ways to address hazards is our most important need relative to advances in food safety. To meet this demand for new technologies and innovations, barriers will have to be overcome. Time, money and fresh ideas are clearly the chief barriers to development and implementation of new technologies.

However, even for those technologies that have been fully developed, scientifically well-documented, and proven safe, regulatory approvals for use have taken far too long. For example, an extensive petition was filed with FDA in July of 1994 for pre-market approval of irradiation for red meat. It was not until December, 1997 that FDA granted the petition, and not until December of 1999 that the final rule making this food safety technology available was issued by FSIS. A petition for use of ultraviolet light for the reduction of pathogens in juice products is still under review by FDA more than a year later.

To overcome these barriers, resources need to be allocated to provide the appropriate but expedited review of food safety enhancements. In addition, funding must be provided to organizations such as the Agricultural Research Service and the Joint Institute for Food Safety Research, for academia, and to private concerns to assist in the development and validation of new technologies and technological innovations. To assure sustained progress Congress must provide appropriate advocacy for technological innovation and frequent oversight of government appropriations to assure that funds allocated for this purpose are being effectively used.

Some Issues in the Food Safety System Must Be Addressed

As noted earlier, it is NFPA's opinion that if progress on food safety issues is to continue, some issues and concerns need to be resolved. One of the key issues is training and management of our food inspection force. Full utilization of HACCP will require a higher level of understanding of potential food safety problems and their resolution by inspection personnel, as well as a shift in attitude.

Thus, in the longer term, there must be a transition to an inspection force more attuned to hazards and their controls and to the potential for certain actions to result in food safety problems. There will be a need to differentiate minor infractions from those that can have a significant adverse impact on the safety of a product. In addition, the system must find a way to provide assistance to those food operations that are eager to do the right thing, if they only knew what the right thing is. All of this will require specialized training, and the ability to actually work together with industry. Regulatory agencies, in particular FSIS, will need flexibility to make changes in inspection modes and make adjustments in

inspection tasks. Toward this end, we applaud the FSIS efforts to modernize its inspection practices through pilot testing inspection changes during the HACCP Implementation Models Project.

In addition, NFPA continues to advocate better coordination between FDA and USDA on food safety policy. We also call the Committee's attention to the Association of Food and Drug Officials estimate that as much as 80% of food-related inspections and regulatory activities are conducted by State and local authorities. Coordination of Federal, State and Local efforts is essential to a uniform and effective inspection system without duplication and unnecessary overlap . We urge Congress to support better coordination of these efforts through funding and oversight of the National Food Safety System and increased uniformity in our federal and state food laws.

Conclusion

We recognize that increased focus on microbiological quality of raw commodities can be of benefit. However we foresee the need for well-based, scientifically accurate criteria applied in a non-punitive way as the vehicle for progress. Thus, we recommend that this area receive the attention of an expert body to more fully explore appropriate establishment and use of microbiological criteria within contemporary food safety assurance programs. In this context, the U.S. National Advisory Committee on Microbiological Criteria for Foods can provide some review of specific items or scientific information. Congress may also wish to request a comprehensive review of this entire topic by an institution such as the National Academy of Sciences.

Thank you for your time and thank you for the opportunity to testify before this Committee.

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Testimony of

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Vice President, Scientific and Technical Affairs
United Fresh Fruit and Vegetable Association

Before the Committee on Agriculture, Nutrition and Forestry
United States Senate

Washington, D.C.
September 20, 2000

Congressional Testimony on Produce Food Safety

Chairman Lugar, thank you for this opportunity to testify before the Senate Committee on Agriculture, Nutrition and Forestry. I am here today on behalf of the United Fresh Fruit and Vegetable Association, as their Vice President of Scientific and Technical Affairs. Through my career that has been focused on food safety, I have gained extensive management and technical experience with both the production and handling of fresh fruits and vegetables.

The United Fresh Fruit and Vegetable Association (United) is keenly interested in the topic of food safety. Over 1,100 member companies and organizations make up United, an association that was founded in 1904. United is the national trade association that represents the interests of producers, wholesalers and distributors of commercial quantities of fresh fruits and vegetables. Our members take very seriously their responsibility to provide consumers with safe, high quality, nutritious produce.

I want to emphasize at the outset of my testimony that fresh fruits and vegetables are remarkably safe products. Despite the recent attention that produce safety issues have received, United is convinced that alarming reports by the media and the fears of some public health officials far

exceed the actual risks associated with the consumption of fresh fruits and vegetables. The evidence indicates that in the majority of cases, when the consumption of fresh fruits and vegetables has resulted in an outbreak of illness, the cause is often related to improper handling or cross-contamination with other potentially hazardous foods during food handling and meal preparation. Nonetheless, United is committed to enhancing the safety of produce and we welcomed the publication of Food and Drug Administration (FDA) guidance. We recognize that growers, packers, shippers and other handlers play an important role in assuring the safety of produce and we are presently using FDA's guidance to help prevent or minimize potential microbial hazards.

In the remainder of my testimony, I will turn to the questions specifically posed by the Committee.

Is microbial contamination the most significant threat to our food safety system?

It is the belief of the U.S. food safety agencies that microbial contamination is the most significant threat to our food safety system. United believes that fresh fruits and vegetables are consistently safe to consume, but we do share the belief that microbial contamination is far more a significant threat than chemical or physical contamination to the safety of the produce industry. The regulated and responsible use of agricultural chemicals in the produce industry is well documented year after year in U.S. federal and state governmental surveys of pesticide residues and pesticide use reporting of both domestic and imported fruits and vegetables. However, a risk or hazard-based food safety program should not neglect potential chemical and physical contamination.

What is the value of the Hazard Analysis and Critical Control Points (HACCP) approach to food safety in addressing microbial contamination?

It is widely accepted among food safety professionals that prevention of microbial hazards is far more effective than trying to ascertain and verify the safety of food after its been produced and handled. Prevention is the core element of HACCP.

The HACCP concept is being promoted as an improved procedure for the management of food safety. The HACCP concept is relevant to all stages throughout the food chain from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. However, certain points in the food chain are better suited to the application of the HACCP principles. We have recognized that certain segments of the produce industry benefit significantly from the development and implementation of HACCP programs, i.e. fresh-cut produce, fresh juice, and sprouts. Unfortunately, in the growing, harvesting and packing of fresh fruits and vegetables an actual HACCP program can most often not be implemented because a critical control point can not be identified or due to the lack of control measures, such as wildlife or climatic environmental conditions. However, the use of certain HACCP principles such as the hazard analysis can be very helpful in identifying potential hazards and/or practices that need improvement.

In general, the produce industry has found more value in the adoption of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) in addressing microbial contamination in the growing, harvesting and packing of fresh fruits and vegetables. In October 1998, FDA and United States Department of Agriculture (USDA) published a guidance document which has been used by growers and packers for the identification of potentially significant microbial food safety risks and appropriate measures to prevent or minimize the occurrence of microbial hazards in produce through the use of GAPs. This document has captured the attention of governments worldwide. In fact, there is keen interest in understanding and using, where possible, the recommendations contained in the guidance among all our major trading partners.

What are the barriers to the development and implementation of new technologies and tools to detect, prevent and reduce microbial contamination?

The current federal approval system is slow to adopt new technologies that can improve food safety due to potential for harm if inadequately evaluated. In some cases, there is little economic incentive to develop or adopt new technologies if it appears that regulatory agencies and/or consumers will not accept it, i.e. irradiation.

Basic understanding and research about the epidemiology, ecology, and molecular mechanisms involved in the array of pathogens confronted and the control procedures needed at the farm level require a larger investment than currently exists. There is no nationally coordinated scientific research agenda among all agencies involved in food safety that stems from a unified mission or centrally focused leadership. This indicates a significant lack of adequate integration of research efforts among federal and state agencies. Federal, state, and local authorities must work with varied amounts of resources, skills, and legal authority that are often inadequate to support a science-based system.

Education of food handlers throughout the farm-to-table continuum is an important component or tool in the prevention or reduction of microbial contamination. As in the areas of food safety research, appropriate funding of grassroots food safety education campaigns for food handlers do not currently exist. Education efforts can be enhanced by private sector efforts, but should be primarily funded through federal and state agencies and institutions.

Are changes needed in the food safety system to aid in the detection, prevention and reduction of microbial contamination?

An effective food safety system must be supported by funding adequate to carry out its major functions and mission which is the public's health and safety. Food safety in the United States lacks allocation of funding based on science and sustained political support.

Also, federal, state, and local agencies should dedicate a significant portion of its resources in preventing food safety problems, rather than dealing with them after the fact. In other words, these agencies must develop and initiated food safety programs that are proactive versus reactive.

Conclusion

I hope the Committee will realize that we cannot rely exclusively on federal and state agencies to assure the safety for fresh fruits and vegetables. In the end, those who actually grow, handle and market the produce that we consume are the same people on whom we must rely to assure the safety of these products. The produce marketplace is highly intolerant of unsafe food and will react swiftly and negatively to outbreaks of foodborne illness. Today, grocery retailers and restaurant operators routinely ask their produce suppliers what measures have been implemented to assure safety. The produce industry has made great strides here and abroad to identify potential sources of microbial hazards in fresh fruits and vegetables, and United's members are willing to implement prudent measures to prevent problems.

However, the safety of the food system could be further enhanced by increasing the allocation of funding and resources for research and education based on sound science and demonstrating a more coordinated effort among federal, state, and local agencies.

Thank you for this opportunity to testify. I look forward to answering your questions.

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Testimony

on behalf of the

NATIONAL CATTLEMEN'S BEEF ASSOCIATION

in regard to Food Safety

Presented and Submitted to

The Senate Agriculture, Nutrition and Forestry Committee
Food Safety Hearing

Chairman Dick Lugar
Tom Harkin, Ranking Member

submitted by

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September 20, 2000

Producer-directed and consumer-focused, the National Cattlemen's Beef Association is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

Good morning. My name is Gary Weber; I am the Executive Director for Regulatory Affairs for the National Cattlemen's Beef Association. On behalf of the more than 230,000 members, 45 State cattle associations and 27 national breed organizations, I want to thank you Chairman Lugar, Senator Harkin and Members of the Committee for holding this hearing to discuss the issue of food safety.

The NCBA commends you and this committee for providing this opportunity to examine the issues affecting our continual efforts to provide consumers with the most safe and wholesome beef supply in the world.

Let me preface my remarks by saying we have been ardent supporters of a more science-based meat inspection system, specifically the principles inherent in the Hazard Analysis and Critical Control Points or HACCP approach.

We have also been supporters of the need to conduct microbial testing as a means of verifying the performance of HACCP plans.

However, we must recognize that we do not have the ability to produce and distribute fresh meat products with current technology that are sterile. Some level of microbial contamination is virtually unavoidable.

Your first question, **"Is microbial contamination the most significant threat to our food supply?"** is an appropriate starting

point for this hearing. On the surface, the simple answer appears to be yes. However, the truth is that individuals greatly influence the microbiological risks inherent in or on foods through their actions in the production, processing, transport, handling and cooking of meat products.

When individuals, from the farm to the table, carry out their respective responsibilities to raise, process, transport, handle and prepare foods correctly, there is little risk to public health from the known, inherent and expected microbial contamination in or on fresh meat products.

This leads to your next question, **"What are the food safety responsibilities of the federal government and the private sector related to microbial contamination?"**

While at each step from the farm to the table, steps can, and arguably must be taken, to reduce the risk of food borne illness; some individuals won't fulfill responsibilities. Hence, historically, the government has regulated the industry at key points in the farm-to-table continuum to protect the safety of the meat supply.

For many reasons, the government's focus has been on the packing and processing phase of the industry. This is thought to be where the greatest benefits can be made to protect public health because it is the funnel through which all meat animals must pass.

With the advent of HACCP, an evolutionary process has begun. The government inspection system is changing incrementally as is the role of the industry. Hopefully, we are moving toward a point where a more collaborative, cooperative relationship will develop between government and industry to ensure continued improvements in food safety. We are not there yet but that must remain the primary focus.

We must be careful not to do anything that would allow or force the government's role in terms of HACCP to return to the "command and control" mode. We must also be careful not to impact the industry in such a way as to stop or reverse the dramatic progress that has been made as the result of industry taking more responsibility for food safety.

In other words, we need to continue to foster the continued evolution of HACCP.

Your question **"What is the value of the HACCP approach to food safety in addressing microbial contamination?"** can be addressed, in part, by focusing on the concept of "critical limits." Once a hazard is identified, such as Salmonella for example, then we have to discuss what the critical limit should be. How much Salmonella should be allowed? When the HACCP rule was written, no one really knew, so the USDA decided to take a shot at it. They developed a set of baseline data for each of the species and decided that the industry should try to be at or below the average. The average was now for all intents and purposes, the "critical limit." This limit had no real

relationship to public health; it was just what the industry seemed capable of doing. It was a starting point in this evolutionary process of implementing HACCP.

I must say the "critical limit" for Salmonella for beef was 25 times less than the one set for poultry. Effectively we can have one packing plant processing poultry running a 25% Salmonella positive rate, while another company processing beef cattle might be shut down by the government because their Salmonella positive rate went over the 1% mark one too many times!

In truth, the microbiological "critical limits" should be based on science and a realistic, rational risk assessment, consistent with identifiable and achievable public health goals and documented benefits, not simply on what the industry is currently doing. I must add, however, that while the government had to start someplace, it seems the time is right to evolve to a more science based "critical limit." That limit, given current technology, is not "zero."

In addition, with respect to microbial "critical limits," these should be viewed as targets rather than absolutes. Levels should be monitored. If found to be moving in the wrong direction, cooperative and collaborated efforts on the part of government and industry should begin. This will result in a better understanding of the situation and a stabilization or shifting of the trend the other way. Most often, this takes time, money and technology.

Your next question relates to the challenges facing the industry in terms of "...**barriers to the development and implementation of new technologies and tools to detect, prevent and reduce microbial contamination.**"

The NCBA has invested millions of Check-off dollars to develop and validate technologies that will reduce the contamination on beef carcasses. We have shown that through the use of a multiple set of interventions such steam vacuuming, antimicrobial rinses and steam cabinet pasteurization; we can reduce microbial contamination levels by over 99%. These interventions are in place and functional in plants that process nearly 90% of all beef cattle in the United States. Today, beef has the best microbiological profile of all meat and poultry inspected by the USDA.

An array of new technologies is being developed that will improve the microbiological profile of meat products. However, despite all the interventions that are in place, no one can ensure these products are totally free of bacteria, either benign or pathogenic.

The development of more rapid, more sensitive and specific microbial testing systems holds promise to offer almost real-time detection of pathogens. These should allow more responsive HACCP based decision-making and enhance the ability of the industry and government to verify systems are under control and meeting their targets.

Your last question, **"Are there changes needed in the food safety system to aid in the detection, prevention and reduction of microbial contamination?"** might be simplified to ask are there changes needed in the food safety system, period. This would include a wider array of options and suggestions.

As I stated earlier, we have viewed development of HACCP as an evolutionary process for both government and industry. It is a process that should embrace the concept of continuous improvement.

The microbial performance targets currently used in the regulatory component of HACCP, the --"critical limits" -- need to be revisited. They need to be more science based, and linked to tangible public health benefits. The pressure to continually reduce the "critical limits" will logically run head long into the law of diminishing returns. We need to ask what is the real significance to public health of the "critical limits" in a science and risk-based assessment.

The regulatory process needs to employ a more cooperative, collaborative approach whereby government and industry work together to achieve mutually established goals that work to protect public safety. The adversarial, command and control approach of the past is not consistent with HACCP.

