



Food Safety and Inspection Service

Office of Public Health Science

Annual Report

2010

A Message from the OPHS Assistant Administrator

The Office of Public Health Science (OPHS) supports the Food Safety and Inspection Service (FSIS) mission by providing expert scientific data, analysis, and recommendations to reduce or eliminate foodborne illness in regulated products and assess potential human health risk along the farm-to-table continuum. During Fiscal Year (FY) 2010, OPHS continued to provide sound scientific leadership to the Agency and enhance scientific methods for estimating the risks associated with foodborne pathogens, detecting these pathogens in the food supply, and responding to foodborne illness outbreaks. During this period, OPHS also worked to identify emerging risks and continued to develop strategies for identifying and applying new microbiological, chemical, and toxicological methods to pathogens of concern.

The FY2010 Annual Report highlights the outstanding work completed by OPHS employees to accomplish the Agency's mission. For example, FSIS developed the first performance standards for *Campylobacter* based on data from previous young chicken and turkey baseline studies. The proposed performance standards will minimize exposure of this pathogen to consumers, resulting in fewer human illnesses. In addition, OPHS linked a multistate cluster of *Salmonella* Montevideo to post-processing contamination of pepper flakes added to an Italian-style sausage product. This investigation led the Agency to re-examine post-lethality control steps to ensure that they comply with safety standards. FSIS also applied a risk assessment model following a new approach and successfully linked public health outcomes to food safety measures and objectives. This new approach may assist the Agency in setting more effective equivalency food safety standards for trade. These are but a few of the many accomplishments achieved by OPHS during FY2010. I am proud of the efforts and dedication of OPHS employees who strive for scientific excellence to ensure the safety of meat, poultry, and egg products that reach national and international consumers.

David P. Goldman, M.D., M.P.H.
Captain, U.S. Public Health Service
Assistant Administrator, OPHS



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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 eliminate foodborne illness. OPHS supports FSIS by informing specific goals within the FSIS mission.

Strategic Plan

FSIS Goal 1 - Enhance inspection and enforcement systems and operations to protect public health.

FSIS Goal 2 - Enhance the use of risk analysis and vulnerability assessments in FSIS' approach to protecting public health.

OPHS Goal 2.1 Integrate FERN activities into FSIS' organizational planning mission execution.

OPHS Goal 2.2 Use Risk Assessment/Hazard Assessment to support emergency management of possible public health incidents involving meat, poultry, and egg products.

FSIS Goal 3 - Enhance the development of science and risk-based policies and systems.

OPHS Goal 3.1 Elevate and solidify OPHS' role in policy development and execution.

OPHS Goal 3.2 Optimize laboratory analytical capability and capacity.

OPHS Goal 3.3 Optimize the efficiency and effectiveness of FSIS' foodborne illness investigations.

OPHS Goal 3.4 Protect public health by utilizing risk analyses to appropriately assign resources.

OPHS Goal 3.5 Enhance the Agency's ability to implement risk-based inspection.

OPHS Goal 3.6 Enhance foodborne illness attribution measurement capability.

FSIS Goal 4 - Enhance the development and maintenance of an integrated and robust data collection and analysis system to verify the effectiveness and efficiency of Agency programs.

FSIS Goal 5 - Enhance the development and maintenance of an innovative infrastructure to support the Agency's mission and programs.

OPHS Goal 5.1 Build a world-class scientific workforce in support of the FSIS public health mission.

OPHS Goal 5.2 Build and maintain laboratory facilities that are green and state-of-the-art.

OPHS Goal 5.3 Build a robust, innovative budget, financial management, and performance integration infrastructure, focused on accountability and internal control.

FSIS Goal 6 - Enhance the effectiveness of Agency outreach and communications to achieve public health goals.

OPHS Goal 6.1 Improve FSIS' regulatory effectiveness through better communication and collaboration.

OPHS Goal 6.2 Institutionalize OPHS' role in the development of Agency public communications.

In support of the FSIS mission, OPHS staff characterize and quantify foodborne pathogens, specifically *Escherichia coli*, *Salmonella*, *Campylobacter*, and *Listeria monocytogenes*, on FSIS-regulated meat, poultry, and egg products. OPHS reports these results in baselines studies, white papers, and other technical documents. OPHS employees develop risk assessment models to predict how changes in Agency policies and practices could affect public health. In addition, employees conduct foodborne illness investigations. The staff at Field Service Laboratories (FSL) analyze for 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), as well as 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 headquarters is divided into 3 scientific divisions and 1 administrative division. The **Microbiology Division** (MD) provides scientific support to FSIS on microbiological issues and assists in developing the scientifically sound policies that protect 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

residues, and foodborne disease agents.

The **Risk Assessment Division** (RAD) supports the FSIS mission by conducting food safety risk assessments to guide rulemaking and predict the public health impact of changes in Agency policies or practices. The Division also allocates inspection resources based on public health risk and evaluates the effectiveness of implemented food safety policies.

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 International Organization for Standardization (ISO) 17025-accredited FSLs located in the eastern, central, and western United States. FSL staff coordinate and conduct analytical services in chemistry, microbiology, and pathology to ensure the safety of meat, poultry, and egg products. All FSL staff analyze for *E. coli* O157:H7, *Salmonella*, *Campylobacter*, and *L. monocytogenes*. Each FSL has responsibility for an exclusive set of chemical analyses.

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 Multiple Loci 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 chemical and microbiological samples.

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 from the National Residue Program for pesticides, beta-agonist growth promoters, and various anti-microbial drugs.

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).

