HEARING TO REVIEW RECENT RECALLS IN THE MEAT INDUSTRY

HEARING

BEFORE THE

SUBCOMMITTEE ON
LIVESTOCK, DAIRY, AND POULTRY

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

WEDNESDAY, NOVEMBER 7, 2007

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WEDNESDAY, NOVEMBER 7, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON LIVESTOCK, DAIRY, AND POULTRY,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Subcommittee met, pursuant to call, at 2:10 p.m., in Room 1300 of the Longworth House Office Building, Hon. Leonard L. Boswell [Chairman of the Subcommittee] presiding.

Members present: Representatives Boswell, Gillibrand, Kagen, Holden, Lampson, Costa, Peterson (*ex officio*), Hayes, Rogers, Conaway, Smith, and Goodlatte (*ex officio*).

Staff present: Adam Durand, Nathan Fretz, Alejandra Gonzalez-Arias, Scott Kuschmider, Rob Larew, John Riley, April Slayton, Kristin Sosanie, John Goldberg, Alise Kowalski, Pam Miller, Stephanie Myers, Pete Thomson, and Jamie Weyer.

OPENING STATEMENT OF HON. LEONARD L. BOSWELL, A REPRESENTATIVE IN CONGRESS FROM IOWA

The CHAIRMAN. The hearing of the Subcommittee on Livestock, Dairy, and Poultry to review recent recalls of the meat industry will come to order. And we will begin with some opening statements, and when the Ranking Member comes back, we will stop where we are at and let him get his statement in. And so I think we will just go ahead and proceed now, and so I will make mine, and then we will probably recognize Chairman Peterson for his.

So I do want to thank everybody for joining, to discuss a very serious subject for American consumers and the meat industry. We have seen an increase in the number of illnesses and recalls related to foodborne pathogens this year and *E. coli O157:H7*, which I will leave the numbers off in the future, *E. coli*, which has been responsible for the majority of these cases.

Last month, when I discussed with Chairman Peterson that we wanted to hold a hearing on the meat recalls, the big story was the Topps recall, which has been linked to 32 illnesses and involved more than 21 million pounds of ground beef products. Since then, additional details have come to light in that case that have raised some questions about how and when recalls occur. We have also seen several more large recalls and *E. coli* since the Topps case, and there are many questions that need to be asked about why we are seeing these increases and what USDA is doing in response. This is an issue that affects every state and every district. Iowa has had 42 illnesses from *E. coli*, and just last Friday, Kayla

Boner, an eighth-grader from my district, died after testing positive for *E. coli*.

Today I am pleased to welcome Dr. Richard Raymond, USDA's Under Secretary for Food Safety, who has been on the job for about 16 months. He brings the experience as the former President of the Association of State and Territorial Health Officials and a state public health official in Iowa's neighbor to the west, Nebraska. As he brings his expertise as a public health official to the Under Secretary's office in the USDA, I hope that he will be able to help us understand how these illness outbreaks in multiple states are tracked and investigated and what we can do better to bring together information and make more informed decisions about recalls when human illnesses are involved.

This hearing is an important step in the exchange of information. We are here today to listen to Dr. Raymond and to collectively come to conclusions about why we are seeing more recalls, what has caused the increase in *E. coli* contamination, and how are we working to come to a reasonable solution. This is not a witch hunt or a time to point fingers, but an opportunity to talk about what we can do as a team to solve problems. There will be some difficult questions today, but the answers will help each of us make better decisions on how to provide the necessary resources for FSIS.

I hope this hearing will be an opportunity for Members of the Committee to learn about the important role FSIS has in protecting food safety and to discuss where we are and what we can do to reduce *E. coli* and other pathogens in the meat, poultry, and egg products that we serve our families. Mr. Under Secretary, thank you for being here today, and we look forward to your testimony.

[The prepared statement of Mr. Boswell follows:]

PREPARED STATEMENT OF HON. LEONARD L. BOSWELL, A REPRESENTATIVE IN CONGRESS FROM IOWA

Good afternoon, I would like to thank everyone for joining us today to discuss a very serious subject for American consumers and the meat industry. We've seen an increase in the number of illnesses and recalls related to foodborne pathogens this year, and *E. coli O157:H7,* which has been responsible for the majority of these cases.

Last month, when I discussed with Chairman Peterson that I wanted to hold a hearing on meat recalls, the big story was the Topps recall, which has been linked to 32 illnesses and involved more than 21 million pounds of ground beef products. Since then, additional details have come to light in that case that have raised more questions about how and when recalls occur. We've also seen several more large recalls for *E. coli* since the Topps case, and there are many questions that need to be asked about why we are seeing these increases and what USDA is doing in response.

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I hope this hearing will be an opportunity for Members of the Committee to learn more about the important role FSIS has in protecting food safety and to discuss where we are and what we can do to reduce *E. coli* and other pathogens in the meat, poultry and egg products that we serve our families. Mr. Under Secretary, thank you for being here today, and I look forward to your testimony.

At this time I would like to recognize my Ranking Member and good friend Robin Hayes from North Carolina for any opening remarks he would like to make.

The CHAIRMAN. At this time I would like to recognize Chairman Peterson for any opening remarks that he might wish to make.

OPENING STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Mr. PETERSON. Thank you, Chairman Boswell, for calling this much-needed hearing. I am sure this Committee will have a lot of questions for Dr. Raymond this afternoon, and I thank him for being with us here today.

Today's hearing is very important for consumers of meat and poultry products, given the high number of recalls and illnesses related to foodborne pathogens this year and this past month in particular. We have seen close to 20 recalls related to *E. coli* in beef in 2007, with seven recalls in the last 30 days alone. To put that in perspective, there were eight recalls for all of 2006. I hope Dr. Raymond can shed some light on what has changed, if anything, regarding the nation's meat and poultry supply and why we have seen these increases. Our hearing today will consider not just the chronology of the Topps beef recall that took place in September, but also the events surrounding the recall that illustrate many important issues regarding inspection, testing, foreign equivalency, cooperation between FSIS and other agencies, and the timely public notification of these issues.

As Dr. Raymond has suggested, the Topps case is a wake-up call, and we need vigorous review of our inspection practices and procedures. In the case of Topps, FSIS said that the company was commingling meat from one day to the next. This makes it nearly impossible to immediately pinpoint the origination of *E. coli*. Also, the overall design of the plant's food safety system was in question. Was Topps following its HAACP plan? Why didn't inspectors, present every day in production, not know that problems existed?

If FSIS cannot identify a problem that would result in a recall of a full year of product, I have concerns about whether inspectors have the necessary training and management to get the job done correctly. Why were there 18 days between the time USDA confirmed *E. coli* from an open Topps package in a consumer's home and the time that it issued the first product recall? And why did it take so long to connect the contaminated product in the Topps case with severe illnesses in Canada, where the product had originated?

In reviewing the increase in recalls today, we should also examine the coordination of efforts between our government agencies,

domestically and internationally, in responding to outbreaks and informing the public. Specifically, how does USDA collaborate in a timely fashion with the Food and Drug Administration, the Centers for Disease Control and Prevention, foreign food safety agencies or other public health entities at the state and local levels? Certainly, in the Topps case, and in the case of the Totino's pizza recall recently, the initiative to act and establish conclusive links between illnesses and tainted products was taken at the state level and not the Federal level. Was this the result of lack of communication between Federal and state agencies? We need to know.

Consumers should have unquestioned confidence in the food that they are buying. The public depends on our agencies to cooperate, share information, and be diligent and comprehensive in informing the public about health risks. To respond in the manner that was undertaken in the Topps case only reinforces many of the criticisms of the structure of our food safety system. The massive meat recalls in 1997 and 2002 brought about significant changes in USDA policies and inspections.

As a Committee with primary jurisdiction over the inspection of domestic and imported livestock, poultry, and meat products, I hope that this Subcommittee can get some good answers today about the tools, training, data, and oversight surrounding these recalls, what FSIS is doing to correct its procedures, to fill in the gaps where necessary, and where we can all move forward to continue to enjoy the safest and most abundant food supply in the world.

Again, I thank the Chairman for his leadership on this issue, and we look forward to the testimony of Dr. Raymond and questions of the Committee, and I yield back the balance of my time.

[The prepared statement of Mr. Peterson follows:]

PREPARED STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Thank you, Chairman Boswell, for calling this much-needed hearing. I am sure this Committee will have a lot of questions for Dr. Raymond this afternoon. I thank him for appearing today.

Today's hearing is very important for consumers of meat and poultry products given the high number of recalls and illnesses related to foodborne pathogens this year, and this past month in particular. We have seen close to 20 recalls related to *E. coli* in beef in 2007, with seven recalls in the last 30 days alone. To put that in perspective, there were eight recalls for all of 2006. I hope Dr. Raymond can shed some light on what has changed, if anything, regarding the nation's meat and poultry supply, and why we have seen these increases.

Our hearing today will consider not just the chronology of the Topps beef recall that took place in September, but also the events surrounding the recall that illustrate many important issues regarding inspection, testing, foreign equivalency, cooperation between FSIS and other agencies, and timely public notification. As Dr. Raymond has suggested, the Topps case is a "wake-up call" and we need rigorous review of our inspection practices and procedures.

In the case of Topps, FSIS said that the company was co-mingling meat from one day to the next, making it nearly impossible to immediately pinpoint the origination of the *E. coli*, and the overall design of the plant's food safety system was in question. Was Topps following its HAACP plan? Why didn't inspectors, present every day of production, not know that problems existed?

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The CHAIRMAN. Thank you, Chairman Peterson. Mr. Hayes is not back, but we will recognize him when he does come.

I would ask that all other Members submit their statements for the record.

[The prepared statements of Messers. Lampson, Smith, and Fossella follow:]

PREPARED STATEMENT OF HON. NICK LAMPSON, A REPRESENTATIVE IN CONGRESS FROM TEXAS

Mr. Chairman, I want to thank you for holding this important hearing to review the recent recalls in the meat industry. This issue is one that affects every rancher, every packer, every retailer—and every American.

Rates for the recall of meat have skyrocketed this year, leading not only to increased illnesses and death, but also to a decrease in consumer confidence. So far this year I have received nearly four hundred letters from constituents demanding a change in the system. They are worried about their health and the health of their children, as am I. And they are concerned that we are not doing enough. USDA's Food Safety and Inspection Service (FSIS) is meant to provide a stop-gap so that tainted meat does not reach the marketplace. But clearly, there is a gap in FSIS's ability to prevent this. Contaminated meat should be prevented from ever reaching store shelves.

Together with the USDA, we must explore steps that we can take—including stepped up inspections, an improved recall system, and better education of consumers—to ensure that our food supply remains the safest in the world. I thank Dr. Raymond for joining us to discuss this vital issue, and I am glad that we are here today to initiate a serious and frank discussion of the issues facing FSIS as they work to monitor and protect our nation's supply of meat, poultry and eggs.

PREPARED STATEMENT OF HON. ADRIAN SMITH, A REPRESENTATIVE IN CONGRESS FROM NEBRASKA

Good afternoon and thank you, Mr. Chairman.

The meat industry is important to Nebraska's economy. The 81 meat packing plants (excluding poultry processing) in the state employ 20,000 Nebraskans and ship $10.5 billion worth of product each year—more than any other state. Producing a safe and quality product that consumers can trust is vital to the beef industry.

America's food supply is the safest in the world. Yet we continually strive to improve our industry's procedures and technologies. Relative to the vast amount of safe and wholesome product produced each year, recalls are rare, but they remind

us that we must remain vigilant and that continued advances in food safety research are needed.

I am pleased that scientists at the USDA Meat Animal Research Center in Nebraska's Third District are developing testing and intervention strategies for *E. coli O157:H7*, and are preparing training materials on proper sampling and inspection. An additional, and important avenue of their research is the investigation of preharvest food safety techniques, which could further enhance food safety.

Each recall event is an opportunity to learn more about how we can protect our food supply. That is why we are here today. I want to thank our witness for testifying, and the Committee and the Chairman for holding this hearing. I look forward to working with you in the future.

PREPARED STATEMENT OF VITO J. FOSSELLA, JR., A REPRESENTATIVE IN CONGRESS FROM NEW YORK

Today's hearing provides an important opportunity for Congress to examine the health-related impacts on individuals impacted by the resent massive beef recall by the Topps Meat Company. As we have all read in various news publications over the last few months, our nation's beef supply, specifically that distributed by the Topps Meat Company, was responsible for the sickness of over 30 individuals, some with *E. coli* poisoning, all across the United States, and putting millions of other American's at great risk.

I would like to thank Chairman Boswell and Ranking Member Hayes for the opportunity to submit this testimony for the hearing this morning. I would also like to thank each of the panelists who have agreed to testify before the Subcommittee this morning.

I come before you today with great concern for two of my constituents; a 12 year old girl and a 19 year old boy, both of Staten Island. The 12 year old girl was hospitalized for nearly a week due to *E. coli* poisoning from hamburger purchased from Waldbaum's convenience store on Staten Island. The hamburger, manufactured at Topps Meat Co., contained the *E. coli* bacteria and forced the little girl into the intensive care unit at Staten Island University Hospital. Unfortunately, this problem is not isolated. We also learned that Topps Meat Co. expanded its initial recall of 332,000 pounds of ground beef to over 21.7 million pounds. These two instances highlight a possible pattern and warrant a full and comprehensive examination by the Federal Government.

I believe the safety of our nation's food supply is one the highest priorities Congress must adhere to. I personally have three young children and being a parent, I want to know that the food supply my family and all American's are consuming is safe from harm. It is my firm belief that parents should feel safe when purchasing food at their local grocery store, yet I come to this hearing today wondering if they can be assured of just that. I ask you this one question today—how can you assure parents and all American's that the food they are purchasing for their families is safe?

I respectfully request a full and comprehensive examination of the current food inspection processes be held on the safety of our nation's food supply and the plants where it is manufactured.

I look forward to working with this Subcommittee, the Department of Agriculture and manufacturers from across the spectrum to pursue the kind of reforms that will direct the focus on what matters most and that is the safety of all American's. Again, I would like to thank the Chairman and Ranking Member for this opportunity today and I look forward to hearing the testimony of our panelists today.

The CHAIRMAN. At this time I think we will go ahead and ask our witness to make his opening comments. And we would like to welcome Dr. Richard Raymond, Under Secretary for Food Safety, U.S. Department of Agriculture. Please share what you have to share with us. Please begin.

STATEMENT OF DR. RICHARD RAYMOND, UNDER SECRETARY FOR FOOD SAFETY, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Dr. RAYMOND. Thank you. Good afternoon, Mr. Chairman, Congressman Hayes, Members of the Subcommittee, and Chairman Pe-

terson. I am Dr. Richard Raymond, the Under Secretary for Food Safety at the United States Department of Agriculture, and I appreciate the opportunity to appear before you today to discuss the Food Safety and Inspection Service's ongoing efforts to protect the public's health.

But I want to begin today by addressing some concerns that have been expressed by Members of Congress regarding comments made by me about risk-based inspection and processing and its relation to the recall by Topps Meat Company. I apologize for making any previous references to RBI and Congress in the context of this recall. I have no basis upon which I could say that RBI would have prevented this recall. There is certainly no correlation between the recall and any Congressional actions, and I hope the Subcommittee will accept my apology.

I also want to notify the Subcommittee that, based on the challenges posed to food safety by *E. coli O157:H7* and what we have learned from the recent recalls, I do believe that we need to take additional time to strengthen our system and our data collection capabilities before moving forward with risk-based inspection and processing. We welcome the Office of the Inspector General's report, expected by the end of the year, which is examining the data used in the development and design of risk-based inspection and processing, and we will use that report to further focus our efforts.

In my testimony today, I will focus on the rise in the number of recalls of FSIS-inspected products related to *E. coli O157:H7* and highlight some of the steps that the agency is taking to drive down the incidence of *E. coli O157:H7*. Since January 2007 there have been 19 recalls, as of today, related to *E. coli O157* in beef this year. Nine of those have been associated with human illnesses. As Chairman Peterson noted, in 2006 there were only eight *E. coli O157:H7*-related recalls, and none of those were related to human illness. In 2005, there were only five *E. coli O157:H7*-related recalls.

This year's experience has made clear why we cannot be satisfied with the progress that we have made. We need to do more to strengthen our policies and our programs. As the increased number of recalls demonstrates, the challenges to public health are constantly evolving, and FSIS must evolve and change with them. We are undertaking new, ongoing, and soon-to-be upcoming actions to protect public health against the risk of *E. coli O157:H7*, including expanded testing and more rapid recalls.