In order for government regulations not to contribute to more consolidation of the livestock industries and corresponding loss of small businesses when problems arise, government should reach for

technical assistance rather than reach for the stick. The paradigm must continue to shift from adversarial command and control to collaboration and cooperation focused on science-based microbial performance targets correlated to real public health benefits.

Let me close by asking the Committee to consider the follow request for assistance.

1. We need more research dollars and a coordinated government, industry and consumer driven priority setting process and better access to plants for research purposes.
2. We must establish a means of developing more science and risk assessment based "critical limits."
3. We need a more rational and logical regulatory framework consistent with the concepts of HACCP and the regulated sector's true "sphere of influence" and enforced in a more cooperative collaborative manner.
4. Last but not least, we need technical assistance education from the farm to the table to aid in our pursuit of an even safer food supply.

Thank you again for this opportunity to address the challenges facing us as we continue to provide consumers in this country and around the world the safest and most wholesome meat products.

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Statement of
Ann Hollingsworth, Ph.D.
President, American Meat Science Association
On behalf of
American Meat Institute and
American Meat Science Association

before the
Senate Agriculture Committee
September 20, 2000

Thank you for inviting me to testify on the best ways to reduce microbial contamination in the U.S. food supply. As a meat scientist and a meat industry executive, I have worked in this arena for more than 20 years. I am speaking today on behalf of the American Meat Science Association, a professional society of 1000 meat scientists and the American Meat Institute, the nation's oldest and largest trade association representing beef, pork, lamb, veal and turkey slaughterers and processors. Based on my training and experience, I'd like to make a few observations at the outset, followed by three key messages.

First, let me share my observations about meat's microbiological safety in the year 2000:

- Pathogens have truly become "public enemy number one" for everyone in the meat processing industry. Twenty years ago the enemy was fat; forty years ago the enemy was animal diseases. But today, it is definitely pathogens. Based on our success fighting animal diseases and too much fat, I expect we will win our "war on pathogens" and move onto some other battlefront before too long.
- Meat has less bacteria of all kinds - harmful and benign - today than it did even 10 years ago. Government and industry surveys show reductions in *Salmonella* and generic *E. coli* on raw meat and poultry, and *Listeria* on ready-to-eat meat and poultry, over the past 10 years.
- Meat slaughtering and processing companies have better food safety technologies and training in place today than ever before, and these have made the major difference in food safety improvements.
- Foodborne illness rates are decreasing, safe food handling awareness is increasing, both of which contribute to better public health.

From my perspective, I definitely see the "glass half full" when it comes to the microbiological safety of meat.

I have three messages to leave with you today:

- First, on the much-discussed topic of microbiological testing, I must tell you that it is an important tool for verifying good process control in a plant, but on its own it does nothing to assure food safety. So it is part of something larger -- and should never be viewed as a "stand-alone" segment of food safety systems.
- Second, we should all be looking harder at technology and education as the true keys to reduced microbial contamination in our food supply. Both the public and private sectors could do more practical research and development, at every segment of the food chain, to identify technological and educational solutions to contamination problems.
- Third, government has not always managed its regulatory resources well in the war on pathogens. For example, declaring pathogens illegal in raw agricultural products (such as *E. coli* 0157:H7 in ground beef) has discouraged industry testing, given consumers a false sense of security and given some in government and industry the false "crutch" of microbial testing to lean upon instead of developing better control measures. Government should reevaluate its efforts to reduce microbial contamination -- in concert with the scientific, public health and industry communities.

Microbiological Testing - An Important Food Safety Tool

Microbiological testing has been used for decades in the food industry - including the meat industry - to verify good plant hygiene or good process control. In fact, 32 meat scientists from government, industry and academia developed a consensus paper in January 1999 on "The Role of Microbiological Testing in Beef Food Safety Programs." The paper is available through the American Meat Science Association and I am submitting a copy with my written testimony. My comments on microbiological testing are largely derived from that paper.

Most scientists agree that successful microbiological testing programs must be associated with achievable and verifiable microbiological criteria. So microbiological criteria - such as the absence or presence, or limited presence, of a microbe - are necessary. And to underscore what may not seem as important to you but are actually critical: the criteria must be achievable and verifiable. In other words, if it's not possible to achieve or measure, it won't work.

Interestingly, the National Research Council assembled a panel of experts to develop recommendations on microbiological criteria for foods in the early 1980s. Their 1985 report addressed 22 groups of foods and food ingredients -- and for raw meats, the experts did not recommend establishing microbiological criteria because such criteria would neither prevent spoilage nor foodborne illness. According to the panel, pathogens of public health concern are often present in small numbers as part of the natural microflora of live animals, and in 1985 - as today - could not be totally eliminated through animal husbandry and meat processing techniques. Therefore, the panel stated

that it would be impractical to set limits for microbiological pathogens in raw meats as it would be impossible to comply consistently with the limits.

Instead, the NRC panel recommended 1) a recognition that low levels of pathogens may be present on raw meats; 2) strict adherence to good food preparation practices; 3) application of new processing procedures designed to reduce the presence of pathogens; 4) education on food handling practices; and 5) implementation of HACCP.

Both AMI and AMSA agree that microbiological sampling is a useful food safety verification tool in the context of a total food safety process control system. The groups also agree that microbiological criteria are useful in a food safety system as long as they are both achievable and verifiable. However, the groups do not support punitive action from USDA if a plant fails to meet microbiological criteria that do not measure plant hygiene or product adulteration.

Technology and Education - Keys to Reduced Microbial Contamination

Just in the past 10 years, the meat industry has made phenomenal reductions in microbial contamination through the use of new technologies. In the beef and poultry sectors, carcass washing and rinsing technologies involving various combinations of heat, cold and chemicals have reduced microbes by up to 95 percent or more. I know it may be hard to believe, with all the publicity over *E. coli*-related beef recalls, but the products today are actually more microbiologically safe than they were 10 years ago.

Education and heightened awareness plays a tremendous role in all manufacturing industries. *Listeria* control is a perfect example. We don't have any significant new technologies for *Listeria* control - yet - but through vigilant sanitation efforts, the incidence of this pathogen in both hot dogs and lunch meats has dropped dramatically over the past 10 years. Again, headlines in the press would lead you to a different conclusion, but according to USDA data, the incidence of *Listeria* in lunch meats dropped from 10.7 percent to 4.6 percent between 1989 and 1999; and the incidence in hot dogs dropped from 7.9 percent to 1.8 percent in the same time period.

And let's not forget consumers and professional food preparers. They have received intensive education about safe food handling from both the public and private sectors over the past 10 years. Those efforts are paying off, with surveys showing consumers more aware than ever of safe food handling and preparation methods.

Some Suggestions for Government Food Safety Improvements

I believe the federal government shares the concern we all have about reducing microbial contamination of foods. I also believe the government has tried to make a positive difference in the safety of the food supply. But, from my perspective, the government in total and USDA's Food Safety and Inspection Service in particular have made some wrong turns and sent some mixed signals that, in some cases, have probably inhibited food safety improvements.

I would like to close by offering seven suggestions for consideration by FSIS that I believe would lead to more constructive use of microbiological criteria and a reduction in microbial contamination in meats.

The challenge for FSIS is how to incorporate a microbiological monitoring and surveillance system into an equitable regulatory scheme that is designed to reduce the pathogen level on raw meat and poultry products. Some points need to be made in this regard:

1. A pathogen monitoring and surveillance system must be designed to measure trends over time. Statistical process control techniques or other appropriate statistical analysis should be used to evaluate the data. For example, an upper limit could be set at three standard deviations above the mean to accommodate normal process variability. Two consecutive data points that exceed the upper limit could trigger an investigation of the plant's control programs. (USDA currently measures performance over time in its existing *Salmonella* performance standards, however, the principle is not based on the principles of statistical process control. Data feedback is too slow and unresponsive for a plant to effect meaningful change.)

2. In theory, each plant should set its own microbiological criteria to accommodate normal process variability, but that would create unjustified inequities between plants regardless of the degree of control exercised by the plant. Therefore, microbiological criteria should be established to allow for differences that are primarily attributable to the live animals entering the slaughter facility. For example, USDA could establish criteria that are based on seasonal, regional, species and class differences. (USDA accounts for species and class differences but not for regional and seasonal differences in its *Salmonella* performance standards.)

3. If microbiological criteria are established to account for seasonal, regional, species and class differences, it must be recognized that the primary objective is to reduce the overall incidence of pathogens in the raw meat and poultry supply. Except for *E. coli* O157:H7 in ground beef, the mere presence of pathogens on raw meat and poultry products does not legally render the product to be adulterated nor does it make the product unfit for human consumption. Therefore, the appropriate regulatory response for a plant that repeatedly does not meet the pathogen performance standard is to require the

plant to reassess its control programs and implement corrective action, as needed. (USDA requires a plant to reassess its control programs and implement corrective actions if the plant fails to meet the codified *Salmonella* performance standard; but three consecutive failures will result in suspension of USDA inspection. The suspension of inspection based on a failure to meet the *Salmonella* standard is currently being litigated.)

4. USDA should also conduct an audit of a plant that repeatedly fails to meet the microbiological criteria to determine if the plant is manufacturing product in a sanitary manner. A finding by USDA that the plant is producing product under insanitary conditions would cause the product to be adulterated and inspection services suspended. (USDA has the statutory authority to suspend inspection if product is produced under insanitary conditions, but the court has ruled USDA cannot suspend inspection based on a failure to meet the *Salmonella* performance standard, which does not measure plant sanitation.)

5. Pathogens that are present in ground product usually originate from the raw materials used to produce the ground product. The only practical means grinding operations have for reducing pathogens is to control the source of raw material they purchase. Proper sanitation and temperature control can retard pathogen growth, but grinding operations cannot reduce pathogens that are present in the raw materials. Therefore, a federally mandated microbiological monitoring and surveillance program should concentrate its resources on slaughter operations to reduce pathogens as far back in the supply chain as possible. (USDA's *Salmonella* performance standard requires both carcass and ground product sampling, but emphasis is placed on ground product sampling in plants that produce both products.)

6. The rate of pathogen testing should be based on the number of carcasses processed in the facility. Samples should be collected throughout the year to properly assess seasonal differences. For example, very small plants that slaughter only a few animals per year could be tested once per quarter and large plants could be tested weekly. The objective is to sample at a rate that is roughly proportional to the amount of product a plant produces. (USDA's current sampling rate is based on completion of data sets without regard to the samples being randomly distributed throughout the year.)

7. In the final analysis, the fundamental question is whether USDA should have the authority to suspend inspection and prevent a plant from operating if the plant fails to meet a pathogen performance standard. That is a public policy question that relates to the inability of a plant to meet a microbiological criterion. It is not a scientific question, but conventional wisdom would dictate that if a determination cannot be made that the product is adulterated and unfit for human consumption, then the plant should be allowed to operate with additional government scrutiny and oversight.

Thank you again for this opportunity to testify. I would by happy to answer any questions.

CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

Testimony of Caroline Smith DeWaal
Director of Food Safety
before the
Senate Agriculture, Nutrition and Forestry Committee
Hearing on "How Our Food Safety System
Should Address Microbial Contamination"

September 20, 2000
Washington, DC

My name is Caroline Smith DeWaal and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a non-profit organization based in Washington, DC. Since 1971, CSPI has been working to improve the public's health, largely through its work on nutrition, food-safety and alcohol issues. CSPI is supported primarily by 850,000 subscribers to its *Nutrition Action Healthletter*, the largest circulation health newsletter in North America.

Food-safety experts believe that contaminated food causes up to 75 million illnesses, 325,000 hospitalizations and 5,000 deaths each year.[1] These estimates underline the fact that food safety is a significant public health burden. For many consumers, the aggregate numbers mean less than the specific cases of illness involving themselves, their friends or family

[1] Paul S. Mead, et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases*, Vol. 5, No. 5 (Sept.-Oct. 1999), p. 607.

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members. For example, just last year, I testified before the Senate Governmental Affairs Committee and Senator Voinovich mentioned during the hearing that his wife had recently had a bout of food poisoning so serious that she was taken from their home in an ambulance. And it is a rare visit to Capitol Hill where a staff member doesn't share with me a food poisoning experience. Clearly, this is a problem that can hit perilously close to home.

In the last thirty years, US consumers have seen many changes in the way food is produced that impact its safety. Food production has evolved from a local industry to one in which production and processing are centralized in different regions of the country. Improved transportation has given consumers greater access to foods from around the world, with both their benefits and potential hazards. The increase in imported foods presents new challenges because it is especially difficult to police the safety of food grown and processed abroad.

Furthermore, foodborne pathogens have become increasingly virulent,[2] while the public has grown increasingly vulnerable to foodborne illnesses due to the aging of the population.

While the food marketplace has changed dramatically, the regulatory tools available to the federal government to prevent food poisoning have changed only minimally. One area of oversight that needs improving is surveillance. Foodborne-disease outbreak investigations tell the stories of who gets sick and why. Today, while headline after headline alert consumers to food-poisoning outbreaks, no agency in the federal government maintains a comprehensive and current inventory of these outbreaks. Such an inventory would allow policy makers and the food

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[2] Robert V. Tauxe, "Strategies for Surveillance and Prevention," *The Lancet, End of Year Review*, Vol. 352 (1998), p. 10.

industry to monitor trends, issue public-health alerts and change production practices. For the public, that ultimately would mean fewer illnesses and deaths caused by contaminated food.

The Centers for Disease Control and Prevention (CDC) is well-situated to collect, analyze, and publish comprehensive and timely information on foodborne-illness outbreaks. It published an annual listing of foodborne-illness outbreaks in the 1980s, but stopped due to funding deficiencies.[3] To help fill that gap, CSPI has been maintaining a database of foodborne-illness outbreaks that have occurred from 1990 to the present. We have documented 865 food poisoning outbreaks over the last decade.[4] This list is the only one of its kind available, but even it includes only a small fraction of the outbreaks that are actually occurring, because foodborne illnesses are significantly underreported.[5]

Outbreak Alert!

Outbreaks are defined generally as two or more illnesses from a single source.[6] The outbreak information listed in CSPI's report "*Outbreak Alert! Closing the Gaps in Our Federal*

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[3] Telephone conversation with Dr. Patricia Griffin, Chief of Foodborne Diseases, Foodborne and Diarrheal Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, January 14, 1999; *e.g.*, Centers for Disease Control and Prevention, "Line Listing of Foodborne Disease Outbreaks, 1982," *Foodborne Disease Surveillance, Annual Summary 1982*, (Atlanta, GA: Centers for Disease Control and Prevention, September 1985), pp. 19-24.

[4] Center for Science in the Public Interest, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net*, (Washington, DC: Center for Science in the Public Interest, Updated August 2000).

[5] Centers for Disease Control and Prevention, "Surveillance for Foodborne-Disease Outbreaks -- United States, 1993-1997," *CDC Surveillance Summaries, Morbidity and Mortality Weekly Report*, Vol. 49, No. SS-1 (2000), pp. 5-6.

[6] Centers for Disease Control and Prevention, "Surveillance for Foodborne-Disease Outbreaks -- United States, 1988-1992," *CDC Surveillance Summaries, Morbidity and Mortality Weekly Report*, Vol. 45, No. SS-5 (1996), p. 1.

Food Safety Net" was obtained from CDC, other government agencies, and medical journal articles.

