

**2008 Explanatory Notes
Food Safety and Inspection Service**

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FOOD SAFETY AND INSPECTION SERVICE

Purpose Statement

The Secretary of Agriculture established the Food Safety and Inspection Service (FSIS) on June 17, 1981, pursuant to legislative authority contained in 5 U.S.C. 301 that permits the Secretary to issue regulations governing the United States Department of Agriculture (USDA). The mission of FSIS is to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, as required by the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). FSIS is composed of two major inspection programs: (1) Meat and Poultry Inspection and (2) Egg Products Inspection.

1. FSIS is the Department of Agriculture's public health regulatory agency responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. FSIS enforces the FMIA, the PPIA, and the EPIA, which requires Federal inspection and regulation of meat, poultry, and processed egg products prepared for distribution in commerce for use as human food. FSIS also enforces the Humane Methods of Slaughter Act, which requires that all livestock at federally inspected establishments be handled and slaughtered in a humane way.

FSIS conducts inspection activities at federally inspected establishments; and for States not under Federal inspection, the Agency ensures that State meat, poultry, and egg products inspection programs have standards that are at least equivalent to Federal standards. FSIS also insures that meat, poultry, and egg products imported to the United States are produced under standards equivalent to U.S. inspection standards, and facilitates the certification of exported goods.

FSIS' science-based inspection system, known as the Hazard Analysis and Critical Control Point (HACCP) system, places emphasis on the identification, prevention, and control of foodborne hazards. HACCP requirements include meeting sanitation, facility, and operational standards, and other prerequisite programs to control pathogen contamination and produce safe and unadulterated food.

2. The Egg Products Inspection Program is authorized by the EPIA. The program ensures the safety and wholesomeness of egg products through continuous mandatory inspection of egg processing plants producing liquid, frozen, or dried egg products to ensure that products sold are wholesome, unadulterated, and truthfully labeled. This program also controls imported egg products to ensure that U.S. requirements are met.

During 2006, the agency maintained headquarters offices in the Washington D.C. metropolitan area; 15 district offices; the Technical Service Center in Omaha, Nebraska; laboratories at Athens, Georgia, St. Louis, Missouri, and Alameda, California; the Financial Processing Center in Des Moines, Iowa; Human Resources Field Office in Minneapolis, Minnesota; the Training Center in College Station, Texas; and a nationwide network of inspectors in approximately 6,282 establishments (including official import facilities and egg plants) in 50 States, Puerto Rico, American Samoa, Guam, and the Virgin Islands. Included are 368 establishments operating under Talmadge-Aiken Cooperative Agreements. Much of the work is conducted in cooperation with Federal, State and municipal agencies, as well as private industry.

As of September 30, 2006, the agency employment totaled 9,029 permanent full-time employees and 104 part-time employees; on that date, there were also 448 temporary employees. Of these, 709 permanent full-time employees and 56 part-time or temporary employees were located in headquarters offices; 225 permanent full-time and 4 part-time or temporary employees were in agency laboratories; and 230 permanent full-time and 7 part-time or temporary employees were in district offices. The balance of 7,865 permanent full-time employees and 410 part-time or temporary employees were in field locations.

OIG Reports

1. 5061-0009-Ch, September 29, 2006, Animal and Plant Health Inspection Service's (APHIS) Control Over the Bovine Tuberculosis Eradication Program.
2. 24601-0007-Ch, September 28, 2006, Review of the Pathogen Reduction Enforcement Program (PREP) Sampling Procedures.
3. 24005-1-At, September 27, 2006, Food Safety and Inspection Service – State Meat and Poultry Inspection Programs.
4. 24601-06-Ch, March 28, 2006, Food Safety and Inspection Service's In-Plant Performance System.
5. 5061-11-HQ, February 17, 2006, USDA Controls for Beef Export Verification Program for Japan.
6. 33601-3-AT, February 9, 2006, APHIS Evaluation of the Implementation of the Select Agent or Toxin Regulations – Phase II.
7. 5061-10-HY, February 2, 2006, APHIS Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II and Food Safety and Inspection Service Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Systems.
8. 24601-05-HY, January 10, 2006, Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System.
9. 50401-56-FM, November 23, 2005, U.S. Department of Agriculture's Consolidated Financial Statements for Fiscal Years 2005 and 2004.