In June 2007, FSIS identified an increased number of *E. coli O157:H7*-positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years. As a result, FSIS increased the number of tests of ground beef for *E. coli O157:H7* by more than 75 percent, from a base level of about 1,100 tests per month to 1,943 in July. Even though the agency saw nothing unusual in the positive sample rate in July, it continued an increased sampling schedule for most raw ground beef establishments of at least once per month, or approximately 1,350 samples scheduled per month.

Earlier this year, the FSIS also began trim testing in the establishments. Trim is the primary component in ground beef, in addition to testing ground beef itself. Based on preliminary data from

the agency's beef trim baseline done last year, which showed that we were more likely to find positive in trim than ground beef, FSIS began trim testing in March of 2007, not waiting for the final analysis of the baseline. By testing earlier in the production chain, FSIS minimizes the likelihood that this contaminated source material could be used in ground beef production that is available to consumers.

FSIS has also recently announced a new initiative to test additional components of ground beef, including head, cheek, and weasand meat. FSIS will be requiring countries whose beef is exported to the United States to conduct the same trim and beef component sampling or an equivalent measure, and the agency will begin doing verification sampling of trim to supplement the agency's ground product sampling at ports of entry. We will begin analyzing imported and domestic product test results to determine whether we need to make further changes to FSIS policies and programs. We have already made progress in getting recalls done more rapidly.

As a result of lessons learned from the Topps Meat Company recall, FSIS now takes into account a broader, more complete range of evidence when evaluating whether to seek a recall or whether to take regulatory action. This gives the agency a credible approach to more rapidly taking action when certain types of evidence are available. In two recent cases, FSIS acted upon epidemiological evidence that linked illness to opened, FSIS-inspected product found in consumers' freezers, where previously, by policy, we believed the agency needed a test result from an intact or unopened package because of the possibility of cross-contamination. More than 1 million pounds of ground beef were recently recalled as a result of this change in our recall procedures.

We have implemented a number of key initiatives targeted to federally-inspected plants that produce raw beef products. The FSIS notified the beef industry that as of November all beef plants will be expected to verify that they are effectively controlling *E. coli O157:H7* during slaughter and processing. The agency also provided the agency specific examples of minimum controls that would meet the minimum criteria for a well-controlled process. Identifying which establishments achieve the minimum criteria and which establishments do not will provide FSIS with the critical information on establishments with vulnerabilities.

FSIS inspection personnel began specialized training during the week of October 29, after which they will be equipped to complete a checklist describing the control measures and interventions used by raw beef suppliers and processors to control *E. coli O157:H7*. These checklists will be completed by November 30 and will be updated quarterly to help the agency more quickly identify potentially significant changes in production controls and to ensure that the plant takes corrective action. FSIS has accelerated its plans to review suppliers and processors based on this new checklist in response to concerns about the increased positives of *E. coli O157:H7*. Implementation for this survey was originally scheduled for April 2008. FSIS will analyze the checklist data and use it to adjust programs or policies as needed, such as where the agency needs to

conduct targeted verification testing and how to prioritize food safety assessments in plants.

The FSIS has determined that these steps were needed to ensure that inspection program personnel in the industry fully understand the nature of the challenge presented by *E. coli O157:H7*. These steps are laid out in much more detail in my written testimony and posted on the FSIS website and include actions such as scheduling food safety assessments upon notification of any Federal, or state positive test result for *E. coli O157:H7* in raw ground beef, increased follow-up testing in plants that have had positive *E. coli O157:H7* test results and suppliers of positive product, and also routine targeted *E. coli O157:H7* testing.

In short, the agency is ensuring that suppliers, processors, and FSIS inspection personnel will be able to identify an emerging problem as early as possible to prevent contaminated product from entering commerce. Agency actions must be based on protecting public health, and I want to emphasize how important this is to me personally. As I have often said, I did not move to Washington to oversee recalls. I came to Washington to help prevent foodborne illness. Even one illness is one too many, and with the actions we have announced and undertaken, I believe that we are on the right track.

In conclusion, we will continue to engage the scientific community, consumers, public health experts, Congress, our own employees, and all other interested parties in an effort to identify science-based solutions to public health issues, to ensure positive public health outcomes. We all know that we can save lives with sensible science-based policies, and together I believe we will do just that.

Mr. Chairman, I thank you again for providing me with the opportunity to address the Subcommittee and to submit testimony regarding the steps that FSIS is taking to remain a world leader in food safety and public health. I look forward to working with you to continue to improve our food safety system.

[The prepared statement of Dr. Raymond follows:]

PREPARED STATEMENT OF RICHARD RAYMOND, UNDER SECRETARY FOR FOOD SAFETY, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Good morning, Mr. Chairman, Congressman Hayes, and other Members of the Subcommittee. I am Dr. Richard Raymond, Under Secretary for Food Safety. I appreciate the opportunity to appear before you today to discuss the Food Safety and Inspection Service's (FSIS) ongoing efforts to protect public health.

I want to begin by addressing concerns expressed by Members of Congress regarding my comments about risk-based inspection (RBI) in processing and its relation to the recall by Topps Meat Company. I apologize for making any reference to RBI and Congress in the context of this recall. I have no basis upon which I could say RBI would have prevented this recall. There is certainly no correlation between the recall and Congressional actions. I hope the Subcommittee will accept my apology.

I also want to notify the Subcommittee that based on the challenges posed to food safety by *E. coli O157:H7* and what we have learned from recent recalls, I believe that we need to take additional time to strengthen our system and our data collection capabilities before moving forward with RBI in processing.

We welcome the Office of the Inspector General's report, expected by the end of the year, which is examining the data used in the development and design of risk-based inspection in processing. We will use that report to further focus our efforts.

In my testimony today, I want to start by briefly describing FSIS' food safety responsibilities. I will then focus on the rise in the number of recalls of FSIS-inspected products, especially related to *E. coli O157:H7*, and highlight some of the steps the

agency is taking to drive down the incidence of *E. coli O157:H7*. I will also explain FSIS' role during recalls, specifically during the Topps recall.

FSIS' Mission

As Under Secretary for Food Safety, I oversee FSIS. FSIS' mission is to ensure that meat, poultry, and processed egg products distributed in commerce for use as human food are safe, secure, wholesome, and accurately labeled. FSIS is charged with administering and enforcing the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act, and the regulations that implement these laws. FSIS also ensures compliance with the Humane Methods of Slaughter Act, which requires that all livestock be handled and slaughtered in a humane manner. The agency is responsible for determining equivalence to Federal standards at the state level and among our foreign trading partners.

Our front-line personnel form the backbone of FSIS' public health infrastructure in establishments, laboratories and import houses throughout the country. In FY 2007, the agency had approximately 7,600 full-time in-plant and other front-line personnel protecting the public health in 6,000 federally-inspected establishments nationwide where FSIS inspection program personnel performed antemortem and postmortem inspection procedures to ensure public health requirements were met in the processing of over 44 billion pounds of livestock carcasses, almost 57 billion pounds of poultry carcasses, and about 3.5 billion pounds of liquid egg products. Approximately 60¢ of every food dollar in the United States is spent on foods that FSIS inspects.

In FY 2007, FSIS inspection program personnel conducted more than nine million procedures to verify that establishments met food safety and wholesomeness requirements. The amount of FSIS-regulated meat and poultry imports has remained approximately the same over the past 5 years, hovering around 4 billion pounds of meat and poultry from 29 of the 33 eligible countries. In addition, about 6 million pounds of egg products from Canada were presented for import re-inspection at U.S. ports and borders during the past year. FSIS also has Program Investigators nationwide who conduct food safety, food defense, and outbreak investigations and enforcement.

Recent Recalls

Since January 2007, there have been 19 recalls related to *E. coli O157:H7* in beef this year. Nine of those have been associated with human illnesses. In 2006, there were eight *E. coli O157:H7* related recalls, none of which were related to human illnesses. In 2005 there were only five *E. coli O157:H7*-related recalls. This year's experience has made clear why we cannot be satisfied with the progress that we have made. We need to do more to strengthen our policies and programs.

As the increased number of recalls demonstrates, the challenges to public health are constantly evolving, and FSIS must evolve with them. Public health is a lot like riding a bicycle. If we're not moving forward, then we're falling down, and in public health there is no such thing as training wheels. We can't and won't let ourselves, our partners, or our nation's food safety system stagnate.

We are undertaking new, ongoing and upcoming actions to protect public health against the risk of *E. coli O157:H7*, including expanded testing and more rapid recalls. In June 2007, FSIS identified an increased number of *E. coli O157:H7* positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years. As a result, FSIS increased the number of tests of ground beef for *E. coli O157:H7* by more than 75 percent (from our base level of 1,100 to 1,943) in July. Even though the agency saw nothing unusual in the positive sample rate in July, it has continued an increased sampling schedule for most raw ground beef establishments once per month (i.e., approximately 1,350 samples scheduled per month).

Earlier this year, FSIS began trim testing, the primary component in ground beef, in addition to ground beef itself. FSIS has also recently announced a new initiative to test additional components of ground beef. By testing earlier in the production chain, FSIS minimizes the likelihood that this contaminated source material could be used in ground beef that is available to consumers. FSIS is also requiring countries whose beef is imported to the United States to conduct the same trim and beef component sampling or an equivalent measure, and the agency will begin doing verification sampling of trim to supplement the agency's ground product sampling at ports of entry. We will be analyzing imported and domestic product test results to determine whether we need to make further changes to FSIS policies and programs.

We have already made progress in getting recalls done more rapidly. As a result of the lessons learned from the Topps Meat company recall, FSIS now takes into account a broader, more complete range of evidence when evaluating whether to seek a recall or whether to take regulatory action. This gives the agency a credible approach to more rapidly taking action when certain types of evidence are available. In two recent cases, FSIS acted upon epidemiological evidence that linked illness to opened, FSIS-inspected product found in consumers' freezers, where previously, we believed the agency needed a test result from an intact or unopened package because of the possibility of cross-contamination. More than 1 million pounds of ground beef were recently recalled as a result of this change in our recall procedures.

We are examining our training and staffing patterns to ensure that inspection program personnel and supervisors are doing their jobs correctly, that they are held accountable, and that they have appropriate workloads and supervision.

We have implemented a number of key initiatives targeted to federally-inspected plants that produce raw beef products. FSIS determined that these steps were needed to ensure that inspection program personnel and the industry fully understand the nature of the challenge presented by *E. coli O157:H7*. The agency is ensuring that suppliers, processors, and FSIS inspection personnel, will be able to identify an emerging problem as early as possible to prevent contaminated product from entering commerce.

Since September 28, 2007, FSIS inspection program personnel have been sending *E. coli O157:H7* samples to FSIS labs for testing, irrespective of the company's test results. Previously, the agency did not submit a sample to the lab if the company destroyed *E. coli O157:H7*-positive product or diverted it to cooking. While this practice of not submitting samples did not pose a human health risk, our new approach will allow us to increase the number of pulsed-field gel electrophoresis (PFGE), or DNA fingerprint patterns entered into PulseNet. PulseNet is the CDC's national molecular sub-typing network for foodborne disease surveillance and has searchable databases of all PFGE patterns from patients and food products in the United States.

On October 12, 2007, FSIS issued a notice instructing its District Offices to have Enforcement Investigation Analysis Officers schedule a food safety assessment upon notification of any Federal or state positive test result of *E. coli O157:H7* in raw ground beef or ready-to-eat (RTE) meat and poultry products. The same action will be taken for positive sample results of *Listeria monocytogenes* or *Salmonella* in RTE products.

On October 12, 2007, FSIS also issued a notice instructing inspection program personnel to collect multiple follow-up samples of beef products in plants that have had a positive *E. coli O157:H7* sample. Previously, FSIS collected only one follow-up sample following a positive test result. FSIS implemented this policy because analysis of *E. coli O157:H7* sample data from 2000 through 2005 showed that plants are more likely to have a second positive sample if they have had a positive sample within the preceding 120 days. Suppliers of *E. coli O157:H7*-positive beef products will also be subject to this increased follow-up testing. Increased follow-up testing will provide the agency with a statistically-based level of confidence regarding the likely presence of *E. coli O157:H7* in FSIS-regulated product.

FSIS notified the beef industry that, as of November, all beef plants will be expected to verify that they are effectively controlling *E. coli O157:H7* during slaughter and processing. The agency also provided the industry specific examples of minimum controls that would meet the minimum criteria for a "well-controlled" process. Identifying which establishments achieve the minimum criteria, and which establishments do not, will provide FSIS the critical information on establishments with vulnerabilities.

FSIS inspection personnel began specialized training during the week of October 29, after which they will be equipped to complete a checklist describing the control measures and interventions used by raw beef suppliers and processors to control *E. coli O157:H7*. These checklists will be completed by November 30, and will be updated quarterly to help the agency more quickly identify potentially significant changes in production controls and ensure the plant takes corrective action. FSIS will analyze the checklist data and use it to adjust programs or policies as needed, such as where the agency needs to conduct targeted verification testing and how to prioritize food safety assessments.

To supplement current hazard analysis surveillance activities, FSIS is developing and will implement in November, a process to assign specially trained investigators to evaluate corporate practices to control *E. coli O157:H7*. These investigators will identify the corporations whose controls are insufficient and may pose a threat to public health. This will help us identify the best practices at the establishments,

generally, and within corporations. Once those best practices are identified, we can encourage better controls across-the-board, rather than on an establishment-by-establishment basis.

By January 2008, the agency will begin using a newly developed test that will detect lower levels of *E. coli O157:H7* contamination.

Also in January 2008, FSIS will begin routine targeted sampling for *E. coli O157:H7* at slaughter and processing facilities. Currently, all plants have an equal chance of being tested. Under this new verification testing program, FSIS will test larger-volume operations and those with recent positive tests more frequently than in the past. Data from the checklists that will be generated by inspection personnel in November will also be used to determine testing frequency for establishments. The results of these checklists, in turn, could lead to new FSIS policies, directives, and regulations.

In Fiscal Year 2008, when FSIS conducts audits of countries exporting raw beef products to the United States, the agency will place special emphasis on *E. coli O157:H7* control measures.

It is critical that all of our food safety partners are informed and have the opportunity to share their ideas about the larger impact of FSIS' policies and regulatory actions on the food safety system. This way, we all work together to create the most effective food safety policies possible, in order to keep moving forward. Communication and trust is integral to that effort.

In September, FSIS participated in an *E. coli O157:H7* workshop in Chicago, sponsored by the North American Meat Processors Association. This workshop focused on small-volume beef processors that specialize in producing ground beef and mechanically-tenderized steaks and roasts.

Beginning in October and continuing into November, FSIS will conduct outreach and training sessions around the country for small and very small processors of raw beef products, other stakeholders, and FSIS inspection program personnel. This training will focus on FSIS' new *E. coli O157:H7* policies, as well as on lessons learned from the recent recalls associated with *E. coli O157:H7*. It will ensure that small and very small plants can effectively implement these measures to protect public health.

On October 17, FSIS, along with the Food and Drug Administration (FDA) and CDC, hosted a public meeting in Washington, D.C., regarding pathogenic *E. coli* organisms other than *E. coli O157:H7*. We expect that as a result of this meeting, we will be able to ensure that any future steps we take to reduce the prevalence of pathogenic non-*O157:H7 E. coli* will be better understood by all of our food safety partners.

On October 18, agency officials held a conference call with all 15 District Offices to fully explain the new policies to combat *E. coli O157:H7* and to discuss implementation and how activities by inspection program personnel in plants will be monitored through agency management controls.

Agency actions must be based on protecting public health. I want to emphasize how important this is to me, personally. As I have often said, I did not move to Washington to oversee recalls; I came to Washington to prevent foodborne illnesses. Even one illness is too many. With the actions we have announced and undertaken, I believe we are on the right track.

FSIS' Responsibilities Related to Recalls

As stated in FSIS Directive 8080.1, Revision 4, the purpose of a recall is to remove product from commerce as quickly as possible when FSIS has reason to believe it is adulterated or misbranded. FSIS may become aware of misbranded or adulterated product in commerce in several ways. For example, FSIS may be alerted to a potential recall situation by: (1) the company that manufactures or distributes the product; (2) test results from FSIS sampling programs; (3) observations or information gathered by FSIS inspection program personnel in the course of their routine duties; (4) consumer complaints; or (5) epidemiological or laboratory data submitted by state or local health departments, other USDA agencies, or other Federal agencies, such as the U.S. Department of Heath and Human Services' (HHS) Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Department of Defense.