These data suggest some striking gaps in our regulatory system. For example, nearly four times as many outbreaks were linked to Food and Drug Administration (FDA)-regulated foods as were linked to US Department of Agriculture (USDA)-regulated foods. (See Appendix 1.) FDA regulates all foods other than meat, poultry, and some processed egg products. Of course, that doesn't mean that meat and poultry products are safe. In fact, data collected by CDC's FoodNet system on individual illnesses clearly demonstrate that *Campylobacter* and *Salmonella*, two pathogens commonly found on chicken, are the principle cause of individual cases of food poisoning.[7] Instead, the outbreak data clearly show that FDA-regulated foods pose a significant public-health problem that is not being addressed adequately. Here are some of our findings:

- **682 outbreaks were linked to FDA-regulated foods, as compared to 179 outbreaks linked to USDA-regulated foods.**
- **237 outbreaks were linked to seafood, including mahi mahi, salted whitefish, tuna, buffalo fish, blue marlin, surgeon, grouper, ahi, crab, and shrimp. Of the seafood outbreaks, 41 were linked to shellfish, including oysters, clams, and mussels.**
- **170 outbreaks were linked to eggs and egg dishes.** Most of the egg-related outbreaks were caused by *Salmonella enteritidis*, a bacterium that can survive in raw or

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[7] Centers for Disease Control and Prevention, *FoodNet Surveillance Report for 1998 (Final Report)*, March, 2000, p. 9 [hereinafter cited as *1998 FoodNet Final Report*]; *see also*, Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Foodborne Illnesses -- Selected Sites, United States, 1999," *Morbidity and Mortality Weekly Report*, Vol. 49, No. 10 (2000), p. 203 [hereinafter cited as *Preliminary 1999 FoodNet Data*].

undercooked eggs and egg dishes. Egg dishes involved in several outbreaks include pudding, stuffing, baked ziti, and ice cream made with shell eggs.

- **91 outbreaks were linked to beef, including at least 40 to ground beef.** Other types of beef were prime rib, roast beef, corned beef, raw beef, and beef jerky.
- **82 outbreaks were linked to produce, including cantaloupe, tomatoes, strawberries, watermelon, potatoes, scallions, lettuce, raspberries, sprouts, basil, and parsley.**
- **52 outbreaks were linked to poultry.** *Campylobacter* is the leading bacterial cause of foodborne diarrhea and current data suggest that more individual cases are linked to poultry than to any other food. However, reported outbreaks linked to poultry are not as common as those linked to beef, probably because the illnesses resulting from poultry products are more likely to occur individually or as part of a family outbreak that is never reported, according to CDC.[8]
- **39 outbreaks were linked to dairy products,** including cheese, pasteurized and raw milk, and ice cream.
- **31 outbreaks were linked to pork, including ham and pork sausage.**
- **14 outbreaks were linked to game, including venison, bear meat, and cougar meat.**
- **Ten outbreaks were linked to juices, including apple cider, apple juice, and orange juice.**
- **Five outbreaks were linked to luncheon meats, such as hot dogs and bologna.**

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[8] Telephone conversation with Dr. Patricia Griffin, Chief of Foodborne Diseases, Foodborne and Diarrheal Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, January 14, 1999.

- **130 outbreaks were linked to FDA-regulated foods with multiple ingredients.** Those include salads, baked goods, and soups.

Our outbreak tracking shows that FDA's foods clearly pose a significant risk of causing a food poisoning outbreak. However, FDA's budget for regulating foods is only about one-third of USDA's food inspection budget.[9] (See Appendix 2.) In essence, FDA regulates more food with less money. If food-safety resources could be applied on the basis of risk rather than on the basis of historical precedent, it is clear that the food categories regulated by FDA would receive a much greater share of the budget.[10] This imbalance led CSPI and other consumer organizations to call for Congress to create a single independent food safety agency, so that the government could apply food safety resources to the food safety hazards that are causing the greatest risk to the public.

The HACCP Solution

To keep up with the changing hazards in our food supply, it is time to change some of the regulatory tools as well. The advent of new systems of preventative controls -- so called "HACCP" systems (for Hazard Analysis/Critical Controls Points) -- coupled with the expanded use of new technologies have the potential to significantly enhance the safety of food. But these

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[9] US Department of Agriculture, Office of Budget and Program Analysis, "U.S. Department of Agriculture 2001 Budget Summary," available at <http://www.usda.gov/agency/obpa/Home-Page/obpa.html>Internet; Food and Drug Administration, "FY 2001 Congressional Budget Request Table of Contents," available at <http://www.fda.gov/oc/oms/ofm/budget/2001/tables/APTcharts4net.htm>Internet [hereinafter cited as *FDA Budget*].

[10] The National Academy of Sciences (NAS) has warned that FDA "appears to have insufficient resources to meet its statutory obligations." Institute of Medicine, National Research Council, *Ensuring Safe Food From Production to Consumption*, (Washington, DC: National Academy Press, 1998), p. 87 [hereinafter cited as *Ensuring Safe Foods*]. NAS concludes: "Congress must provide appropriate resources for the tasks demanded of FDA." *Id.*

benefits will not be fully realized until the underlying regulatory systems for inspection and technology approvals are modernized as well.

HACCP focuses on preventing foodborne illnesses by applying science-based controls to food production and has been endorsed by many scientific groups. However, HACCP implementation in the seafood, meat and poultry industries has graphically highlighted the weakness in the fragmented regulatory system.

HACCP Implementation Inconsistent Between USDA and FDA

Due to the different regulatory approaches at FDA and USDA, the meat, poultry and seafood HACCP systems share almost as many differences as similarities. For example, while USDA requires both frequent inspection and product testing for meat and poultry products, FDA requires neither for seafood products.[11] That makes seafood HACCP an industry honor system of dubious value and unworthy of public support.

HACCP became a mandatory program for seafood processors in December 1997 when FDA implemented a HACCP rule applicable to approximately 4,000 seafood plants nationwide.[12] The following month, in January 1998, the USDA's Food Safety and Inspection Service (FSIS) implemented HACCP in the 300 largest meat and poultry slaughter and processing plants.[13] Another 2,300 small and medium-sized meat and poultry plants started using the new system in

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[11] Caroline Smith DeWaal, "Delivering on HACCP's Promise to Improve Food Safety: A Comparison of Three HACCP Regulations," *Food and Drug Law Journal*, Vol. 52, No. 3 (1997), pp. 331-335.

[12] Department of Health and Human Services, Food and Drug Administration, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule," Federal Register, Vol. 60, No. 242 (1995), pp. 65096-65202 [hereinafter cited as *FDA Seafood HACCP Rule*].

[13] US Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule," Federal Register, Vol. 61, No. 144, pp. 38806-38989 [hereinafter cited as *FSIS Meat and Poultry HACCP Rule*].

January 1999, and the final group, 3,100 very small meat and poultry plants, in January 2000.[14] Although both FDA and FSIS began to implement their HACCP programs at about the same time, the results have been very dissimilar.

There have been few surprises with respect to implementing HACCP in meat and poultry plants. Six months after the large plants were brought into the HACCP program, the industry had a 93 percent compliance rate.[15] This past year, even after small plants were brought into the system, compliance increased to 96 percent.[16]

In comparison with meat and poultry plants, the seafood industry has done a dismal job in implementing HACCP. FDA required all seafood processors, both large and small, to develop and implement HACCP plans in December 1997.[17] But data from FDA inspections in 1999 -- the second year of implementation -- showed that only 24 percent of all seafood firms had fully implemented HACCP plans deemed adequate by FDA.[18] Thirty percent of the seafood firms inspected in 1999 had inadequate HACCP plans or were failing to properly implement their plans

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[14] US Department of Agriculture, Food Safety and Inspection Service, "Very Small Plants Successfully Implement HACCP," News Release, March 21, 2000.

[15] "HACCP Implementation in Small Plants -- The Role of FSIS," Remarks prepared for delivery by Thomas J. Billy, Administrator, Food Safety and Inspection Service, US Department of Agriculture, before the Small Plant HACCP Implementation Meeting, September 19, 1998, Raleigh, NC, available at <http://www.fsis.usda.gov/OA/speeches/smallplant.htm>Internet.

[16] "FSIS Experiences With HACCP," Remarks prepared for delivery by Thomas J. Billy, Administrator, Food Safety and Inspection Service, US Department of Agriculture, before the Fisheries Council of Canada, October 6, 1999, Halifax, Nova Scotia, available at <http://www.fsis.usda.gov/oa/speeches/1999/tb_fish.htm> Internet.

[17] *FDA Seafood HACCP Rule.*

[18] Mary Losikoff, "Compliance with Food and Drug Administration's Seafood HACCP Regulations," Presentation Before the International Association for Food Protection , August 2000, Atlanta, GA. The data were drawn from forms filled out by FDA inspectors and sent to the FDA Office of Seafood [hereinafter cited as *FDA Seafood Data*].

(or both). Sixteen percent of the firms inspected in 1999 failed to have *any* HACCP plan in place, even though FDA inspectors believed they needed an HACCP plan. The remaining 30 percent of the seafood firms had no HACCP plan, but FDA inspectors did not think that a plan was necessary. (See Appendix 3.) (FDA's *de facto* exemption of nearly one-third of the seafood industry from HACCP requirements stands in stark contrast to FSIS's position. In its HACCP final rule, FSIS stated: "FSIS is currently unaware of any meat or poultry production process that can be deemed categorically to pose no likely hazards."[19])

FDA and FSIS differ on more than just the applicability of their HACCP programs. Unlike meat and poultry plants, which have statutorily-mandated daily on-site inspections by FSIS, FDA's inspections of seafood plants are infrequent--dropping from 3,146 inspections in 1998 to 2,796 inspections in 1999. That's equivalent to one inspection per year in approximately 70 percent of seafood firms.[20]

FDA's failure to enforce implementation of the seafood HACCP regulation obscures another critical weakness in the program. FDA failed to mandate any government or industry testing for verification of the HACCP program. While FSIS requires HACCP verification testing of food samples both by the government and the industry,[21] the FDA made product testing optional. As a result, in many seafood plants, pathogens are not adequately controlled. For example, the FDA's 1999 inspection data showed that 71 percent of the smoked fish processors,

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[19] *FSIS Meat and Poultry HACCP Rule*, p. 38824.

[20] *FDA Seafood Data*. In general, FDA inspects food processing plants under its jurisdiction only once every ten years. Government Accounting Office, *Food Safety: Opportunities to Redirect Federal Resources and Funds can Enhance Effectiveness*, (Washington, DC: Government Accounting Office, 1998), p. 8.

[21] *FSIS Meat and Poultry HACCP Rule*.

69 percent of the vacuum-packed fish industry, and 63 percent of the cooked, ready-to-eat seafood firms lacked adequate pathogen controls in their HACCP plans.[22] (See Appendix 4.)

The meat and poultry HACCP rule, by contrast, has clear tools to evaluate its success. After two years of product testing in large plants, *Salmonella* contamination has been cut in half in chicken and pork products and has declined substantially in ground beef and ground turkey as well.[23] HACCP performance in small plants has been equally impressive. After one year of testing in small meat and poultry plants, *Salmonella* contamination in ground beef has been reduced by more than 40 percent, and contamination in chicken by nearly 20 percent.[24] (See Appendix 4.)

This success is further supported by FoodNet data collected by CDC. In the years 1996-1998, the rate of *Salmonella* illness declined from 14.5 cases per 100,000 people to 12.3 cases per 100,000.[25] CDC concluded that this decline "may also reflect disease prevention efforts, particularly for campylobacteriosis and salmonellosis. These efforts include changes in meat and poultry processing in the United States mandated by the USDA HACCP rule."[26] While this evidence is promising, it is too early to tell for sure whether this is a continuing trend.[27]

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[22] *FDA Seafood Data.*

[23] US Department of Agriculture, Food Safety and Inspection Service, "FSIS Reports Continued Decline of *Salmonella*," News Release, March 21, 2000.

[24] *Id.* The only exception to the downward trend in *Salmonella* contamination was the performance of small swine plants. *Id.*

[25] *1998 FoodNet Final Report,* p. 9.

[26] *1998 FoodNet Final Report*, p. 4.

[27] *Preliminary 1999 FoodNet Data*, p. 203.

Improving HACCP Means More, Not Less, Testing

The lessons of HACCP are clear. Without government-enforced performance standards, it is impossible to measure either the relative performance of different processors' HACCP plans or the overall success of the HACCP system to control food-safety hazards. Consumers can be much more confident in the meat and poultry HACCP system, because the industry has complied with the regulation and the government is monitoring its effectiveness using performance standards. In contrast, the seafood industry has a very poor record of compliance with FDA's HACCP regulation, and there is no government testing to monitor its success. Consumers will not continue to support HACCP if the weak FDA model prevails. Performance standards enforced by government testing are essential to ensure that HACCP is not just an industry honor system.

It is a well-known management concept that "You manage what you measure." USDA's meat and poultry regulation was the first effort to manage food safety hazards using a HACCP system, which included regular microbial testing. A recent report by USDA's Office of the Inspector General (OIG) recommended that USDA expand pathogen testing in order to increase food-safety protections offered by the HACCP rule. The OIG investigative report said, "One of the keys to the success of HACCP is microbial testing, and sound management practices dictate that known harmful pathogens should be monitored through an effective testing program."[28]

Now that we have seen the success of a pathogen-based performance standard, it is time to expand this concept to cover additional hazards in food. This year, CSPI petitioned USDA to

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[28] US Department of Agriculture, Office of the Inspector General, *Food Safety and Inspection Service: Implementation of the Hazard Analysis and Critical Control Point System*, Report No. 24001-3-At, June 2000, Section I, p. 33.

require ready-to-eat processed meat products to be tested for *Listeria monocytogenes* and also urged the agency to require slaughterhouses to test beef carcasses for the harmful *E. coli* O157:H7.[29] We have also urged FDA to mandate product testing to improve its seafood HACCP rule.[30]

It is clear that consumers would benefit from increased testing by both industry and the government to monitor for food-safety hazards. Congress should require USDA and FDA to establish performance standards to demonstrate that their HACCP programs actually reduce food safety hazards.

The Big Fix: An Independent Food Safety Agency

Inconsistent HACCP implementation is just one of numerous problems that arise from having several agencies with separate responsibilities for food safety regulation. Other problems include gaps in consumer protections, conflicting public health standards, regulatory redundancies, and slow approvals of new technologies. In addition, gaps in food safety oversight mean that few resources are aimed at preventing hazards at the farm and animal production level, in part because neither agency is exercising farm-to-table food safety responsibility.

A National Academy of Sciences (NAS) committee completed a report two years ago, called *Ensuring Safe Food From Production to Consumption*, that determined that the "current

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[29] Center for Science in the Public Interest, "Petition for Regulatory Action to Require Microbial Testing By Industry for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Products," January 13, 2000; Center for Science in the Public Interest, Comments on Recent Developments Regarding Beef Products Contaminated With *Escherichia coli* O157:H7; Public Meeting (Docket No. 99-060N), (April 11, 2000).

[30] Center for Science in the Public Interest, Comments on Performance Standard for *Vibrio vulnificus* (Docket No. 98P-0504), (Jan. 21. 1999), pp. 9-13; Center for Science in the Public Interest, Comments on Program Priorities in the Center for Food Safety and Applied Nutrition (Docket No. 98N-0359), (Sept. 30, 1999), pp. 1-3; Center for Science in the Public Interest, Comments on Program Priorities in the Center for Food Safety and Applied Nutrition (Docket No. 98N-0359), (Aug. 25, 2000), pp. 3, 5-6.

fragmented regulatory structure is not well equipped to meet the current challenges."[31] In its report, the NAS found glaring disparities that result from the multiple agency system of food safety regulation and concluded that:

> [A]n identifiable, high-ranking, presidentially-appointed head [is needed], who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food safety efforts; [and] the structure should have a firm foundation in statute . . . . Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single unified agency headed by a single administrator -- an agency that would incorporate the several relevant functions now dispersed . . . among three departments and a department level agency.[32]

The NAS committee also called for new federal food safety statutes so that resources could be better allocated according to assessments of risk to public health.

In response to the NAS report, President Clinton appointed a Food Safety Council that promised to coordinate its way out of these problems,[33] but the experience with HACCP implementation shows that coordination isn't enough. More fundamental reform is needed.

