Food Safety and Inspection Service

Office of Public Health Science

Annual Report

2011

A Message from the OPHS Assistant Administrator

Despite serious fiscal constraints in Fiscal Year 2011 (FY2011), the Office of Public Health Science (OPHS) met its mission critical priorities and successfully contributed to the mission of the Food Safety and Inspection Service. OPHS received a planning allocation of $60.6 million. The anticipated budget contained several initiatives for outbreak investigations and Hazard Analysis and Critical Control Point (HACCP) testing. Unfortunately, the Continuing Resolution (CR) did not include these initiatives in the OPHS budget.

Anticipating additional painful cuts, OPHS took decisive action by implementing a hiring freeze in November 2010. The office halted action on 17 recruitment actions, which saved the Agency well over $1 million. OPHS correctly measured the pulse of the situation, preceding the Agency's hiring freeze by several months. In addition, the Field Service Laboratories worked with OPHS headquarters to realign funding to cover the anticipated deficit. FSIS reduced independent peer reviewers' contract funds for activities related to the quality and accuracy of food safety risk assessments by $140,000. In addition, the Office cut $275,000 for new contracts on ad hoc scientific endeavors and $100,000 for training. On May 20, 2011, OPHS received the CR budget of $49.7 million, which was more than $170,000 short of the anticipated allocation minus the initiatives.

Despite these challenges, OPHS continued to fund mission critical projects. In particular, FSIS used an OPHS risk profile to determine whether non-O157 STEC represent an "unusual and urgent food safety problem" as defined by FSIS officials in 1994 when defending FSIS' policy on *E. coli* O157:H7 in a Federal district court. The risk profile examined non-O157 STEC based on six criteria used to define *E. coli* O157:H7 as an adulterant. FSIS used the OPHS risk profile to make the important policy position and announced six non-O157 STECs as adulterants in beef on September 20, 2011 in a *Federal Register* Notice.

In addition, FSIS collaborated with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) on the Interagency Food Safety Analytics Collaboration (IFSAC). IFSAC offers a forum where the three agencies can generate more accurate estimates of foodborne illness source attribution across the broad range of commodities as well as locations in the food supply chain. This fiscal year, the group drafted a Strategic Plan that provides an overview of the steps to generate pathogen-specific illness attribution estimates with uncertainty bounds. These improved estimates of foodborne illness source attribution will provide information critical to create effective food safety initiatives and polices that will help reduce the number of foodborne illnesses in the U.S. population.

The National Residue Program developed a new sampling plan and scheduling algorithm. This bold new sampling approach provides a broader scan of potential chemical residues. With more intensive testing, FSIS will improve its ability to determine true chemical exposure in regulated products and respond more nimbly to emerging chemical residue issues that threaten public health. Furthermore, the new scheduling algorithm will reduce the oversampling complaints from industry and provide more information with fewer resources.

Other successes to highlight include the Office's participation in the Codex ad hoc Task Force on Antimicrobial Resistance, which developed guidelines to address the risks associated with food and animal feed. OPHS coordinated with the CDC on the investigation of *Salmonella* Heidelberg in ground turkey, which led to one of the largest recalls of ground turkey in the nation's history. OPHS invited suggestions from stakeholders for the *Listeria monocytogenes* risk assessment on ways to reduce the risk of listeriosis in ready-to-eat foods. Finally, OPHS reached out to international partners and encouraged them to adopt safe microbiological standards to ensure the safety of food products for the international community and for import into the United States.

Despite a budgetary contraction, OPHS accomplished important goals that contributed to the FSIS mission. I am proud of how our employees pulled together and completed projects in a timely and professional manner. This document includes a select group of accomplishments that illustrate the accomplishments of this Office during the fiscal year. I encourage you to review these examples and contact our office to learn more about any this important work.

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Introduction

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) aims to ensure that meat, poultry, and processed egg products distributed in commerce for use as human food are safe, wholesome, and accurately labeled. FSIS received statutory authority to accomplish these goals through four acts:

- The Federal Meat Inspection Act of 1906;
- The Poultry Products Inspection Act of 1957;
- The Egg Products Inspection Act of 1970; and
- Voluntary inspection under the Agricultural Marketing Act of 1946.

The Office of Public Health Science (OPHS) provides a sound scientific, medical, veterinary, analytical, and epidemiological foundation to FSIS and USDA to reduce or prevent foodborne illness. OPHS supports FSIS by achieving specific goals within the FSIS mission.

2011–2016 Strategic Plan

Strategic Theme: Prevent Foodborne Illness

Goal 1: Ensure that food safety inspection aligns with existing and emerging risks
Goal 2: Maximize domestic and international compliance with food safety policies
Goal 3: Enhance public education and outreach to improve food-handling practices
Goal 4: Strengthen collaboration among internal and external stakeholders to prevent foodborne illness

Strategic Theme: Understand and Influence the Farm-to-Table Continuum

Goal 5: Effectively use science to understand foodborne illness and emerging trends
Goal6: Implement effective policies to respond to existing and emerging risks

Strategic Theme: Empower People and Strengthen Infrastructure

Goal7: Empower employees with the training, resources, and tools to enable success in protecting public health
Goal 8: Based on the defined Agency business needs, develop, maintain, and use innovative methodologies, processes, and tools, including the Public Health Information System (PHIS), to protect public health efficiently and effectively and to support defined public health needs and goals.