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

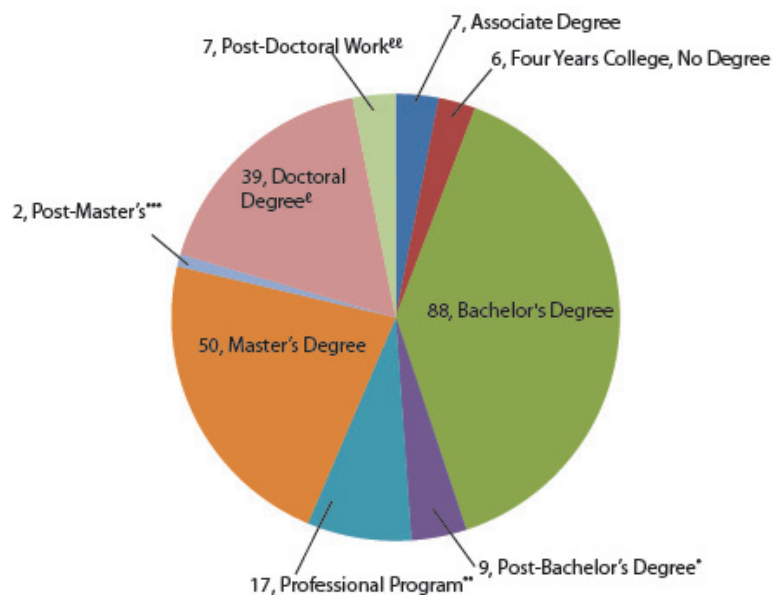


Figure 1. Distribution of OPHS professional and educational experience

The dynamic, educated OPHS staff supports the Agency's mission to ensure the safety of meat, poultry, and egg products.

*Post-Bachelor work indicates higher-level course work beyond the Bachelor's degree, but no additional higher degree.

**Professional program signifies the completion of academic requirements for selected professions based on programs requiring at least 2 academic years of previous college work and at least 6 academic years of college work.

***Post-Master's work includes higher-level course work beyond the Master's degree, but no additional higher degree.

†Doctoral degree includes Doctor of Education, Doctor of Juridical Science, Doctor of Public Health, and the Ph.D. (or equivalent) in any field.

‡Post-Doctoral indicates higher-level course work beyond the Doctoral degree, but no additional higher degree.

Figure 2. OPHS FY2010 budget allocation

OPHS distributed the FY2010 allocation for personnel, travel, and operations at headquarters (HQ) and FSLs.

FY2010 Allocation

	Overall	Labs	HQ
Salary and Benefits	\$32,345,210	\$23,093,266	\$9,251,944
Operating	\$28,116,400	\$22,211,800	\$5,904,600
Travel	\$484,745	\$239,744	\$245,001

Percent of FY2010 Allocation

	Overall	Labs	HQ
Salary and Benefits*	53.1%	37.9%	15.2%
Operating	46.1%	36.4%	9.7%
Travel	0.8%	0.4%	0.4%
Total	100.0%	74.7%	25.3%

*This figure includes spot awards, extra effort awards, and Public Health Human Resources System (PHHRS) bonuses.

Figure 3. FSIS FSL sample analyses

The tables below show the number of samples analyzed at each laboratory by analysis type for each quarter of FY2010. Eastern Laboratory data is presented in the top table, Midwestern Laboratory data is presented in the middle table, and Western Laboratory data is presented in the bottom table. Directed samples were not scheduled for January 2010. As a result, second quarter residue chemistry numbers are low.

Activity	Q1	Q2	Q ¹	Q ²	Total	Q1	Q2	Q3 ¹	Q4 ²	Total
Food Chemistry	56	149	187	131	523	183	598	750	493	2,024
Food Microbiology ³	4,839	4,024	5,255	4,706	18,824	18,743	14,468	19,969	17,695	70,875
HACCP <i>Salmonella</i>	1,684	2,800	3,598	2,694	10,776	1,795	3,082	3,850	2,910	11,637
Outbreak	112	116	132	120	480	212	151	216	193	772
Residue Chemistry	3,467	2,470	2,287	2,741	10,965	22,633	17,317	16,283	18,831	75,064
Residue Antibiotics	0	0	0	0	0	0	0	0	0	0
Pathology ⁴	1,541	1,449	1,505	1,498	5,993	11,824	11,307	12,296	11,804	47,231
Total	11,699	11,008	12,964	11,890	47,561	55,390	46,923	53,364	51,926	207,603

Activity	Q1	Q2	Q3 ¹	Q4 ²	Total	Q1	Q2	Q3 ¹	Q4 ²	Total
Food Chemistry	0	0	0	0	0	0	0	0	0	0
Food Microbiology ³	4,074	3,891	4,581	4,182	16,728	15,057	13,309	15,804	14,721	58,891
HACCP <i>Salmonella</i>	1,797	2,710	3,652	2,720	10,879	1,877	2,801	3,835	2,829	11,342
Residue Chemistry	485	255	459	400	1,599	545	315	459	448	1,767
Residue Antibiotics	3,981	3,601	3,765	3,782	15,129	75,009	71,184	66,942	71,102	284,237
Pathology ⁴	0	0	0	0	0	0	0	0	0	0
Total	10,337	10,457	12,457	11,084	44,335	92,488	87,609	87,040	89,100	356,237

Activity	Q1	Q2	Q3 ¹	Q4 ²	Total	Q1	Q2	Q3 ¹	Q4 ²	Total
Food Chemistry	0	0	0	0	0	0	0	0	0	0
Food Microbiology ³	4,283	3,558	4,317	4,052	16,210	12,609	12,674	15,973	13,777	55,033
HACCP <i>Salmonella</i>	1,517	2,452	3,398	2,456	9,823	1,665	2,587	3,602	2,628	10,482
Residue Chemistry	1,543	824	1,443	1,270	5,080	26,144	17,360	30,981	25,184	99,669
Residue Antibiotics	0	0	0	0	0	0	0	0	0	0
Pathology ⁴	0	0	0	0	0	0	0	0	0	0
Total	7,343	6,834	9,158	7,778	31,113	40,418	32,621	50,556	41,589	165,184
Lab Totals	29,379	28,299	34,579	30,752	123,009	188,296	167,153	190,960	182,615	729,024

¹Third quarter numbers derived by taking the average of 63 days of actual numbers × 78 days for the quarter.

²Fourth quarter numbers are derived by taking the average of the first three quarters.

³Includes canned foods

⁴Includes extraneous materials

Figure 4. Investigations and watches in FY2010

In FY2010, AED conducted 24 investigations and 48 watches for meat, poultry, and egg products.