Over the last thirty years, many policy makers -- from congressional committees to White House councils -- have reached similar conclusions. Most recently, a major industry trade association, the Food Marketing Institute (FMI), issued a paper calling for Congress and the President to create a single food safety agency. In its position paper, the FMI says "new challenges have arisen that, taken together, threaten to overwhelm the ability of our current

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[31] *Ensuring Safe Foods*, p. 12.

[32] *Id.*, p. 13.

[33] President's Council on Food Safety, "President's Council on Food Safety Assessment of the NAS Report: *Ensuring Safe Food from Production to Consumption*," last updated on March 19, 1999, available at <http://www.foodsafety.gov/~fsg/creport2.html>Internet.

regulatory system to respond effectively. We believe that designating a single agency responsible for the safety of our food is essential if we are to maintain a food supply that remains the envy of the world."[34] Many other organizations, including the National Cattleman's Beef Association, S.T.O.P.-- Safe Tables Our Priority (a food poisoning victims support and advocacy organization), Consumer Federation of America, American Society for Microbiology, Institute for Food Technologists, and the American Meat Institute, have signaled an interest in moving to a single food safety agency to achieve a more rational system of food safety regulation. (See Appendix 5.)

Legislation has been pending in Congress since 1997 that would establish a single, independent food-safety agency.[35] Senator Richard Durbin played a leading role in examining the effectiveness of our current food-safety system and initiating this legislation, which is called the Safe Food Act. The Safe Food Act also was introduced in the House by Representatives Tom Latham, an Iowa Republican, and Rosa DeLauro, a Connecticut Democrat. That bill represents the most important improvement to the federal food-safety system that has been proposed in the last several decades.[36]

Senator Tom Harkin has also sponsored many other important food safety changes pending before Congress, including mandatory recall and civil penalty authority for USDA; a

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[34] Food Marketing Institute, "It's Time to Designate A Single Food Safety Agency," Food Marketing Institute Board Approved Policy, May 6, 2000.

[35] H.R. 2801, "Safe Food Act of 1997," 105th Cong., 1st Sess.; S. 1465 "Safe Food Act of 1997," 105th Cong., 1st Sess.

[36] H.R. 2345, "Safe Food Act of 1999," 106th Cong., 1st Sess.; S. 908, "Consumer Food Safety Act of 1999," 106th Cong., 1st Sess; S. 1281, "Safe Food Act of 1999," 106th Cong., 1st Sess.

significant expansion of FDA's food safety mandates; and improved FDA oversight of produce.[37] These bills provide for incremental changes that could easily fit with a single food safety agency; they deserve your support and speedy action by the Senate Agriculture Committee.

While it is clear that a creating a single food-safety agency must be done thoughtfully, it is also clear it should be done soon. Consumers can't afford to wait years and even decades for the agencies to resolve their competing agendas. The current system is highly inefficient, and that inefficiency is putting consumers at risk. It is time for Congress to make a more coherent food-safety system a reality. It is time for Congress to respond with concrete actions, and not mere words.

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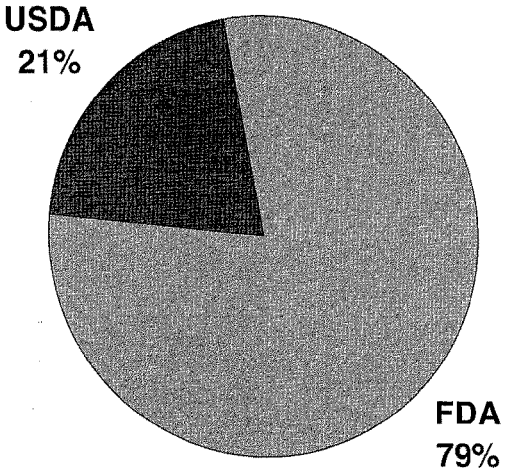
[37] S. 18, "Safer Meat and Poultry Act of 1999," 106th Cong., 1st Sess.; S. 823, "Fruit and Vegetable Safety Act of 1999," 106th Cong., 1st Sess.

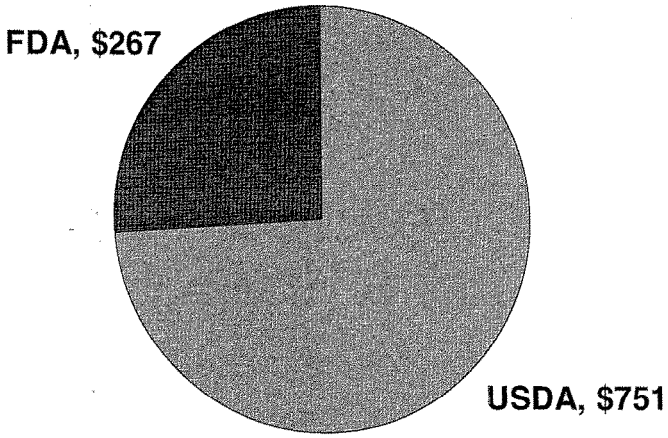
Percent of Outbreaks Linked to FDA- and USDA-Regulated Foods



Appendix 2

Food Safety Funding for FDA and USDA

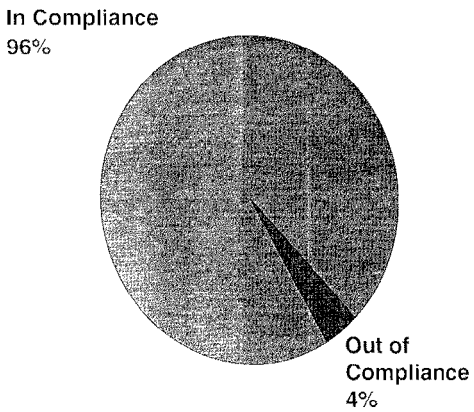
FY 2000, Millions of Dollars



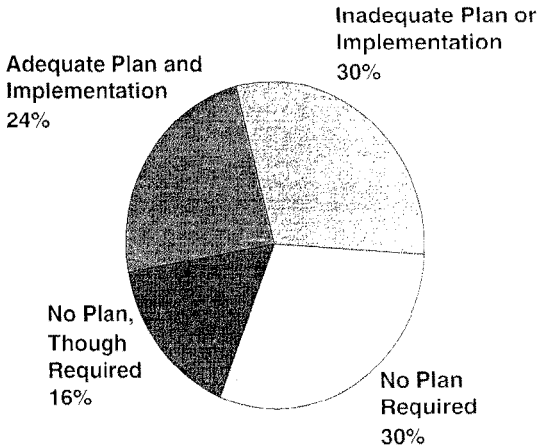
Appendix 3

HACCP Compliance Rates, 1999

Meat and Poultry Industry



Seafood Industry



HACCP Monitoring

USDA

Salmonella Testing Results:

- Chicken
  - Down 20 - 50%
- Pork
  - Down 50% in large plants
- Ground Beef
  - Down 20 - 40%
- Ground Turkey
  - Down 30% in large plants

FDA

No Test Results but Inspection Findings:

- Smoked Fish
  - 71% Inadequate Pathogen Control
- Vacuum-Packed Fish
  - 69% Inadequate Pathogen Control
- Ready-to-Eat Fish
  - 63% Inadequate Pathogen Control

Source: USDA and FDA

Appendix 5

Comments Supporting a Single Food Safety Agency (As filed with the President's Food Safety Council docket on the food safety strategic planning process)

American Association of Retired Persons:
The President's Council on Food Safety should pursue "Option V" of the plan, which creates a new, consolidated, stand-alone federal food safety agency. . . . We believe that a single agency can best assure that inspection and regulation are risk-based, resources are properly allocated, imports are adequately scrutinized, food safety technologies are reviewed expeditiously, and food safety problems do not fall through the cracks.
(Comments to the Docket, February 17, 2000)

American Meat Institute:
AMI agrees in principle that consolidating resources and expertise can help harmonize the varying degrees of regulatory oversight that federal, state and local governments exercise over different segments of the food industry.
(Comments of J. Patrick Boyle to the Docket, October 2, 1998.)

American Public Health Association:
APHA strongly supports the creation of a single federal public health agency with inspection and enforcement authority for the safety of the U.S. food supply. We believe the U.S. government's ability to assure a safe food supply is compromised by the fact that authority for food safety is currently divided among several federal agencies, and the legal authority and resources which these agencies have for both domestic and imported food sources is inadequate. This single federal agency should be provided with sufficient scientific and enforcement resources to include food safety inspections (using performance-based standards) to monitor effectively and to assure the safety of the U.S. food supply.
(Comment to the Docket, February 11, 2000)

American Society for Microbiology:
In terms of administering federal food safety programs, ASM agrees with the National Academy of Sciences that the best option for this purpose is to bring the disparate elements in the current system into a single agency with a single director at its head. This option corresponds to the "New Consolidated, Stand Alone Food Agency" described in the draft strategic plan.
(Comment to the Docket, February 14, 2000)

Association for Professionals in Infection Control and Epidemiology, Inc. (APIC):
APIC contends . . . that a centralized agency (with adequate representation from other relevant agencies) may be most effective to carry out the goals [of the NAS report]. It will be important to streamline as much as possible in order to most efficiently implement the goals of the plan and take corrective action when necessary, without duplication of efforts across agencies.
(Comment to Docket, January 5, 1999)

Center for Science in the Public Interest (CSPI):
The Council should revise the strategic plan to call for the establishment of a single agency and provide a road map for consolidating all food-safety functions in that agency. If the Council is unwilling to take that action, it should turn the decision over to the President. Consumers cannot wait any longer for the federal government to replace the existing patchwork with a coherent, logical system that ensures the safety of all foods irrespective of artificial and outdated bureaucratic divisions. . . .

. . . Option V, the creation of a consolidated, independent agency, would eliminate the numerous problems described above and is the best mechanism for maintaining consumer confidence while achieving the unified and seamless food-safety system envisioned by the NAS and the President. A newly created agency would provide fertile ground for the development of a modern, risk-based approach to food safety, without the innovation-stifling effects of entrenched bureaucratic systems or the wastefulness of inter-agency turf battles. Such an agency could draw upon the strengths of the existing framework, weaving the best of the current system into a coherent program while eliminating duplicative functions, needless divisions, and archaic, ineffective regulations. Moreover, consumer confidence would be strong in a new, independent agency that lacks the FDA and USDA's historical problems.
(Comment to the Docket, February 14, 2000)

Consumer Federation of America (CFA):
In order to increase the effectiveness and efficiency of federal food safety regulation, CFA supports streamlining the current food safety functions into an independent food safety administration. We also support a review and modernization of federal food safety laws to assure that the U.S. government has all of the resources and powers necessary to achieve a safe food supply.
(1999 Policy Resolutions, Consumer Federation of America, p. 64.)

CFA and CU wish to be recorded as endorsing the comments filed by the Center for Science in the Public Interest.
(Comment to the Docket, February 14, 2000)

Consumers Union, publishers of Consumer Reports magazine (CU):
CFA and CU wish to be recorded as endorsing the comments filed by the Center for Science in the Public Interest.
(Comment to the Docket, February 14, 2000)

Senator Richard Durbin of Illinois:
A single, independent agency with uniform food safety standards and regulations based on food hazards would provide an easier framework for implementing U.S. standards in an international context. When our own agencies don't have uniform safety and inspection standards for all potentially hazardous foods, the establishment of uniform international standards will be next to impossible.

Research could be better coordinated within a single agency than among multiple programs. Currently, federal funding for food safety research is spread over at least 20 federal agencies, and coordination among those agencies is ad hoc at best.

New technologies to improve food safety could be approved more rapidly with one food safety agency. Currently, food safety technologies must go through multiple agencies for approval, often adding years of delay.

In this era of limited budgets, it is our responsibility to modernize and streamline the food safety system. The U.S. simply cannot afford to continue operating multiple systems.
(Comment to the Docket, February 11, 2000)

Food Animal Concerns Trust (FACT):
FACT wants a system that is led by one agency, with one purpose, having clear roles and responsibilities, that can enforce what it regulates, and that starts where food starts--on the farm. We want this system to be focused entirely on food safety, where the American public will know who is responsible.
(Comment to the Docket, February 11, 2000)

Institute of Food Technologists (IFT):
IFT stated in its Guiding Principles, that consistency in oversight and regulation would be enhanced if responsibility for food oversight were focused in a single policy/regulatory unit that tightly adhered to objective criteria and risk analysis.
(Comment to the Docket, January 8, 1999)

National Cattlemen's Beef Association (NCBA):
Creation of a central organization could be useful. However, jurisdiction over current agencies by different congressional bodies could prevent creation of this type of agency. NCBA supports the development of a single meat, poultry, and seafood inspection system within the Department of Agriculture. A single inspection agency would have the ability to oversee inspection across all food products, ensuring their equity. Achieving national food safety goals requires a farm-to-table strategy.
(Comment to the Docket, December 29, 1998)

Safe Tables Our Priority -- S.T.O.P.:
S.T.O.P. strongly supports the implementation of a single, independent food safety agency. The safety of the food we feed our families is of critical importance and deserves the uncompromised scrutiny and attention of an agency unencumbered with other conflicting responsibilities such a trade and marketing issues.
(Comment to the Docket, February 14, 2000)

12

Testimony of the American Public Health Association

Concerning Food Safety and Microbial Contamination

Richard Levinson, MD, DPA

Presented to the Senate Committee on Agriculture, Nutrition and Forestry

September 20, 2000
9:00 AM

Testimony of the American Public Health Association Concerning Food Safety and Microbial Contamination

Presented to the Senate Committee on Agriculture, Nutrition and Forestry September 20, 2000

Mr. Chairman and members of the committee, my name is Richard Levinson. I am the Associate Executive Director of the American Public Health Association. APHA is the oldest and largest public health association in the world, representing more than 50,000 public health professionals in the United States and abroad. I appreciate this opportunity to discuss our members' views on the subject of the microbial safety of our food supply.

I plan to discuss surveillance and performance-based standards as effective public health tools generally, and specifically as they affect the microbial safety of foods.

Surveillance

The Merriam-Webster dictionary defines surveillance as "close watch kept over something." Public health surveillance is defined as the "ongoing, systematic collection, analysis, and interpretation of health-related data, essential to the planning, implementation and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control." Public health surveillance has been conducted since at least the 1600's, when mortality statistics were first collected in England.

The global eradication of smallpox was an extraordinary public health achievement. It resulted not only from massive vaccination campaigns, but also from targeted campaigns that were based on an extensive global surveillance system. Even in remote and developing areas, cases of smallpox would not go unnoticed, but would be recognized, confirmed quickly and accurately, and followed with targeted vaccinations to stop further spread. We are nearing the global eradication of polio, again based upon an extraordinary, rapid and accurate surveillance system.

With increasing recognition of the role of microbial pathogens in foodborne illness, public and private-sector surveillance for foodborne pathogens has increased. In some cases, such as *E. coli* O157:H7 and *Cyclospora*, newly-emergent foodborne pathogens were discovered. In other cases, such as non-typhoidal *Salmonella* and *Campylobacter*, these pathogens were important decades earlier, but we weren't looking for them.

It has been said that testing food for pathogens doesn't make food safer. In a broad sense this is untrue. Microbial testing at appropriate Critical Control Points is essential to establish, and later to verify, the effectiveness of preventive measures and critical limits, ensuring that the entire process is producing a safe end product. People manage what they measure. Pathogen surveillance is an essential first step in pathogen control.

We have an outstanding new surveillance system for foodborne illness. The FoodNet system, a collaboration of USDA, CDC, FDA, and nine state health departments, allows us, for the first time, to know with some confidence both the burden of foodborne illness, and whether we are doing better or worse over time. And there is good news. For most of the foodborne pathogens under surveillance, the incidence of reported illness has declined just within the four years FoodNet has been in place.