In support of the FSIS mission, OPHS characterizes and quantifies foodborne pathogens, specifically *Escherichia coli*, *Salmonella*, *Campylobacter*, and *Listeria monocytogenes*, in FSIS-regulated meat, poultry, and egg products in order to support the Agency efforts to prevent or remove unsafe product from commerce. OPHS reports these results in baselines studies, reports, scientific publications and presentations, and other technical documents. OPHS employees develop risk assessment models to predict how changes in Agency policies and industry practices could affect public health. In addition, employees conduct foodborne illness investigations. The Field Service Laboratories staff analyzes samples for the presence and concentration of pathogens, as well as violations in chemical residues and veterinary drugs in FSIS-regulated products. To accomplish these goals and efficiently use Federal resources, OPHS coordinates and collaborates with other USDA agencies, including the Foreign Agricultural

Service (FAS), Agricultural Research Service (ARS), and Agricultural Marketing Service (AMS). In addition, OPHS coordinates with other Federal agencies, including the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA).

OPHS Organization
OPHS employs 300 staff at headquarters in Washington, DC, 3 Field Service Laboratories, and several field offices.

Headquarters staff works in three scientific divisions and one administrative division.

The **Microbiology Division** (MD) provides scientific support to FSIS on microbiological issues and assists in developing the scientifically sound policies for the protection of meat, poultry, and egg products.

The **Applied Epidemiology Division** (AED) supports the FSIS mission by working with Federal, State, and territorial partners to investigate and prevent exposure to potential foodborne hazards, including physical contaminants, zoonotic diseases, antimicrobial resistance, and foodborne disease agents.

The **Risk Assessment Division** (RAD) supports the FSIS mission by conducting food safety risk assessments to guide rulemaking, predict the public health impact of changes in Agency policies or industry practices, allocate inspection resources based on public health risk, and evaluate the effectiveness of implemented food safety policies. In addition, the division participates in the multi-agency National Residue program (NRP) to identify and test for chemical residues in food animals and egg products.

The **Resource and Program Management Staff** (RPMS) manages the planning and execution of budget, personnel management, and other essential administrative functions to ensure the efficient utilization of program resources to accomplish program strategic goals.

OPHS operates four ISO 17025-accredited Field Service Laboratories located in the eastern, central, and western United States. Field Service Laboratory staff coordinate and conduct analytical services in chemistry, microbiology, and pathology to ensure the safety of meat, poultry, and egg products. All Field Service Laboratories analyze for *E. coli* O157:H7, *Salmonella*, *Campylobacter*, and *L. monocytogenes*. Each Field Service Laboratory is responsible for a designated set of chemical analyses that collectively provide for all the chemicals tested within the NRP.

The **Eastern Laboratory,** in Athens, GA, analyzes chemical, microbiological, pathological, and outbreak samples. The Outbreaks Section of the Eastern Laboratory (OSEL) processes outbreak samples and performs pulse field gel electrophoresis (PFGE). In addition, OSEL performs other molecular techniques, such as Multi-Locus Variable Number Tandem Repeat (MLV-VNTR) analyses on *E. coli* and molecular serology on *Salmonella sp.* isolates.

The **Midwestern Laboratory,** in St. Louis, MO, analyzes tissue samples for a broad range of antibiotics and chemical residues. Additionally, it analyzes for foodborne pathogens on samples submitted for microbiological testing.

The **Western Laboratory,** in Alameda, CA, analyzes chemical and microbiological samples, as well as all bacteriological analyses of canned and vacuum-packed regulated products. In addition, the chemical section of the laboratory analyzes samples for the NRP for pesticides, beta-agonist growth promoters, and various anti-microbial drugs.

The **Food Emergency Response Network** (FERN) section coordinates Federal, State, and local laboratories on emergency response and recovery activities. FERN assists in emergencies associated with food products, as well as national or regional emergencies involving the food infrastructure.

The **Laboratory Quality Assurance Division** (LQAD) administers chemical, microbiological, and veterinary pathological quality assurance and oversees laboratory alignment with ISO-17025 accreditation. LQAD manages the laboratory programs for non-Federal analytical laboratories, including the Accredited Laboratory Program (ALP), Pasteurized Egg Product Recognized Laboratory Program (PEPRLab), and Trichinella Approved Laboratory Program (TALP).

Tables and Figures

Figure 1. OPHS FY2011 budget allocation
OPHS distributed approximately $50.2 million based on the 2011–2016 Strategic Plan. The Office received an additional $280,000 at the end of the fiscal year to purchase lab supplies.

FSIS Goal	Percent Budget	Budget Allocation
GOAL 1	51.5%	$26.2M
GOAL 2	9.9%	$4.91M
GOAL 4	10.4%	$5.16M
GOAL 5	13.5%	$6.66M
GOAL 8	14.7%	$7.26M