	Investigations/ Watches	Illnesses	Hospital- izations	HUS [†] Cases	Deaths
<i>E. coli</i> Investigations	10	138	45	8	3
<i>L. monocytogenes</i> Investigations	2	14	13	0	6
<i>Salmonella</i> Investigations	11	661	79	0	2
<i>Clostridium perfringes</i> Investigations	1	42	1	0	0
<i>E. coli</i> Watches*	17	217	61	13	3
<i>L. monocytogenes</i> Watches*	7	36	19	—	12
<i>Salmonella</i> Watches*	24	2,744	85	—	2

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

*A watch monitors unlinked clusters of illnesses associated with FSIS-regulated products.

Figure 5. Consumer Complaints Monitoring System (CCMS) Investigations in FY2010

AED monitors the CCMS and coordinates investigations, commonly focused on foreign objects, illnesses, and off-characteristics in meat, poultry, and egg products. The pie chart provides an overview of the percent of each type of investigation conducted by the group in FY2010.

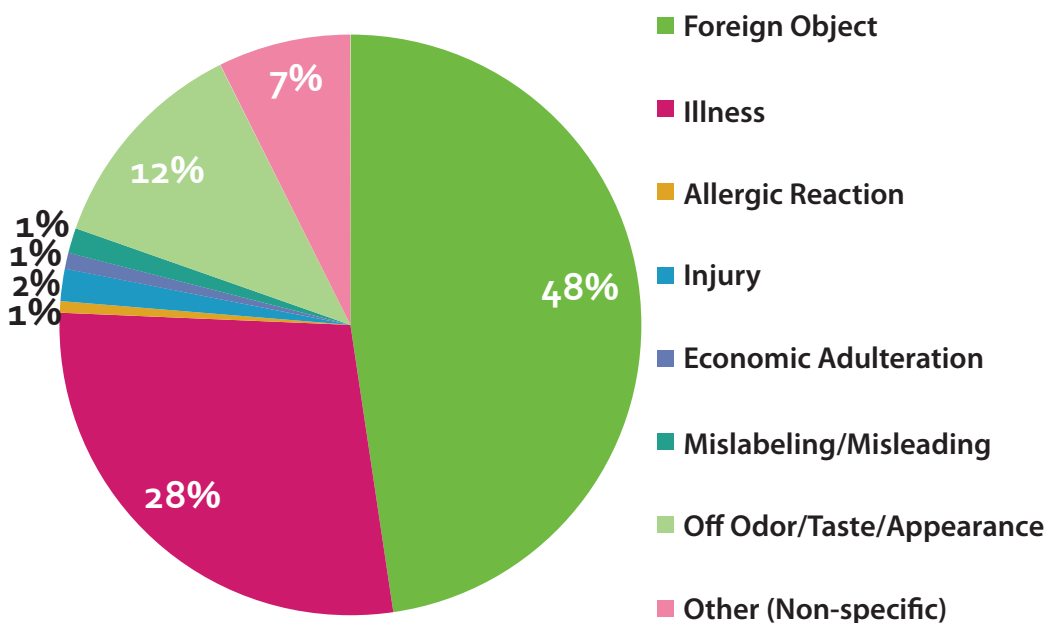
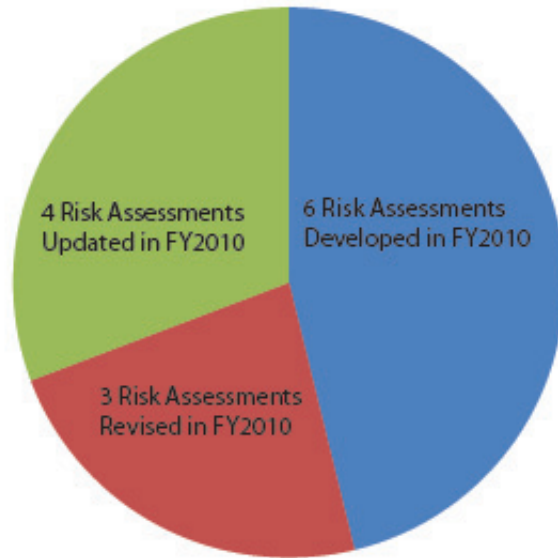


Figure 6. Risk Assessments Developed, Revised, and Updated in FY2010

Developing a quantitative risk assessment is a multistep, iterative process that requires updates with current information, data, and revisions based on multiple peer reviews provided by both internal and external reviewers (e.g., scientists, USDA, Office of Management and Budget (OMB), other Federal agencies). Many FSIS risk assessments are developed to inform major policies and require peer review by the USDA Office of Risk Assessment and Cost-Benefit Analysis (Public Law 103-354, 1994 Reorganization for Agriculture) and the White House OMB (Executive Order 12866).



OPHS 2010 Accomplishments

OPHS Goal 2.1

Integrate FERN activities into FSIS' organizational planning mission execution.

Validating a method to detect melamine

A harmful chemical additive led to new analytical methods, which offer a template for future response.

Melamine is an industrial chemical used in the manufacture of plastic and flame-retardant products. Relatively non-toxic to humans and animals, its use as a food adulterant boosts the nitrogen content of food products, mimicking protein, the usual and more costly source of nitrogen. The detection of melamine in pet products in 2007 and the subsequent health effects in children exposed to melamine-adulterated milk in China 1 year later heightened the need to develop a method to detect this chemical. Although an unacceptable food additive, scientists were at first unable to explain the rash of illnesses in U.S. pets and Chinese infants associated with melamine. Subsequent studies showed that cyanuric acid in the presence of melamine forms a complex, which is insoluble in water. The cyanuric acid-melamine complex formed crystals in the kidneys of exposed individuals, resulting in kidney failure and death.

The economic incentive to spike a product with melamine to boost nitrogen levels is a continued concern. In response to this crisis, FERN developed a Liquid Chromatography Tandem Mass Spectroscopy (LC-MS-MS) technique to test ground beef and RTE meat products for the presence of melamine.

This method is available at the three FSLs for future surveillance work, as well as other public and private laboratories through the FSIS Chemistry Laboratory Guidebook Web site. In addition, this laboratory method provides a template to develop future rapid response methods to address chemical or biological adulterants.

Detecting industrial dyes in aquaculture products

A baseline study provides data on antifungal agent in catfish.