GAO Reports

1. GAO-06-832, August 17, 2006, The Federal Workforce: Additional Insights Could Enhance Agency Efforts Related to Hispanic Representation.
2. GAO-06-644, May 19, 2006, Homeland Security: Management and Coordination Problems Increase the Vulnerability of U.S. Agriculture to Foreign Pests and Disease.
3. GAO-06-713, May 11, 2006, Continuity of Operations: Selected Agencies Could Improve Planning for Use of Alternative Facilities and Telework during Disruptions.
4. GAO-06-460, April 6, 2006, Hurricane Katrina: Comprehensive Policies and Procedures Are Needed to Ensure Appropriate Use of and Accountability for International Assistance.
5. GAO-06-324, March 31, 2006, Human Capital: Agencies Are Using Buyouts and Early Outs with Increasing Frequency to Help Reshape Their Workforces.
6. GAO-06-161, January 17, 2006, Combating Terrorism: Determining and Reporting Federal Funding Data.
7. GAO-06-114, October 12, 2005, Higher Education: Federal Science, Technology, Engineering, and Mathematics Programs and Related Trends.

FOOD SAFETY AND INSPECTION SERVICE
Available Funds and Staff-Years
2006 Actual and Estimated 2007 and 2008

Item	Actual 2006		Estimated 2007		Estimated 2008	
	Amount	Staff Years	Amount	Staff Years	Amount	Staff Years
Salaries and Expenses:						
Appropriation	\$837,756,000	9,339	\$830,081,000	9,339	\$930,120,000	9,430
Rescission from Appropriation	-8,378,560					
Unobligated balance forward from prior years.....	1,425,000		722,000			
Subtotal, salaries and expenses.....	830,802,440	9,339	830,803,000	9,339	930,120,000	9,430
Transfer from DA for Congressional Relations.....	248,000		250,000		250,000	
Total, Salaries and Expenses.....	831,050,440	9,339	831,053,000	9,339	930,370,000	9,430
Obligations under other USDA appropriations:						
National Appeals Division	256,285		260,000		268,000	
APHIS Blood Sample	425,000		425,000		425,000	
BSE Surveillance/Telecommunication	1,250,000		750,000		758,000	
Miscellaneous Reimbursements	309,975		200,000		206,000	
Total, Agriculture Appropriations.....	2,241,260		1,635,000		1,657,000	
Other Federal Funds:						
FDA, Microbiological Advisory Committee	26,000		27,000		27,000	
Commerce, Microbiological Advisory Committee	26,000		27,000		27,000	
DOD, Microbiological Advisory Committee	26,000		27,000		27,000	
CDC, Microbiological Advisory Committee	10,500		11,000		11,000	
DHS, Bioterrorism	2,015,377		11,000		11,000	
Total, other Federal Funds	2,103,877		103,000		103,000	
Non-Federal Funds:						
Meat, Poultry and Egg Products Inspect	136,130,076	37	123,947,500	37	127,665,925	37
Accredited Labs	263,281	2	322,500	2	332,175	2
All other	963,509					
Trust Funds	6,260,666	46	6,642,240	46	6,841,507	46
Total, Non-Federal Funds	143,617,532	85	130,912,240	85	134,839,607	85
Total, Food Safety and Inspection Service.....	979,013,109	9,424	963,703,240	9,424	1,066,969,607	9,515

FOOD SAFETY AND INSPECTION SERVICE

Permanent Positions by Grade and Staff Year Summary
2006 Actual and Estimated 2007 and 2008