Figure 2. FSIS Field Service Laboratories sample analyses for FY2011

FY2011 Eastern Laboratory Sample Analyses

	Completed Samples					Completed Analyses				
Activity	**1st Qtr**	**2nd Qtr**	**3rd Qtr**	**4th Qtr**	**TOTAL**	**1st Qtr**	**2nd Qtr**	**3rd Qtr**	**4th Qtr**	**TOTAL**
Food Chemistry	245	214	144	179	782	298	228	287	338	1,151
Food Microbiology*	4,609	4,559	4,710	4,696	18,574	11,424	11,357	12,321	12,100	47,202
HACCP Salmonella	2,203	1,776	1,430	2,608	8,017	2,336	1,846	1,524	2,823	8,529
HACCP Salm/Campy	0	0	0	459	459	0	0	0	2,274	2,274
Outbreak	9	2	75	82	168	14	2	78	86	180
Residue Chemistry	2,199	1,862	1,889	2,235	8,185	3,422	3,250	3,168	3,800	13,640
Pathology*	1,679	1,470	1,198	1,224	5,571	2,481	1,748	1,362	1,463	7,054
Total	10,944	9,883	9,446	11,483	41,756	19,975	18,431	18,740	22,884	80,030

***Includes for Pathology: Extraneous Materials; For Microbiology: Species ID**

FY2011 Midwestern Laboratory Sample Analyses

	Completed Sample					Completed Analyses				
Activity	**1st Qtr**	**2nd Qtr**	**3rd Qtr**	**4th Qtr**	**TOTAL**	**1st Qtr**	**2nd Qtr**	**3rd Qtr**	**4th Qtr**	**TOTAL**
Food Microbiology	4,184	3,872	3,864	4,421	16,341	8,274	8,156	7,532	8,860	32,822
HACCP Salmonella	2,376	2,254	2,065	2,967	9,662	2,547	2,506	2,163	3,235	10,451
HACCP Salm/Campy	0	0	0	366	366	0	0	0	1,535	1,535
Residue Antibiotics	3,301	2,987	3,029	3,004	12,321	6,520	5,989	5,701	5,402	23,612
Total	9,861	9,113	8,958	10,758	38,690	17,341	16,651	15,396	19,032	68,420

FY2011 Western Laboratory Sample Analyses

	Completed Samples					Completed Analyses				
Activity	**1st Qtr**	**2nd Qtr**	**3rd Qtr**	**4th Qtr**	**TOTAL**	**1st Qtr**	**2nd Qtr**	**3rd Qtr**	**4th Qtr**	**TOTAL**
Food Microbiology**	4,002	4,147	3,996	4,631	16,776	6,706	6,912	6,458	7,685.	27,761
HACCP Salmonella	1,826	1,755	1,368	2,364	7,313	1,891	1,962	1,449	2,772	8,074
HACCP Salm/Campy	0	0	0	365	365	0	0	0	1,147	1,147
Residue Chemistry	1,129	1,110	827	1,146	4,212	1,496	1,642	1,214	3,548	7,900
Total	6,957	7,012	6,191	8,506	28,666	10,093	10,516	9,121	15,152	44,882

****Includes for Microbiology: Canned Foods**

Overall Lab Totals	**27,762**	**26,008**	**24,595**	**30,747**	**109,112**	**47,409**	**45598**	**43,257**	**57,068**	**193,332**

Figure 3. Investigations and watches in FY2011

In FY2011, AED received and evaluated 744 consumer complaints; the Division investigated 104 of the complaints. The group investigated 38 foodborne illnesses and watches. The Division initiated seven recalls from six foodborne illness investigations. These investigations initiated the recall of more than 36 million pounds of FSIS-regulated product and more than 72,000 pounds of State-regulated product.

	Number of Investigations/ Watches	Number of Illnesses	Number of Hospitalizations	Number of HUS[†] Cases	Number of Deaths
E. coli Investigations	10	68	28	4	1
L. monocytogenes Investigations	1	8	4	N/A	3
Salmonella Investigations	7	699	130	N/A	1
Clostridium perfringes Investigations	0	.	.	.	.
E. coli Watches[*]	12	145	33	11	3
L. monocytogenes Watches[*]	2	147	142	N/A	30
Salmonella Watches[*]	5	71	9	0	0

[†] Hemolytic uremic syndrome (HUS) is a disorder resulting from an infection in the digestive system that produces toxic substances that destroys red blood cells and causes kidney injury.

[*] A watch is defined as possible involvement of FSIS-regulated product and human illnesses. In these cases FSIS-regulated product was not implicated by public health officials.

OPHS 2011 Accomplishments

FSIS Goal 1: Ensure that food safety inspection aligns with existing and emerging risks

OPHS Participates in Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance: When pathogens become resistant to antimicrobial agents, the effectiveness of current treatments diminishes. This situation can result from use of antimicrobial agents and the spread of antimicrobial resistance genes in the environment. The Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance (ITFAR) was formed within the Codex Alimentarius Commission, an intergovernmental body established to implement the Joint Food and Agriculture Organization/World Health Organization Food Standards Programme.

ITFAR provided guidance for addressing zoonotic foodborne antimicrobial resistance on an international level. The task force included participants from 36 member countries, 1 member organization, and observers from 9 international organizations. In 2007, ITFAR began a four-year term to develop guidance for assessing and managing the risk of zoonotic foodborne antimicrobial resistance. In FY2011, the Codex Alimentarius accepted the work of the task force and published *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*, CAC/GL 77- 2011.

Antimicrobial resistance is a major global public health concern and a food safety issue. The Task Force achieved consensus and completed the task on time. These guidelines provide national authorities and other risk managers and assessors with a structured risk analysis framework to address the risks associated with the transmission of antimicrobial resistant microorganisms or antimicrobial resistance genes through food and animal feed.