The aquaculture industry previously applied the industrial dyes malachite green and crystal violet for their antifungal properties. This practice stopped when the industry learned the dyes had carcinogenic properties. The catfish inspection program initiated a large baseline study to determine the residual amount of antibiotics and key environmental contaminants (described here as malachite green and crystal violet) in both domestic and imported catfish.

FERN validated two methods to detect these dyes rapidly and economically. The method consists of an effective screening technique based on ELISA (Enzyme-linked immunosorbent assay) technology that uses a series of antibody labeling schemes to detect the sum of both dyes and their metabolites in the catfish down to one part per billion. Catfish samples that test positive for one of the dyes are sent for confirmation testing using an LC-MS-MS technique developed by ARS. This method is limited to aquaculture, the only food commodity that uses the dyes as an antifungal agent.

OPHS Goal 2.2

Use Risk Assessment/Hazard Assessment to support emergency management of possible public health incidents involving meat, poultry, and egg products.

OPHS issues a recall on Brazilian product

OPHS import re-inspection stops shipment of corned beef in violation of ivermectin.

In May 2010, FSIS intercepted shipments of cooked corned beef during import reinspection of products from Brazil. The corned beef contained residue of ivermectin, a drug that kills parasites in cattle. Most of the product was held, but a portion was released before the laboratory results were confirmed. The laboratory results, validated in a corned beef matrix, indicated that the drug levels exceeded a level of health concern. OPHS employees met with sister agencies to discuss the situation. Ultimately, the Secretary of Agriculture issued a Class II recall, indicating that there was a remote probability of adverse health consequences from the consumption of the product. The recall totalled 20 million pounds of product.

Investigating life-threatening food allergens

After careful review, OPHS recalled a product for undeclared egg proteins.

OPHS investigates and recalls FSIS-regulated food products that may contain undeclared allergens. A food allergy is a term applied to a group of disorders characterized by abnormal or exaggerated immunologic responses to a specific food protein that result in a variety of symptoms. The symptoms of a reaction can range from a mild rash to a severe anaphylactic response that could result in death.

The Food Labeling and Consumer Protection Act identifies egg as 1 of the 8 allergens that cause 90 percent of allergic responses to food.

On December 30, 2010, an Alabama establishment recalled approximately 180,000 pounds of breaded chicken wings due to the undeclared presence of egg. The recalled product included 20-pound boxes of uncooked hot and spicy breaded chicken wings, drumettes, and wing portions, as well as 10-pound boxes of uncooked hot and spicy breaded chicken wings. The recalled product contained no published information to indicate that the threshold of egg protein would elicit an allergic reaction in sensitive individuals. OPHS assessed the hazard as serious and recommended the initiation of a Class I recall, which signified that the product contains an ingredient that may cause serious adverse health consequences or death. The recall committee accepted the recommendation and the company concurred.

OPHS Goal 3.1

Elevate and solidify OPHS' role in policy development and execution.

Revising pathogen performance standards in poultry

OPHS focuses standards to reduce 2 persistent pathogens in young chicken and turkeys.

Salmonella and *Campylobacter* are the leading microbial pathogens that cause foodborne illness. The 1996 Hazard Analysis and Critical Control Point (HACCP) Final Rule established performance standards to reduce *Salmonella* on meat and poultry products and, thus, reduce the incidence of foodborne illness associated with the consumption of these products. Since implementing this standard, the incidence of this pathogen in beef and pork has decreased; however, the incidence in poultry has continued to increase, especially since 2005. The original *Salmonella* performance standard identified

an establishment out of compliance (i.e., “failed a set”) if more than 12 of 51 samples tested positive. *Campylobacter* and *Salmonella* data from the Young Chicken and Young Turkey baseline surveys informed the new rule. An establishment is now out of compliance if more than 5 of 51 samples test positive for *Salmonella*. The new guidance aims to decrease the incidence of these pathogens at the establishment and reduce exposure to the consumer. Two years after the implementation of the revised performance standards, OPHS analysts estimate a reduction in illness attributed to *Campylobacter* by 39,000 and *Salmonella* by 26,000.

OPHS baseline studies provide details on pathogen loads

OPHS initiates baseline studies for market hog carcasses and chicken parts.

OPHS initiated the Nationwide Market Hog Baseline Data Collection program in August 2010, which collected data from approximately 180 Federal establishments throughout the country. FSL staff analyzed carcass sponge samples for *Salmonella*, generic *E. coli*, Enterobacteriaceae, coliforms, and aerobic plate counts. This baseline provides national prevalence data of these bacteria for market hogs, which was last updated in 1997.

OPHS initiated the Nationwide Raw Chicken Parts Baseline Survey (RCPBS) in March 2010, targeting Federal establishments processing raw chicken parts intended for U.S. retail. This baseline will examine chicken breasts, legs, wings, and internal organs. The samples will be analyzed for the presence and levels of *Salmonella*, *Campylobacter*, generic *E. coli*,

Enterobacteriaceae, coliforms, and aerobic plate counts. These baseline studies provide critical data for the future development of risk assessment, performance standards, and the exploration of regulatory policy options.

***L. monocytogenes* risk assessment informs policy**

Joint study conducts the first scientific overview of L. monocytogenes in the retail environment.

L. monocytogenes is the bacterium responsible for listeriosis, one of the most virulent foodborne illnesses. Scientists attribute more than 2,500 illnesses in the United States to this pathogen every year, with as many as 20 percent of cases resulting in death. A recent article in the Journal of Food Protection linked the majority of deli-related listeriosis cases to deli-meats prepared at retail. In collaboration with the FDA, FSIS initiated the development of the first quantitative risk assessment model to evaluate practices at retail that contribute to the cross-contamination of deli meats, cheeses, and other RTE foods. The risk assessment model serves as a “virtual deli,” designed to evaluate the impact of current retail practices on public health. This highly interactive project marked a novel way to study the transmission of *L. monocytogenes* at retail. This achievement involved extensive interagency collaboration at the Federal level, targeted data collection efforts by academia, and stakeholder participation upfront and throughout the development of this risk assessment model. FSIS will use this model to identify potential interventions to reduce or prevent the presence of this pathogen in RTE food that is sliced, prepared, and/or packaged at retail facilities.