Much of this progress can be attributed to the new HACCP system for meat and poultry inspection and, especially, the Salmonella performance standard. In the first two years under the Salmonella standard, the prevalence of Salmonella on meat and poultry products declined as much as 50% from baseline levels measured a few years earlier. It is unreasonable to feel that these declines are irrelevant, given parallel declines in rates of foodborne illness. It is also logical to believe that these reductions were achieved, at least in part, because we were looking for them.

Performance standards

Performance-based standards achieve the best balance of public and private intervention in public health. Regulating according to relevant outcomes is an efficient use of federal funds, and has been repeatedly mandated by Congress, as in the Clean Air and Clean Water Acts. It is not the best role of government to dictate how to keep pathogens out of the food supply, but rather to test and assure that products meet established standards.

Enforcing performance-based standards leaves technological innovation and creativity within the private sector, where it belongs. Food suppliers can incorporate interventions they feel are effective in meeting standards, whether before, during or after harvest or slaughter. For example, processors are free to negotiate voluntary microbial standards into purchasing contracts. In the first two years of the USDA's Salmonella compliance program, plants have met the standard 87% of the time.

APHA members submitted comments to USDA in support of the Salmonella performance standard when the HACCP/ Pathogen Reduction rule was first proposed. We believe that only mandatory and frequent end-product microbial sampling will prove that HACCP systems work and give consumers confidence that they are getting safe products. Microbial testing at appropriate Critical Control Points is essential to establish, and later, to verify, the effectiveness of preventive measures and critical limits, ensuring

that the entire process is producing a safe end product. There is simply no other effective means by which to evaluate the efficacy of a HACCP plan in action.

APHA members support S. 823, The Fruit and Vegetable Safety Act, which would establish good manufacturing practices and process verification standards for processed fruits and vegetables. While APHA recognizes that the Food and Drug Administration and industry have taken important steps in developing guidance for producers of fresh fruits and vegetables, we think it is likely that a voluntary program provides an insufficient level of safety. Microbial foodborne illnesses have been linked to produce as well as meat and poultry. FDA should make the commitment to begin the process of developing microbial performance standards for these foods.

APHA supports the efforts of the USDA Agricultural Marketing Service to develop microbiological standards for their school lunch ground beef purchases. Just as industry must consider its source materials when developing Critical Control Points for microbial safety, government must also use the power of procurement contracts to assure the safety of foods in the federal feeding programs.

APHA recognizes that industry should have and use food safety tools that are technologically timely and appropriate. In 1998, APHA members endorsed the use of irradiation from electronic sources as a food safety intervention, and called upon USDA and FDA to support this technology, along with HACCP, good manufacturing practices, and consumer safe handling methods, in a coordinated public health education campaign.

APHA members are serious about performance-based standards. APHA is working with the Centers for Disease Control and Prevention, and with state and local public health partners, to develop measurements of public health performance. We believe that excellence in public health practice will follow from recognized, science-based standards. The National Public Health Performance Standards Program stresses three goals of performance measurement; improved quality and performance, accountability, and a better science base for public health practice.

The National Public Health Performance Standards Program (NPHPSP) is based on three basic principles: public health must be accountable to its constituencies; public health professionals need a system for ensuring that the provision of essential public health services meets a defined level of quality; and the public health decision-making process must be based on strong scientific evidence. Through a series of performance measurement tools, the NPHPSP will identify system strengths and weaknesses, provide policy makers with information necessary to implement effective health interventions, and assist decision makers in targeting resource investments.

This is one of the most significant events of my lifetime. It will be the main thing that will carry public health forward in the new century.

Mr. Chairman, this concludes my prepared remarks. I thank you for the opportunity to present our views to the Committee, and would be happy to answer any questions.

DOCUMENTS SUBMITTED FOR THE RECORD

SEPTEMBER 20, 2000

The Role of Microbiological Testing in Beef Food Safety Programs

The Scientific Perspective

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Consensus of the 1999 Symposium

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Foreword

The American Meat Science Association's mission is to contribute to the betterment of human life through discovery and application of sound scientific and technological principles of the meat sciences in research and education.

On January 20-22, 1999, the AMSA Board organized a symposium and invited over 35 experts from academia, government and the meat industry to discuss the role of microbiological testing in a beef food safety program from the scientific perspective. The goal of the symposium was to document the science behind the sampling process and to present clear recommendations for the evaluation of sampling programs. Thus, the following objectives were identified:

1) To assess current the concept of microbiological testing in a food safety system.
2) To describe and define the process to make standardized procedures for microbiological sampling.
3) To identify and assess valid statistical approaches to evaluate microbiological sampling plans.
4) To assess or examine strategies for *E. coli* O157:H7 sampling for industry applications and economic considerations of these strategies.

Drs. Chris Calkins and Mohammad Koohmaraie co-chaired the symposium and assigned participants to the following working groups: Harvest to Carcass, Fabrication/ Trimmings, Ground Beef, and Sanitation. Individual committee reports were presented during the symposium followed by discussion of the reports by those in attendance. A consensus conference was held on the last day in which summaries from each group were presented in an effort to reach a consensus on the points presented. Eight consensus points were agreed upon by the participants.

The decision to conduct microbiological testing on beef products by a company will be based on a variety of factors such as: science, humanitarianism, public relations, politics and legal liability. The consensus points agreed upon by the participants of the symposium were, however, based on the availability of scientifically verified data. Microbiological testing is but one component of a food safety assurance program and should not be viewed as a stand-alone approach to food safety. The relative value of microbiological testing for pathogens is always being re-evaluated in light of legislative, legal and public relations concerns and will undoubtedly change with the advent of new detection technologies. Because specific sampling recommendations were made by some working groups within the context of their discussions, these conclusions have been included in the Appendix.

Jimmy T. Keeton
President

Executive Summary

Public concerns over the wholesomeness of the food supply have increased greatly in recent history. These concerns have resulted in increased efforts by the industry to improve the microbiological status of beef products, and by regulatory authorities to implement new requirements and procedures in meat inspection. Another outcome of these concerns and efforts is an increased emphasis on testing products for pathogens (e.g., *Escherichia coli* O157:H7 in raw beef) as a means of assuring consumer safety. The emphasis on product testing has been the subject of debate in the scientific community.

Microbiological testing is an area where a large amount of scientific research has been conducted, yet there is increasing confusion among regulators, industry and the public concerning what can and cannot be accomplished with testing. In January, the American Meat Science Association convened a group of 35 scientists to address the role of microbiological testing in beef food safety programs. The primary achievement of this group was the development of eight consensus points focusing on the effective use of sampling and testing to support a food safety program. The group agreed that:

1. The main purpose of microbiological testing of foods is to validate and verify process control measures in the context of a properly implemented HACCP system.
2. Effective microbiological testing programs are based on sound Food Safety Objectives with definable microbiological performance criteria.
3. Pathogen testing at any stage will not assure food safety.
4. Foodborne pathogens will not be detected consistently when they are not randomly distributed and/or occur at a low incidence.
5. Pathogens or other microorganisms at a low incidence cannot be used to assess process control.
6. Testing for appropriate non-pathogenic organisms will allow validation and verification of process control systems designed to improve food safety.
7. Declaration of a foodborne pathogen as an adulterant in raw products (e.g. *E. coli* O157:H7 in beef)...
   - discourages testing for that pathogen,
   - leads to a false sense of security among consumers,
   - discourages evaluation of potential control measures, and
   - encourages the inappropriate use of microbiological testing.
8. Microbiological testing of foods in production is important, but is only a part of the overall strategy for controlling food safety. Education concerning proper handling and cooking is essential.

A detailed rationale for these consensus points follows in the next section.

During the course of the meeting, the scientists worked in focus groups to address specific areas of interest. Reports from each of the following groups are included as Appendices to this report.

Sampling and Testing Ground Beef For E. coli O157:H7

Science-Based Applications of Microbiological Testing (Sampling and Analyses) to Fabrication and Trimmings

Harvest to Carcass

Role of Microbiological Testing With Regard to Sanitation of Beef Plants

Consensus Paper

Introduction

Successful commercial production of a food product requires control of microbiological contamination and activity to achieve maximum shelf life consistent with safety of the product. Microbiological testing programs may be applied to validate and verify hygiene monitoring or the process of a food, but such programs need to be associated with achievable and verifiable microbiological criteria. Thus, microbiological criteria can provide a tool for evaluating the acceptability of a process or food. However, development and application of microbiological criteria must follow established basic scientific and statistical principles, and success will depend upon a thorough understanding of the raw materials, the food production process, and the significance of various members of the microbial flora.

A microbiological criterion is a standard upon which a judgement or decision regarding acceptability of a food or food product can be made. In most cases, a criterion will specify that a certain microorganism, a group of microorganisms, or a microbial toxin be absent or limited in presence in a specified quantity of food or ingredient. A microbiological criterion should include the following information (NRC, 1985):

1. a statement describing the identity of the food or food ingredient,
2. a statement identifying the contaminant of concern,
3. the analytical method to be used for the detection, enumeration, or quantification of the contaminant of concern,
4. the sampling plan, and
5. the microbiological limits considered appropriate to the food and commensurate with the sampling plan.

Microbiological criteria may be used to assess the safety of a food ready for consumption and, therefore, may involve tests for specific pathogens or toxins of concern. Tests for indicator organisms may be used successfully only when sufficient data have been collected to establish or indicate a relationship between the occurrence or level of the indicator organism and the likely presence or control of a pathogen or toxin. The use of appropriate indicator organisms is especially helpful for validating process implementation and for verifying control at a specific critical control point (CCP) within a hazard analysis critical control point (HACCP) system. The ultimate purpose of these criteria is to protect the consumer's health.

Microbiological criteria may also be used to make decisions regarding the acceptability of products, or the efficacy of processes, if such criteria are designed to measure adherence to Good Manufacturing Practices (GMPs), HACCP and sanitation standard operating procedures (SSOPs). Criteria can be used to determine the appropriateness of a food or ingredient for a specific purpose. In addition, industry quality assurance programs may use criteria to monitor or predict the potential shelf life of perishable foods.

Sampling

An essential component of a microbiological criterion is an effective sampling plan. To examine a food for the presence of microorganisms, either the entire lot must be assayed or a representative sample should be obtained. A lot is defined as a discrete quantity of product produced, handled, and stored within a limited time period under uniform conditions. The lot is made up of sample units; a sufficient number of units must be selected from the lot for microbiological evaluation in order to determine the acceptability of a lot. Since it is impractical to assay the entire lot, statistical concepts of population probability and sampling must be used to determine the appropriate size of the sample from the lot and permit conclusions to be drawn from the analytical results. The sampling plan must be designed so that it rejects inferior lots with a set level of confidence. Detailed information regarding statistical concepts of population probabilities and sampling, choice of sampling procedures, decision criteria, and practical applications in food microbiology can be found in a publication by the International Commission on Microbiological Specifications for Foods (ICMSF, 1986).

Two-class plans. A simple method for determining whether to accept or reject a food lot can utilize a microbiological test conducted upon several randomly-selected sample units (n) with a preset maximum number of sample units allowed to yield unsatisfactory results (c). The test will either determine the presence/absence of an organism or it will determine whether microbial levels are above or below a preset concentration (m). Thus, in a two-class

sampling plan designed to make a presence/absence decision on the lot, $n=5$, $c=2$ means that 5 sample units are obtained and examined; if more than 2 of the samples show the presence of the organism of concern, the lot is rejected.

Three-class plans. Three-class plans were designed for situations in which the quality of the product can be divided in three attribute classes based upon the concentration of the organisms within the sample units; 0 to m, m to M, and greater than M. The level of the test organism which is acceptable in the food is denoted by m. M is a hazardous or unacceptable level of contamination. Any count above a concentration M is considered unacceptable; therefore, a count from any of the n sample units exceeding M will result in rejection of the lot. In a three-class plan, c indicates the number of sample units that can contain a concentration above m but only up to and including M. This m to M classification of sample units has been determined to be less than desirable, but some level of microbial contamination of a few sample units (c) will be allowed without rejecting the lot. Thus, in a three-class sampling plan, the food lot will be rejected if the microbial level of any one of the sample units exceeds M or if the number of sample units with contamination levels from m to M exceeds c.

The sampling plan specified in a microbiological criterion should be appropriate for the severity of the hazard expected and its expected incidence in the food. The severity of the expected hazard should reflect not only the type of organism expected to be encountered, but also the handling conditions expected to be applied to the food after sampling. A more stringent sampling plan should be used as the expected degree of hazard increases and the incidence of the hazard decreases. Stringency is affected by both n and c; the more severe the hazard, the higher the n and the lower the c (NRC, 1985; ICMSF, 1986).

Microbiological Components and Analytical Methods

Microbial components of microbiological criteria of foods include pathogenic bacteria, microbial toxins, and indicator organisms. Adequate, practical and validated methods must be available to detect or enumerate the microbiological component if the criteria are to be effective. Pathogenic bacteria useful as components of microbiological criteria include those that are likely to be found in a ready-to-eat food. Suitable indicator organisms are those whose presence indicates:

1. the likelihood that the pathogens or toxins of concern may be present, or
2. the likelihood that faulty manufacturing practices, or failure of control processes, occurred and may have adversely affected the safety or quality of the product, or
3. that the food or ingredient is not suitable for the intended use.

The significance of indicator organisms as food contaminants can be understood only by having a thorough knowledge of the microflora of the ingredients, the usual source or reservoir of the indicator, the production environment and the process, and by recognizing that the point of sampling may influence the validity of the results.

Recommendations for Application of Microbiological Criteria

In September, 1980, the National Marine Fisheries Service, the U.S. Department of Agriculture, the Food and Drug Administration, and the U.S. Army Natick Research and Development Center requested that the National Research Council (NRC) assemble a panel of experts to develop principles for the establishment of microbiological criteria for food. A report was prepared that provided detailed information on the application of microbiological criteria to 22 groups of food and food ingredients (NRC, 1985). Microbiological criteria were not recommended for raw meats because such criteria would neither prevent spoilage nor foodborne illness. According to the committee, microorganisms of public health concern are often present in small numbers as part of the natural microflora of live animals, and current production and processing procedures cannot eliminate those microorganisms from raw meat. Therefore, it would be impractical to set limits for microbiological pathogens in raw meats as it would be impossible to comply consistently with the limits. Rather, the NRC committee recommended (1) a recognition that low levels of pathogens may be present on raw meats, (2) strict adherence to good food preparation practices, (3) application of new processing procedures designed to reduce the presence of pathogens, (4) education on food-handling practices, and (5) implementation of HACCP. Developments in the U.S. during the last five years have contributed to implementation of most of these recommendations. Through research, industry initiatives, consumer demands, news media scrutiny, and regulatory reform (FSIS, 1996b), adherence to GMP principles is improving, various interventions are being applied to reduce raw meat contamination, HACCP principles are being implemented, and various educational programs have been developed for food handlers and the consumer.

The Codex 'General Principles for the Establishment and Application of Microbiological Criteria for Foods'

(Codex, 1981, 1997) state that a microbiological criterion should be established and applied only where there is a definite need and where application is both practical and likely to be effective. Since current livestock production practices cannot provide pathogen-free live animals, the occurrence of pathogens in raw meat and poultry cannot be entirely prevented by the application of strict sanitary and hygienic principles. Exclusion of pathogens from raw meat and poultry is unlikely without the application of verifiable CCPs which result in pathogen inactivation. The distribution of pathogens in live animals, carcasses and raw meat products such as trimmings and ground beef is extremely variable (non random or unevenly distributed). This variability severely limits the degree of confidence with which a sampling plan can indicate the absence of a particular pathogen in a lot. For example, *Escherichia coli* O157:H7, which has been declared an adulterant in certain raw beef products, occurs sporadically, in low numbers, and is unevenly distributed in those products.