Grade	2006			2007			2008		
	Wash DC	Field	Total	Wash DC	Field	Total	Wash DC	Field	Total
Senior Executive Service	25	1	26	25	1	26	25	1	26
GS-15	58	32	90	58	32	90	58	32	90
GS-14	128	85	213	128	85	213	128	85	213
GS-13	240	394	634	240	394	634	240	394	634
GS-12	97	1,027	1,124	97	1,027	1,124	97	1,047	1,144
GS-11	45	253	298	45	253	298	45	253	298
GS-10	1	403	404	1	403	404	1	403	404
GS-9	42	1,892	1,934	42	1,892	1,934	42	1,892	1,934
GS-8	12	930	942	12	930	942	12	944	956
GS-7	55	3,120	3,175	55	3,120	3,175	55	3,174	3,229
GS-6	11	46	57	11	46	57	11	46	57
GS-5	8	232	240	8	232	240	8	232	240
GS-4	6	36	42	6	36	42	6	39	45
Total Permanent Positions	728	8,451	9,179	728	8,451	9,179	728	8,542	9,270
Unfilled Positions end-of-year	19	131	150	-	-	-	-	-	-
Total Permanent Full-Time Employment, end-of-year	709	8,320	9,029	728	8,451	9,179	728	8,542	9,270
Staff Year Estimate 1/	760	8,664	9,424	760	8,664	9,424	760	8,755	9,515

1/ Includes other than permanent (part-time, intermittents, etc.)

MOTOR VEHICLE FLEET DATA

Size, composition and cost of agency motor vehicle fleet as of September 30, 2006 are as follows:

**Size, Composition, and Annual Cost
(in thousands of dollars)**

Agency: Food Safety and Inspection Service

Fiscal Year	Number of Vehicles by Type*					Total Number of Vehicles	Annual Operating Cost (000s)
	Sedans and Station Wagons	Light Trucks, SUVs and Vans		Medium Duty Vehicles	Food Safety Mobile		
		4X2	4X4				
FY 2005	1,280	33	1	2	1	1,317	\$6,683
Change from 2005	103	-2		-2		99	-\$160
FY 2006	1,383	31	1		1	1,416	\$6,523
Change from 2006	0					0	\$860
FY 2007	1,383	31	1		1	1,416	\$7,383
Change from 2007	6					8	\$500
FY 2008	1,389	33	1		1	1,424	\$7,883

*These numbers include vehicles that are owned by the agency, leased from commercial sources, and leased from GSA.

Notes:

- FSIS inspects over 6,000 meat, poultry and egg products plants located throughout the United States. A large number of FSIS inspection personnel have responsibilities in multiple plants and work "patrol/relief assignments" traveling from plant to plant on a daily basis. In fiscal year (FY) 2002, all FSIS vehicles were leased from GSA's fleet. In 2006 FSIS leased 103 more vehicles, however, operating cost decreased due to less mileage used.
- FSIS plans to replace up to 359 vehicles in FY 2007.

FOOD SAFETY AND INSPECTION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Salaries and Expenses:

For necessary expenses to carry out services authorized by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, including not to exceed \$50,000 for representation allowances and for expenses pursuant to section 8 of the Act approved August 3, 1956 (7 U.S.C. 1766), [\$757,470,000] \$930,120,000, of which no less than \$839,130,000 shall be available for Federal food safety inspection; and in addition, \$1,000,000 may be credited to this account from fees collected for the cost of laboratory accreditation as authorized by section 1327 of the Food, Agriculture, Conservation and Trade Act of 1990 (7 U.S.C. 138f): Provided, That of the total amount made available under this heading, no less than \$20,653,000 shall be obligated for regulatory and scientific training: Provided further, That not to exceed \$565,000 is for construction of a laboratory sample receiving facility at the Russell Research Center in Athens, Georgia: Provided further, That this appropriation shall be available pursuant to law (7 U.S.C. 2250) for the alteration and repair of buildings and improvements, but the cost of altering any one building during the fiscal year shall not exceed 10 percent of the current replacement value of the building.