OPHS Goal 3.2

Optimize laboratory analytical capability and capacity.

Laboratory accelerates sample results efficiently and economically

*OPHS transitions to 325-g samples to detect *E. coli* O157:H7.*

OPHS conducted a comparative evaluation of two analytical methods for detecting *E. coli* O157:H7 in raw beef samples. The reference method consisted of five 65-gram subsamples for a total sample size of 325-g, which were incubated in an enrichment broth at a 1:10 sample-to-broth ratio. The alternate method consisted of a single 325-g portion incubated in an enrichment broth at a ratio of 1:4. FSL scientists tested each analytical method at the lower and upper pathogen limits (e.g., 1 or 5 CFU per sample). A single-laboratory validation determined the point of "fractional recovery" (i.e., the lower limit of detection). A multi-laboratory verification assessed the overall performance of both methods by inoculating samples at a level expected to yield 100 percent recovery (i.e., upper limit of detection). LQAD and the FSL determined that the alternate method produced accurate results and offered a suitable approach for regulatory sampling programs. By transitioning to the alternate method, the FSL will save analyst time and laboratory supplies for processing samples, with an estimated savings of \$1 million.

Enhanced chemical multi-residue method increases analytical testing capability

OPHS enhances screening for residues in beef.

Midwestern Laboratory and LQAD successfully implemented the first of two multi-residue methods to enhance the testing of veterinary drugs that are of interest to FSIS. The method

analyzes for nine unique aminoglycosides in bovine tissues and relies on ultrahigh performance liquid chromatography-tandem mass spectrometry (UHPLC-MS-MS) for the screening and confirmation of these compounds. This method and subsequent multi-residue methods provide crucial screens for augmenting the goals of the U.S. National Residue Program (NRP).

Baseline studies optimized to improve efficiency

Software improves baseline study management.

MD incorporated Mind Manager 9 to improve tracking, communication, and management of baseline studies. Division managers estimate that the program shortened the planning phase by 3 to 4 months, ensuring baseline studies began sooner. The new technology also allowed the group to track their spending in real-time. Careful consideration of the budget allowed the management team to extend deadlines and order additional supplies as needed. The team applied these efficiencies to the egg baseline and saved tens of thousands of dollars, which allowed them to better utilize time and funds for sample collection and analysis.

OPHS Goal 3.3

Optimize the efficiency and effectiveness of FSIS foodborne illness investigations.

Salmonella Montevideo illness cluster linked to peppered Italian-style salami

OPHS links illness to spices added to product after the lethality step.

In September 2009, FSIS noted a multistate cluster of *Salmonella* Montevideo infections with an indistinguishable PFGE pattern (XbaI PFGE pattern JIXX01.0011). The outbreak

included 272 cases in 44 States and the District of Columbia from July 1, 2009 to April 14, 2010; 26 percent (52 of 203) of the patients were hospitalized, with no deaths reported. An outbreak investigation identified pepper-coated Italian-style sausage as the product responsible for the illnesses. In particular, the investigation identified crushed black and red pepper, added to the product after the lethality step, as a medium for foodborne pathogen transmission. The production company issued the first recall on January 23, 2010, which accounted for 1,263,754 pounds of RTE varieties of Italian-style sausage products. An expansion of the recall occurred on February 4, 2010, to include an additional 24,000 pounds of product. The final expansion of the recall occurred on February 16, 2010, to include an additional 115,000 pounds of product. After the 2010 pepper-coated salami outbreak investigation, FSIS issued a notice to all inspection program personnel (IPP) regarding the addition of ingredients after final processing steps. FSIS inspectors now examine post-lethality control steps to ensure the process complies with standards to ensure food safety.

OPHS Goal 3.4

Protect public health by utilizing risk analyses to assign resources appropriately.

Linking public health to food safety measures

Using representative data, the Agency can use the model to link public health outcomes to food safety measures and objectives.

OPHS creates risk assessment models to assess food safety along the farm-to-table continuum. Consider a model as a straight line with the farm on one end and the consumer on the other. The models aim to insert performance objectives linked to public health that build

safety into the process. In a Journal of Food Protection article, OPHS scientists describe a risk assessment model that works backwards from the end goal, the consumer. The scientists applied appropriate levels of protection (ALOP)—phytosanitary measures to protect human health—to develop safety in the food chain. To study this approach, the scientists focused on one pathogen, *Clostridium perfringens*, in one RTE product, hotdogs. *C. perfringens* forms hardy spores during adverse conditions, like high cooking temperatures. During sporulation, some types of this pathogen produce a toxin that may induce diarrhea in a person who consumed the contaminated food. The risk assessment model allows scientists and policymakers to select the most practical and efficient performance objective based on national public health goals. These public health requirements would not only apply to food produced in the United States, but imports as well. Each country develops its standards of safety. This objective approach can ease the variation in setting equivalence between countries' safety standards, thereby easing trade barriers and improving safety.

OPHS Goal 3.5

Enhance the Agency's ability to implement risk-based inspection.

Characterizing *L. monocytogenes* in retail establishments

*Two studies examine the location and primary modes of *L. monocytogenes* movement in the retail environment.*

OPHS contracted with two universities to characterize *L. monocytogenes* at retail. Cornell University, in Ithaca, NY, conducted a survey of *L. monocytogenes* contamination in the retail grocery store environment. The research group

collected product samples to determine the prevalence, level, and sub-type of this pathogen in the retail setting. The group mapped the location of the pathogen, returning to stores on multiple occasions to determine if trends exist. Virginia Polytechnic Institute and State University, in Blacksburg, VA, designed a “mock deli” to track pathogen transmission within the retail grocery store environment. Both studies provided specific data needed to evaluate how conditions, behaviors, and practices contribute to the transmission of *L. monocytogenes* in FSIS- and FDA-regulated products at retail. OPHS also established an interagency agreement with the CDC to collect data on grocery store employee sanitary practices and behaviors when handling and preparing RTE foods. In addition, the FSIS-FDA Interagency Retail *L. monocytogenes* Risk Assessment team obtained retail information from stakeholder groups, including the Association of Food and Drug Officials (AFDO), American Meat Institute (AMI), Food Marketing Institute (FMI), Center for Science in the Public Interest (CSPI), and academic colleagues.