OPHS Participates on Interagency Task Force on Antimicrobial Resistance: OPHS collaborated with 10 different Federal agencies, experts, stakeholders, and the public to revise the Interagency Task Force on Antimicrobial Resistance (IFTAR) Action Plan. The plan, entitled *A Public Health Action Plan to Combat Antimicrobial Resistance*, articulates the Federal Government's strategy for addressing antimicrobial resistance on a national level. The revised Action Plan, published in August 2011, is the first in a decade and articulates to the public the Federal Government's strategy for addressing antimicrobial resistance that will be critical in the next three to five years. The Action Plan includes action items organized into four focus areas: Surveillance, Prevention and Control, Research, and Product Development. The Action Plan outlines, by focus area, specific goals, projects, or implementation steps important for addressing the problem of antimicrobial resistance. Participating agencies include the CDC, FDA, the National Institutes of Health (NIH), USDA, the Department of Defense (DoD), the Department of Veterans Affairs (VA), EPA, the Health Resources and Services Administration (HRSA), and the Department of Health and Human Services (HHS).

OPHS Participates in NACMCF to Enhance Safety of the Food Supply: OPHS played a critical role in re-establishing the charter for the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). NACMCF consists of a panel of food safety experts who provide external advice on scientific and technical food safety issues to FSIS. Past NACMCF recommendations to OPHS include the Hazard Analysis and Critical Control Points (HACCP) system and microbiological baselines.

NACMCF resumed functions in FY2011. The group focused on two projects—the Subcommittee on Control Strategies for Reducing Foodborne Norovirus Infections and the Subcommittee on Study of Microbiological Criteria as Indicators of Process Control or Insanitary Conditions. These projects are on-going. In addition, the USDA Agricultural Marketing Service (AMS) collaborated with NACMCF to strengthen the beef purchase specifications that affect the School Lunch Program. Finally, NACMCF benefitted from the viewpoint of Ms. Susan Grooters, a consumer representative and newest member to the committee.

OPHS Continues Baseline Studies to Evaluate Industry Practices: In 1992, FSIS began estimating the prevalence of target pathogens in regulated food commodities using data collected during baseline surveys. OPHS statisticians examined this data to address industry performance standards and provide future guidance to industry regarding effective process control. In FY2011, OPHS completed the Market Hog Baseline survey to update a risk assessment for a market hogs industry performance standard. In addition, OPHS began the Raw Liquid Egg Baseline Survey in collaboration with the FDA. OPHS will share baseline survey samples with the FDA, and they will analyze the samples using a new sub-typing system for *Salmonella*. FSIS Field Service Laboratory staff will compare this methodology to the traditional immunological method of serotyping, which is considered the "gold standard." If the new system is capable of delivering comparable results in less time and lower cost, the technology may become a staple for future baseline studies and regulatory testing. The new technology also shows promise for identifying the serotype of *Salmonella* at the time of pathogen identification. With further development and evaluation, this and similar technologies could be particularly useful for rapidly identifying contaminated products associated with a specific foodborne pathogen outbreak. In addition, the collaboration with FDA promises a long and close relationship.

OPHS Leads Investigations and Recalls of Tainted Products: The Consumer Complaint Monitoring System (CCMS) logged 744 consumer complaints. Of these complaints, 104 (14%) resulted in an in-plant investigation that either verified regulatory compliance or prompted corrective actions to be taken by the establishment. OPHS participated in 40 investigations and watches. The Office collaborated with CDC on nine investigations that spanned multiple states. In addition, OPHS collaborated with FDA on one multistate investigation. Six investigations resulted in 7 recalls, totaling 36,396,460 pounds of FSIS-regulated product and 72,800 pounds of State-regulated product. Two investigations involved *S.* Heidelberg and *S.* Hadar, resulting in recalls of 36,239,960 pounds of ground turkey products. Three investigations involved *E. coli* O157:H7, resulting in recalls of 227,100 pounds of beef products. One investigation involved *E. coli* O157:NM, resulting in a recall of 2,200 pounds of ground beef products.

FSIS Goal 2: Maximize domestic and international compliance with food safety policies

OPHS Removes Dangerous Product from Shelves—Saves Lives: In FY2011, CDC noted 136 illnesses, 37 hospitalizations, and 1 death from salmonellosis. It linked the increased number of cases to ground turkey. This discovery was made with the combined teamwork of OPHS and CDC. OPHS used epidemiological data to trace consumed product to a specific turkey slaughter and grinding facility. Because of these efforts, the establishment recalled approximately 36 million pounds of ground turkey products in August 2011. Following the recall, OPHS reviewed plant programs to assess corrective actions and efficacy of the establishment's pathogen control programs. OPHS established an Incident Investigation Team (IIT) and developed a sampling scheme to conduct an in-depth, on-site investigation to pinpoint sources of contamination. The Office collaborated with LQAD to organize sample collection and test samples to identify trends that might indicate challenges for process control. All samples went to the Western Laboratory where they were cultured, and organisms were isolated for identification. The data showed that the establishment programs were not sufficient to prevent contamination by the outbreak strain. OPHS identified the outbreak strain at the establishment during environmental testing. Because of this work, FSIS issued a Notice of Intended Enforcement (NOIE), and the establishment recalled an additional 185,000 pounds of contaminated raw ground turkey. By the end of FY2011, the establishment had implemented a voluntary suspension of raw ground turkey production until it established confidence that the raw ground product leaving the facility was wholesome and free of the pathogens. As of December 1, 2011, the establishment continued to divert all ground products to cooked product to reduce risk to the consumer. Follow-up testing continued into April 2012.