FOOD SAFETY AND INSPECTION SERVICE

SALARIES AND EXPENSES - CURRENT LAW

Estimate, 2007	\$830,081,000
Budget Estimate, 2008	<u>930,120,000</u>
Increase in Appropriation.....	<u>+100,039,000</u>

FOOD SAFETY AND INSPECTION SERVICE

SUMMARY OF INCREASES AND DECREASES - CURRENT LAW

(On basis of appropriation)

<u>Item of Change</u>	<u>2007 Estimated</u>	<u>Pay Costs</u>	<u>Program Changes</u>	<u>2008 Estimated</u>
Federal Food Safety & Inspection	\$742,763,000	+\$43,130,000	+\$53,237,000	\$839,130,000
State Food Safety & Inspection	56,912,000	+1,248,000	+2,758,000	60,918,000
International Food Safety & Inspection	19,355,000	+895,000	+604,000	20,854,000
Public Health Data Communication Infrastructure System (formerly FAIM)	8,079,000	--	-1,976,000	6,103,000
Codex Alimentarius	2,972,000	+114,000	+29,000	3,115,000
Total Available	<u>830,081,000</u>	<u>+45,387,000</u>	<u>+54,652,000</u>	<u>930,120,000</u>

FOOD SAFETY AND INSPECTION SERVICE
PROJECT STATEMENT - CURRENT LAW
(On basis of appropriation)

	2006 Actual		2007 Estimated		Increase or Decrease	2008 Estimated	
	Amount	Staff Years	Amount	Staff Years		Amount	Staff Years
1. Federal Food Safety and Inspection	742,753,647	9,155	\$742,763,000	9,159	+\$96,367,000 (1)	\$839,130,000	9,250
2. State Food Safety and Inspection	53,252,000	29	56,912,000	29	+4,006,000 (2)	60,918,000	29
3. International Food Safety and Inspection	19,355,000	144	19,355,000	144	+1,499,000 (3)	20,854,000	144
4. Public Health Data Communication Infrastructure System (formerly FAIM)	8,079,000	0	8,079,000	-	-1,976,000 (4)	6,103,000	0
5. Codex Alimentarius	2,972,000	11	2,972,000	7	+143,000 (5)	3,115,000	7
Unobligated balance lapsing	3,214,793	--	--	--	--	--	--
Total Available or Estimate	829,626,440	9,339	830,081,000	9,339	100,039,000	930,120,000	9,430
Transfer from Departmental Administration for Congres- sional Relations activities	-248,000	--	a/	--			
Rescission	8,377,560		--	--			
Total Appropriation	837,756,000	9,339	830,081,000	9,339			

a/ Amount to be determined.

PROJECT STATEMENT - CURRENT LAW
(On basis of availability)

	2006 Actual	Staff Years	2007 Estimated		Increase or Decrease	2008 Estimated	
	Amount		Amount	Staff Years		Amount	Staff Years
1. Federal Food Safety and Inspection	742,304,917	9,155	\$743,485,000	9,159	+\$95,645,000 (1)	\$839,130,000	9,250
2. State Food Safety and Inspection	58,152,974	29	58,153,000	29	+4,006,000 (2)	62,159,000	29
3. International Food Safety and Inspection	15,067,976	144	17,486,000	144	+1,499,000 (3)	18,985,000	144
4. Public Health Data Communication Infrastructure System (formerly FAIM)	10,497,190	0	8,079,000	-	-1,976,000 (4)	6,103,000	0
5. Codex Alimentarius	3,599,464	11	3,600,000	7	+143,000 (5)	3,743,000	7
Total Obligations.....	829,622,521	9,339	\$830,803,000	9,339	+99,317,000	930,120,000	9,430
Unobligated balance lapsing	3,214,793	--	--	--	--	--	--
Unobligated balance forward from prior years	-3,933,313	--	-722,000	--	+722,000	--	--
Unobligated balance forward to next year	722,000	--	--	--	--	--	--
Total Available or Estimate	829,626,001	9,339	830,081,000	9,339	+100,039,000	930,120,000	9,430
Transfer from Departmental Administration for Congres- sional Relations activities	-248,000	--	a/	--			
Rescission	8,377,560						
Total Appropriation	837,755,561	9,339	830,081,000	9,339			

a/ Amount to be determined.