Revamping the National Residue Program to improve food safety

Agencies collaborating on the NRP define roles and responsibilities

FSIS collaborated with the FDA and EPA to develop a risk-based sampling program to identify chemical compounds, including veterinary drugs, of concern in meat, poultry, and egg products. This program tests and analyzes compounds of concern, reports the results to the establishment and the public, and identifies regulatory follow-up testing for

chemicals reported at violative levels. In 2010, FSIS, FDA, and EPA set up an interagency, senior-level working group to resolve long-standing issues and make the program more relevant in ensuring the safety of the Nation’s food supply. FSIS, along with FDA and EPA, anticipates that the work of this group will help define the future direction of the NRP.

OPHS supports science-based inspection activities

OPHS conducts scientific reviews to support Food Safety Assessments and special investigations.

OPHS provided expert technical support to the Office of Field Operations (OFO), including analysis of industry food safety programs, microbiological testing methods, and data. Some requests were high profile investigations, including the participation in an Incident Investigation Team (IIT), which assessed *E. coli* O157:H7 contamination in a beef slaughter and fabrication establishment. OPHS provided technical expertise to the Office of Policy and Program Development (OPPD), responding to numerous AskFSIS requests, including numerous Enforcement Investigation and Analysis Officer (EIAO) requests for assistance in assessing industry microbiological testing methods. There were a number of additional ad hoc queries from multiple sources, including rapid test manufacturers, the food industry, academia, and foreign countries. To support FSIS inspection personnel, OPHS conducted predictive microbial modeling to assess process and chilling deviations.

OPHS Goal 3.6

Enhance capability to measure foodborne illness attribution.

Baseline studies inform *Campylobacter* method

Campylobacter added to inspection of FSIS-regulated products.

The CDC identified *Campylobacter* as the leading foodborne pathogen responsible for bacterial-induced diarrhea, causing an estimated 845,000-foodborne illnesses annually. As such, FSIS proposed a performance standard to determine if in-plant HACCP interventions are effective at reducing the level of this pathogen on poultry carcasses. The Agency used data from the young chicken baseline (2007 to 2008) and young turkey baseline (2008 to 2009) to assess the presence and levels of *Campylobacter* in these commodities. OPHS developed the method based on guidance from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). OPHS laboratories refined and validated the baseline testing method by incorporating *Campylobacter* testing into existing *Salmonella* testing programs. OPHS anticipates reallocating the savings in sample collection and transportation to other testing programs. With this method and testing program, FSIS aims to lower the level of *Campylobacter* on regulated products to ensure public health.

Interagency collaboration progresses on issues of food safety

Interagency Foodborne Illness Attribution hits the ground running to address food safety.

In February 2010, FSIS leadership met with their counterparts at the CDC and FDA in Shepherdstown, WV, to develop an approach for interagency collaborations on high-priority analytical projects. The leadership team agreed

to formalize the collaborations and identified analytical projects that attributed human illness to specific foods as an initial focus. As the year progressed, the tri-agency collaborators drafted a charter, identified a steering committee, and named the group the "Interagency Food Safety Analytics Collaboration" (IFSAC). The steering committee members include David Goldman and Christopher Alvares (FSIS), Christopher Braden and Patricia Griffin (CDC), and Jeff Farrar and Debra Street (FDA). At the end of FY2010, the IFSAC steering committee was poised to identify the initial high-priority foodborne illness attribution analytical projects for the next fiscal year.

OPHS Goal 5.1

Build an excellent scientific workforce in support of FSIS public health mission.

OPHS builds a dynamic workforce

New talent continues OPHS efforts to ensure the safety of the nation's food supply.

OPHS welcomed Dr. Vivian Chen as its Deputy Assistant Administrator. Dr. Chen brings 25 years of talent, expertise, and experience to the Agency, which includes time as a Commissioned Corp Officer in the U.S. Department of Health and Human Services (HHS). In addition, she held an appointment as the Chief Professional Officer for Health Services, and Health Operations Director at the City of Milwaukee Health Department. According to Chen, "My work as the operations director in the Milwaukee Health Department immersed me in food safety issues. It's a thrill to be at OPHS working on food safety from the national policy perspective and to work for Dr. Goldman and USDA on this vital mission."

The RAD welcomed a former summer intern as a new risk analyst, who brings certifications

in quantitative foods safety risk assessment modeling to OPHS. In addition, the division has benefitted from two American Association for the Advancement of Science (AAAS) fellows, who bring their unique skills and expertise to conduct rapid risk assessment for chemical and microbial hazards. One fellow worked on the FSIS catfish risk assessment, publishing papers during her fellowship. The second fellow worked on microbial risk assessment projects, in particular, a non-O157 *E. coli* risk profile. The division hired a new Branch Chief with skills in veterinary science and food safety policies related to residues. The division also hired a food toxicologist with strong risk assessment modeling skills. Finally, RAD welcomed summer interns with engineering skills who assisted with R-program *L. monocytogenes* risk assessment models for young chickens.

AED hired a senior epidemiologist, who worked closely with CDC. The division also expanded to include an epidemiologist, who analyzed and evaluated data in the Consumer Complaint Monitoring System related to meat, poultry, egg, and catfish products. Finally, AED welcomed a summer intern, who assisted with Public Health Veterinarians at a cattle slaughterhouse in Long Prairie, MN.

MD hired a biological statistician to serve as a Contracting Officer's Technical Representative (COTR) for the Agency's microbiological baseline work. In addition, MD hired a Staff Officer/Biological Scientist to provide support to diverse divisional activities and for special projects on behalf of the Director.

The FSL welcomed 11 full-time staff. The new employees brought their skills and talents in biotechnology, microbiology, and chemistry to identify foodborne pathogens and chemical residues to continue the OPHS mission of ensuring that the Nation's food supply is safe. In addition, the LQAD welcomed a new Chemistry

Branch Chief, who has enhanced all aspects of the residue and food chemistry programs for FSIS. The FSL also benefited from the skills of laboratory support and laboratory technicians. Finally, the FSL welcomed summer interns, who developed valuable scientific skills during summer research projects.