Meat processing controls microorganisms and enhances food safety through the development and use of procedures designed to restrict microbial contamination and growth. Control of processes designed to ensure microbiological safety is managed and monitored by a HACCP system as required by current United States regulations (FSIS, 1996b). The retrospective nature of microbiological testing makes it inappropriate for use in monitoring a CCP if the product is out of control of the producer by the time the results are available. Analysis of the product and the processing environment can be used to validate and verify the effectiveness of a CCP as well as the effectiveness of GMPs and sanitation practices. Aerobic plate counts (APC), or counts of other commonly-accepted indicator microorganisms (e. g., coliforms, *Escherichia coli* biotype I, *Enterobacteriaceae*), can be used to verify proper application of processing procedures, sanitation programs and GMPs. Criteria based upon such examinations are a valuable aid in establishing effective control programs. While these criteria may be effective for evaluating processing conditions (including sanitation, carcass dressing, fabrication and grinding) at the point of production, the perishable nature of the product and the potential for subsequent contamination and microbial growth limit the validity of using microbiological criteria at the retail level or at port of entry. In 1973, the state of Oregon (State of Oregon, 1977) set microbiological standards for fresh and frozen red meat at the retail level and revoked the standards four years later because: (1) the standards were unenforceable and created a general adverse reaction, (2) there was no evidence of reduction of foodborne disease or improvement in quality characteristics of the meat, and (3) the standards may have created erroneous consumer expectations of improved quality and decreased hazard.

Microbiological Sampling for Pathogens

In what would seem to be the simplest and most direct method for determining the presence of pathogenic bacteria in beef, production lots can be sampled and tested directly for the microorganism using any of several classical or rapid microbiological tests. The principal question is, how many sample units must be collected and analyzed to have a high probability of detecting the presence of the pathogen? Suppose that a large number of sample units (hundreds) have been collected from the lot and analyzed, and that all the samples appear to be negative for the target pathogen. Does this mean that the lot is free of the pathogen? If the producer has data indicating the probable frequency of a pathogen in sample units from a lot, it is possible to determine the probability that all samples collected and analyzed from the lot will be negative for the target pathogen. For example, using data from the FSIS Nationwide Federal Plant Raw Ground Beef Microbiological Survey (FSIS, 1996a) and the ongoing ground beef sampling program (FSIS/OPHS, 1998), one can expect to find *E. coli* O157:H7 in 0.1% of ground beef nationwide. If 100 samples are collected and analyzed from a lot of ground beef, what is the probability (Pr) that all 100 samples will be negative?

$$Pr = e^{-100(0.001)} = 0.90$$

In 9 of every 10 examinations of this lot, all 100 samples are likely to be negative. Conversely, the analyst would expect to detect a positive sample in the lot only 1 out of every 10 occasions that 100 samples from this lot are examined (Dodge and Romig, 1959; Messer et al., 1992). Of course, it is assumed that the pathogens will be detected by the analytical method used (when, in fact, they may not be), and that the pathogen is randomly or evenly distributed within the product (which is highly unlikely). Therefore, the fact that 100 sample units from the lot have been examined without detecting the target pathogen does not eliminate the possibility that the pathogen may still be present in the lot.

Another way to view the problems inherent in sampling plans for the detection of low levels of pathogens within a lot is to determine the number of sample units needed to detect a known or expected level of contamination. Again, accepting the expected incidence of *E. coli* O157:H7 in ground beef as 0.1%, and assuming that at least one sample unit per lot is determined to be contaminated, the following number of samples (n) from a contaminated lot must be examined in order to detect the pathogen with probabilities of 0.90, 0.95 and 0.99:

$n = -\ln(0.10)/(0.001) = 2{,}303$ samples at a probability of 0.90

$n = -\ln(0.05)/(0.001) = 2{,}996$ samples at a probability of 0.95

$n = -\ln(0.01)/(0.001) = 4{,}605$ samples at a probability of 0.99.

Even if it were to be assumed that *E. coli* O157:H7 is present at an incidence ten times higher (1.0%) than that detected by FSIS in their nationwide ground beef survey and ground beef sampling program (FSIS, 1996a; FSIS/OPHS, 1998), the number of samples needed to detect a contaminated lot is still very high:

$n = -\ln(0.10)/(0.01) = 230$ samples at a probability of 0.90

$n = -\ln(0.05)/(0.01) = 300$ samples at a probability of 0.95

$n = -\ln(0.01)/(0.01) = 461$ samples at a probability of 0.99.

Recognizing that the expected incidence of *E. coli* O157:H7 is extremely low, it may be instructive to run these same statistical scenarios using a pathogen with a higher incidence in raw beef. Using FSIS survey data for an expected incidence of *Salmonella* of 7.5% in ground beef (FSIS, 1996a), the following number of samples from a contaminated lot (n) must be examined to detect the pathogen with probabilities of 0.90, 0.95 and 0.99, when at least one positive sample unit is detected:

$n = -\ln(0.10)/(0.075) = 31$ samples at a probability of 0.90

$n = -\ln(0.05)/(0.075) = 40$ samples at a probability of 0.95

$n = -\ln(0.01)/(0.075) = 61$ samples at a probability of 0.99.

Again, even when collecting sufficient samples for a 0.99 probability of detection, nonuniform distribution of pathogens within the lot will still result in a chance that the consumer will be exposed to contaminated product from a lot deemed to be safe by microbiological testing. It is clear that establishment of microbiological criteria for pathogens on carcasses, trimmings or raw ground beef will require extensive microbiological sampling and testing at a significant cost, and still will not guarantee absence of the target pathogen in the lot.

Food Safety Objective

The ICMSF has recommended steps for the management of microbiological hazards in foods in international trade (ICMSF, 1998). The same principles can be applied to food in domestic trade and to beef safety. The steps incorporate existing Codex documents that can be applied in a logical sequence. In Step 1, the Principles and Guidelines for the Conduct of Microbiological Risk Assessment are applied to provide an estimate of the public health impact associated with the hazards in food. This information provides the scientific basis for subsequent risk management decisions.

In Step 2, options that may be available for managing the identified risk(s) are considered. One outcome of the risk management option assessment process may be to establish a Food Safety Objective (FSO). FSOs are the result of deliberations of risk managers in consultation with risk assessors, affected industry and consumers (ICMSF, 1998). The FSO can be defined as the maximum level of microbiological hazard in a food considered acceptable for consumer protection. Establishment of the food safety objective must consider public health impact and technological feasibility. Whenever possible, FSOs should be quantitative and verifiable. The safety margin of FSOs should reflect the confidence in the risk assessment. Thus, the FSO must be more stringent when the risk assessment is more uncertain.

FSOs must be technically achievable through the application of General Principles of Food Hygiene and the HACCP system. In addition, because good hygiene practices (GHP – a European term similar to the American "GMP") and HACCP are the only tools available, FSOs must be based upon a realistic assessment of what can be achieved through GHP/GMP and HACCP.

One disadvantage of microbiological criteria is that they do not take into account a scientific assessment of the hazard's estimated impact on the public's health. Risk managers are frequently at a loss in developing criteria that are meaningful in addressing key public health issues. It is the intention that FSOs would fill this void. A FSO deals with food safety issues and does not address issues of quality and stability. FSOs are broader in scope than microbiological criteria and are intended to communicate the level of hazard that is considered acceptable to the consumer (ICMSF, 1998).

Consensus and Conclusion

The following consensus points were agreed upon by the participants in the symposium. Consensus points are listed in the order in which they were discussed; listing order is not intended to indicate priority.

1. *The main purpose of microbiological testing of foods is to validate and verify process control measures in the context of a properly implemented HACCP system* (Codex, 1997; NACMCF, 1998). Safety of beef products may only be assured through a chain of controls from production through consumption. Microbiological control measures within processing steps in that chain may be validated by microbiological testing. If sufficient data are available to indicate that the behavior or incidence of a particular pathogen or indicator organism is correlated with appropri-

ate levels of process control, process control points may be developed through research, validated during initial implementation, and verified periodically using microbiological testing. Pathogen testing as a means of HACCP verification is only supportive if incidence is high, distribution is random, and numbers are high enough to reliably permit detection. Expected low numbers and nonrandom distribution of pathogens in meat and poultry products severely impair the usefulness of pathogen testing for verification. Sampling plans used to detect indicator organisms in order to monitor and verify processes may be based, when appropriate, on ICMSF and Codex guidelines (Codex, 1981; ICMSF, 1986).

2. *Effective microbiological testing programs are based on sound Food Safety Objectives (FSOs; ICMSF, 1998) with definable microbiological performance criteria.* FSOs are the result of deliberations of risk managers in consultation with risk assessors, affected industry and consumers. The FSO can be defined as the maximum level of a microbiological hazard in a food considered acceptable for consumer protection. Establishment of the FSO must consider public health impact and technological feasibility and, whenever possible, food safety objectives should be quantitative and verifiable. The safety margin of FSOs should reflect the confidence in the risk assessment; thus, the FSO must be more stringent when the risk assessment is more uncertain.

3. *Pathogen testing at any stage in food processing will not assure food safety.* Incidence of pathogens, such as *E. coli* O157:H7, on live animals, carcasses, trimmings and ground beef products is non-random and infrequent. Therefore, even when collecting sufficient samples to permit a 0.99 probability of detection, there is still a possibility that pathogens will be present but undetected in a lot of product.

4. *Foodborne pathogens will not be detected consistently when they are non-randomly distributed and/or occur at a low incidence.* Even when collecting sufficient samples for a 0.99 probability of detection, nonuniform distribution of pathogens within the lot will still result in a chance that the consumer will be exposed to contaminated product from a lot deemed to be safe by microbiological testing. The scientific application of microbiological criteria for pathogens in raw beef will require an extensive amount of microbiological sampling to detect low numbers of pathogens of low incidence at a significant cost, and still will not guarantee absence of the target pathogen. Proper implementation of scientific HACCP principles is a better investment for effective pathogen reduction than is product testing. Implementation of the principles of HACCP and product testing for pathogens of infrequent, low and nonrandom occurrence are not comparable in effectiveness for process control. Testing for pathogens in the present context is too unreliable and would be no substitute for the HACCP approach.

5. *Pathogens or other microorganisms which typically occur in the food at a low incidence cannot be used to assess process control.* Effective verification of process control by microbiological sampling and testing requires the analysis of microorganisms that are present or absent with predictable regularity and in numbers that permit reliable detection. Further, the level of presence of the target microorganisms must change in response to the process. Sampling for a pathogen which is normally present infrequently and nonrandomly is expected to provide almost no information about process control, since an inability to isolate the pathogen could be due to either the process or simply due to the absence of the microorganism at that particular time in that particular product.

6. *Testing for appropriate non-pathogenic (indicator) organisms will allow validation and verification of process control systems designed to improve food safety.* For instance, if a processing control point designed to reduce the presence of pathogens is challenged with the pathogen under experimental conditions, a level of possible control can be established. If parallel data are collected using appropriate indicator organisms (e.g., coliforms or *E. coli* biotype 1 to indicate control of enteric pathogens), a similar level of reduction or control can be established. Control of the indicator organism may then be reliably used to indicate expected pathogen control in commercial application.

7. *Declaration of a foodborne pathogen as an adulterant in raw products (e.g., E. coli O157:H7 in certain raw beef products): discourages testing for that pathogen; leads to a false sense of security among consumers; discourages evaluation of potential control measures; and, encourages the inappropriate use of microbiological testing.* The unavoidable, infrequent, and nonrandom presence of *E. coli* O157:H7, and the lack of a process to assure the elimination of this organism in raw beef products all argue against its classification as an adulterant. Legal liability issues centered on the adulterant classification severely impede attempts to learn more about *E. coli* O157:H7 in raw beef, and to develop better control procedures.

8. *Microbiological testing of foods in production during processing is important, but such testing is only a part of the overall strategy for controlling food safety. Education concerning proper handling and cooking is essential.* All too often, a discussion of food safety in the news media concentrates on the microbiological testing of food. While microbiological testing is a helpful tool in the overall assurance of food safety, statistical expectations and microbiological realities make testing insufficiently reliable for stand-alone use. With extensive public outcry from various groups to implement more and more testing, the industry is under intense pressure to invest significant time and resources into weaker areas of process control, possibly leading to neglect of other, more effective aspects. Education of the consuming public and the news media is needed – the message must be that the safety of food cannot be assured predictably through testing, but can only be attained through process control. The industry should emphasize the continuous improvement of process control measures instead of extensive pathogen testing programs that are intrinsically unreliable.

The intense coverage of foodborne outbreaks in the news media in recent years has placed responsibility for safety problems mostly on the food industry and regulatory authorities. While blame for a problem is certainly expected to be a major part of any news media coverage, limited understanding of food processing leads the media to make poor assignments of responsibility for food safety. In the process, the food handler and consumer are not always adequately instructed on how to easily protect the food and themselves from exposure to enteric pathogens. It is encouraging to note that recent food safety news stories often include segments on proper food handling, sanitation and hygiene. Also, it should be recognized that news media coverage has increased interest and awareness in food safety issues and has contributed to the support of activities that enhance food safety. Nevertheless, education programs for food handlers, consumers and the news media are needed to better address this problem and contribute to an overall enhancement of the safety of our food supply. Educational efforts must also be aimed at elementary and high-school students in order to ensure that safe food handling practices become a part of our collective conscience.

In conclusion, a number of outbreaks of foodborne illness caused by *Escherichia coli* O157:H7 have been linked with consumption of undercooked ground beef. Retrospective investigations of these outbreaks have shown that when the organism can be isolated from implicated lots of ground beef, it is present only in a small percentage of samples examined and at low levels (less than 500 cfu/g; usually much less). Also, undercooked product consumed in the vast majority of these outbreaks was not just slightly undercooked, but grossly undercooked. Available evidence indicates that most outbreaks of *E. coli* O157:H7 illness linked to ground beef can be attributed to product contaminated at low, often undetectable, levels which has been grossly undercooked before consumption.

Microbiological testing can be applied within a HACCP system to verify process control or application of a pathogen intervention procedure at a specific CCP. It is important to note, however, that verification activities are more accurate when used to verify the effectiveness of the process which will control hazards at a CCP rather than to verify the safety of the final food product. Implementation of the principles of HACCP and assurance of food safety through product testing for pathogens of infrequent and nonrandom occurrence are two mutually exclusive concepts. The principles of HACCP were developed because end product testing for pathogens was unreliable to assure food safety. With sufficient prior data collection, the reduction of a bacterial indicator at a point in processing can indicate that a specific pathogen also is being controlled effectively. This application of indicator organism testing is especially useful when pathogens are distributed unevenly and at levels too low to allow confirmation of process control through their testing. Although these conditions do apply to pathogen contamination of ground beef, production of raw ground beef currently does not include a processing step capable of consistently reducing the presence of pathogens, so indicator organism testing to ensure process control is a moot point.

Currently, food establishments usually include microbiological testing of end-products as verification activities in their HACCP plans (Hatakka, 1998). However, if microbiological verification activities are limited to end-product testing for pathogens, the ability to isolate the target pathogen will be affected by uneven distribution and infrequent occurrence of the pathogen on the product. Furthermore, testing end-products for the presence of an indicator organism without knowledge of the relative levels of the microorganism throughout the process and within the plant environment provides little information regarding process effectiveness. Since raw ground beef processing does not include a step capable of reducing the presence of enteric pathogens, verification of the effectiveness of a CCP in this process only provides confir-

mation that pathogens, if present, are not becoming a greater problem.