JUSTIFICATION OF INCREASES AND DECREASES

Maintain the Gold Standard in Meat and Poultry Inspections (+ \$80,308,000 and 91 FTE)

1. An increase of \$80,308,000 to enhance the safety and wholesomeness of meat, poultry, and egg products through effective inspection and policy implementation.

- a. An increase of \$19,178,000 for pay costs, consisting of
- \$18,721,000 for Federal Food Safety and Inspection;
 - \$105,000 for State Food Safety and Inspection;
 - \$312,000 for International Food Safety and Inspection Service; and
 - \$40,000 for Codex.

The increase for pay costs assumes an FY 2008 salary increase of 3.0 percent and annualization of the 2.2 percent salary increase from 2007.

- b. An increase of \$35,800,000 for changes in salaries, consisting of
- \$34,946,000 for Federal Food Safety Inspection
 - \$197,000 for State Food Safety Inspection
 - \$583,000 for International Food Safety Inspection; and
 - \$74,000 for Codex.

FSIS has a statutory mandate for carcass-by-carcass slaughter inspection and continuous presence for processing inspection. The permanent statutory obligations of FSIS to provide continuous inspection of meat, poultry, and egg products is a labor intensive mandate, thereby making its salary costs relatively inflexible.

Salaries and benefits amount to approximately 80 percent of the overall budget of FSIS. Overtime, salaries and benefits, along with fixed costs, have eroded the available funds needed to perform agency functions. It is difficult for the agency to absorb reductions from rescissions and remain effective while 80 percent of its budget is needed for staff costs. Examples of work not getting done in FY 2006 include: postponement of 6 equivalency audits of foreign meat and poultry systems; 20 percent reduction in the number of Food Safety Assessments, including a 50 percent reduction in evaluations of food safety system designs for control of *Listeria monocytogenes*; postponement of a number of investigations; and a significant reduction in the performance of "Other Consumer Protection" activities dealing with economic fraud and labeling. In addition, the inability to hire non-frontline positions means that the agency is not refreshing its workforce or infusing the existing workforce with new talent and ideas.

- c. An increase of \$5,353,000 for two extra work days in FY 2008, consisting of
- \$5,225,000 for Federal Food Safety and Inspection;
 - \$29,000 for State Food Safety and Inspection;
 - \$88,000 for International Food Safety and Inspection Service; and
 - \$11,000 for Codex.

In FY 2008, there are 262 work days, an increase of two days over the 260 work days in FY 2007. FSIS will incur \$2,676,500 in salary obligations for each extra day.

- d. An increase of \$2,596,000 for State inspection programs including State salary costs and State equal to status, consisting of
- \$2,596,000 for State Food Safety and Inspection.

State salary costs

An increase of \$946,000 is necessary for salary costs in cooperating State meat and poultry inspection programs. Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS has the responsibility for setting a national standard for meat and poultry inspection. Also pursuant to the FMIA and PPIA, States may enter into cooperative agreements with USDA to operate their own

inspection programs if they meet and enforce requirements “at least equal to” those imposed under the FMIA (21 U.S.C. 641-645) and the PPIA (21 U.S.C. 460). States may enter into a cooperative agreement for meat inspection, poultry inspection, or both meat and poultry inspection. However, product produced under State inspection is limited to intrastate commerce at this time.

FSIS reimburses the States up to 50 percent of the estimated cost of administering State inspection. FSIS requests an increase of 2.2 percent above the amount in the Grants, Subsidies and Contributions object class for salary increases in the cooperating States.

State Equal to Status

An increase of \$1,650,000 to support State “equal to” status. About 2,100 meat and poultry establishments are inspected under State Meat and Poultry (MPI) programs. Many of these establishments are small or very small. State and local governments have an increasingly important role in helping improve public health through food safety and food defense. FSIS provides guidance and assistance on the use of science-driven, risk-based approaches to the control of foodborne hazards. States and local governments help oversee the raising and transporting of food producing animals, the administration of inspections to intrastate meat and poultry processing facilities, and the regulatory oversight of retail and inspection-exempt businesses handling those products.