OPHS Goal 5.2

Build and maintain laboratory facilities that are green and state-of-the-art

Going green saves energy and reduces waste at the Eastern Laboratory.

Eastern Laboratory incorporates energy efficient facilities and dynamic recycling programs.

The Eastern Laboratory constructed a new sample receipt building that integrated environmentally friendly practices. The building uses low-volume flush toilets, double-paned tinted windows, low-wattage T8 bulbs, additional insulation, energy-efficient heat pumps, hot water heaters, and refrigerators. In addition, the lab hired a "green company" to install computer and phone lines for the new building. Of the 85 freezers in the new building and laboratory, only 5 use R12 coolant (Freon™). The laboratory continues to practice good environmental management protocols consisting of a dynamic recycling program (i.e., plastics, paper, aluminum, cardboard, glass, batteries, printer cartridges, computer equipment, polystyrene, plastic grocery bags, bound books, magazines, and furniture). The laboratory recycled and replaced Mercury containing ballasts from the light fixtures with electronic ballasts. The laboratory is working toward redesigning chemistry methods to reduce or eliminate solvent from analytical methods. This work earned the Eastern Laboratory and ARS the "Recycler of the Year" award from the local county recycling division. In addition,

these efforts comply with the Greening the Government through Leadership in Environmental Management, Executive Order 13148.

OPHS Goal 5.3

Build a robust, innovative budget, financial management, and performance integration infrastructure focused on accountability and internal control.

FY2010 budget managed within one-tenth of 1 percent

RPMS staff walks a thin line to use monies efficiently and effectively.

No one enjoys creating a family budget, but imagine maintaining a budget with more than 300 employees. The RPMS staff managed the \$60.6 million OPHS budget within one-tenth of 1 percent. RPMS manages the funds that maintain headquarters and laboratory system divisions in Georgia, Missouri, and California, as well as field offices in Colorado, Minnesota, and Nebraska. In addition to funding OPHS employees, these funds resource the sample collection and analysis of baseline studies and food surveillance programs, like FoodNet and OutbreakNet. The staff negotiated and contributed to interagency collaborations with ARS, CDC, EPA, and FDA. The RPMS staff navigates these different tasks by meeting with division directors and the Executive Associate for Laboratory Services throughout the fiscal year to ensure that monies are allocated to address the Agency's evolving priorities.

OPHS improves process efficiencies

The Resource and Program Management Services staff processed more than 300 personnel actions in FY2010.

Two RPMS staff members managed the paperwork for a variety of personnel actions

for headquarters staff. These actions included paperwork to coordinate, advertise, and bring 19 new hires into the Agency, as well as process other personnel actions, such as reassignments, transfers, resignations, promotions, and spot awards. The staff accomplished this goal by improving efficiencies for each action. In the past, staff faxed or mailed personnel actions to the Human Resources Office (HRO) in Minneapolis, MN, according to Agency procedure. Many actions were delayed due to files that were not received or misplaced. Staff now scan and email all personnel actions to HRO to reduce the processing time, confirm receipt of actions, and ensure the protection of personal information. In addition, RPMS staff gained access to the HRO database to retrieve reports (previously provided by HR) detailing the status of personnel actions, employee count, and roster data. Timely access to these data assists senior management during budget and staffing discussions.

OPHS Goal 6.1

Improve FSIS' regulatory effectiveness through better communication and collaboration.

Communicating the safety of U.S. pork

A collaborative effort ensures the safety of the Nation's pork supply to domestic and international partners.

H1N1 influenza was originally, but falsely, called "swine flu" due to similarities with the virus that affects pigs in North America. This misnomer raised questions among agricultural producers about the virus as an emerging animal health issue that could affect trade. To retain consumer confidence, the Federal government developed a plan to communicate the safety of U.S. pork. OPHS participated in the H1N1 meetings that were composed of public relations

experts, industry representatives, government representatives, and academia. The participants identified the communication challenges surrounding the H1N1 issue and ways to address these challenges. OPHS worked with scientists to confirm that H1N1 had never been isolated from swine muscle tissue. OPHS and the H1N1 partners reiterated the fact that pork is safe to eat. The impact of this messaging boosted global consumer confidence in the safety of U.S. pork products. The Secretary of Agriculture recognized these efforts with an Honor Award.

OPHS Goal 6.2

Institutionalize OPHS' role in development of Agency public communications.

Improving the food safety public health information system

Three OPHS staff epidemiologists evaluated the Consumer Complaint Monitoring System.

Public health surveillance systems occur at the local, State, and Federal level to collect, assess, interpret, and disseminate information on foodborne illness. These surveillance systems issue warnings and notifications, as well as guide public policy and strategies to improve early interventions. In 2001, USDA-FSIS established the Consumer Complaint Monitoring System (CCMS) program to centralize the monitoring, management, and coordination of food-related investigations of FSIS-regulated products. During FY2010, the CCMS team evaluated the program to improve customer service for system users and consumers. The survey identified opportunities for improvement of business workflow and technical problems that spanned communication, training, outreach, investigation process, reports and analyses, and interconnected applications.

System improvements are on-going and the resulting recommendations aim to enhance the investigation and response process, guide the allocation of Agency resources, and support policy changes to limit physical, chemical, and biological foodborne hazards. In FY2010, the group developed talking points and closing statements to aide operators and investigators during consumer interviews. The group continues to update reporting features to develop detailed, customized reports offering valuable statistics to aide investigations and trend analyses.

OPHS risk models available to a wider community

Using a freeware program, OPHS risk models are available to everyone.

RAD creates computer models to evaluate how different interventions, performance standards, inspection activities, and technologies can reduce the public health risk associated with FSIS-regulated products. The division acknowledged the importance of sharing these models with stakeholders, academics, and others. Traditionally, RAD used commercial software packages to develop risk assessment models, but the software was expensive to purchase and maintain, effectively limiting open access to the broader community. In addition, the commercial software resulted in high-operating costs for the division. To remedy this situation, the division made a concerted effort to develop computer models using a well-known freeware program, commonly used by risk analysts and engineers, known as "R." R-software is available to stakeholders, who can readily access and apply it to understand FSIS risk assessment models. RAD used this platform to develop the 2010 Catfish Risk Assessment, which evaluated *Salmonella* interventions. This model is available to stakeholder groups, improving

the transparency of this risk assessment for rulemaking. RAD anticipates that the greater accessibility of the risk assessment models will expand their impact with stakeholders, academics, and other Federal agencies to reduce illness and improve public health.