Midwestern Laboratory Expands KIS™ Test on Swine: In FY2011, FSIS sought to extend a new field test for antibiotics to replace the older Fast Antimicrobial Screen Test (FAST), which was no longer commercially available. OPHS introduced the Kidney Inhibition Swab test (KIS™) during three phases. FSIS previously applied the KIS™ field test at beef establishments during the Phase I and II transition. Phase III of the transition included designated swine establishments. The Midwestern Laboratory identified, documented, and justified the funds for Phase III and used existing materials to achieve this transition despite a constricted budget.

Eastern Laboratory Improves Identification of Foodborne Pathogens: The Eastern Laboratory performs all molecular sub-typing of isolates for FSIS-regulated products. The analyses include PFGE, molecular serotyping for *Salmonella*, and MLVA for *E. coli* O157 and *Salmonella* Typhimurium isolates. The laboratory revised and enhanced the *E. coli* non-O157 STEC method. At the same time, laboratory technicians continued to evaluate and test technologies to improve molecular capabilities for *Salmonella, E. coli* O157:H7, and *L. monocytogenes*. With this information, the Agency can focus limited resources on organisms that are more likely to be associated with human illness and perhaps assist in the development of interventions to reduce exposure to these organisms along the farm-to-table continuum.

FSIS Goal 3: Enhance public education and outreach to improve food-handling practices

OPHS Supports Industry in Improving Food Safety: OPHS participated in a group organized by the National Environmental Health Association. The group developed a course to educate industry officials on how to assist during investigations of foodborne illness outbreaks. During the course, industry representatives learned about actions that they can take to reduce or prevent the onset of additional illnesses. OPHS distributed the course to managers of a national supermarket and fast-food restaurant chains to field-test the program's effectiveness.

FSIS Goal 4*:* Strengthen collaboration among internal and external stakeholders to prevent foodborne illness

OPHS Provides Food Safety Outreach Domestically and Internationally: The USDA Foreign Agricultural Service (FAS) requested technical assistance from FSIS to evaluate the microbiological standards proposed by member countries of the Central American Free Trade Association (CAFTA). CAFTA proposed certain microbiological standards for food products that were not based on current scientific evidence. OPHS determined that these standards were unlikely to be feasible for food safety enforcement of domestic products within their member countries and were likely to be a barrier for trade with other countries around the world, including the United States. OPHS representatives along with representatives from FAS, FSIS, and FDA met with the Ministers of Health and Agriculture from Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, and the Dominican Republic in April 2011. Over the course of the three-day meeting, OPHS provided in-depth scientific insight into the design of sampling plans, the application of effective testing methods, and enforcement of food safety regulations. In addition, OPHS led discussions on how CAFTA member countries could apply current scientific data more effectively to achieve a cost-effective, robust, and enforceable regulatory approach for food safety that could be equitably applied to domestic and imported food products. Based on the success of the April meeting, everyone agreed to a second meeting in July 2011, which included delegates from Panama, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, and the Dominican Republic. The follow-up meeting examined scientific underpinnings of microbiological standards, the specific interactions between testing and enforcement activities, logistical considerations for microbiological sampling, testing for baseline studies, and FSIS regulatory testing of both domestic and imported products in the United States. At this time,

OPHS addressed concerns and questions from government scientists and officials. The Ministers of Health and Agriculture ultimately agreed to changes to the CAFTA microbiological standards that are more in line with the international standards used within the United States. OPHS participation leveraged changes in international policy that will produce safer food for consumers in CAFTA member countries and U.S. consumers of imported products.

OPHS and Federal Partners Establish Guidelines for Consistent Testing Methods: Industry food safety programs provide the first line of defense for protecting consumers. Industry increasingly uses sampling and testing to verify that their foodborne pathogen control programs are effective in preventing and eliminating contamination. For this reason, it is critically important that the sampling and testing methods used by the industry and their laboratories are effective in detecting and identifying foodborne pathogens or other microbiological indicators of process control. In FY2011, OPHS provided guidance on microbiological testing conducted outside of FSIS, both within the United States and internationally. OPHS published scientific guidance on the FSIS Web site in September 2011, and OPHS staff presented this information at international scientific meetings, including the American Society for Microbiology (ASM) and American Organization of Analytical Chemist (AOAC) meeting. These discussions spurred new interest in evaluating rapid test systems that meet meat, poultry, and egg industry food safety needs. At the request of FDA and AOAC, OPHS played an active role in the International Stakeholder Panel for Alternative Methods (ISPAM) seeking to establish greater consistency for method validation studies conducted around the world. OPHS collaborated with FDA to initiate a Technical Advisory Group (TAG) to focus on international standards for method validation. These collective efforts of the scientific community ensure that a broad range of testing methods and rapid test kits meet the needs of industry and government food safety programs around the world.