FSIS' Recall Management Staff coordinates and convenes the recall committee, which makes recommendations for all recalls of FSIS-inspected meat and poultry products. When a company conducts a recall, which can and does occur 24 hours a day and 7 days a week, FSIS notifies the public through a press release, which is posted on FSIS' website along with a photo of the product, when practicable. The agency also issues recall information as quickly as possible through list-serves, e-mails, and faxes sent directly to stakeholders, including Members of Congress; news

media; Federal, state, and local public health partners; and constituents. We have begun translating more of the recall releases into Spanish. Individuals can also subscribe to receive automatic e-mail notification of recall updates, including press releases, directly from FSIS' website.

The USDA Meat and Poultry Hotline (1–888–MPHotline or 1–888–674–6854) is staffed by food safety specialists who speak English and Spanish and can be reached from 10 a.m. to 4 p.m. Eastern Time, Monday through Friday. Recorded messages are available 24 hours a day on the Hotline, and during most recalls, FSIS records a message to inform the public of pertinent recall information.

AskKaren, FSIS' virtual representative, is available 24/7 to answer questions from the public about safe food preparation and handling. AskKaren includes information about recalls, including FSIS' role during recalls, how recalls are conducted, and how FSIS notifies the public during recalls. AskKaren also shows consumers where they can find information on specific recalls of FSIS-regulated products.

After the recall occurs, FSIS conducts effectiveness checks to ensure that consignees have received notice of the recall and are making reasonable efforts to retrieve and destroy the recalled product or return it to the recalling firm. Upon compliance, the recalling firm is officially notified by letter that the recall is completed, and no further action is expected.

In certain cases where FSIS has had good evidence that no adulterated product remains in commerce, meaning there is nothing to recall, but believes consumers may still have product in their homes, the agency has issued public health alerts, which may contain all of the pertinent information found in a recall press release (i.e., company name and contact information, pounds of product implicated, epidemiological information, product labels, product production dates). In these cases, the agency feels it is imperative to notify consumers of the potentially contaminated products that may still be in their homes—for example, product that may be in their freezers.

To protect public health, FSIS has also issued public health alerts when the agency has had evidence to implicate certain types of products in causing foodborne illness but is not able to definitively link the products to a specific establishment.

We also rely on our Federal, state and local public health partners in government, as well as consumer and industry representatives, to share this information with the public. Since public health alerts are very widely used in the public health community to warn consumers of potential health concerns (i.e., heat advisories, potential side effects of vaccinations, etc.), public health alerts are likely to get widespread local news media coverage, because it is framed as a public health issue instead of a business issue.

In order to improve voluntary recalls of meat and poultry products, FSIS published a proposed rule on March 7, 2006, which would allow FSIS to make available to the public lists of retail establishments that have likely received the products that are subject to the recall. The agency held a public meeting on the proposed rule on April 24, 2006, and the public comment period ended on June 11, 2006. The agency has reviewed the public comments and is currently revising the final rule.

FSIS issued this proposal because it concluded that making retail information available to the public will help consumers to better identify the recalled product. This valuable new information should help consumers to better protect themselves and their families.

Experience has shown that during a public health emergency, early, detailed, accurate and consistent information is one of our greatest tools to prevent panic, illnesses, and a collapse in consumer confidence. By working closely with our partners at all levels of government and industry, and among consumers, we can ensure that people have the information they need to keep themselves and their families safe.

Topps Meat Company Recall

The Topps recall of frozen ground beef products showed us that we needed to strengthen our policies and programs. I will outline the timeline of the actions that the agency took, beginning with a report of a human illness, which is where we often start our active investigations.

This case was somewhat different because it began with an illness reported directly to USDA by a consumer, rather than a public health partner. On August 31, 2007, our Consumer Complaint Monitoring System received a report of a possible *E. coli O157:H7*-related illness concerning a consumer in Florida.

According to agency protocols, that very same day, it was logged into our system and FSIS field investigators collected leftover product from that patient's freezer in Florida. Also that same day, this product was sent to our regulatory lab in Athens, Georgia, for testing.

On September 7, 2007, the agency reported a positive *E. coli O157:H7* test result from the product left over from that patient's freezer. At this point, we were not able to take recall action based on this initial test. Although we knew we were dealing with the *O157:H7* strain, we wanted to conduct further testing to characterize this pathogen and determine definitively that it was linked to the Florida patient's illness.

The next line of testing was initiated, in the form of a pulsed-field gel electrophoresis or PFGE test. This is the so-called DNA fingerprint of a pathogen. It is a secondary test done to characterize the pathogen more completely. The test was initiated on September 7, and, as usual, this test took several days to complete.

Meanwhile, on September 8, 2007, regulatory lab in Athens, Georgia, had received an intact box of product from the Topps plant. Our protocol calls for 13 sub-samples to be tested. We treat each of them as an individual sample, and from this same product that had presumably caused the Florida patient's illness, we received 13 negative test results.

On September 14, 2007, we finally received the result of our PFGE fingerprint testing. By that time, the Florida Department of Health officials had uploaded their PFGE test results from the patient and CDC PulseNet, and CDC's PulseNet database managers confirmed that the PFGE patterns were indistinguishable. We then had information that linked the patient to the exposure, and in this case, again, it was leftover, opened product from the patient's freezer.

In accordance with our past protocol, the agency did not immediately convene the recall committee. On September 20, 2007, FSIS learned of two additional illnesses in New York State. At that point, we were told that the illnesses were associated with Topps product, but the PFGE test results were not yet complete.

On September 22, 2007, we did get a report that the PFGE test results were complete in New York State, and that PFGE fingerprinting had linked these two illnesses with the products associated, but they differed from the *E. coli O157:H7* fingerprint from the Florida case.

In other words, we had discovered three different PFGE patterns related to three different products from the same establishment, which caused three different illnesses.

Our investigators worked to solidify the link between the processing plant and attempted to explain the three different *E. coli O157:H7* fingerprints. On September 24, 2007, New York State alerted FSIS to the fact that its state officials had already tested an unopened box of hamburger patties that they obtained in a supermarket, and that this box also tested positive for *E. coli O157:H7*. The next morning, September 25, FSIS reconvened its recall committee and that day, the Topps Meat Company issued its recall of 331,582 pounds of frozen ground beef products because of possible contamination with *E. coli O157:H7*. The product recalled was from three specific production dates in the plant and three separate PFGE patterns were linked to patients and ground beef products for those dates.

Also on September 24, 2007, FSIS began a food safety assessment, a thorough scientific review of the plant, in response to the illnesses associated with the consumption of Topps ground beef patties. The food safety assessment indicated that controls were insufficient to eliminate or reduce *E. coli O157:H7* in the raw ground beef products.

On September 26, 2007, FSIS suspended inspection at the plant based on the September 25 recall; reported human illnesses; and the agency's food safety assessment of the establishment, which found inadequate raw ground process controls and sanitation concerns. FSIS began reviewing Topps' suppliers, and on September 29, Topps expanded its original recall to include a total of approximately 21.7 million pounds of frozen ground beef products. The recall was expanded based on additional positive product testing reported by the New York Health Department, reported illnesses, and findings from the food safety assessment.

On October 4, 2007, FSIS took regulatory action (a Notice of Intended Enforcement) due to concerns about inadequate process controls for the plant's raw "not ground" operations. That same day, FSIS publicly outlined the timeline of the Topps recall, the preliminary findings from its investigation of the Topps recall, actions already taken by the agency and further steps to reduce *E. coli O157:H7*.

On October 5, 2007, Topps announced it was going out of business.

As the result of the Topps Meat Company recall investigation, FSIS delisted Ranchers Beef, Ltd., on October 20, 2007. No product from that firm has been eligible to come into the United States since that date.

As announced on October 26, 2007, a joint investigation between the Canadian Food Inspection Agency (CFIA) and FSIS has identified a likely source of the multistate outbreak of *E. coli O157:H7* infections linked to the Topps Meat Company.

On October 25, 2007, the CFIA provided FSIS with PFGE patterns, or DNA fingerprints, from tests of beef trim from a Canadian firm, Ranchers Beef, Ltd. (Canadian establishment number 630). This firm provided trim to the Topps Meat Company. While the firm, which had been located in Balzac, Alberta, ceased operations on August 15, 2007, some product remained in storage and was collected and tested by CFIA as part of the joint investigation of the Topps recall and as part of CFIA's own investigation into 45 illnesses in Canada from *E. coli O157:H7*.

This piece of information, with the assistance from our food safety partners in Canada, helped us to determine a likely source of contaminated product which led to the September 29 Topps Meat Company expanded recall. We have a long history of cooperation and collaboration with CFIA.

On October 26, 2007, PulseNet provided verification to FSIS that this PFGE pattern indistinguishable from those of the patients who were ill and from positive tests conducted by the New York Department of Health on product (both intact packages and open packages from patients' homes) that was later recalled by the Topps Meat Company on September 29. PulseNet is the CDC's searchable database of all PFGE patterns from patients and food products in the United States.

As of October 26, 2007, CDC reported 40 illnesses under investigation in eight states, with 21 known hospitalizations. The latest onset of illness is September 24, 2007. This summer was the first time this rare PFGE pattern had been seen in North America. Thirty-one of the 40 illnesses were indistinguishable from this rare PFGE pattern. Investigations continue in order to find the source of the other two PFGE patterns linked to Topps.

FSIS notified industry on October 26 to hold all boneless beef manufacturing trim from Ranchers Beef, Ltd., or raw products produced in whole or in part from these products until the joint investigation is completed. The agency, on that same day, issued a notice to inspection program personnel in the field to retain these products.

As I announced on November 3, 2007, FSIS immediately began an audit of the Canadian food safety system that will focus on Ranchers Beef, Ltd. and will include other similar establishments that export beef to the U.S.

FSIS has instituted additional import requirements for meat and poultry products from Canada. Effective this week, FSIS will increase testing for *Salmonella, Listeria monocytogenes* and *E. coli O157:H7* and will require that shipments be held until testing is complete and products are confirmed negative for these pathogens. In addition, Canadian meat and poultry products will receive increased levels of re-inspection by FSIS to confirm they are eligible to enter commerce when presented at the U.S. border.

The audit and stepped up actions at the border are being conducted because of concerns about testing practices at Ranchers Beef, Ltd., that were discovered as part of the ongoing investigation. FSIS will review the preliminary findings of this audit to determine whether there is need to continue these additional interim requirements.

These measures are being taken to further ensure the equivalency of the system already in place. We continue to work together with our food safety partners both domestically and internationally to ensure imported meat and poultry products are produced under food regulatory systems equivalent to those in the United States, and provide the same level of protection against food hazards as is achieved domestically.

On November 2, 2007, FSIS Administrator Alfred Almanza and an additional senior FSIS food safety official met with their counterparts at the CFIA to inform them of increased testing and re-inspection requirements.

Conclusion

We will continue to engage the scientific community, consumers, public health experts, Congress, our own employees and all interested parties in an effort to identify science-based solutions to public health issues to ensure positive public health outcomes. We all know that we can save lives with sensible science-based policies and together we'll do just that.

Mr. Chairman, thank you again for providing me with the opportunity to address the Subcommittee and submit testimony regarding the steps that FSIS is taking to remain a world leader in food safety and public health. I look forward to working with you to improve our food safety system.

The CHAIRMAN. Well, thank you, Mr. Secretary, and we do recognize the lengthy statement you have prepared, at 20 some pages, and we think that review is quite thorough, and we appreciate

that, that you have taken the time to prepare that for us; and you called attention to it, your website.

At this time I would like to recognize Ranking Member Hayes for any opening comments that he might make.

OPENING STATEMENT OF HON. ROBIN HAYES, A REPRESENTATIVE IN CONGRESS FROM NORTH CAROLINA

Mr. HAYES. Thank you, Mr. Chairman and Chairman Peterson. This is a very valuable hearing, very necessary. We are here for one purpose and one purpose alone, to ensure that we do have the highest standards of food safety. Very appropriate that we are here today.

We have the safest food system anywhere in the world. I will submit my prepared statement for the record, but again, I would reemphasize that we are here to examine and confirm that our processes and procedures are effective and accurate and ensure the safety that connects consumer, processor, and producer. So, Dr. Raymond, thank you for your commitment to medicine and the general health of everybody, and, Mr. Chairman, thank you for doing this.

[The prepared statement of Mr. Hayes follows:]

PREPARED STATEMENT OF HON. ROBIN HAYES, A REPRESENTATIVE IN CONGRESS FROM NORTH CAROLINA

Thank you, Mr. Chairman, for holding this hearing relating to the safety of our food supply. I cannot stress enough how important this topic is to all of our constituents. It is always worrisome when Federal regulators request that food or consumer products must be recalled for safety reasons, and tragic when a contaminant in our food supply results in even a single case of foodborne illness.

In recent years, our food safety system has undergone dramatic changes which have resulted in improvements across the board. Industry has made improvements in their internal systems; new technologies have been introduced which have mitigated the risk of contamination with foodborne pathogens; and our regulatory agencies have implemented some fairly progressive enhancements in their inspection systems.

Despite these laudable efforts, the magnitude of the recent recall of ground beef has received a great deal of press attention which I fear has left the public with the impression that our food safety system is failing them.

As of today, there have been 19 recalls of beef products resulting from contamination with *E. coli O157:H7*. This compares with eight recalls in 2006, five in 2005, and six in 2004. Fourteen of these recalls have occurred since the beginning of June when the Food Safety and Inspection Service began observing an increasing prevalence of *E. coli O157:H7*.

Today, I would like to hear from the Under Secretary about what research is being conducted to determine the cause or causes of the increasing prevalence of *E. coli O157:H7*? What actions have the agency and industry taken to mitigate this risk? What can consumers do to further minimize the risk of foodborne illness?

Mr. Chairman, thank you again for holding this hearing. I yield back.

The CHAIRMAN. You bet. We appreciate your comments and, for other Members, if they want, the chair requests they submit their opening statements for the record so that we can get on with our process.

At this time I am going to vary the system a little bit, with the concurrence of my Ranking Member, and recognize Mr. Peterson for the questions he might have, because of his schedule. Mr. Peterson?

Mr. HAYES. I concur.

The CHAIRMAN. Thank you.

Mr. PETERSON. Well, thank you very much, Mr. Chairman, and thank you and Mr. Hayes for your leadership and, again, for this hearing. Dr. Raymond, how much does it cost FSIS to take samples on an annual basis.

Dr. RAYMOND. Mr. Chairman, I don't have that number available, but I certainly will make it available to you from my staff.

Mr. PETERSON. Okay. Also, can you tell me how much it costs FSIS to take each individual sample?

Dr. RAYMOND. How much per test? Dr. Goldman tells me it is just a little over $100 for each test that we do, and our budget is about $45 million per year for our testing program—$15 million, I am sorry.

Mr. PETERSON. Fifteen million dollars. If you can give me the breakdown on how many samples you are taking and so forth.

Dr. RAYMOND. Absolutely.

Mr. PETERSON. Yes. How often does FSIS take samples at each plant?

Dr. RAYMOND. Currently it is about once per month. We will be changing that in January, when we begin a more targeted sampling that will be based on the plant's history and production volume.

Mr. PETERSON. And how often do the plants themselves take their own samples?

Dr. RAYMOND. That varies plant by plant. Some do not take samples at all, and others take samples as often as every 15 minutes.

Mr. PETERSON. And why is that?

Dr. RAYMOND. That is a corporate decision.

Mr. PETERSON. And you don't have any problem with that; that there is such a wide disparity?

Dr. RAYMOND. A lot of that is dependent upon the volume the plant produces and also, obviously, cost-effectiveness. We do not mandate the plants do testing, so, no, I have no problem with it.

Mr. PETERSON. Do we know how much it costs the plants to do these samples?

Dr. RAYMOND. I do not.

Mr. PETERSON. Is there any way to find that out?

Dr. RAYMOND. Yes, there is, and we will get that for you, too.

Mr. PETERSON. Good. How many Notices of Intent to Delist were issued to Canada during your last audit?

Dr. RAYMOND. Six.

Mr. PETERSON. Six? Do you treat Canada the same as you do all other countries that import meat products to the United States, even though, according to the FSIS audit report, it appears that they have inadequate systems in place? According to your own audit report, I guess.

Dr. RAYMOND. Our audit report found some deficiencies which were corrected quickly, promptly, by the Canadian system and by the plants that were involved. This is not unusual, when we do our annual audits, to find a plant or two or more that have deficiencies. It is not unusual to either delist a plant or send a Notice of Intent to Delist. It is the same as sometimes happens with us when we are audited by our international partners.

Mr. PETERSON. So the problems that you found have been solved?

Dr. RAYMOND. Yes, they have.

Mr. PETERSON. Do we know how the problem occurred with the Canadian meat that came in that caused the *E. coli* problem in Topps?