OPHS Impacts

Reducing *Listeria monocytogenes*, an evolving story

*OPHS risk assessments are critical to establishing policies to reduce *L. monocytogenes* in the Nation's food supply.*

CDC estimates that *L. monocytogenes* is responsible for 1,600 illnesses, 1,500 hospitalizations, and 260 deaths annually (Scallan et al., 2011). Proper cooking techniques eliminate this pathogen in RTE food products, such as cheese, deli meats, smoked fish, hot dogs, and deli salads, but it survives refrigeration temperatures, contaminating other products in the retail environment.

To address this important issue, RAD conducted a series of risk assessments starting in the late 1990s. The first *L. monocytogenes* risk assessment, conducted in collaboration with FDA, identified deli meats as the food product posing the greatest risk for listeriosis in the United States. The model results surprised stakeholders because there had been no large-scale outbreaks of listeriosis associated with deli meats. The following year, the United States experienced a massive foodborne outbreak of listeriosis. After an investigation, they determined deli meat was the culprit. A few months after this outbreak, FSIS developed another risk assessment that shifted FSIS policy focus from the sampling of food preparation areas in processing establishments to the adoption of control measures incorporating the benefits of both

reformulating products with antimicrobial agents and using post-lethality interventions to control *L. monocytogenes* in RTE foods. The risk assessment predicted that these measures would save 120 lives per year. These findings led to the interim final Listeria Rule, published in 2003 that encouraged industry to adopt more stringent control measures to prevent *L. monocytogenes* contamination and transmission.

In 2005, RAD analysts integrated components of these *L. monocytogenes* risk assessments to develop a statistical algorithm to allocate FSIS-inspection resources based on the industry adopting *L. monocytogenes* processing control measures deemed effective from prior risk assessments. Since that time, FSIS testing programs have shown a decline of *L. monocytogenes* in RTE meat and poultry products. The industry has heralded the adoption of these controls as a success.

Although the prevalence of *L. monocytogenes* in RTE meat and poultry products, as measured by FSIS' HACCP verification testing, has declined, human illnesses from listeriosis have plateaued in recent years. This outcome suggests that another source of the pathogen continues to contaminate food products and sicken consumers. In 2010, FSIS published another *L. monocytogenes* risk assessment, which associates approximately 83% of listeriosis cases to deli meats sliced and packaged at retail. As a follow-up to this finding, FSIS collaborated with FDA to begin its fourth *L. monocytogenes* risk assessment to understand how the organism contaminates foods in delicatessens and determine the most effective interventions for preventing the spread and contamination in RTE foods. FSIS has contracted with two universities to identify modes of transmission, areas of harborage, and specific sub-types of *L. monocytogenes* in the retail environment. OPHS also continues to work with their Federal partners, industry, and other

stakeholder groups to encourage collaboration among experts and form partnerships. With additional information, the partnerships can refine the current risk assessment to guide policies and protect public health.

OPHS Committees

National Advisory Committee on Microbiological Criteria for Foods (NACMCF)

provides impartial, scientific advice to Federal food safety agencies to develop an integrated national approach to the food safety of domestic, imported, and exported food along the farm-to-table continuum. USDA has deemed the Committee as an important source of scientific advice for U.S. food safety programs and has renewed the NACMCF charter biennially since 1988. The Committee reports to the Secretary of Agriculture and to the Secretary of Health and Human Services. NACMCF provides FSIS with the highest level of scientific expertise applied to its microbiological food safety initiatives, fortifying the scientific input to FSIS programs. NACMCF is managed through an interagency food safety partnership between the USDA-FSIS, HHS' CDC and FDA, the Department of Commerce's (DoC) National Marine Fisheries Service (NMFS), and the Department of Defense's (DoD) Veterinary Services Activity (VSA). In 2010, the Secretary of Agriculture re-established the NACMCF charter and appointed 18 qualified scientists to serve on the Committee for a 2-year term.

During FY2010, NACMCF published several articles in peer-reviewed scientific journals, including:

Determination of the Most Appropriate Technologies for the Food Safety and Inspection Service to Adopt in Performing Routine and Baseline Microbiological Analyses, which updates FSIS on pathogen detection methodology.

Parameters for Inoculated Pack/Challenge Study Protocols, which provides guidance to regulatory agencies and industry on the design of studies to assess the time/temperature control for food safety for various food products.

Assessment of Food as a Source of Exposure to Mycobacterium avium subspecies paratuberculosis (MAP), which reviews the exposure of humans to MAP through foods, as well as the detection and control methods, and points out related research needs.

The Codex Alimentarius Commission (Codex)

serves as an internationally recognized reference point for food standards. Codex is a collection of standards, codes of practice, guidelines, and other recommendations to harmonize food standards. This harmonization contributes to the protection of consumer health and international trade. FSIS' participation in Codex focuses on groups that deal with food hygiene, antimicrobial resistance, pesticides, contaminants, and veterinary drugs.

In FY2010, the Codex Intergovernmental Task Force on Antimicrobial Resistance completed a timeframe and draft guidelines for assessing and managing risks from foodborne antimicrobial resistance, with the aim of adopting the approved guidelines in FY2011. During this period, the Codex Committee on Food Hygiene began the revision of Principles for the Establishment and Application of Microbiological Criteria for Foods to reflect the latest practice and knowledge of microbiological criteria, introduce new risk management metrics, and provide guidance on the use of these metrics in new risk management measures. In FY2010, the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) began developing guidance for the following items: Performance Characteristics for Multi-residue Methods, Revision of the Risk Analysis Principles Applied by the CCRVDF and Developing Sampling Plans for Residue Control for Aquatic Animal Products and Derived Edible Products of Animal Origin.

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