FSIS Goal 5: Effectively use science to understand foodborne illness and emerging trends

OPHS Engages Stakeholders to Develop Risk Assessments and Models: OPHS uses risk assessments to guide food safety policies. In FY2011, OPHS actively shared information on the development of its risk assessments with stakeholders, State public health professionals, and international delegations. OPHS gathered input on the models, data, or scenarios considered. FSIS and FDA Directors held several one-on-one meetings with various stakeholder groups, including the Food Marketing Institute, American Meat Institute, Grocery Manufacturers Association, Center for Food Action, and Center for Science in the Public Interest. These meetings examined the *Interagency Retail Listeria monocytogenes Risk Assessment* model, as well as current data collection efforts and research. In particular, OPHS asked the stakeholders to suggest scenarios that may contribute to or reduce the risk of listeriosis from ready-to-eat (RTE) foods. The consumer and industry groups applauded the interagency efforts to involve them at the beginning and throughout the development of the risk assessment and risk assessment model. Outputs of this model are based on “what if” scenarios posed by both FSIS and FDA risk managers, and, just as importantly, those posed by consumer groups and industry.

OPHS Breathes New Life into the National Residue Program (NRP): In FY2011, OPHS staff represented FSIS while coordinating with the FDA and EPA to resolve long-standing interagency issues within the NRP. The agencies formed the Senior Executive Council (SEC), consisting of senior management who met regularly in 2011. The meetings addressed problems that have existed for years and enabled the interagency members to coordinate at the technical level. These improvements will allow the agencies to achieve NRP-related mission goals more efficiently. As part of the collaboration, OPHS laboratories worked to implement newer chemical testing methods that screen for more chemical residues in NRP samples. OPHS used risk-based principles to develop the NRP sampling plan for the 2011 calendar year and developed a list of chemicals to test in FSIS-regulated products. In a collaborative manner, the officials selected chemicals ranked by relative toxicity and potential for abuse by industry.

Western Laboratory Modernizes Pesticide Program to Ensure Safety of FSIS Products: In FY2010, the Western Laboratory collaborated with the EPA, FDA, and AMS to modernize the pesticide program. The agencies focused on pesticides with expired registrations and environmental contaminants without tolerances. The new program ranks pesticides by true risk rather than by compound class or method. In FY2011, the Western Laboratory validated a new screening method that expanded the pesticide panel to 56 analytes from 10 different compound classes compared to the previous test for only one class—chlorinated pesticides. The new multi-residue method required instrumentation with improved detection limits along with powerful software programs to process the vast amount of data produced. In addition, the new technique required training for lab support staff, upgrading lab instrumentation and sample collection instructions to the field, and establishing electronic reporting mechanisms. Since implementation of the pesticide screen, the laboratory analyzed 1,000 samples, yielding approximately 56,000 analytical results. Through this work, the laboratory identified a pattern of low-level pesticide contamination and one violative finding. This updated pesticides program is now delivering an abundance of relevant analytical results that will aid future risk assessments.

OPHS Focuses on Retail Food Safety: *L. monocytogenes* infections cause an estimated 1,500 hospitalizations and 260 deaths in the United States each year, mostly attributable to the consumption of contaminated RTE foods. A previous FSIS comparative risk assessment attributed 83 percent of listeriosis cases in the United States to deli meats, especially those sliced and prepared in retail grocery stores. Cross-contamination of RTE foods in the retail environment is a real concern for the spread of listeriosis. In FY2011, FSIS collaborated with FDA, ARS, and CDC, as well as academia, to collect targeted data. FSIS contracted with Virginia Tech to evaluate the transmission of *L. monocytogenes* in a "mock deli" and with Cornell University to obtain real world retail environmental contamination data. FSIS also established an interagency agreement with ARS to gather data on *L. monocytogenes* contamination in retail RTE meat and poultry products. This study is being conducted in collaboration with FDA, which is also working with ARS to test for *L. monocytogenes* in other RTE foods, including seafood, cheese, deli salads, fruits, and vegetables. In addition, FSIS continues to work with CDC and the states to gather nationwide data on grocery store food handling and sanitation practices. FSIS aims to integrate these studies into the interagency retail

L. monocytogenes risk assessment. The results will enable FSIS and FDA to evaluate the effectiveness of grocery store food safety controls and sanitary practices in preventing cross-contamination of *L. monocytogenes* in RTE foods during preparation and handling in grocery stores. Currently, the model is complete and awaiting additional data. FSIS revised this risk assessment in response to peer review comments in FY2011.

FSIS Goal 6: Implement effective policies to respond to existing and emerging risks

Enhancing the Capacity of FSIS to Evaluate Food Safety Risk: In FY2011, OPHS developed a quantitative risk assessment to guide policy development and inspection resources. Of the 15 large-scale risk assessments completed, 8 of these assessments were new. The remaining risk assessments were revised based on peer review and public input. The risk assessments included

- a risk profile and scenario analysis for non-O157 STEC in beef:
- an updated evaluation of the public health impact of changes in poultry slaughter inspection;
- a comparative risk assessment for STEC in non-intact beef versus intact beef; and
- an evaluation of beef slaughter controls to mitigate the public health risks from enteric pathogens.

OPHS uses these analyses as the scientific basis for establishing FSIS policies. For instance, the Agency used the data to modernize poultry slaughter inspection, declare six non-O157 serotypes as adulterants, develop new labeling requirements for non-intact beef products, and provide guidance to retailers to prevent *L. monocytogenes* cross-contamination of RTE foods. To facilitate the risk assessments, OPHS developed mathematical approaches that underlie some of these assessments. In addition, OPHS acquired access to high-speed computers and supercomputers to complete more complex food safety computer models. These risk assessments, some required under Presidential Executive Order 12866 and the 1994 Reorganization Act for Agriculture, were integral to evaluate changes in industry controls, agency inspection, retail practices, and consumer behaviors.