Dr. RAYMOND. Yes, sir, we do.

Mr. PETERSON. So that has been tracked down? But you are satisfied with what the Canadians are—well, apparently you aren't, because now you are holding the trucks at the border until they can certify that the test results are okay. Is that, I understand, how you are doing things?

Dr. RAYMOND. Yes, sir, that is correct. I have asked our inspection personnel at the import houses to do that as a matter of caution, until we can complete an audit of this particular plant and its products. We want to make sure that none of that product is still coming across the border, and also to make sure that that was an isolated incident and has not been repeated in any other slaughter plants in the Canadian system.

Mr. PETERSON. Thank you. In responding to my letter asking questions about the public health alert issued by FSIS on August 30, on the second page it suggests that in certain cases when FSIS has evidence that all product in question may still be in people's refrigerators or freezers, FSIS has issued public health alerts that include information similar to what would be found in a recall press release. But later on the same page it says that the agency has not previously issued a public health alert similar to the one issued August 30. Can you clarify for the Committee how the agency determines if a product may be in consumers' freezers and why a recall was not necessary in this case?

Dr. RAYMOND. Yes, sir. I will do my best. In this particular case, the product involved was 1 pound packages of fresh, raw ground beef with a very limited sell-by/use-by date. By the time that we were made aware of the investigation that had been going on in the Northwest, and they had identified these eight to ten cases that were linked epidemiologically, the sell-by/use-by dates had long since gone by. We sent some of our investigators from OPEER and the field office into some of the retail outlets and found no product remaining on the shelves or in the coolers of these particular stores. At the same time, this particular company was also surveying their list of consignees, and they all said that there was no product left on their shelves. It had all been sold or destroyed or returned to be cooked by those use-by dates, and, again, our investigators confirmed that finding. So we felt that probably, because they were small, 1 pound packages, they probably had pretty much been consumed. But we realized there may be some in someone's freezer or some in someone's refrigerator that hadn't been used by the consume-by date, and we felt the public needed to be aware of that, especially since there had been illnesses. And that is why we did issue the public health alert, so the public would be aware that if they bought this particular product and still had it in their refrigerators or freezers they should either destroy it or return it.

Mr. PETERSON. Mr. Chairman, I have one last follow-up. In response to my September 14 letter, we asked, prior to issuing the public health alert on August 30, did the FSIS recall committee at any point request that Interstate Meat Distributors conduct a recall of the product named? Your answer was, yes, you did, but then

FSIS changed your answer because of new information. Can you explain what kind of information you received and what was involved in that decision process?

Dr. RAYMOND. Yes, sir, I can. It was the same day that we had requested that the company consider a recall. They informed us that they had done this survey of the people they sell to, and that there was no product left on the shelves. It was actually that very same day, that very same hour, that we made that request that our folks in the field reported back that they had found no product on the shelves. That is why we changed from asking them to do a recall to doing the public health alert.

Mr. PETERSON. Has FSIS ever changed their position in asking for a recall before this occurrence? Has that ever happened?

Dr. RAYMOND. Not that I am aware of, sir.

Mr. PETERSON. Yes. All right. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. We have a vote request, or a vote call, going on, but I think I will start the questions just for the couple here, and then we will break and go do our vote. But, Dr. Raymond, in 2004, six out of 48 recalls were associated with *E. coli*, but in 2007, 16 out of 40 have been due to *E. coli*. Can you explain why we have seen this increase? What is your evaluation?

Dr. RAYMOND. I think there are several factors, Mr. Chairman, and I will admit that these are my feelings and beliefs, and I don't have science. But, for instance, I mentioned in my opening remarks there have been a couple recalls that we have done since Topps that we would not have done a year ago because of open product in patients' freezers, and I do believe that that is a reason to do a recall, so there are two of them that would not have occurred in the past. That is one example. We do a much better job with our outbreak investigations than we have in the past, partly because of a system called PulseNet that is cosponsored by FDA, the USDA, and the CDC, and this allows PFGE patterns, the fingerprint of the *E. coli O157*, to be submitted to CDC and put into a common computer system, and it is a system that also includes *E. coli* from our plant product testing. And we can now link what ordinarily might have been isolated instances of illnesses, and we can link them into clusters, and we can better identify the source. Each year, we get better with that. The other theories that I have, and we are doing some research on most of these, and there are probably other ones that we will find out at a meeting that we are conducting this fall with top food scientists, industry, and consumers to see what they all think about the rises. Some factors that may enter into this is the inclement weather that we saw this year in the Southwest, with severe drought, and severe moisture in the Midwest, where a lot of cattle are on the hoof. Weather changes like that do stress cattle and do cause higher *E. coli* levels. We have seen elevated corn prices because of biofuel use, and feeders are changing what they feed cattle because of costs, and when you change what you feed cattle, you do change the contents of their intestines. And we are doing research at the Animal Research Center in Clay Center, Nebraska, under the ARS of USDA to determine different feeding patterns. And hopefully we will actually find some feed patterns that will lower *E. coli*, but we need to find out if the patterns we

have seen now have increased it. We have also seen an increase in turn-over of skilled employees at some of our plants, and when you have a turn-over of skilled employees and get less skill, you are more apt to see some human errors also. Again, theory, not proof. There are probably other factors that we are looking into. I do not believe it is because the industry has gotten careless or sloppy. I do not believe it is because our inspectors have become less diligent. I do believe there has been a change in the ecology of the bug. It also may be that this particular pathogen has changed, has morphed. We know that bacteria develop resistance to antibiotics. There is no reason to believe that *E. coli O157* might not develop resistance to some of the antimicrobial treatments that we have been using in the plants for the last 10 years. Those are all things we need to find out. I think it is further upstream than in the plants. I think it is starting with the animals' environment.

The CHAIRMAN. Well, I appreciate what you have said about the theory, and are you taking steps to put science to some of that, to ensure that your theory is correct?

Dr. RAYMOND. I don't know that it will ensure my theories are correct, but we are certainly taking steps to find out if they are correct or not. We are also doing other research to look into the causes for the increase, yes, sir.

The CHAIRMAN. Okay. With that, I think we will stop now and go take care of this voting, and we will return as quick as we can. We have two votes, and then we will be back. I think the second vote is a 5 minute, so we hope to be back shortly.

[Recess.]

The CHAIRMAN. I think we will continue with my questions. I have a couple minutes left, and by that time I think Mr. Hayes will be back, and we will continue on. Doctor, you may have answered this question. I think you did, part of it, in that first address, but I guess I was thinking about during operations centers and things in my own background. It seemed like we need something like this going on. And I am just wondering if FSIS, the CDC, state Departments of Health, and FDA are working together and how that is going on? I think you touched on it. Would you just elaborate a little bit, if that is happening, and how it is happening?

Dr. RAYMOND. Absolutely. Be glad to. When there is a foodborne illness, it is usually identified by a healthcare practitioner, based on a culture. Once that culture is back, depending on state laws, it is usually mandatory, particularly for *E. coli O157*, that the result will be reported to the state and/or local health department. It is the state or local health departments that do the epidemiological work to start with, to try to figure out the source of the infection and to link it to others within that state. At the same time, when they get the PFGE, they will forward that to the CDC, so the CDC can help coordinate interstate investigations and bring them together. FDA and USDA will get involved early on in situations like that, oftentimes before a product is identified, so that we are made aware of it, so we can work with them. Although, we do not ordinarily do any of the investigative work. Our work is to work with the plants on recalls, *et cetera*, although, we coordinate very closely. Sometimes we will be made aware of an infection by the consumer hotline directly. A patient can call in to us and say, "I

think I have a foodborne illness, or I have a foodborne illness. My doctor just told me it is *E. coli O157*," and we will be made aware of it that way, by other channels. But usually it starts out with state and local and then it goes up the Federal ladder. I hope that is what you were looking for.

The CHAIRMAN. It is, and I appreciate that. I am going to now ask Mr. Hayes to go right in with the questions he might have, and we will go through a 5 minute process with different Members as they arrive and so on. And we will probably have more than one round, so I will be back to you in a little bit. So, Mr. Hayes.

Mr. HAYES. Thank you, Mr. Chairman, and you answered my question about the round. I do have several questions. Dr. Raymond, again, thank you for being here. When requesting a meat recall, you rely on the cooperation of the industry to carry out the request. Some observers fear that if legislation granting mandatory recall authority is enacted, cooperation between the agency and industry would disappear, and some recall orders would be litigated under the company's right to due process. FSIS will certainly have to create a formalized review process if recall authority became mandatory. Will you support mandatory recall authority for meat, poultry, and egg products?

Dr. RAYMOND. No, we do not support it, sir. We think our system works very well.

Mr. HAYES. Okay. There were 14 recalls related to contamination with *E. coli*, and you know the numbers, since the beginning of June, three of which were announced last week alone. Is this indicative of a problem with our Food Safety and Inspection Service?

Dr. RAYMOND. No, I do not believe it is a problem with the program itself.

Mr. HAYES. Okay. I will come back to that in just a minute. This past June, FSIS observed an upward trend in *E. coli* prevalence. When were you made aware of these data, and what actions did you personally undertake to determine the cause? You sort of touched on that before, but if you could hone in on it a little more?

Dr. RAYMOND. I believe, to the best of my recollection, I was probably made aware of the increase in product sampling that was coming back positive probably in April or May. It was a very slight increase, but some of our scientists didn't know if it was a blip or if it was the start of a trend, but they wanted me to be aware of it at that time. Because it was a very small increase, I did not ask them to do anything different with it but just to keep me posted and keep an eye on it. It was in the next couple months that trend continued, and we began to see some increase in recalls due to illnesses. It was in June that we sat down and initiated some of those policies, the first and most simplest being nearly doubling the testing in July to try to see how big this problem might be.

Mr. HAYES. *E. coli* is a naturally occurring bacteria that is out there all the time. That is my understanding. I want to make sure we affirm that. Correct?

Dr. RAYMOND. Yes, it is, sir.

Mr. HAYES. All right. Is it your view that you need new legal authority to address current food safety challenges, or are you able to do so within your existing rule-making capabilities? How are you adapting that to the Topps recall?

Dr. RAYMOND. I believe we have all the legal authorities that we need to do our job, and we obviously can use rule making at times. We can also use notices and directives when that is permissible under the HAACP regs, *et cetera*.

Mr. HAYES. Dr. Raymond, there has been a lot of trouble with other imported ingredients outside of your agency's jurisdiction? What do you do at FSIS that sets you apart with regard to meat on equivalency?

Dr. RAYMOND. Sir, there is quite a bit, and I will try to highlight it very quickly. If a country asks for permission to export a meat or poultry product to this country, we will audit that country's system first. We will take a look at the paperwork, make sure they have the legal authorities, regulatory authorities, make sure they have the Federal inspectors, *et cetera*, like we do. If the paper audit appears favorable, we will do an in-country audit, where we will actually inspect the plants, laboratories, headquarters, *et cetera*. If their whole food safety system is found to be equivalent to ours for a particular product, they may be asking for poultry, they may be asking for beef or pork, they may be asking for all, it is determined equivalent for that particular species. We will work with our sister agency, APHIS, the Animal and Plant Health Inspection Service, to make sure they have no problems with product coming in from that country that might endanger our animals of the same species. For instance, in Brazil they can only ship cooked beef, because of hoof-and-mouth disease. After we made the equivalence determination, that it is equivalent, we then go through a formal rule-making process, which, as you know, could be quite lengthy. We will write a proposed rule which will go through clearance. It will get printed in the *Federal Register*, 60 to 90 days for public comment, and then we have to address those comments. We then write a final rule, go back through clearance, and then eventually get it printed in the *Federal Register*. We have done that for 33 countries, 29 of them currently are shipping product to this country. Once we have determined equivalence and they are allowed to ship, we then do annual audits, in-country, to make sure they are maintaining that equivalence, or, if we have changed any equivalency issues, that they have adjusted. And then the third thing that we do to assure that this product is safe is we also re-inspect nearly every shipment that comes into this country, and ten percent of the boxes or loads are opened up and visually inspected for content. The boxes are examined for being intact and not damaged or tampered with, and about five percent of product that comes into this country, meat and poultry products, will be microbiologically tested for pathogens and/or residues.

Mr. HAYES. Thank you, Dr. Raymond, for your concise answers, and Mr. Chairman, I will yield and wait for the second round.

The CHAIRMAN. Okay, well, thank you, Mr. Hayes. At this time I noticed that we have been joined by Ranking Member of the full Committee, Mr. Goodlatte, and I would like to recognize him for any remarks he might like to make.

OPENING STATEMENT OF HON. BOB GOODLATTE, A REPRESENTATIVE IN CONGRESS FROM VIRGINIA

Mr. GOODLATTE. Well, Mr. Chairman, thank you very much. I regret I wasn't able to be here when the hearing started, but I want to thank you for calling this hearing. This is a very important issue. In fact, I would say, of all the issues this Committee is responsible for, I don't believe that there is anything more important than assuring the safety of our nation's food supply.

While the media attention to recent recalls of meat and poultry products has led some of our colleagues to question the effectiveness of current food safety law and regulation, I would suggest that, prior to assigning blame, we should first seek to understand what if anything may be wrong with the system. More importantly, we have to determine why the prevalence of *E. coli* is an increasing trend. It is my understanding that this past summer managers within the Food Safety and Inspection Service began to observe trends in their microbiological test results, indicating increased prevalence of *E. coli O157:H7*. I suspect that the agency has been working diligently to determine the cause, and I look forward to a discussion of their actions and working theories.

The most important aspect of this hearing is to determine how the agency, from the Under Secretary down to the line inspectors in the plant, responded to this information and what lessons can be learned from their subsequent actions. Working to ensure food safety requires constant vigilance and a capacity to incessantly review and improve the safety process and procedures. In the event that mishaps do occur, and it would be unrealistic to believe that they won't, every effort must be made to identify the source of the problem, take corrective action, and incorporate increased vigilance and preventive efforts into daily operations.

Again, Mr. Chairman, thank you for holding this hearing. I yield back at this time, and at a later time I will ask some questions of the witness.

The CHAIRMAN. Well, thank you, Mr. Goodlatte. At this time the Chair recognizes the gentleman from California, Mr. Costa, for 5 minutes.

Mr. COSTA. Thank you very much, Mr. Chairman, for your time and the efforts of Members of the Committee to deal with this very important issue.

I would like to start today by reflecting, as I think a number of Members have, that when you look at the size of the production of the American beef industry, that produces over 25 billion pounds of high-quality beef each year, 36 billion pounds of poultry, and 21 billion pounds of pork, that it is a remarkable accomplishment. Due in fact, that we have the high level of standards that we do. Certainly, detection of *E. coli*, *Listeria,* and *Salmonella* and any other pathogens in our food supply is a concern to all of our consuming public. We should do everything we possibly can from the administrative effort as well as what makes good public policy here in Washington.

Dr. Raymond, I want to ask you a number of questions, and if time doesn't allow I will submit them for your written testimony response. But I want to first of all talk about the issue of risk management *versus* risk assessment. You spoke, in your closing com-

ments in your opening statement about that one illness is one too many, to paraphrase your comment. And I agree. One death is one too many.

We provide a framework of policy for food safety in America. We do the same as it relates to automobile safety. When we are talking about risk assessment *versus* risk management, we have to try to do our very best, but I want to get an understanding from you, given the pathogens that exist within the food system, whether or not the notion that somehow you create an expectation level that we can create zero risks. I mean, we have over 40,000 deaths with people who get into their car every day and drive throughout the year: 40,000 Americans that lose their lives throughout the year being in an automobile, yet we try to provide auto safety. The deaths that we have, or the illnesses, by comparison, relative on food safety, is far safer to get up in the morning and to have your breakfast or to have a nice dinner. What is the expectation level that you think is realistic that we can provide for the American consuming public as it relates to our beef and the other meat products that we consume?

Dr. RAYMOND. I thank you for the question, Congressman. We obviously are in no position to tell the American public that raw meat and poultry are declared pathogen free. We don't have the science to make that kind of a statement, so we do need to work with the American public to make sure they know how to properly handle, prepare, and cook meat and poultry products. In relation to ground beef, for the last 3 years, our product testing, our sampling of product in the plants, was positive at a consistent rate of 0.17 percent.

Mr. COSTA. Repeat that number?

Dr. RAYMOND. 0.17 percent. That is pretty good. To put it in perspective, out of about 12,000 tests that were drawn, 20 were positive. That is really good. But that is such a virulent pathogen, that is 20 times product would have gone out into commerce if we had not tested it and detained it, and that could have made a lot of people really ill.