Available "investigative" sampling plans, developed by organizations such as the ICMSF, have been adopted for certain applications; the stringency of these plans is higher when the disease is more severe and the incidence of the agent is low. End-product sampling and testing for enteric pathogens of low and nonrandom incidence, such as *E. coli* O157:H7, may periodically allow detection of extremely contaminated lots of ground beef, but their occurrence is unpredictable. Thus, results of microbiological sampling and testing may mislead the public regarding the safety of raw ground beef, and fail to accomplish the greater goal of protecting the safety of this product.

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Appendix 1

Sampling & Testing Ground Beef for *E. coli* O157:H7

The deliberations of this group were geared towards the larger grinding operations that cater to large food-service establishments. These recommendations assume the existence of control systems to manage microbiological safety and the use of microbiological sampling and testing plans to support those systems. These recommendations may not be suitable for smaller operations, and are not relevant at the retail level.

Because *E. coli* O157:H7 usually occurs sporadically in very low numbers, and is unevenly distributed, it is not possible, by any practical means, to sample ground beef sufficiently comprehensively to determine whether it is free from the organism (Table 1). In rare instances, levels of contamination are higher and these levels may be detected by the use of an appropriate sampling plan. Thus, it may be possible to reduce the number of cases of human illness due to *E. coli* O157:H7 by excluding affected raw product from the human food chain. Whether this reduction in illness will be quantifiable will be dependent upon our ability to demonstrate a significant reduction in illnesses attributed to ground beef (e.g. number of cases/100,000/year).

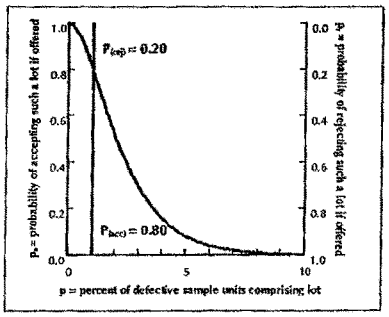
An equally acceptable alternative to finished product testing would be the use of pre-tested raw materials. The use of raw material testing to monitor the efficacy of intervention technologies and process controls at the slaughter level would permit the exclusion of known contaminated raw materials and, thus, reduce the requirement for finished product testing. While no sampling and testing program can assure the complete exclusion of *E. coli* O157:H7, screening of raw materials used to make ground beef can preclude the use of those materials that test positive.

A sampling plan established for ground beef should be based upon the Codex principles. For those establishments that choose to sample ground beef as a management tool, it is recommended that the sampling plan consist of 15 samples per lot (e.g. per half shift or 4 hours of production). This proposed sampling plan will provide a 95% confidence level that acceptable product will contain no more than 1 CFU *E. coli* O157:H7 per 125 g (i.e., no more than 20% of 25-g sample units in the lot will contain *E. coli* O157:H7).

TABLE 1. Probability of accepting a defective lot with indicated proportion of defective sample units.

	Number of sample units tested			
% Defective	15	30	60	100
0.1	0.99	0.97	0.94	0.90
0.5	0.93	0.86	0.74	0.61
1.0	0.86	0.74	0.55	0.37
2.0	0.74	0.55	0.30	0.13
5.0	0.46	0.21	0.05	0.01

FIGURE 1.



The operating characteristic curve for n = 82, c = 1, i.e. the probability of accepting lots, in relation to the proportion defective, among the sample units comprising the lots.

An appropriate sampling plan and criteria based on this approach would include the following components:

1) the nature of the microbiological hazard (e.g. *E. coli* O157:H7);
2) lot definition (e.g. half shift);
3) the number of sample units to be collected (e.g. number of patties, or quantity of ground beef);
4) a description of how the samples are collected;
5) a description of the analytical unit(s);
6) a description of both the sample preparation method and the analytical method; and

7) lot acceptance criteria (n = 15, c= 0).

Different sampling plans should be utilized for different pathogens based upon the risk to consumers and whether the risk will change between the time the product is sampled and the food consumed. The sampling plan will also depend upon the incidence and distribution of the target pathogen in ground beef.

Several voids in our knowledge of *E. coli* O157:H7 were identified during the development of the recommendations presented in this ground beef document. The group believes that answers to these knowledge voids may help clarify certain assumptions used to develop the sampling and testing plans that are recommended in this document. Knowledge voids include:

1) baseline data on the prevalence of food borne illnesses caused by ground beef;
2) information on the distribution of *E. coli* O157:H7 throughout the beef production chain;
3) verification of the validity of composite sampling for *E. coli* O157:H7 in ground beef; and
4) information on the persistence or removal of *E. coli* O157:H7 in a processing system during a production run.

Appendix 2

Science Based Applications of Microbiological Testing (Sampling and Analyses) to Fabrication & Trimmings

The preferred method for microbiological (pathogen) control is the implementation of HACCP. However, in the absence of a step capable of reducing or eliminating microbiological contamination, a sampling/testing plan for trimmings could be integrated with the HACCP plan. This approach would be expected to reduce the chances of contaminated raw beef materials being further processed into ground beef.

The group does not believe that data from microbiological sampling and testing of trimmings can be used for decision making to improve food safety. This is because 1) no sampling and testing regimen (short of 100% testing) can eliminate the risk of pathogen presence; and 2) current preparation protocols for beef trimmings do not have a processing step capable of excluding or destroying pathogens. The group recognizes that data from microbiological sampling and testing can be used to improve the safety of beef trimmings. Specifically, sampling and testing can be used to:

1) detect more highly contaminated lots of trimmings which are more likely to yield ground beef which is associated with disease;
2) validate or verify process control;
3) identify out-of-control processes;
4) verify control of the process environment & equipment;
5) identify critical stages of the process as sources of contamination;
6) identify location, concentration and frequency of contamination;
7) establish an individual plant baseline; and
8) determine when the process produces trimmings of a microbiological quality which differs from that of the baseline.

Sampling plans

If sampling is done, it should be done according to a statistically valid sampling plan with a known probability of detecting a microbial contaminant, assuming that incidence is statistically random.

Identification of a Lot

A combo holds approximately 2,000 lbs. of trim. A lot is a maximum of 5 combos. A load is 20 combos.

Sampling of the Lot

Sampling plan is based on Case 13 of the ICMSF Plan (corresponding to Category 3 of the FDA Guidelines). Take five random samples (cores) from each combo to make a total of 13 lbs per combo. Grind each of the five samples individually and take three 25 g sub-samples from each sample. Combine the 15 sub-samples (25 g each) into a 375 g compose sample which will be tested after enrichment for the target pathogen (e.g. *E. coli* O157:H7).

If the composite sample tests positive for the pathogen, reject the lot

If the composite sample tests negative for the pathogen, accept the lot

Alternatively, different load sizes can be sampled by using the pallet as a basis for sampling. Three boxes from each of 5 pallets per load can be randomly selected. One (or more) core samples can be taken at random from each box to obtain a 25 g sample. The 15 sub-samples per lot can then be composited to obtain a 375 g sample from the lot. This composite sample can then be enriched and tested.

Assumptions and Limitations

- Pathogens may or may not be randomly distributed in beef trimmings
- If pathogens are randomly distributed, a sampling plan can perform at this confidence level:
  - <1 organism/125 g with a 95% confidence level for lot (no more than 20% of 125-g sample units in the lot will contain the pathogen)

    or
  - <1 organism/500 g with a 95% confidence level for load (no more than 5% of 500-g sample units in the load will contain the pathogen)

Validation studies on sampling plans

The group believes that validation studies should be performed on any sampling/testing plan that is used for beef trimmings. Core/drilling sampling of the lot has been an accepted procedure in the collection of microbiological samples from a variety of bulk food commodities. The microbiological sub-sample that results from the coring/grinding protocol is indicative of the microbial concentration in the finished product.

The place of sampling

In the absence of a process step capable of reducing or eliminating microbial contamination on beef trimmings, a sampling/testing program is recommended. The sampling plan presented in this report is internationally accepted and used. Based on published risk assessment studies, this sampling plan will minimize the health risks associated with consuming food from the process. A similar sampling testing program has been accepted by USDA-FSIS for fermented sausage that is intended to be further cooked.

Appendix 3

Harvest to Carcass

The goal of this team was to develop a science-based microbiological sampling and testing program to be used in the validation and verification of harvest to carcass HACCP systems. The overall objective is to contribute to a reduced risk of foodborne illness from microbial pathogens.

The role of microbiological testing during slaughter is to facilitate the implementation, validation and verification of HACCP programs. Testing may be done before and after each operational SOP and CCP to determine the effectiveness of a particular process step for reducing microbial contamination. In the group's opinion, testing for indicator organisms (Aerobic Plate Count & *Escherichia coli* biotype I) is the best approach to the validation and verification of a process control system that is designed to reduce the incidence of microbial contamination. Not only are aerobic organisms and biotype I *E. coli* indicative of environmental and fecal contamination, but the higher expected frequency of these organisms makes them much more suitable as process-control indicators than are pathogens. Following validation and routine HACCP implementation, microbiological criteria may be set for end product process verification testing. In the event that problems are encountered or a process is changed, it may be necessary to repeat testing before and after each operational SOP and CCP in order to assess the situation.

The group believes that sampling carcasses for pathogens serves no valid scientific or statistical purpose, as pathogens are typically present at low levels and at a low incidence on carcasses and are not randomly distributed. These limitations make it impossible to statistically justify the use of pathogens for the validation or verification of a HACCP system in a beef slaughter plant. While localized or spot contamination of carcasses with pathogens can possibly occur, it is highly unlikely that such contamination will be detected by routine carcass testing. More likely contamination will only be detected after it spreads to fabrication equipment or is distributed in comminuted products.

The prevalence of *E. coli* O157:H7 on beef carcasses in the FSIS baseline studies (0.2%) and New Zealand baseline survey (0/2840 carcasses) prior to the use of decontamination interventions, and the expected lower prevalence with the use of such interventions, deems carcass testing statistically unjustified. For instance, statistical analysis [n=-ln(0.05)/(0.002)] indicates that a total of 1,498 samples would be required to provide a 95% confidence of detecting one positive carcass at a prevalence rate of 0.2%. The frequencies and period in which the one *E. coli* O157:H7-positive sample could be expected to be detected on beef carcasses are presented in Table 1.

TABLE 1. Frequency of carcass testing needed to detect *E. coli* O157:H7 when present at pre-intervention incidence levels (FSIS & New Zealand data)

If sample at this frequency	It will take this average time period before a positive sample is detected
1 carcass/month	125 years
1 carcass/week	28 years
1 carcass/day	4 years
1 carcass/300 carcasses	115 days (assuming 3,900 head/day are slaughtered)

Suggested Sampling Plan for APC & *E. coli* Biotype I on Beef Carcasses

Frequency of sampling:

For SOP or CCP validation:

Five randomly selected carcasses from each of five consecutive lots. A sample size of 25 provides 95% confidence of detecting a 0.5 log change in the mean count with a standard deviation of 0.6.

For routine process verification:

The same as for validation.

Recommended sampling procedure:

For operational SOP or CCP validation:

One randomly selected 100 cm^2 carcass site sampled by swabbing (e.g. by following the FSIS *E. coli* carcass-sampling procedure). Randomly selected carcasses should be sampled before and after each operational SOP or CCP. When validating a SOP or CCP for an operation that affects only a limited area of the carcass, targeted sites (likely to be impacted by that process step) must be sampled.

For process verification:

At least one randomly selected 100 cm^2 anatomical carcass site per carcass in the chiller. Alternative verification procedures may be used if they are demonstrated to be equivalent to random sampling for defining the performance of the process.

Methods of analysis:

Any analytical method accepted by FSIS and/or any method having AOAC approval.

Microbiological criteria:

Total plate counts:

The target total plate count should initially be set below plant baselines. The goal should be to progressively reduce levels to ≤ 2 log CFU/cm^2.

Escherichia coli biotype I counts:

E. coli biotype I counts should at least meet current FSIS regulatory requirements. The goal should be progressive reductions with process improvements; the ultimate goal is to reach undetectable levels with the stipulated sampling and analytical procedures.

Appendix 4

Role of Microbiological Testing With Regard to Sanitation of Beef Plants

The goal was to examine the role of microbiological testing in assessing the effectiveness of sanitation in beef plants. Essentially, sanitation is a microbial intervention step that impacts the safety of food products by addressing the food production environment and equipment.

Environmental sampling and testing programs may be designed to assess Sanitation Standard Operating Procedures (SSOPs), verify the efficacy of a particular sanitation program, or evaluate the effectiveness of sanitation chemicals or sanitation personnel. Environmental sampling and testing programs must consider the exact objective of sampling & testing (e.g. general monitoring or specific trouble-shooting); the organism or organisms being targeted; the stage at which sampling is conducted (pre-operational versus operational); and the use to which the data will be put. Individuals writing the sampling program need to have an extensive knowledge of the equipment and the plant environment in order to identify sampling sites appropriate to a particular objective. The sampling and testing program must provide results which are useful in a retrospective sense since microbiological data are not available for at least 24 hours. Finally, a microbiological sampling and testing program must provide a framework within which results may be interpreted and tied to appropriate actions. In some cases, an environmental test result may have consequences for product manufactured in that facility or on that equipment; this is especially true of plants manufacturing ready-to-eat products.

Most microbiological testing of the plant environment is directed towards pre-operative sanitation since the microbial load in the plant environment and on equipment will increase once product is brought into the area. In addition to gauging whether sanitation procedures have been effective, microbiological testing can also be used to ensure that "niches" of pathogen growth do not exist. Sampling the plant environment and equipment for *Listeria* during production is useful in plant areas where ready-to-eat products are handled but would serve no purpose in slaughter or ground beef plants since animals and raw meats would be expected to carry a variety of *Listeria* species into those environments. Collection of environmental samples at various times during production is a strategy frequently used when trouble-shooting spoilage or pathogen contamination issues.

Microbiological sampling and testing programs used to evaluate sanitation are much less formal and structured than are sampling plans directed at product. Statistics are seldom (if ever) used when developing environmental sampling plans. Limited statistical analyses (e.g. trending) may be conducted on quantitative data but data are more likely to be informally compared to a historical baseline, yielding a subjective conclusion as to the acceptability of sanitation procedures.

With the exception of standardized laboratory studies of sanitizer activity against known test organisms, quantitative data on the microbiological effectiveness of detergents or sanitizers are rare. Quantitative studies of sanitation efficacy (e.g. the "D-value" type approach) are rarely done, either by food plants or by companies selling sanitation chemicals. In part, this is because such data would be nearly impossible to obtain in the real world where microbial attachment is influenced by a multitude of difficult-to-measure variables and microbial removal or inactivation during sanitation are similarly subject to a variety of unmeasurable influences.

Microbiological sampling protocols — environmental samples

Sample-collection methodologies applicable to environmental samples have been described in the scientific literature. Methodologies include sponge sampling, cotton-gauze sampling, swab sampling, and direct-contact sampling methods. Sponge and swab sampling are probably used most frequently. Standardized environmental sampling plans are uncommon in the meat industry – most plants have their own, internal, sampling plan. Suggestions on sampling for *Listeria* in ready-to-eat processing areas are available (e.g. the AMI *Listeria* guidelines for ready-to-eat products) but typically those guidelines are less detailed than (for example) the ICMSF sampling plans. The number of environmental samples collected varies widely between plants, as does the range of analyses that are conducted on the samples. Typically, the extent of environmental sampling and testing is prescribed by plant or corporate per-

sonnel since there are no regulatory requirements on environmental sampling.

Pre-operational sampling may include both food-contact surfaces and non-food contact surfaces. Sampling hard-to-clean areas is likely to provide the most useful information. Pre-operational sampling may also target such things as air coming from air lines, water, and filters on equipment or air lines. Unless specifically employed as a trouble-shooting tool (e.g. in running down a spoilage issue), in-process environmental sampling is unlikely to be useful in a plant handling raw products.