OPHS Advances the Mission of the Food Safety Working Group: OPHS increased its collaboration with the CDC and FDA in efforts to strengthen their ability to conduct food safety risk assessments, a critical goal of the President's Food Safety Working Group. Fifteen Federal agencies chartered the Interagency Risk Assessment Consortium (IRAC). The consortium aims to strengthen interagency information exchange and to develop food safety risk assessments. This effort led to a two-day workshop focused on available data and methods for deriving an updated dose-response relationship for *L. monocytogenes.* Because of this meeting, IRAC produced an interagency publication on the current science and modeling methods for *L. monocytogenes* dose-response relationships, currently *in press* in the scientific literature. This information is critical to improving the certainty of risk estimates for *L. monocytogenes*. In addition, the agencies formed the Interagency Food Safety Analytics Collaboration (IFSAC) to increase collaboration among risk assessors and epidemiologists and facilitate the development of methods to attribute foodborne illness to specific foods regulated by FSIS and FDA.

OPHS Risk Profile on non-O157 Shiga toxin-producing *E. coli* Informs Policy: FSIS developed its first risk profile to guide a proactive public health policy. These policies evaluate the public health risk for emerging foodborne hazards based on a thorough review of the scientific literature, epidemiological and contamination data, and consumer cooking studies. In 2011, OPHS developed a risk profile for six non-O157 STECs. The risk profile used the same scientific criteria that established *E. coli* O157:H7 as an adulterant under the Federal Meat Inspection Act. In September, FSIS presented this proposed regulation, along with the risk assessment and cost-benefit analysis, in a *Federal Register* Notice for public comment. FSIS declared six non-O157 STEC (e.g., O26, O103, O45, O111, O121, and O145) as adulterants in beef. The Agency began testing for these pathogens in June 2012.

OPHS Improves Food Safety by Effectively Analyzing Risk: OPHS developed and published standard methods for microbial risk assessment, setting the foundation for growth in this field. OPHS finalized mathematical models that link performance objectives and microbial criteria to specific public health outcomes for *L. monocytogenes, Salmonella,* and *Campylobacter* in RTE meat and poultry products. The Office plans to share this information with stakeholders through a series of publications that are being developed. The Office published two methods for streamlining mathematical approaches used in prior quantitative food safety risk assessments and developed a third standardized approach that has been submitted for publication. One new method used an innovative approach to evaluate the effectiveness of FSIS policies, specifically the impact HACCP on salmonellosis from poultry in the United States. This methodical approach allowed risk assessors to evaluate the effectiveness of Agency food safety policies quantitatively.

FSIS Goal 7: Empower employees with the training, resources, and tools to enable success in protecting public health

OPHS Participates in Inter-agency Coordination to Prevent Foodborne Illnesses: During the week of January 31, 2011, FSIS hosted an outbreak orientation team meeting with CDC and FDA in Washington, DC. OPHS took the lead in coordinating and managing the logistics of the meeting. Throughout the week, participants learned about inspection, enforcement, and import activities at Federal meat, poultry, and egg product establishments, as well as catfish inspection. In addition, participants discussed labeling requirements, recall process, PHIS, CCMS, foodborne illness investigations, and laboratory functions. The group received an update on *Salmonella* and new *Campylobacter* performance standards, microbial risk assessments, and the impact of FDA's new egg rule on egg products processing establishments.

OPHS Benefits from the Skills of New Employees: Despite hiring restrictions to accommodate a constricted budget, OPHS hired several employees to fill critical roles at headquarters and Field Service Laboratories. The Field Service Labs welcomed four front-line microbiologists to respond to new and increased sampling initiatives to ensure the safety of the food supply. They also welcomed a physical science technician to monitor the arrival and distribution of samples throughout the laboratories. At headquarters, OPHS welcomed a new director for the Applied Epidemiology Division, who brought more than ten years of public health experience in preventative medicine and epidemiology to the Office. In addition, the Office welcomed several epidemiologists to assist in foodborne investigations. A Public Health and Epidemiology liaison brings her skills in applied epidemiology, disease investigation, veterinary science, and data analysis to FSIS. A Senior Epidemiologist brings her skills in preventive medicine, applied epidemiology, and fieldwork. In addition, headquarters benefitted from American Association for the Advancement of Science (AAAS) and Presidential Management fellows. The fellows contributed an array of skills to the NRP, the non-O157 *E. coli* risk profile in beef, the *Salmonella* risk profile, and to the systematic rapid risk assessments for chemical exposures of FSIS-regulated products. Finally, the Office benefited from the skills of a writer/editor, who brings more than eight years experience to assist employees in fulfilling the President's plain language initiative.

FSIS Goal 8: Based on the defined Agency business needs, develop, maintain, and use innovative methodologies, processes, and tools, including PHIS, to protect public health efficiently and effectively and to support defined public health needs and goals

Eastern Laboratory Expands Tests for Chemical Residues: The Eastern Laboratory revised, developed, and/or implemented a series of analytical methods for testing FSIS-regulated products. The laboratory staff developed the Avermectin Determinative and Confirmation and the Screening and Confirmation of Sulfonamides to monitor for these residues in FSIS-regulated products. Avermectin and sulfonamides are used to treat parasites and infections in animals. The laboratory is extending the mercury method to all product classes. In addition, the laboratory began the process of bringing an aminoglycoside and multi-metals method on line. These new methods will allow the Agency to test for multiple compounds in a single sample and expand the list of drugs tested under the NRP. Finally, laboratory staff modified the operation of analytical instrumentation used for the analysis of nitroimidazoles. This step reduced the waste stream generated from the analysis by 80 percent. The changes described enable the laboratory to identify and remove harmful residues from the food supply while reducing waste and saving money.