Mr. COSTA. Understandable, but in terms of a comparative analysis, as I was attempting to do a moment ago with automobile——

Dr. RAYMOND. Right.

Mr. COSTA.—safety, if we could attain that level of safety for American drivers, it would be phenomenal.

Dr. RAYMOND. It would be, sir, and, but with all due respect, I just need to point out that the testing percentage for this year has gone up considerably, and that is my concern, is that we are not at that 0.17 level any more.

Mr. COSTA. Well, let me get to that point, because I have a number of questions. The meat industry, have they been cooperative in this effort to deal with *E. coli O157*, in your opinion?

Dr. RAYMOND. They are extremely cooperative.

Mr. COSTA. What are the most significant ways in which the pathogen can be reduced or eliminated in the harvesting or processing and the operations, in your opinion now?

Dr. RAYMOND. The most significant way would be to eliminate it from the intestine of the cow, and that would be with either vac-

cines or bacteriophages that are being developed and hopefully will be able to be used soon.

Mr. COSTA. Has the implementation of the new regulatory process, in your opinion, helped make meat products safer for consumers?

Dr. RAYMOND. If you are referring to HAACP, yes.

Mr. COSTA. Yes.

Dr. RAYMOND. Yes, that is what we have seen, and we have seen an 80 percent drop in product testing, and we have seen a 32 percent drop in foodborne illness.

Mr. COSTA. Are we going to reach out on an international level to provide that same standard?

Dr. RAYMOND. HAACP is an internationally-recognized——

Mr. COSTA. But I mean, in the alliance, to provide the technical and the regulatory support, is it there?

Dr. RAYMOND. Yes, it is.

Mr. COSTA. Okay. I have a number of other questions, Mr. Chairman, but my time has expired, and I will submit them for the record. I want to thank you again for this hearing.

The CHAIRMAN. Thank you. Mr. Goodlatte, do you have any questions?

Mr. GOODLATTE. Yes, thank you, Mr. Chairman. Dr. Raymond, in response to the Topps recall, senior managers with FSIS indicate that they would be evaluating the training records of the in-plant inspectors to determine if there were any inadequacies in the instructions related to HAACP compliance inspections. Can you update the Committee on the agency's findings?

Dr. RAYMOND. Ken, are we done? Okay. Dr. Peterson, who is the Assistant Administrator for the Office of Field Ops., says we would be happy to submit this for the record, the detailed report, that it is part of the revised training that is being developed right now to address those issues.

Mr. GOODLATTE. All right. Two recalls in the past few weeks have occurred because ready-to-eat products such as frozen pot pies and frozen pizzas were linked to foodborne illness outbreaks. It is my understanding that all tests of intact product have come back negative for the adulterant. Under your policy, if a ready-to-eat product was a common food source in a foodborne illness outbreak, but you could not verify the presence of the pathogen in any intact packages of the product, would USDA request the company to recall it?

Dr. RAYMOND. If the epidemiological evidence linked to the product, yes, we absolutely would request them to do a recall. And we have on many occasions.

Mr. GOODLATTE. And have you ever had them not comply with those voluntary recall requests?

Dr. RAYMOND. No, we have not.

Mr. GOODLATTE. Very good. What role does trace-forward play in recalls?

Dr. RAYMOND. If I understand the question, trace-forward is just what we do when we ask for a recall, and a company does the recall. Our inspectors, part of our workforce, go into the stores to make sure it has been removed from the shelves, if that is the question. And obviously once we have done that we either find that

the recall is done and the product has been removed, or, if it hasn't been removed, we readdress the issue.

Mr. GOODLATTE. Do you have cooperation in that regard? Does your trace-forward program indicate companies are removing the product from the shelves when requested to do so?

Dr. RAYMOND. With very rare exceptions, and the exceptions are when it is maybe perhaps massive, and all the stores didn't get the message at the same time. But, yes, it has been extremely successful.

Mr. GOODLATTE. What are the weakest links in your ability to track the products through commerce?

Dr. RAYMOND. Well, I think actually the weakest link is knowing who bought it. I think we have good, strong links in linking it to the retail stores and to the restaurants, but it is the who bought it and what did they do with it is where we need to get better at. We also need to identify the retail stores when we do recalls, so the consumers that have it in their refrigerators or on their shelves will know, "I bought it at X supermarket on this date, and that is the supermarket where they say it was sold at." I think that will strengthen that link between the retail store and the consumer.

Mr. GOODLATTE. So the increasing use of technology by the distributors and the retailers in getting the message to that end-user is something that can be enhanced?

Dr. RAYMOND. That can be enhanced, but the recalls can also be enhanced by identifying retail stores.

Mr. GOODLATTE. Very good. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Goodlatte. At this time we would like to recognize Mr. Lampson for questions he might have. Five minutes.

Mr. LAMPSON. Thank you. It seems that a lot of illnesses occur due to cross-contamination and improper cooking methods. What steps has the USDA taken to better educate consumers when it comes to safe food preparation?

Dr. RAYMOND. We have a very, very active consumer education program. We work with our food safety education partners, which includes both consumer organizations and industry, quite closely. They help us a lot. They actually provide some of the funding for what we do and what they do. We have the Clean, Separate, Cook, and Chill campaign that is widely recognized throughout the country. We just within the last year instituted the new Be Food Safe campaign with our food safety education partners. We have made pamphlets, brochures, things that are available to use in newspapers, or in media, available to our state and local health partners in food safety. They can use our materials, and they can put their own logo on so that they get some recognition. I feel that people out in rural America will listen to their local health official more than they will listen to me, speaking from D.C. So far we have had 7,000 requests for that information, those packets, those brochures. We obviously have public service announcements on a regular basis. We do film clips for PSAs, for events like Thanksgiving and Super Bowl, where people gather in large numbers and sometimes don't practice safe food handling, because they leave things out after Thanksgiving dinner, watch the football game, or whatever. We try to address those. We try to do a lot of our communications

multi-lingually. We try to involve personalities when we can that might get the public's attention, again, more than me. It has been very successful, and it is a big part of what we do. It didn't used to be. We used to be the regulatory agency. Now we try to put the "and" in Food Safety *and* Inspection Service.

Mr. LAMPSON. The State of New York has a policy of issuing a consumer warning when an outbreak is suspected so that citizens can take some kind of proper precaution. Would it be possible for the USDA to issue a consumer warning as an investigation is taking place so that consumers can take precautions when preparing meat, in order to reduce possible illnesses?

Dr. RAYMOND. Congressman, I don't think that would be helpful. It probably would cause concern and perhaps less trust than they currently have in the system if we put out a warning and then, 2 days later, said, "False alarm. You don't need to worry." As soon as we have a link to a product that we know is solid, we will do the recall or the public health alert, whichever is most appropriate. To your previous question, a couple other things we do have. We have the AskKaren hotline, which is a 24 hour line people can call in and ask food safety questions. It is a virtual line, that they will get an answer. And then we also have the M&P hotline, so when people are preparing Thanksgiving dinner and they wonder, can you cook a frozen turkey, or how long, we do have those information sources also available for public education. They are widely utilized.

Mr. LAMPSON. The next one, currently when adulterated products are discovered, the FDA and FSIS have the ability to request a voluntary recall or to seize and detain products. The President yesterday announced a proposal to give the FDA mandatory recall authority when a company refuses a voluntary recall. What implications would giving this authority to FSIS have?

Dr. RAYMOND. I do not believe it would improve what we do at all, because I think we do a really good job with recalls at this point in time. Once the product is recognized, and the illness is attributed to a product, we have no problem with industry. They have always complied with our requests for voluntary recalls.

Mr. LAMPSON. Then is this unnecessary?

Dr. RAYMOND. I believe it is totally unnecessary and might be bothersome, because I don't want to take a system that really works well and run the risk that it will work less well.

Mr. LAMPSON. According to news reports, New York and Florida were both investigating an outbreak that apparently FSIS was not informed as to the state of their investigations or test results. Can you discuss what procedures are in place to facilitate communication between various agencies, including state Departments of Health, the CDC, FDA, and FSIS?

Dr. RAYMOND. Certainly. The states have laws that require reporting of certain illnesses. They do vary state by state, but most of the common foodborne pathogens are mandatory reporting by the state. If a healthcare provider detects a foodborne pathogen in an ill patient, that will be reported to the state Health Department in most states. State Health Departments work closely with their local health departments. Each state is different, but someone will go do an epidemiological investigation on that illness, and some-

times even the state Departments of Agriculture will get involved if there are samples to be taken from retail stores, *et cetera*. So multiple local partners and state partners get involved first. They report their findings to the CDC, and the CDC will then coordinate a broader epidemiological investigation that involves more than one state border. They will try to tie these isolated incidents together with PulseNet and say, "We have an outbreak." At some point in time, the investigation will begin to point a finger at a product, hopefully, but not always. Most outbreaks do not have attribution. They do not point a finger at meat or poultry or produce. When they do, that is when we get involved, or the FDA gets involved, and sometimes we get involved jointly, because it may be the pizza that has been mentioned here, or the pot pies. Those pot pies have wheat, and they sometimes have dairy products. They certainly have produce in them, as do the pizzas. It takes a great deal of work together to determine whether it is a product we regulate or a product they regulate.

Mr. LAMPSON. Thank you very much, Dr. Raymond. I yield back my time, Mr. Chairman. My time has expired.

The CHAIRMAN. Thank you. The Chair recognizes Mr. Rogers for 5 minutes.

Mr. ROGERS. Thank you, Mr. Chairman. I want to go back and follow up on the questioning that Mr. Costa was talking about risk-based assessments or inspections. You were talking about the contamination level this year was higher than last year's baseline level of .17.

Dr. RAYMOND. Yes, sir.

Mr. ROGERS. How are you establishing that baseline for inspection?

Dr. RAYMOND. We do about 12,000 ground beef samples per year in plants that produce ground beef. That is our baseline, and we have been doing this for quite a few years. We saw an 80 percent drop from 2003 to 2004 and maintained at that 0.17, and this year. I could look up the exact number we have done so far, but the percentage positive is about 0.22 percent.

Mr. ROGERS. In these 12,000 samples, is there some risk-based criteria that you apply to those samples to discern which ones you are going to test and which ones you are not?

Dr. RAYMOND. No, sir, there is not at this time, but we are taking corrective actions to put some targeting to the way we sample currently. A small plant is just as likely to get sampled as a large plant, and that just doesn't make sense to me. The agency has developed a system that will be implemented in January that will do more targeted sampling. The larger plants will get more sampling, just because more people can be exposed. Sampling will be based on the plant's past history. If they have had positive samples in the recent past, they are going to get more sampling, be they big or small, *et cetera, et cetera.*

Mr. ROGERS. Are those the only two criteria that you are going to be looking at——

Dr. RAYMOND. No.

Mr. ROGERS.—the volume and their history?

Dr. RAYMOND. No, sir.

Mr. ROGERS. What other criteria might be applicable?

Dr. RAYMOND. What other criteria besides volume and past samples? Plant performance on PBIS, our own inspection service, noncompliance reports that indicate the plant is doing less than a stellar job in enforcing their policies, consumer complaints that may be related to the plant can do that. If our inspection force sees a lack of process control, carry-over from one day to the next of a work product without a way to isolate that, things that create risk will create increased testing.

Mr. ROGERS. You said that this year's rate of contamination was higher. What is it this year compared——

Dr. RAYMOND. It is about 0.22.

Mr. ROGERS. That is about a 50 percent increase in what you had last year?

Dr. RAYMOND. About a 33 percent, I believe, sir.

Mr. ROGERS. Okay. It is my understanding that some meat imports are further packed or processed in USDA-inspected facilities. Is this packaging and processing carried out under continuous inspections by USDA?

Dr. RAYMOND. Slaughter is carried out under continuous inspection processing, and packing is under daily inspection.

Mr. ROGERS. Okay. The last thing I want to know, is there any statutory authority that you need from this body to be able to better do your job?

Dr. RAYMOND. No, sir, I do not believe so.

Mr. ROGERS. Thank you. That is all I have, Mr. Chairman.

The CHAIRMAN. Thank you. The Chair recognizes Mr. Kagen for 5 minutes.

Mr. KAGEN. Thank you very much, Mr. Chairman, for holding this very important hearing today. Thank you, Dr. Raymond, for all you have done and the people that work with you. I very much applaud your efforts. It is very difficult to chase down bacteria. It is difficult to chase down where the *E. coli* came from, but, in your experience, would you make a determination or a close "guestimate" as to whether or not a consumer should make in part their decision on where they are going to purchase their meat products based upon where the meat was butchered? Is it, for example, safer for a consumer to purchase a meat product that is produced and butchered locally as opposed to some distant place, where it might be under a mass production facility?

Dr. RAYMOND. Congressman Kagen, my job and the agency's job is to make certain the meat product or the poultry product that you or your spouse or someone else purchases at a retail store is safe to eat, and it should not make any difference whether it is a small plant, a large plant, a local plant, or even an international plant.

Mr. KAGEN. But in your experience or from the body of evidence that you have had an opportunity to review, is it more likely to find *E. coli*, *Salmonella*, or *Listeria* at a smaller production plant or a larger plant?

Dr. RAYMOND. In my experience, it is across the board. We have some large plants that do not perform well in *Salmonella* sets, we have some very small plants that perform extremely well, and some that do not.

Mr. KAGEN. And what is the process whereby you or your staff will determine the sampling techniques? Will you sample each run

of slaughtering process on a daily basis or is it intermittent? What is the method you use to sample the product?

Dr. RAYMOND. It depends on what the product is, sir, and what the sampling is. For instance, for *Salmonella* on poultry we will do a set of carcass washes or rinses, 53 consecutive work days, and we will do that. And if this plant comes in below a certain level of positive carcasses, they may not get another sample set for 2 years. If they come in above a certain level, set, they will get another sample set started immediately upon termination of the certain set.

Mr. KAGEN. You bring up an interesting question, that is, the threshold limit. What is your threshold limit of safety for toxic *E. coli*?

Dr. RAYMOND. Zero.

Mr. KAGEN. Zero. So if you have a sample that comes up with *E. coli*, toxic variety, can you trace that back to the ranch or the production facility?

Dr. RAYMOND. We try to trace it back as far as we can into the slaughterhouse that provided the product that may have been ground into ground beef. That is where we would like to get to. That is where the problem has occurred, and that is where we need to take steps to keep it from happening again.

Mr. KAGEN. You mentioned also in an earlier question that the system works fairly well. Is that correct?

Dr. RAYMOND. I believe it does, sir.

Mr. KAGEN. And yet the sampling rate for imported foods is 1/10 of 1 percent of the product that comes in. Yet, we have had some foods that have been contaminated and some human illnesses have resulted from that. So would you say that there are some improvements that need to be made, and if so, where are these improvements to be made?

Dr. RAYMOND. Congressman, with all due respect, about 3 or 4 years ago the amount of product that was sampled for pathogens that was meat or poultry under our inspection was about 0.2 or 0.3 percent. The last couple years, it has been four percent of all product that comes into this country, meat and poultry, has been sampled for pathogens and/or residues.

Mr. KAGEN. And has that resulted in a number of catches, so to speak?

Dr. RAYMOND. Actually, we have seen very few catches. We have not had issue with the product coming across the border to any great degree.

Mr. KAGEN. Very good. On another subject, in the remaining time that I have, you have a number of education programs for consumers——

Dr. RAYMOND. Yes, sir.

Mr. KAGEN.—on purchasing and preparation of foods. Is there a program that you would like to highlight at this time?

Dr. RAYMOND. The Be Food Safe campaign that we launched about a year ago is showing to be extremely popular with our food safety partners, the local and state health officials, the epidemiologists, *et cetera*. They are using this extensively in their local campaigns, and that is where I think we really need to get is local rather than coming from inside the beltway.

Mr. KAGEN. Very good. Thank you much, and I yield back my time.

The CHAIRMAN. Thank you. The Chair recognizes Mr. Conaway for 5 minutes.

Mr. CONAWAY. Thank you, Mr. Chairman. Dr. Raymond, on the 12,000 samples, I missed what Mr. Costa said on billions of pounds of ground beef. Is that a statistically valid sample across everything that is going to be produced in a year? I mean, how did you determine that 12,000 samples are enough to do what you need to do?

Dr. RAYMOND. I didn't personally determine that. Our scientists do those numbers, and I have a great deal of confidence in them that it is statistically significant. We are trying to make it more statistically significant by doing more targeting, starting in January.

Mr. CONAWAY. I recall recently that Cargill recalled a million pounds of ground beef on their own. Maybe I am making that up, but do companies, I would assume the responsible companies are doing their own inspections, their own testing? Is that an unusual circumstance to have a company recall its own product without having intervention? There was nobody else involved, as I understand it. Is that unusual?