Current allocation levels are not sufficient to allow all Grantee State Programs to maintain their required “equal to” status. In 2006, FSIS issued allocations to each of its 28 State MPI members. The total amount allocated was equal to that allocated in FY 2005, however, due to documented shortfalls in several State programs, 20 States received an average of 1.8 percent less than the documented need for FY 2005. Of these members, 19 States have filed letters of concern associated with the level of funding.

The total requested increase is \$2.596 million. This initiative is aimed at adequately funding the actual costs of enforcing inspection requirements to meet Federal standards. Future budget allocations must be able to cover travel costs, vehicle maintenance, and fuel charges.

- e. An increase of \$8,400,000 for Federal employee benefits beyond the amounts covered in annual pay raises, consisting of
 - \$8,197,000 for Federal Food Safety and Inspection;
 - \$46,000 for State Food Safety and Inspection;
 - \$139,000 for International Food Safety and Inspection Service; and
 - \$18,000 for Codex.

While FSIS salary rates have risen 22 percent from 2000 through 2005, employee benefits for the same period have risen 38 percent. The additional increase is due mainly to rising costs of the Federal Employee Retirement System (FERS) and the Thrift Savings Plan (TSP) contributions as Civil Service Retirement System (CSRS) employees leave the agency, Federal retirement, and health benefits costs.

The migration of agency employees from CSRS to FERS occurs through attrition of the longer tenured employees who are part of the CSRS. This change increases the agency’s retirement cost due to the higher percentage of salaries the agency pays for FERS retirement, Federal Insurance Contributions Act, and the required contribution to TSP for employees in FERS.

The requested increase above the pay raise percentage is also needed to provide for increases in Federal Employee Health Benefits costs projected by the Office of Personnel Management. The rise in benefits in excess of salaries is about \$2.8 million annually. Escalating benefits costs, similar to pay costs, cannot be deferred and require increased funding to avoid a reduction of inspection, laboratory, and support personnel. Again, salaries and benefits cannot continue to absorb these costs without crippling or shutting down critical public health and food defense programs.

- f. An increase of \$8,981,000 and 91 staff years to support increased demand for front-line inspection services, consisting of:
 - \$8,981,000 and 91 staff years for Federal Food Safety and Inspection.

In accordance with FSIS' statutory mandate to provide carcass-by-carcass inspection for slaughter and continuous inspection for processing, the agency requests an increase in funding and additional staff to meet increased industry demand for in-plant inspection services.

Domestic inspectors: At the start of 2006, FSIS began seeing signs of an upsurge in growth for the meat industry. USDA estimated that the US cattle herd totaled 97.1 million or 1.7 percent higher than one year earlier. Cattle on Feed in February 2006 were at 12.1 million or six percent higher than the previous year and a record for any month. USDA's Chief Economist made projections for CY 2006 which indicated growth in demand for beef at 6.4 percent, pork at 2.7 percent, and chicken at 2.3 percent. The Office of the Chief Economist maintained these estimates for CY 2006 and projected additional increases for CY 2007. Per capita meat consumption was projected to increase 1.4 percent by the end of CY 2006. USDA's *Livestock, Dairy and Poultry Outlook* includes baseline projections for the agricultural sector through 2015, and projects increases in the commercial demand for beef, pork, and poultry product. The Economic Research Service has also projected that total U.S. pork consumption will grow because of an expansion of the U.S. population. Export market openings, especially in Korea and Japan, are expected to demonstrate additional increased demand for beef.

The projected growth in demand for meat and poultry products will create an estimated 78 new assignments in slaughter inspection to meet statutory requirements for carcass-by-carcass inspection. These inspection personnel will be stationed at those locations where industry production and establishment of new plants, slaughter lines, or additional shifts creates additional inspection assignments.