Eastern Laboratory Adapts for *E. coli* non-O157 Testing: Despite budget constraints, the Field Service Laboratories accelerated their capability to analyze for *E. coli* non-O157 STEC. This process required validation of improved enrichment medium, primers, and probes, as well as changing the polymerase chain reaction (PCR) platform and the antibiotic concentrations in Rainbow Agar. In addition, the laboratory added a latex agglutination step. To accommodate these changes, the laboratory revised MLG Chapter 5B.01 "Detection and isolation of non-O157 Shiga toxin-producing *E. coli* strains (STEC) from meat products." OSEL collaborated with ARS scientists to prepare O45 and O121 IMS beads and latex agglutination kits to help in the detection process. In addition, Eastern Laboratory developed a PCR method for detecting *E. coli* O104:H4 by using published primers and probes. In addition, the laboratory developed educational materials, including manuals, PowerPoint presentations, and live feed conferencing, to train field laboratories for *E. coli* non-O157 STEC sampling. The implementation of a non-O157:H7 testing program allows the Agency the latitude to declare a group of potentially dangerous pathogens as adulterants, identify them in FSIS-regulated product, remove them from commerce, and further protect human health.

Midwestern Laboratory Improves and Expands Methods to Ensure Food Safety: The Midwestern Laboratory improved FSIS testing capacities. Laboratory staff developed a broad-based multi-residue antibiotic screen/confirmation method. In addition, Midwestern Laboratory staff developed two Chemical Laboratory Guidebook methods. The Multi-residue Antibiotic Screen/Confirmation Method screens and confirms a broad number of antibiotic compounds within numerous antibiotic classes. The Aminoglycosides Screen/Confirmation Method screens and confirms compounds within a specific antibiotic class of aminoglycosides. The laboratory staff also implemented and extended these methods to several additional species or tissues to enhance detection of beta-lactams, sulfa drugs, tetracyclines, and flunixin. These methodological improvements and extensions ensured FSIS compliance with FDA residue tolerances for FSIS-regulated products. This work will allow FSIS to address inappropriate use of veterinary products to ensure the safety of food products regulated by the Agency.

Midwestern Laboratory Provides Training to Ensure Food Safety: Midwestern Laboratory trained additional analysts on advanced residue testing methodologies that enable greater laboratory efficiencies and achieve better sensitivity than previous FSIS antibiotic screening methods. In addition, the staff trained their counterparts at the Eastern and Western Laboratories on the Aminoglycosides Screen/Confirmation method and Multi-residue Antibiotic Screen/Confirmation method. This critical training expanded FSIS laboratory capabilities to screen samples at all of the laboratories for the potential presence of antibiotic residues in FY2012. This enhanced capability aligns with other FSIS public health initiatives to improve food safety of FSIS-regulated product.

OPHS Impacts
The work completed by OPHS is iterative. The accomplishments of one year often invoke the force of change for future work. The OPHS impacts section provides significant work completed in previous fiscal years that continues to have beneficial effect today.

OPHS Foodborne Investigations Benefit the Nation: Prior to 2008, guidance for conducting foodborne illness investigations was limited to standard operating procedure documents, informal rules, and historical routines. In 2007, OPHS collaborated with the FSIS Office of Policy and Program Development (OPPD) to convene an Agency-wide workgroup and began drafting the first directive covering foodborne illness investigations. FSIS Directive 8080.3, *Foodborne Illness Investigations*, issued in November 2008, revolutionized foodborne illness investigations. Since the issuance of the directive, FSIS has conducted foodborne illness investigations more efficiently and with less duplication of effort. Program areas have identified roles and responsibilities in the multi-disciplinary investigation team, enhancing communication and coordination. In an era when prompt public health response and action is expected, FSIS can now respond with the flexibility and agility necessary to identify the product and pathogen of interest to protect public health.

OPHS Foodborne Investigation Documents Pathogenetic *E. coli* non-O157: Between August and September 2010, State public health laboratories uploaded three unrelated clinical isolates of *E. coli* O26 with indistinguishable PFGE patterns to PulseNet. Interviews conducted by Maine and New York State health officials revealed that all three case-patients either consumed or handled ground beef prior to illness onset. With the consent of case-patients, FSIS, along with the State health officials, utilized shopper card information to assist with traceback investigations. In addition, New York collected leftover ground beef from the case-patient's home for testing. The product tested positive for *E. coli* O26 with indistinguishable PFGE pattern combination from the outbreak strain. This information identified Establishment A as the only common supplier of ground beef products among the three case-patients. On August 28, 2010, Establishment A recalled approximately 8,500 pounds of ground beef products produced on June 11, 2010. This investigation is the first non-O157 STEC-implicated recall of ground beef in the United States. As the Agency promotes new policy regarding non-O157 STEC, this investigation provides additional documentation that pathogenic non-O157 STECs are injurious to health.

2011 OPHS Publications and Presentations

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