Dr. RAYMOND. Well, first of all, let me, so that everybody is on the same page, when the companies do their own testing they generally hold and test, test and hold. And if they have a positive product they either destroy that product or they cook that product. They do not send it out as raw ground beef. If a company is testing product and just goes ahead and sends it out and it comes back positive, they are going to voluntarily withdraw that product. It is the same when we test product. Some of it is held, and some of it is ground into commerce. I would like to go into the one you are talking about.

Mr. CONAWAY. Sure.

Dr. RAYMOND. I believe that you are talking about the most recent Cargill one. This gives an example of one of the reasons we have 19 recalls, and one of the reasons that is not all bad. Two recalls ago, a company that we tested the product, tested positive. It was a very small company. They produced 50 pounds of ground beef that day, and they voluntarily recalled it. It had all been sold to restaurants. None of it had been served to customers yet, so there were no illnesses involved. Our investigation into that particular product linked it back to a Cargill plant. At the Cargill plant, we went through their records with them, and they realized a limited time where that product could have been produced, and they recalled about a million pounds of product. So there were actually two recalls based on one sample test, which shows, I believe, that we are doing our job. Because it was our sample that caught the positive, and not just in the 50 pounds, but perhaps a wider net when they pulled the million pounds back. I believe we have prevented illnesses with what we do.

Mr. CONAWAY. One last question. On the things that you look for, the pathogens that you look for, the consumer is ultimately the last line of defense with proper handling and cooking. Are there patho-

gens that you are concerned about that are not controlled by proper cooking, at the end of the day?

Dr. RAYMOND. The one thing we do worry about is *Listeria monocytogenes*, which is in ready-to-eat products. It is products that you should not have to expect to cook at home: it is beef jerky; it is cooked hams; it is issues like that, that the pathogens should be cooked out of those products, but unfortunately there are environmental issues. Sometimes the product is properly cooked but then contaminated by the environment. Or, as in the botulinum recall, we found out there was an error in the cooking process in that particular plant, so, yes, those you can't cook out at home.

Mr. CONAWAY. Okay. But the raw meats that you buy at the store and you bring home, if you properly cook the chicken, beef, or turkey, to the ultimate temperatures, that would handle all these pathogens?

Dr. RAYMOND. The temperatures that we recommend for cooking will kill all of those pathogens that that temperature is for, yes.

Mr. CONAWAY. Okay. So the consumer can ultimately protect themselves, no matter what you do, from these issues?

Dr. RAYMOND. Yes, sir.

Mr. CONAWAY. Okay. You bet. Thank you for sharing.

The CHAIRMAN. Thank you, Mr. Conaway. The chair recognizes Mrs. Gillibrand for 5 minutes.

Mrs. GILLIBRAND. Thank you, Mr. Chairman, for holding this important hearing, and thank you, sir, for being here. I just want to return to the issue of the risk-based inspection system and the baseline of 12,000 samples. Is that something that you are going to change, the baseline number of samples? Will it increase or decrease? And you talked about changing some of the criteria and targeting. Can you talk a little bit more about what you will change?

Dr. RAYMOND. Yes, and thank you for the question, because it gives me an opportunity to go back to one of the recent questions that I didn't answer quite correctly. The 12,000 samples that we use for ground beef is verification testing. It is not statistically significant, but it is verification that the plant's passive plans and other procedures are in place. The trim testing is statistically significant. I want to make that clarification. And we do about 6,000 samples per year. We have started in March, and we will do about 6,000 samples per year on trim, in addition to the 12,000 in ground beef.

Mrs. GILLIBRAND. And which criteria for testing will you change?

Dr. RAYMOND. There will be multiple criteria changed. Right now the sampling is just routine and random for the ground beef, and what we will change is to look at a plant's record. We will be looking at their past history of testing. We will be looking at their systems, and processes that are in place. We will be taking a look at our own inspection workforce. We will take a look at previous positives, and those will all go into the thought process as to who to target with more intense testing.

Mrs. GILLIBRAND. And then will you report back to Congress, or how will you publish your changes in systems?

Dr. RAYMOND. We will always respond to any request from Congress, of course, for information relating to our Food Safety and Inspection Service.

Mrs. GILLIBRAND. So when you formulate your new system, will you make sure you advise us on what you are now doing, going forward?

Dr. RAYMOND. Absolutely.

Mrs. GILLIBRAND. Okay. I also heard from my colleague, Dr. Kagen, that there are now vaccines for cows for *E. coli* that gives them immunity to it. Is that something you are looking at or that will be discussed?

Dr. RAYMOND. The vaccine has been developed but has not been approved yet, at this time in the United States. That is not something that we have any control over. It is the USDA that is looking at that, and, yes, we are very interested, and we follow that very closely.

Mrs. GILLIBRAND. Is that something that would be preventive? What is your understanding of the effectiveness of that course of action?

Dr. RAYMOND. Well, as a physician I believe strongly in vaccines. They prevent millions of illnesses a year in this world, tens of thousands of illnesses in this country. We have eradicated smallpox, for instance. Can we eradicate *E. coli O157*? Doubtful. And it won't be perfect, because when we are talking cattle, we are talking two different age groups. If you are talking just cattle that will be slaughtered for steaks and other cuts like that, under 30 months, the vaccine probably will be wonderful. But if a farmer has to give it to a dairy cow for 13 years, who is going to pay for the vaccine before the dairy cow gets ground up into our ground beef? Those are issues that need——

Mrs. GILLIBRAND. To be addressed.

Dr. RAYMOND. Yes.

Mrs. GILLIBRAND. Thank you. Just one last question. Can you talk a little bit about the recall for the Topps products, because it was something we heard a lot about in New York. I would like your comments on what happened and whether, under your new risk-based inspection system, there would be any difference, whether it would have been caught.

Dr. RAYMOND. I cannot say with any degree of certainty that it would have been caught under a risk-based inspection system. What I can say is that under a risk-based inspection system, after the incident happened at Topps, they definitely would have moved to the right and received more intensified, longer inspection, because of the points that would have been scored against them for their demonstration of the inability to control risk in their plant. Because they were making a high-risk product and because they were making a high volume of the high-risk product, all those factors would have entered in. I am very confident they would have gone to the upper tier of inspection for subsequent grinding if they had stayed open.

Mrs. GILLIBRAND. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mrs. Gillibrand. I appreciate the questions. We will go another round for those that would like. I kind of triggered something. You said 30 month, and we are not

going into the 30 month Canada situation, but there are some concerns about that. I just want you to know that. But, having said that, what is the FSIS role in regard to the shipment of meat from a foreign country?

Dr. RAYMOND. Well, our role, Mr. Chairman, in the shipment of meat from a foreign country; first, starts with determining if that country has an equivalent food safety system to ours. Second, it is annual audits to make sure they are maintaining that equivalency and performing the way we want them to perform, to be allowed to export. Third, it is re-inspection of that product as it comes across the border. And last, it is opening ten percent of those boxes and visually inspecting that product and doing the microbiological testing that we have already talked about, and the residue testing. At that point, I think our responsibility ends, and it goes into the rest of the product that we inspect on a regular, daily basis.

The CHAIRMAN. It has come to light that some of the meat that was contaminated with *E. coli* came from Canada. Could you tell it why did it take so long for FSIS to receive this information?

Dr. RAYMOND. Yes, sir. The Topps recall, I believe, was on September 25. It got expanded on September 29, I believe, after we had done the food safety assessment. It was not too long after that, and I don't know if I want to call it a sister company, but J&B meats had some link with Topps, not 100 percent corporate, but there were some linkages there. And J&B meats became a plant of interest to us. We did have one patient became ill from a product that linked to J&B meats by an open box in their freezer, another one that would ordinarily not have been recalled under the past conditions. When we took a look at J&B meats and the Topps meats for those two products that were linked to human illnesses, we found three common sources of three common suppliers for those days, and we immediately focused our attention on those three suppliers of record, one Canadian and two domestic. It didn't mean any of them had produced product that was contaminated, but the three plants that produced to those two processing plants, and we notified the Canadian Government of our interest in the plant in Canada. At that same time we delisted that plant until we could be certain that they were not a producer of record of the contaminated product. The Canadian Food Inspection Agency went and inspected that plant, which had gone into receivership and was no longer producing but had product being held in their warehouses during their legal processes. They sampled product from that date that we had linked, and that product came back positive for *E. coli O157* with the matching fingerprint, the PFGE that I talked about. It matched the fingerprint of the *E. coli O157*. It was present in at least 31 of the patients in our outbreak and also matched the fingerprint of the one down at J&B meats. And that is how we made the link, usually we are not successful in our trace-backs. I really don't think this took actually very long at all. We were just happy to be successful.

The CHAIRMAN. I appreciate that. I am told that each time a lot or a batch is changed out at the grinders', they are supposed to be torn down and go through the cleaning process and the equipment. How often does this happen, and is it something inspectors look for?

Dr. RAYMOND. Our inspectors obviously are tasked with a lot of activities, and a lot of them, of course, are the plants' procedures for the good hygiene within the plant and the physical environment. Yes, it is one they look for. I think the frequency is going to vary upon the plant, the size, the product, so I can't give you a definitive answer as to how frequently that does occur.

The CHAIRMAN. Having visited a plant and even worked there many, many years ago, I am just concerned at the pace they have to do that, what they do when they change products, and clean the equipment, to make sure it is ready to go with the new grinding that will take place. So I appreciate that you are watching for it. What happens if the grinder is found not to be doing it?

Dr. RAYMOND. If it is in their HAACP plans and is one of their critical control points, we could actually pull the inspection workforce if we wanted to. Most likely what would happen, a non-compliance report would be written up, and they would be expected to take corrective actions immediately.

The CHAIRMAN. I appreciate that. At this time I recognize Mr. Schmidt—Mr. Smith. You have joined us. Would you like to have a question or two? We will recognize you for 5 minutes.

Mr. SMITH. Thank you, Mr. Chairman. Thank you, Dr. Raymond. My greetings from Nebraska.

Dr. RAYMOND. Great. Thanks.

Mr. SMITH. You mentioned in response to an earlier question that the best way to improve food safety with respect to *E. coli* is to eliminate it from the animal's digestive tract. How much of an impact could the pre-harvest measures impact the incidence of foodborne illness, and when do you expect that some of the pre-harvest tools will be available to the industry?

Dr. RAYMOND. Congressman Smith, I really can't speculate as to when those pre-harvest things that we have talked about, the phages, and the process that those things have to go through for clearance. I don't want to give you a date that I can't back up scientifically.

Mr. SMITH. Sure. I appreciate that, but I appreciate your acknowledging the possibilities that are out there. Also, we know that the industry is evolving somewhat, and we know that there are some niche markets out there in the meat industry. At the same time that brings about smaller operators, which I think is great value-added opportunity in agriculture. Could you describe the programs that are in place, or could be in place, that will ensure that future processors and small businesses are not negatively impacted by positive findings when they test raw materials?

Dr. RAYMOND. Yes, sir. Thank you for the question. One of the things that we have done right, very well, in the last couple years, that I am very proud of, is our outreach to small and very small plants. We conducted several listening sessions across the country late in the summer of 2005. What we found was it was apparent that small, very small plants did not really have robust HAACP plans and really had not engaged with HAACP. They really had not received the training, education, and support that they needed to get those HAACP plans done so that we could say their product was just as safe as a larger plant. And we developed an outreach program based on that. We worked with our international HAACP

alliance for a 2 day conference. They worked with us and developed this outreach plan. We have a new person that is in charge of that particular program, not a new hire, but a new position, totally in charge of that. And that is what this person does, day in and day out, both that and training for our workforce of specialists in the area. We conduct many sessions per month for small and very small plant outreach across the country, attended by plant management and also by our own employees so they are hearing the same thing at the same time and they are getting a consistent message. We have worked with the technical center in Omaha to provide one consistent message for their questions. We weren't doing a very good job in that area. We have a website specifically for small, and very small plants, frequently asked questions. I think we actually have a new brochure we just started producing just a few weeks ago that goes to the small, very small plant operators with updates to help them. They don't have the resources to scan the Web and everything else that the large companies do, so we are trying to help them stay intact and up front with their policies.

Mr. SMITH. Okay. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. And I apologize to you, Mr. Smith, for calling you Mr. Schmidt.

Mr. SMITH. Close enough. I didn't even realize it.

The CHAIRMAN. Oh, well, then, I am sorry I brought it up then. At this time the Chair recognizes Mr. Hayes for second round, 5 minutes.

Mr. HAYES. Thank you, Mr. Chairman, and Dr. Raymond, again, thank you for your concise answers. We have talked a lot about sampling, and we have talked about testing. We have talked about tracing and recalls, all of which are important parts of our food safety program. Would you spend a couple minutes talking about the prevention policies that the Department has in place? By prevention, I mean from the time the animal leaves the farm until he ends up on the shelf. I think it would be helpful, particularly given the nature of the situation we are dealing with, to reinforce how stringent your policies are in terms of how the animals are handled, processed, and packaged. So, if you would walk us through that, I think it would be helpful and kind of complete this picture.

Dr. RAYMOND. I will sure try to do that, Congressman Hayes. First of all, handling. Humane handling, of course, there is a law about humane handling, and that is one of the things that we do make certain happens in all plants that we are responsible for. Humane handling does decrease the risk of contamination with fecal contents. Our Agriculture Research Center is also doing research into the holding pens and how can we reduce contamination within the holding pens? We know, when the cattle leave the feed lot, there is a certain amount of carcass contamination. We know, when the carcass is pulled, there is a whole lot more, just in the shipping and transporting. We need to figure out how to reduce that. But that said, once the animal is knocked down and we go to the hide pull, there are certain measures that plants are taking there to try to reduce scatter and splatter when the hides are pulled off these animals. That is where the greatest risk of contamination comes from. It is really not intestinal spillage. It is contamination from the hide, during the hide pull. There are rinses. There are anti-

microbial rinses. There are different temperatures that have been developed by the Agriculture Research Center, out in Clay Center, Nebraska. Many of these companies are following that advice, their practices that help reduce the amount of fecal contamination. Obviously the inspection by our workforce, looking for any signs of feces or fecal contamination on the floor, on the walls, and the hides on the carcasses. Some plants have actually very sophisticated machinery that the carcass goes through that would detect almost microscopic amounts of fecal contamination on the carcass and will stop the line instantly until that carcass is removed, derailed, and retreated. Obviously, testing is important and needs to comply to HAACP plans. They are probably the most important thing. I mean, the rinses and the chemicals are all nice, but the HAACP plans that the plants have all put into place have been required since the year 2000, and that is when we really saw *E. coli* begin to decrease as a foodborne illness as a result of those HAACP plans. That is the most important factor, I believe, in getting *E. coli* numbers down, preventing it from getting onto your dinner plate or my dinner plate.

Mr. HAYES. What I just heard you say is that you have very stringent and strict processes and procedures that are consistently followed from large plants to small plants, east, west, north, south, so that the same, consistent behavior and procedures will result in the best and safest meat possible. And I think that is pretty clearly what you said. Did I repeat you correctly?

Dr. RAYMOND. The one thing I just want to clarify is that the procedure is not exactly the same from plant to plant. The plants do develop their own HAACP plans, and then they must follow their HAACP plans. Variation is allowed. One thing the industry has done that has been very proactive is they declared public health not to be a competitive nature. They share best practices in most of the industry, and not a practice for a plant that is slaughtering 365 head an hour, because the same practices don't apply to the small, custom, exempt slaughterer. So they are not exactly the same, but they are very stringent procedures, and they must follow them.

Mr. HAYES. But you make sure that the appropriate procedure is used for the expected outcome, which is safe food.

Dr. RAYMOND. Yes, sir.

Mr. HAYES. And is your research department and other individuals within your department, are they always monitoring and looking to see if the antimicrobial, which I can't say very well, and the other chemicals and processes are the most effective? They are appropriate for strains and mutations of *E. coli* and other bacteria that are developing, so you stay on top of that both in research and application? Is that a fair statement?

Dr. RAYMOND. Yes, sir. And, again, just for a point of clarification is the Agriculture Research Service, which is another branch of the USDA, but it is the USDA that is actively doing this research, along with a lot of other universities, land-grant institutions, and the industry itself are also doing research.

Mr. HAYES. Well, thank you again, Dr. Raymond. I think you have done an excellent job. Mr. Chairman, I think you have with this hearing made it very clear that food safety is crucial. Mon-

itored continuously, anything can be done and we have proven, but day in and day out we are on the case.