Microbiological testing protocols — environmental samples

It is important to realize that no official methods (e.g. FSIS) exist for the collection or analysis of environmental samples. AOAC, the organization that serves as a referee for microbiological methods used to analyze food product samples, typically does not address environmental samples. In general, it is more important that methods used in the analysis of environmental samples for indicator organisms give rapid results than precise results since the data are reviewed only for trends. Microbiological data interpretation – environmental samples

Quantitative results indicate either a detectable level of microorganisms or a level below the limit of detection ($\neq 0$). Environmental criteria involving indicator organisms may be based on recommendations (e.g. from a trade group) or on an arbitrarily chosen level or on plant-specific data obtained on environmental samples collected prior to production of microbiologically-acceptable product. No official criteria for environmental samples exist in the U.S. Australian guidelines suggest a maximum APC (at 25°C) of 300 CFU/100 sq. cm. for pre-operational surfaces. In the case of pathogen testing, only qualitative results (presence or absence) are obtained since enrichment procedures are used. The presence of pathogens on pre-operational surfaces is unacceptable and indicative of inadequacies in the sanitation program.

QUESTIONS AND ANSWERS SUBMITTED FOR THE RECORD

SEPTEMBER 20, 2000

Food and Drug Administration Responses to Questions from Senator Richard Lugar

1. **In your testimony you mention that FDA published a guide to minimize the microbial hazards for fresh produce and that FDA has conducted training sessions for the domestic and foreign agricultural communities. Could you elaborate on this training provided? What kind of response have you received? Do you expect that the practices recommended in the guidance will be widely adopted?**

As you know, in 1998, the Food and Drug Administration (FDA or the Agency) published a document, "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guide was published as part of President Clinton's Initiative to ensure the safety of imported and domestic fresh fruits and vegetables. It provides science-based guidance that will help reduce microbial hazards that are common to the growing, harvesting, washing, sorting, packing, and transporting of fresh produce. It provides information on agricultural and management practices industry may use to enhance the safety of these products. To promote the application of these practices, FDA and USDA have been working with industry, academia, international organizations, other Federal agencies, and with foreign governments to disseminate the guide and provide training worldwide. Publication of the guide in four languages (English, Spanish, French, and Portuguese) has also facilitated its application worldwide. A copy of each of these versions of the Guide is enclosed for the record.

Domestically, FDA and USDA have provided funding for a team of agriculture educators in five states (New York, Florida, California, Washington, and Michigan), under the leadership of Cornell University Cooperative Extension, to develop educational materials and train domestic farm owners and operators, packing house managers, field workers, and packing house staff on good agricultural practices (GAPs) for growing fresh fruits and vegetables. The program promotes awareness of GAPs and provides a check-off list of GAPs for on-farm use, a resource manual, a slide program, posters, and videos. So far, over 30 workshops have been held domestically using these materials.

A similar project has been funded by the Agency for the Food and Agriculture Organization and the University of Arkansas to develop materials for use internationally. International and regional training programs on the GAPs were held in Costa Rica, bringing together agriculture experts and health officials from Central America. Training programs were also held in Chile, and an outreach program was held in Mexico. As recently as September 2000, GAPs were a major focus in a food safety and trade meeting in New Zealand that brought together agriculture experts and health officials from the Pacific region.

In addition to educating food producers about GAPs, FDA has also undertaken an extensive program to educate consumers on the safe handling of fruits and vegetables. The Agency's support of the Partnership for Food Safety Education has enabled further education about the safe handling of fruits and vegetables in a program for students in grades 4-6. Information about washing fruits and vegetables is included in a presenter's guide for teaching students in grades K-3 and was included in a Food Safety calendar created by the Partnership.

The GAP guidance and subsequent training have been well received by both the domestic produce industry and by foreign firms that export produce to the United States (U.S.). We expect that the GAPs will be widely adopted. Many produce trade associations have modified their own food safety manuals, how-to guides, and general guidance to be consistent with FDA's. Industry groups have been actively promoting GAPs among their members since the Agency's guidance was in development. Several major retailers are requiring that their fresh produce suppliers provide evidence, such as through third party certification, that they are following GAPs. To ensure consistency in certification, a group of trade associations developed a checklist (based on practices in FDA's guide) for evaluating farms and packing houses. This concept has also caught on internationally. For example, FDA has been contacted by Mexican industry members about establishing a certification program for growers.

The guide is also the basis for several international standards, including the Draft Code of Practice for the Primary Production and Packing of Fresh Fruits and Vegetables under development by the Codex Alimentarius

Committee on Food Hygiene. Many countries will consider adopting this document as their national standard once it is completed.

To measure adoption of the GAPs, we have worked with USDA's National Agricultural Statistics Service to perform an extensive survey of growers and packers in the U.S. The first survey was performed in early 2000. This survey gathered data on the types of practices (e.g., agricultural water source, manure use) covered in the guide. A report of the survey results is expected in late 2000 or early 2001. Repeating the survey in the future will allow us to measure changes in practices. The University of Costa Rica is testing a similar survey for use internationally.

2. **One of the issues of interest to me and this Committee is irradiation. This is one way to reduce and prevent microbial contamination of foods. What irradiation petitions are pending before FDA and what is the status of them?**

Five petitions related to irradiation of food for microbial control are currently under review at FDA. In addition, the Agency recently approved three petitions.

Under review:

National Fisheries Institute, Inc. & Louisiana Dept of Agriculture and Forestry FAP 9M4682
Use of ionizing radiation for the pasteurization of fresh or frozen molluscan shellfish

USDA FAP 9M4695
Use of ionizing radiation on nonrefrigerated as well as refrigerated meat products

USDA FAP 9M4696
Increase maximum allowed dose of ionizing radiation on nonrefrigerated, refrigerated, and frozen poultry products

National Food Processors Association FAP 9M4697
Use of ionizing radiation on a variety of preprocessed as well as unprocessed foods

The National Center for Food Safety and Technology FAP 0M4711

Use of all energy sources listed for treatment of food under Title 21, Code of Federal Regulations (CFR) section 179.26(a)(1-3) for packaging listed under 21 CFR 179.45

Recently approved:

Edward S. Josephson FAP 8M4584 - approved July 21, 2000
Use of ionizing radiation for the reduction of Salmonella in fresh shell eggs

Caudill Seed Co., Inc. FAP 9M4673 - approved October 30, 2000
Use of irradiation to control microbial pathogens in alfalfa and other sprouting seeds

California Day-Fresh Foods, Inc. FAP 9M4676 - approved November 29, 2000
Use of ultraviolet light for the reduction of microorganisms on juice products

3. Many are wary that consumer acceptance of this technology will preclude its widespread use in the marketplace. How can consumer acceptance of irradiation be increased? Is there a Federal government role?

A number of factors are important for consumer acceptance. The Federal government has a role to play, as do the food industry and the general food safety community, including academia.

FDA is the Agency responsible for ensuring that irradiation of food has been demonstrated to be safe before the irradiation is approved for use for the intended conditions. For example, FDA recently approved irradiation for control of microbial pathogens on seeds for sprouting. Specifically, through a statutorily mandated food additive petition process, FDA conducts a rigorous evaluation of the data relevant to the safety of the irradiation of certain foods covered by the petition, and makes its analysis publicly available. For each rule approving a new use of irradiation, the Agency prepares a written document that summarizes the data relevant to safety, analyzes such data, and explains how the data demonstrate safety. This document is published in the Federal Register. These documents are publicly available and provide information

for other regulatory bodies, scientists, the news media, and other interested parties. Such information may also be used to prepare educational materials for consumers.

FDA scientists have presented information to consumers and professional groups through a variety of means such as written brochures, presentations at professional meetings and meetings with consumer organizations, information on FDA's Internet site, and countless interviews with broadcast and print news media. For example, FDA worked with other Federal agencies and industry organizations to prepare a widely distributed brochure for consumers called, "Food Irradiation: A Safe Measure." Co-sponsors of the brochure were the American Meat Institute, Food Marketing Institute, Grocery Manufacturers of America, National Cattlemen's Beef Association, National Food Processors Association, and the American Dietetic Association. The Agency has sought to provide objective information on food irradiation to children through curriculum advancements in middle level and high school science courses. In a soon-to-be released supplementary food safety curriculum, sponsored by FDA and the National Science Teachers Association, students are given an opportunity to learn about food irradiation in both the video and activity components of the programs. Students will use the Internet, for example, to study and search for information about irradiation as one of many food safety technologies. In such presentations, the Agency has emphasized that irradiation is a technology intended to complement other means for ensuring a safe product.

It is very important for the public to understand that irradiation will not be used as an alternative for other, essential, sanitation measures. It is also critical that consumer education efforts remain balanced and objective so that irradiation and other antimicrobial interventions are placed in proper context in the overall effort to ensure food safety. FDA's role is to provide information to enhance food safety but, as the Federal safety evaluator, not to promote any particular technology for achieving that goal.

Industry also has a role to play by providing accurate information and by demonstrating that irradiation is being used to provide enhanced value to the consumer. Consumers must also see irradiated foods in stores and have a first

hand opportunity to sample such products to gain the assurance that irradiated foods are not different in any significant way from their non-irradiated counterparts.

Finally, food safety professionals in academia must share their expertise to build consumer confidence in the safety and effectiveness of this technology. They need to provide the tools and information that will allow consumers to weigh various claims and choose appropriately.

Food and Drug Administration Responses to Questions from Senator Tom Harkin

1. **What are your plans for addressing levels of mercury in seafood that exceed FDA's action level, and what is your timeline for revising that action level in light of the recently released National Academy of Sciences review of mercury toxicity.**

The overwhelming majority of commercial seafood species have very low or trace levels of methylmercury for which no regulatory controls are warranted. For the few commercial species that have high average amounts of methylmercury relative to other species, (e.g., shark, swordfish), when the action level is exceeded, typically it is by small amounts. Given that consumption of these species is relatively low, such as once per quarter for the average consumer of swordfish, and a single serving typically does not add measurably to the human body burden for methylmercury, FDA's policy has been to provide consumption advice for these species directly to the highest risk consumers, i.e., women of child bearing age who are pregnant or may become pregnant. Regulatory controls would become warranted if there were an industrial incident, or similar event, that would cause levels in commercial seafood to become dangerously high relative to normal background levels.

In light of the recent National Academy of Sciences report, however, the Agency is in the process of reviewing its longstanding consumption advice to determine whether it should be updated. The Agency is also revising its risk assessment and will revisit its action level for methylmercury on the basis of that risk assessment. FDA intends to publish a draft risk assessment for public comment before finalizing it; then we will publish any proposed updated regulatory level and obtain public input on that proposal as well.

2. **Several parties have raised concerns about FDA's increasing delegation of inspection activities to the States. According to the Inspector General, 61 percent of inspections of food firms are conducted by State inspectors. Yet, FDA has no comprehensive program for ensuring States have the capacity to conduct these**

inspections or a mechanism such as a yearly audit to ensure the quality of the inspections. Additionally, the IG report echoed the complaints of several stakeholders that FDA provides virtually no information to the public about its reliance on State inspectors to fulfill its mission, or how it ensures the adequacy of State inspections. What is FDA doing to address the concerns raised in the IG's report?

As you know, the Office of Inspector General (OIG) issued its report "FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability" in June 2000. FDA welcomed the OIG report as a tool to strengthen Federal oversight of State food safety inspections. Indeed, Agency management requested the study to provide a benchmark of our oversight activities at the time and to provide a template of what these oversight activities ought to be in order to assure consumer confidence. We believe American consumers must have assurances that they receive the same level of protection whether inspections are conducted by Federal, State, or local officials. FDA had already taken steps prior to the publication of the OIG study to address many of the issues identified. We plan further action in Fiscal Year (FY) 2001.

The OIG agreed that the States offer a valuable source of inspection coverage and expertise and that an effective food safety system depends on the collective efforts and coordination of Federal, State, and local levels of government. The report noted that the States agreed that Federal oversight is essential and needs to be enhanced. The States also agreed that such oversight must be comparable for all State food inspections, whether they are conducted under State contracts or partnership agreements.

In the short term, we are working to ensure consistency of inspections by training our staff in techniques for auditing inspections performed under State contracts or partnership agreements, by increasing the number of joint audit inspections with both a State and FDA investigator, and by working to standardize inspection data. While at present the Agency is focusing on consistent inspections, in the long-term, we are working toward Manufacturing Regulatory Program Standards (MRPS) to ensure that the States have equivalent food safety programs not just equivalent inspections. These standards are being developed by a committee of Federal, State, and local food

safety personnel. The standards encompass criteria such as the regulatory foundation for the program, the training of the staff, having a uniform inspection program, the response to foodborne illness outbreaks, having sufficient resources, among other issues. Our goal is to implement them through the State contracts by Fiscal Year 2005.

With regard to our training activities, FDA's Office of Regulatory Affairs (ORA) will hold three audit-training courses in upcoming months in the east coast, mid-west, and west-coast regions. These courses will train Agency staff in the techniques for auditing inspections conducted under State contracts or partnerships. In addition, any State personnel can attend these three auditing courses at State expense. During the next contract year, FDA will provide funds in the contracts to enable State contractors to attend an auditing course to understand the auditing process and to learn how to audit their own staffs and programs.

With regard to increasing joint audit inspections, in FY 2000, the Agency directed that five percent of the total number of inspections assigned to the States would have a joint audit inspection with both an FDA and a State investigator. That number will increase to seven percent in FY 2001 and cap at 10 percent in FY 2002. Further, FDA Districts will conduct at least one joint inspection with 33 percent of the State inspectors each year. This will result in having all the State inspectors participate in at least one joint inspection within a three-year cycle.

The Agency is encouraging its District Offices to work closely with their States to schedule inspections throughout the year, conducting joint inspections with those inspectors that do the largest number of inspections first. To ensure consistency of data, FDA will review all State Establishment Inspection Reports prior to entry into the Agency's new database. The Agency will provide the State with the results of FDA's document reviews and joint audits.

With regard to standardizing inspection data, FDA will pilot the use of its FACTS data system with two States this fiscal year. This will enable them to enter data directly into FACTS. If the pilot is successful, the rest of the States under contract will also be required to enter data into the system. This system will result in

States reporting standardized information to FDA. We estimate that it will take until FY 2002 to complete this transition. In addition, the Agency is working with the State of California to develop TURBO-EIR. This is a computerized report writing program that will allow standardized inspection data to be transferred between State and FDA data systems. For example, it will allow our staff to look at Establishment Inspection Reports (EIRs) filled out by State staff and vice versa. It will also standardize the information in the EIRs.

You asked about public access to inspection data. The Agency has launched a new Internet site to increase public disclosure of its oversight of State food firm inspections. The Internet site lists all the State contracts, dates and numbers of inspections, and provides a summary of the audit results. This information will be updated quarterly. One may locate this information by going to FDA's home page, www.fda.gov, selecting Information for State/Local Officials and then selecting Partnerships-Contracts.

The Agency agrees with the OIG that we should draw on multiple external sources of information in assessing State program performance. We will have access to that information when we complete the development of the Manufacturing Regulatory Program Standards. The MRPS will incorporate criteria for each State food safety program to have some form of an outreach committee that includes industry, consumers, and others interested in such programs. This will allow public input into the entire State food safety regulatory program, not just the relatively small component of inspection oversight.

FDA, in cooperation with the States, will continue to investigate ideas that would obtain relevant feedback from the regulated industry on the protocols, techniques, and outcomes of State contract inspections. However, we believe that the most appropriate avenue for industry and consumer participation is through the State Food Safety Task Force network. FDA initiated this network in 1999 to enhance communication at the State and local level. (A model State Food Safety Task Force Partnership Agreement is available at www.fda.gov/ora under partnership agreements.)

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