The CHAIRMAN. I appreciate you saying that. It is exactly right. Second round, Mr. Kagen, for 5 minutes.

Mr. KAGEN. Thank you, Mr. Chairman. Dr. Raymond, you had indicated earlier in questioning that the safe level of exposure to *E. coli O157* is 0, and if that is the case, I am confused about why it took so long with regard to the Topps case for your agency to work and get the job done. I will quote David Goldman. "Let me be clear from the beginning. At this point we weren't able to take action based on the initial test." Well, if a test came up positive, and the safe level is 0, why wasn't that the time to act?

Dr. RAYMOND. Congressman Kagen, at that time the policy of the agency was that we would not take a product that had been opened. We would test it, but even if the test came back positive we would not feel we had a strong enough link to do a recall or to seize and detain if we were forced to seize and detain. That is why a recall was not done at that time. That policy has changed. I did not agree with that policy, especially if it is a frozen product. The reasoning behind this is the product may have been contaminated by the person in the home. I will use an example. If someone had just changed a baby's diapers, and, you know as a physician, we all have *E. coli*. We just don't have *O157:H7* fortunately. But if you get a culture back on a product in the refrigerator, and it has *E. coli* in it, and you haven't got down any further than that, that could be easily contaminated from a person.

Mr. KAGEN. So as a result of the Topps situation, the policy has changed?

Dr. RAYMOND. Yes, it has.

Mr. KAGEN. And, in your view, it has changed for the better?

Dr. RAYMOND. Absolutely.

Mr. KAGEN. Okay. And with regard to this issue, in New Jersey, at a Topps facility, the USDA noted that there were some safety violations. Can you state for the record what those violations were?

Dr. RAYMOND. First of all, they were not doing any testing for *E. coli*. In the past, they had been, and they had stopped that.

Mr. KAGEN. How long had they stopped testing?

Dr. RAYMOND. We had done a food safety assessment in that plant in 2005, and their food safety assessment at that time, which is a very detailed inspection investigation, they had done very well. They showed well on that, and they were testing, I believe, monthly at that time, and the last year they were not.

Mr. KAGEN. And I am certain you are pursuing the reasons why, perhaps top personnel, a technologist, moved on, and no one replaced him or her?

Dr. RAYMOND. It changed ownership, sir.

Mr. KAGEN. Okay, so a different owner had a different style of practice, but it wasn't in keeping with the good health of the consumer?

Dr. RAYMOND. That is the assumption I would make, yes.

Mr. KAGEN. Okay. The final question I have has to do with the visual inspections that inspectors do on meat packaging, and also on meats when they are being cooked. In my lifetime of experience when I am cooking meat, I look at it to see if it is well cooked, and,

unfortunately, it is my understanding that if meat has been preserved with carbon monoxide that I have lost my ability to visually determine if the meat is fully cooked. Is that a fair statement?

Dr. RAYMOND. We do not recommend visual observation to see if meat is fully cooked. We recommend everyone use a food thermometer, sir.

Mr. KAGEN. Well, excuse me. I have never used a thermometer. In my medical practice I have, but not when I am preparing food for the family. I daresay that most people don't measure the temperature of their hamburger meat or their steaks when they are cooking it. They use their visual eyes, so if you will just go along with me in assume that most people in America don't use a thermometer when cooking meat, and most people in Canada probably don't, or maybe Central America, South America. If we can't use our eye, and we don't have a thermometer in the kitchen, how do we judge if we are cooking it thoroughly? And again I am coming after the issue of carbon monoxide treatment of pinking up the meat.

Dr. RAYMOND. I will go along with you.

Mr. KAGEN. Well, let me just make it easy for you, okay? Do you routinely use a thermometer to cook your hamburger?

Dr. RAYMOND. Yes, sir, I do.

Mr. KAGEN. I am flabbergasted. I daresay you are probably the only one in the room.

Dr. RAYMOND. I think that the row right behind me had better be using a food thermometer, because none of us can afford to have a foodborne illness with *E. coli O157* and say we didn't use a thermometer. I think the choir is behind me on this one, but I will agree with you, that I am in the minority. You are in the majority, and I need to get myself in the majority, and you in the minority, through our consumer education. But back to your question, carbon monoxide maintains the healthy, pink color of the meat because it doesn't interact with the oxygen. Cooking, it will not maintain that pink when it cooks. I mean, it has nothing to do with the color of the meat when it is being cooked. It has to do with the color of the meat when it is sitting in your refrigerator.

Mr. KAGEN. So if I cook it to the temperature of 160 degrees Fahrenheit, the carbon monoxide in the meat will change color and look fully cooked. Is that correct? Is that your expert testimony?

Dr. RAYMOND. Yes. Yes, sir, to the best of my understanding.

Mr. KAGEN. Thank you very much for your answers, and thank you, Mr. Chairman.

The CHAIRMAN. Well, that brings us to the close of questions. I did have one last one that I would like to ask you, Mr. Secretary. You mentioned that as of this month all beef plants will have to verify they are controlling *E. coli* during slaughter and processing. Can you tell me how they will be expected to do this, what your oversight will be?

Dr. RAYMOND. Yes, there is about a 47 page survey that our inspectors have received special training on. They will be doing their surveys of the plants, all these different processes and steps to see if they are using them or not using them. That report will be looked at at the district level by supervisors and other staff, and they will take a look at these plants. If a plant does not have the

proper steps in place they will probably get a food safety assessment sooner than later, and they will have to verify or justify why they do not have these processes in place. If they have something better, that is fine, but if they don't have something better, we will work with them to get those processes in place. What we are really trying to do is get a baseline. We do not know for sure how many plants have adopted our 2002 guidelines and how many have not. What we have found is, Topps was not using it, but they had been 2 years before, and we do feel that was a large part of the problem with the Topps plant. I want to know if that was an isolated incident or if this is something a little bit more pervasive. If it is a little bit more pervasive we will have to take a look at future policies, maybe rules and regulations in fact, to make some of these things regulatory rather than suggested.

The CHAIRMAN. I appreciate that. Now we focused a lot on beef and *E. coli*. Is this just a problem for beef, or does this also have a relevance to pork, and are there processes that are different?

Dr. RAYMOND. This is beef. We are doing this in the 1,500 plants that slaughter and/or process beef. That is where our issue with *E. coli* has been this year, not with pork.

The CHAIRMAN. Not any evidence with pork?

Dr. RAYMOND. No.

The CHAIRMAN. Well, I appreciate that. Does FSIS certify that a plant's HAACP plan is effective for ensuring food safety? Do you have any kind of a certification process?

Dr. RAYMOND. We don't certify the plants, sir. We make sure they follow their plans.

The CHAIRMAN. They make their plan, and you check that they are following their own plan?

Dr. RAYMOND. That is correct.

The CHAIRMAN. Well, I appreciate what you have had to say. Before we adjourn, does the Ranking Member have any remarks you would like to make in closing?

Mr. HAYES. Good hearing, Mr. Chairman. Thank you.

The CHAIRMAN. Okay. Well, I want to thank you, Mr. Secretary, for coming and sharing with us today. I think we are on the same concern, that we want our producers to do the very best they can. We want to protect them. I make no apologies that I am one of those and want them to have every opportunity to stay in their business and can grow their business. Of course we all have to base this on consumer protection and making sure that consumer gets what they think they are getting and are getting it safely. And so some of the comments you have made today were encouraging. I appreciate the things that you are concerned about and what innovations you are setting into motion. We thank you for doing that, and we will probably keep a continuing dialogue with you about how that is going and wish you continued success in doing so. So with that, I want to thank you for the time you spent with us today. In closing and adjournment, under the rules of the Committee, the record of today's hearing will remain open for 10 days to receive additional material and supplementary written responses from the witness to any questions posed by Members of the panel. The hearing of the Subcommittee of Livestock, Dairy, and Poultry is hereby adjourned.

[Whereupon, at 4:00 p.m., the Subcommittee was adjourned.]
[Material submitted for inclusion in the record follows:]

QUESTIONS SUBMITTED TO DR. RICHARD RAYMOND, UNDER SECRETARY FOR FOOD SAFETY, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Canada

Question 1. During FSIS' audit of Canada's meat, poultry and egg products inspection system (May 1–June 6, 2007), CFIA delisted one establishment and issued Notices of Intent to Delist to an additional six establishments (out of 24 total establishments visited) for deficiencies in their Hazard Analysis and Critical Control Point (HACCP) systems, sanitation standard operating procedures (SSOP), and/or sanitation performance standards (SPS). Further, according to FSIS' audit report, auditors found numerous deficiencies at the Canadian plants, including:

- "In 20 of 21 establishments, CFIA was not enforcing all of the U.S. regulatory requirements, which are equivalent to Canadian requirements." (p. 7)
- "Seventeen of the 20 slaughter and/or processing establishments (including cold storage) audited had deficiencies in the implementation, maintenance, corrective actions, and/or record-keeping requirements of the SSOP. These deficiencies resulted in both potential and direct product contamination." (p. 11)
- "Nineteen of the 20 slaughter and/or processing establishments (including the cold storage) audited had deficiencies in SPS." (p. 11)
- "Three of the nine slaughter establishments had deficiencies in the generic *E. coli* testing program." (p, 14)
- "There was no Canadian method for *Salmonella* analysis of meat and poultry products that had been deemed equivalent by the U.S." (p. 16)
- "Some inspection personnel were not well-trained in the performance of their inspection tasks." (p. 16)

Based on these findings, how did FSIS conclude that the Canadian inspection system is equivalent to the U.S. system?

Answer. When conducting audits, the program auditors of the FSIS Office of International Affairs' International Audit Staff usually identifies some issues and deficiencies that have not been adequately addressed by the Central Competent Authority (CCA) in each of the countries that export meat, poultry, and processed egg products to the United States. Each of these issues and deficiencies must be evaluated as they relate to the entire inspection system, and FSIS considers all of these issues and deficiencies when the agency is determining whether or not the system is equivalent. The CCA is expected to recognize the concerns raised by the auditors and to address and correct them in a timely manner, in the same way that the management of a domestic establishment is expected to address concerns and deficiencies raised by FSIS inspection personnel.

The deficiencies identified during FSIS' May 1–June 6, 2007, audit of Canada's meat, poultry, and processed egg products inspection system, taken as a whole, were not of such a nature, extent, and degree that the system was deemed not equivalent to that in the United States. For example, even though the methods that Canada was using to test meat and poultry products for *Salmonella* species were not the same as those employed by FSIS and had not been submitted to FSIS for equivalence determination, they were nonetheless methods considered adequate by other recognized authorities, such as the Association of Official Analytical Chemists.

The finding that some inspection personnel "were not well-trained in the performance of their inspection tasks" referred, for the most part, to a minority of frontline inspectors who did not adequately understand the need for conducting hands-on pre-operational sanitation inspection each time the task arose in Canada's computer-generated task-assignment program. According to one of the auditors who participated in the May–June 2007 audit of Canada, the CCA had already initiated a program to increase the field inspectors' awareness and understanding of the duties in question.

As part of FSIS' implementation of additional requirements for imported meat and poultry products from Canada, the agency increased reinspection and testing for *Salmonella, Listeria monocytogenes*, and *E. coli O157:H7* at import houses beginning on November 9, 2007. Normal levels of testing for *Listeria monocytogenes* and *Salmonella* in ready-to-eat product resumed on November 28, 2007 after the increased testing revealed no problems with Canadian products exported to the United States.

Question 2. On November 3, FSIS announced that it would immediately conduct a follow-up audit of the Canadian food safety system that will include beef exporting establishments similar to Ranchers Beef, Ltd. What has that audit team found?

Answer. Regarding the Canadian Food Inspection Agency's (CFIA) *E. coli O157:H7* controls:

- CFIA has a monitoring program for testing all federally registered ground beef establishments for *E. coli O157:H7*. This includes establishments certified to export ground beef to the United States.
- CFIA is using *E. coli O157:H7* laboratory testing methods (MFLP 80 and MFLP 90) that have not been deemed equivalent by FSIS. This was a finding identified during FSIS' May–June 2007 audit. These two methods were submitted to FSIS on November 8, 2007, for equivalence approval.
- At the time, CFIA did not have an *E. coli O157:H7* program for testing beef trimmings produced for the domestic or the export market. FSIS has required that CFIA have such a program, as is the case for all of our trading partners. It began on January 20, 2008.

Regarding a review of beef slaughter establishments similar to Rancher's Beef in start-up and operations:

- Three establishments have been identified as being similar to Rancher's Beef, i.e., opened for the purpose of handling an abundance of cattle that were not eligible to be exported to the United States due to USDA's Animal and Plant Health Inspection Service's (APHIS) restrictions on importation of cattle more than 30 months of age.
- Audits of these three establishments were conducted on Nov. 9 and Nov. 13, 2007.
- Two of these establishments were audited on site and the third had a records audit of controls and testing for *E. coli O157:H7* in raw beef products and raw beef manufacturing trim intended for export to the United States for use as raw ground beef.
- The two establishments that were audited on site identified *E. coli O157:H7* as a hazard in the HACCP plan, were testing lots of product for *E. coli O157:H7*, were not re-testing positive (or presumptive positive) lots, and were using an intervention (lactic acid application to carcasses) in slaughter.
- CFIA was not performing verification testing for *E. coli O157:H7* in either of these establishments, but was receiving copies of lab reports from establishment *E. coli O157:H7* testing.
- In the establishment in which the records audit was performed, no issues arose regarding food safety programs or monitoring documentation.

Question 3. As part of FSIS' institution of additional requirements for imported meat and poultry products from Canada, the agency will increase testing for *Salmonella, Listeria monocytogenes*, and *E. coli O157:H7* at import houses.

If a sample of Canadian product taken by FSIS during re-inspection comes back positive for *E. coli O157:H7*, will the Canadian firm that produced the product be subject to follow-up sampling by the Canadian Food Inspection Agency (CFIA), pursuant to FSIS Notices 17–07 and 62–07?

Answer. Yes.

Question 4. Will the same supplier be subject to an audit by CFIA that is equivalent to a food safety assessment, pursuant to FSIS Notice 64–07?

Answer. Yes.

Question 5. Finally, will the Canadian firm be put in to Systems Tracking *E. coli O157:H7*-Positive Suppliers database, pursuant to FSIS Notice 66–07?

Answer. Yes.

Outbreak Investigation Coordination

Question 6. It appears that states are conducting outbreak investigations in silos, rather than communicating with each other or the Federal Government. For example, on November 1, FSIS issued a recall release for 3.3 million pounds of frozen meat pizza that had been linked to a foodborne illness outbreak spanning ten states and that included 21 reported illnesses. The Tennessee Department of Health had conducted a case control study and determined that meat pizza was the common thread in the patients, yet, according to FSIS officials, FSIS only learned about the outbreak 6 days prior to the recall.

Is it typical that FSIS is made aware of potential foodborne illness outbreaks only after a state concludes its investigation?

Answer. Working closely with state public health agencies is a key priority for FSIS. The point at which state public health agencies contact FSIS varies from state to state. Many states inform FSIS very early in an investigation, while others wait until they're ready for Federal agency food trace-back and/or recall actions. Generally speaking, FSIS is notified when a state begins to suspect FSIS-regulated product is associated with illness. FSIS has been forging better relationships with its public health partners and has made significant improvements. In pursuit of doing still better so we can learn about outbreaks earlier and improve public health, FSIS will host a meeting and tabletop exercise focused on "Better Communications, Better Public Health Outcomes: Strategies for Improved Coordination During Foodborne Outbreaks" in early 2008.

Question 7. Was it CDC that first notified FSIS about the outbreak related to frozen meat pizza?

Answer. Yes. The Centers for Disease Control and Prevention (CDC) alerted FSIS about the outbreak related to frozen meat pizzas. In many situations, states report details on outbreak investigations to FSIS if and when they suspect FSIS-regulated product is associated with illness. In some instances, states provide CDC with their initial report. CDC will, in turn, report details on an outbreak investigation to FSIS if a FSIS-regulated food product is suspected or confirmed to have caused the outbreak. The latter occurred during the outbreak associated with frozen meat pizzas.

Question 8. How can FSIS and the Federal Government improve communication between state health departments and the Federal Government?

Answer. FSIS works to continually improve communications with state health departments. FSIS Public Health and Epidemiology Liaisons make routine contact with state public health officials and has made big strides toward achieving this goal. FSIS is a member of the Council to Improve Foodborne Outbreak Response (CIFOR). The Council's goal is to improve foodborne disease surveillance, outbreak detection, investigation, and reporting at the local, state, and Federal levels. CIFOR was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. FSIS is also a partner in OutbreakNet, a network of public health epidemiologists at the local, state, and Federal levels who investigate foodborne disease outbreaks. FSIS helps improve communications between state health departments and Federal agencies through participation in these activities. FSIS will host a meeting and tabletop exercise focused on "Better Communications, Better Public Health Outcomes: Strategies for Improved Coordination During Foodborne Outbreaks" in early 2008. The meeting will include CDC, the Food and Drug Administration, state and local public health agencies, and industry and consumer organizations.

Question 9. Is there any agreement under which states are compelled to report foodborne illness outbreaks or *E. coli* illnesses to the CDC or FSIS?

Answer. FSIS is not aware of any agreements that compel or require states to report outbreaks. However, CDC and FSIS strongly encourage states to report foodborne outbreaks. It is important to note that the lead responsibility for outbreak and illness investigation is held by state and local public health agencies. CDC and FSIS assist states in their investigations. FoodNet (which is centrally managed by CDC and cosponsored by FDA and USDA, and involves the participation of ten state health departments), includes performance standards for outbreak reporting. The performance standards for outbreak reporting are set as goals, not requirements. Regarding the reporting of *E. coli O157:H7* illnesses, laboratory-confirmed infections caused by *E. coli O157:H7* were added in 1994 to CDC's Nationally Notifiable Disease List.

Question 10. FSIS issued a public health alert on October 9, followed by a recall 2 days later, for pot pies that were linked to an outbreak of salmonellosis. In fact, according to the CDC, there were 238 illnesses with matching genetic fingerprints identified in 34 states between January 1 and October 19, 2007. When was FSIS first notified about this outbreak?

Answer. On July 31, 2007, CDC informed FSIS of its investigation of a cluster of 78 cases identified by molecular subtyping using single enzyme pulsed-field gel electrophoresis analysis. At that time, the cluster was not considered an outbreak because it was unclear whether or not a common source of infection was the underlying cause of the rise in cases.

Question 11. Was there any coordination of the outbreak investigations, or were investigations conducted independently by the states?

Answer. The investigation was centrally coordinated by CDC. States investigated illnesses identified in their respective states and provided details on each case to CDC.

Question 12a. After 10 months of the outbreak, what led FSIS to initially issue a public health alert, and then, only 2 days later, issue a recall for an "undetermined amount" of products?

Answer. The CDC began to assist states and centrally coordinate the multi-state investigation in late July 2007. State public health investigators had investigated illnesses in states prior to CDC's involvement. Despite considerable investigative effort by CDC and state public health agencies, the food vehicle remained elusive until October 4, 2007, when pot pies were identified by a state as a suspect food vehicle. The multi-state epidemiologic case control study led by CDC implicated pot pies as the likely food vehicle on October 8, 2007. The findings of the study were presented to FSIS on October 8, 2007, and investigative findings at the manufacturing plant led to the issuance of the public health alert by FSIS and the subsequent recall of pot pies.

Question 12b. What changed in 2 days?

Answer. On October 3, 2007, the CDC launched a multi-state case control study with detailed questions on chicken and egg consumption. Based on additional information provided by the Minnesota Department of Health, CDC added questions to the study on October 5, 2007, focusing on frozen chicken and turkey pot pie product consumption. CDC notified FSIS on October 5, 2007, that states had identified an FSIS-regulated product as the potential source of contamination.

After discussions with CDC and the states throughout the weekend, on October 8, 2007, FSIS personnel began to gather additional information at the establishment where these frozen pot pie products were produced. The company voluntarily ceased operation of their pot pie line on October 8, 2007.

On October 9, 2007, FSIS issued a public health alert that Banquet brand and generic store brand frozen not-ready-to-eat pot pie products with "P–9" printed on the side of the package might have been the potential source of reported illnesses caused by *Salmonella*. This determination was based on epidemiological evidence collected by the CDC and state public health departments.

On October 10, 2007, FSIS sent a team of specially-trained Enforcement, Investigation, and Analysis Officers (EIAOs) to conduct a food safety assessment at the establishment.

On October 11, 2007, based on the findings of FSIS' food safety assessment, ConAgra Foods voluntarily recalled an undetermined amount of all varieties of frozen pot pie products in commerce that might have been linked to an outbreak of salmonellosis.

Inspection

Question 13. In a staff briefing following the Topps recall in New Jersey, FSIS officials explained that they had found that in a recent analysis, inspector in the plant had only completed four out of 20 HACCP 02 procedures. In addition, officials explained that it's not clear when inspectors complete a procedure, exactly which verifications took place. For instance, FSIS management personnel had no way of determining whether the inspectors that had completed a HACCP 02 procedure had actually verified that the plant had Certificates of Analysis from their beef suppliers.

Has FSIS considered making changes to the Performance-Based Inspection System in order to allow inspectors to specify exactly which verifications they conduct during a shift?

Answer. FSIS is currently making a change to its inspection methodology that will be one key component of the Public Health Information System (PHIS). As part of the data collection for PHIS, FSIS inspection personnel will be expected to document which set of factors were considered in arriving at a determination of regulatory compliance or noncompliance. Full deployment is scheduled for late FY 2009. In the meantime, FSIS is developing plant-specific Performance-Based Inspection System schedules and other reports that a district analyst in each district office will routinely prepare and provide to the front-line supervisor. The front-line supervisor will use this information to manage the appropriate implementation of inspection activities in each establishment under his or her purview.

Question 14. Has FSIS determined the reason that the inspector at the Topps plant only completed four of 20 HACCP 02 procedures leading up to the recall? If so, please explain the reason.

Answer. Performance-Based Inspection System (PBIS) data revealed that the procedure 03B02 was scheduled 20 times and not performed 16 times during the sum-

mer of 2007. In three instances an unscheduled HACCP 03B01 was performed on the same day instead of the scheduled HACCP 03B02 procedure (HACCP 03B02 procedures take longer to perform then HACCP 03B01 procedures). Once in July, and two additional times in September, the CSI performed an unscheduled 03B02 procedure on individual days when that procedure was not scheduled. Although the 03B01 scheduled procedures were performed at a high rate of 80 percent, the scheduled 03B02s were performed at a lower than expected rate.

There are two HACCP procedures: an "01" procedure and an "02" procedure, for verifying that an establishment is meeting the regulatory requirements of 9 CFR Part 417, which are the HACCP regulations. The 03B is the raw, ground process and so the 03B01 is a HACCP "01" procedure performed for a raw ground process and the 03B02 procedures is a HACCP "02" procedure for the raw, ground process.

The HACCP 01 procedure is for verifying, at random, one or more of the HACCP regulatory requirements. There are five regulatory requirements—monitoring, verification, corrective actions, record-keeping, and reassessment. The inspector is to use a random process for selecting the regulatory requirements to be verified.

The HACCP 02 procedure is for verifying all applicable regulatory requirements (monitoring, verification, record-keeping, corrective actions, and reassessment) at all of the CCPs in the HACCP plan for a specific production.

Since the HACCP 01 procedure focuses on only one aspect of the HACCP system at a time and allows the inspector to select the specific aspect of the HACCP system he/she will verify, it is less likely to uncover a systemic problem with the system. Because the HACCP 02 procedure is performed on a specific production lot, it is possible that on the occasions the procedure was performed everything had been properly executed. The HACCP 02 procedures are scheduled often enough to ensure that if there are systemic problems with the company's execution of its HACCP and prerequisite programs, such noncompliance would be discovered. That is why it is important to perform the scheduled procedures often enough to ensure that over time, these problems can be uncovered through these and other verification activities, such as agency sampling programs.

FSIS generally expects that scheduled procedures will be conducted as scheduled, but we realize there also needs to be some flexibility to allow substitution of other procedures when the conditions in the plant warrant this. The district analyst reports referenced in the response to *Question 13* and *Question 16* will provide better, more routine, data to front-line supervisors to enable them to make timely corrections in work activity by the assigned CSI.

As discussed in the briefings, FSIS believes that inspection personnel at this and other establishments did not fully understand the verification expectations regarding Certificates of Analysis and Letters of Guarantee. The agency issued training in association with FSIS Notice 65–07 that addressed this incomplete understanding of the verification expectations.

Question 15. Is it common at other grinding establishments that HACCP 02 procedures are performed at such a low rate?

Answer. The low rate of scheduled 02 procedures performed at this plant during this time period is not common. Although the 03B01 scheduled procedures were performed at an acceptable rate of approximately 80 percent, the scheduled 03B02s were performed at a lower than expected rate. In addition, the unscheduled 03B02 procedures were performed at a higher than expected rate. FSIS generally expects that scheduled procedures will be conducted as assigned. The district analyst reports referenced in the response to *Question 13* and *Question 16* will provide better, more routine, data to frontline supervisors to enable them to make timely corrections in work activity by the assigned CSI.

Eighty percent completion exceeds the AssuranceNet performance measure for HACCP scheduled procedures. That performance measure was based on the annualized output of approximately 2,500 inspector assignments conducting nine million food safety procedures.

Question 16. Are District Managers or other FSIS personnel responsible for reviewing inspectors' assignments and recognizing when assigned tasks are not being completed? What does FSIS personnel responsible for supervising inspectors do when assigned tasks are not being completed?

Answer. Yes. FSIS currently has management control data that is routinely viewed by the district and field supervisors that indicate whether minimum performance rates of certain assigned tasks (such as various quality procedures including finished product standards in poultry or labeling) are being conducted. The management control identifies the performance rate at the district and the circuit level, but not down to the plant level. Currently, FSIS is working with the districts and an external contractor to identify which specific analytical tools and reports are

needed by the district office management team to identify issues specific to an assignment and individual plant. This assessment will include a detailed analysis of the types of software tools and reports used to track procedures performed below the front-line supervisor level and is expected to be completed by the end of February 2008. The district and field supervisors will then have uniform reports that they will use to provide improved supervisory oversight of the execution of in-plant inspection activities.

However, it should be noted that not all tasks are equal in priority. Public health tasks take precedence.

Question 17. Why does FSIS not require an establishment to notify the agency when the establishment changes its HACCP plan?

Answer. Establishments are required by regulation (417.2(d)) to sign and date their HACCP plans whenever the plans are modified. Although FSIS regulations do not require direct notification of FSIS, inspectors are tasked with reviewing the establishments' plans, and are then informed by the dates and signatures that the plans have been modified. Instituting a requirement that establishments notify FSIS would require notice and comment rulemaking under the Administrative Procedures Act.

Inspectors are expected to be in the establishment daily making observations. In addition, weekly, inspectors meet with plant management to discuss the week's inspection findings and concerns. At this time, FSIS considers these actions to be sufficient for FSIS inspection program personnel to be informed about changes made to the HACCP plan. Moreover, when the HACCP plan is substantively modified to require a reassessment, the plant is obligated by the current regulations to ensure that the changes are validated and that on-going verification demonstrates that the food safety system is working as intended. Should FSIS determine that its current procedures are insufficient, FSIS will consider rulemaking to mandate such notification. Meanwhile, in the public health information system under development to replace the current PBIS process for scheduling inspection verification procedures, FSIS is designing the replacement system to cause the in-plant inspection personnel to document the process controls in place in the establishment and then, on a regular basis, capture when changes are made to the system on file, as well as to capture how the system was changed. By focusing the in-plant inspection personnel on knowing what the current design is of the food safety system, FSIS believes that inspection program personnel will become more attune to subtle changes in the establishment's food safety system.

Question 18. Does USDA–FSIS approve companies' HACCP plans or review them to ensure that they include adequate procedures to prevent likely hazards from occurring? Does FSIS approve any changes to companies' HACCP plans?

Answer. The HACCP regulations were written to provide industry with the flexibility and responsibility to identify food safety hazards specific to their process and a method specific to their process for preventing the identified hazards. FSIS determines implementation compliance through verification activities by in-plant personnel and through assessment of the plant's HACCP plan design by individuals trained in analysis of food safety systems. If the HACCP plan is deemed inadequate, the agency uses due process to advise the establishment of its finding. The establishment is typically provided an opportunity to comply with HACCP regulations before FSIS effects a suspension of inspection personnel because of an inadequate food safety system.

Question 19. What has FSIS found following the *E. coli O157:H7* control reassessments at beef establishments and the subsequent "Responses to the Reassessment" document that inspectors submitted pursuant to Notice 65–07?

Answer. FSIS is in the final stages of analyzing the data. Thus, the information provided below is preliminary. The agency will be pleased to provide a briefing when the information is complete.

As of January 11, 2008, 96.2 percent of establishments reassessed their HACCP Plans. Of those who reassessed, 32.6 percent changed their HACCP Plans, 14.7 percent changed their SSOP Plans, and 35.0 percent changed their prerequisite programs as a result of the reassessment.

FSIS has received a variety of reasons why beef establishments responded the way they did to Notice 65–07, depending on whether or not the establishment changed its HACCP Plan, Sanitation Standard Operating Procedures Plan, or prerequisite plan or program. Among the reasons for changing HACCP plans, for example, were: adding or modifying one or more critical control points; no longer using table beef trim in ground beef; requesting Certificates of Analysis from beef suppliers; testing bench beef trimmings that are used in products; increasing the frequency of sampling and testing; increasing the testing of the water supply; having

stopped grinding beef; and having changed the raw-not-ground plan by stopping the tenderization of raw intact meat from the processing plan.

Question 20. How many plants was the inspector assigned to Topps responsible for inspecting at the time of this recall? Was the workload for that inspector similar, heavier or lighter than other inspectors responsible for similar kinds of facilities? Approximately how many hours per day did the inspector spend in the Topps facility?

Answer. Overall, the average number of plants on assignments with similar facilities was 3.47 plants per assignment. The Topps assignment was changed from four plants to five plants, which lasted for approximately 1 year. The assignment was changed again to three plants just before the recall occurred. These adjustments were due, in part, to plants moving into the Elizabeth, New Jersey, area and more recently, the opening of a new plant in that geographic area.

Inspection program personnel who have been assigned to Topps have spent, on average, 1½ to 2 hours per day at Topps as part of their normal 8 hour shift. The plants in the Topps assignment are in a metropolitan area and are within proximity of each other, so there is little travel time involved in the workday.

Question 21. When there is a shortage of inspectors in a given area, how does USDA ensure that each plant is visited by an inspector each day?

Answer. FSIS has relief inspection personnel whose job is to fill a position when there is a vacancy or personnel are on previously scheduled leave. Further, FSIS' general structure of assignments is such that, if an unforeseen staffing shortage occurs (e.g. due to sick leave or short-term training), the work in the vacant assignment can be distributed to other assignments nearby on a short-term basis. In the latter situations, inspection personnel prioritize their work activity.

Question 22. When an inspector is assigned to more than one processing plant, how many hours is the inspector expected to spend in each plant? How many hours is an inspector assigned to a single processing plant expected to spend in the plant?

Answer. FSIS is obligated to provide inspection coverage. Inspection assignments are determined through a work measurement process that takes into consideration factors such as administrative time, within-the-plant travel based on the square footage of the facility, and the time required to accomplish the necessary food safety and other consumer protection tasks per plant. These tasks were studied, timed, and annualized to determine the staff year associated with the task being performed in an establishment. The amount of time an inspector assigned to more than one processing plant spends in each plant is dependent, in part, on the complexity of activities that occur in each plant. For example, if the work measurement determines a single processing plant to have a workload that constitutes a full workload for one person, the inspector would spend all day at that one assignment. This exceptional situation typically only occurs in remote areas where there are no other plants within commuting distance. Geographical and logistical reasons also affect inspector assignments; adding travel time between distantly situated plants may or may not be an acceptable trade-off, given the situation.

Question 23. When FSIS takes samples for *E. coli O157:H7* and finds positive samples, are those routinely sent for PFGE analysis and are those PFGE patterns routinely entered into PulseNet?

Answer. All *E. coli O157:H7* isolates from FSIS' sampling program are sent to the FSIS Lab in Athens, Georgia, for pulsed-field gel electrophoresis analysis and subsequent uploading into the PulseNet database.

Question 24. Does USDA receive test results for samples taken by companies who have their own microbiological testing programs? If yes, are positive samples sent for PFGE analysis? Are those PFGE patterns routinely entered into PulseNet?

Answer. FSIS inspectors review the test results for samples taken by companies who have their own microbiological testing programs. It is FSIS' understanding that most company testing does not include a culture confirmation component, which would result in an isolate that could be subjected to pulsed-field gel electrophoresis (PFGE) analysis. Even if a PFGE analysis were conducted, private laboratories are not part of the PulseNet Network.

PulseNet is a national network of public health and food regulatory agency laboratories coordinated by CDC. The network consists of: state health departments, local health departments, and Federal agencies (CDC, USDA FSIS, and FDA).

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