Program Investigators: Growth in the agency's food safety and food defense responsibilities is reflected not merely in the volume of product inspected and shipped, but also dramatically in the need to cover complex public health issues associated with the handling of meat, poultry, and egg products outside of the Federally inspected establishments. These responsibilities include surveillance of the transportation, storage, and distribution of inspected products for intentional and non-intentional chemical, biological and physical contamination of inspected products; conduct of investigations to detect, prosecute and deter criminal violations; perform food defense activities including assessment and emergency response; coverage and follow-up of recalls; conduct illness outbreak and consumer complaint investigations; and audit and review of State and foreign inspection programs. The investigative staff will also provide FSIS with the ability to synthesize findings from case studies to identify common trends in plant performance and inspection program operations, root causes of development problems, and options for proactive solutions. FSIS is requesting 13 program investigators to support these growing responsibilities.

The ability to perform food safety and food defense surveillance activities, conduct investigations, and respond to emergency situations presents a continuing challenging in the major metropolitan areas of the United States due to the large number of facilities transporting, storing, importing, exporting, and distributing meat, poultry and egg products. Additional program investigators in these areas are essential to ensure continued protection of the welfare of consumers and the public interest. These positions will be assigned as follows: one to the New York City metro area, two to the New England metro corridor, one program investigator to the Buffalo/Rochester metro areas, three to the Los Angeles/Long Beach/San Diego metropolis, two to the San Francisco/Oakland Bay area, one to Denver, one to Las Vegas, one to the city and surrounding locals of Chicago and one to the Indianapolis metro area.

Improving the Efficiency and Effectiveness of the Risk-Based Inspection (RBI) Systems

Public Outcomes

- Inspection is concentrated at points of greatest risk to the safety of meat, poultry, and egg products.
- Food safety regulatory controls and enforcement actions are legally and scientifically supportable.
- Risk-based measures strengthen regulatory verification and enforcement contributing to safer meat, poultry, and egg products for the consumer.

Why is this initiative necessary?

FSIS is designing procedures to replace traditional inspection systems for processing operations. Under an optimal risk-based inspection system, the type and intensity of inspection activity at each establishment would be determined by an analytical process that permits inspectors to anticipate problems and focus their efforts on those processes and establishments most likely to have control issues and pose a public health risk. FSIS recognizes each step taken toward risk-based systems must further protect public health.

In FY 2008, FSIS continues its major focus on the design and implementation of this more robust risk-based inspection system. While the agency maintains that its current system is strong, the agency must adapt to the ever-changing realities of food safety and public health. The agency envisions a number of advantages offered by a more robust risk-based system. In particular, a risk-based system can be fluid, rapidly adapting to emerging hazards. It can more easily find problems that have occurred and anticipate problems to minimize risk. This more robust system should allow us to align agency resources with the corresponding level of risk posed by specific hazards, products and processes.

FSIS has already made progress toward a risk-based approach to food safety, especially in our risk-based approach to pathogen control. An example is the FSIS verification sampling program for *Listeria monocytogenes*. Under this initiative, FSIS tailors its verification activities to the interventions that plants choose to adopt and to the potential for *Listeria* growth in their products. In other words, FSIS conducts less sampling in those plants that have the best control programs for *Listeria* and more sampling, as well as in-depth Food Safety Assessments, in plants that adopt less vigorous programs.

FSIS' goal is to further enhance and strengthen this risk-based system. Based on the agency's progress with *Listeria*, FSIS has been developing a risk-based verification system for *E. coli* O157:H7, and announced in February 2005 an 11-step strategy for *Salmonella*. FSIS will take this risk-based approach further by using inspection data and other information to determine the hazard from product type and plant performance to determine the intensity of inspection at processing plants.

Implementation of the RBI System in Poultry Slaughter (Cost neutral – Potential Savings in Outyears)

As the next step, FSIS is building a more robust risk-based inspection system for slaughter and processing operations that can adapt to the ever-changing realities of food safety and public health. A risk-based system will provide the means for inspection program personnel to anticipate problems and to focus their efforts on processes and establishments in which there are most likely control issues and thus a public health risk. The risk-based system must rely heavily on data to identify those establishments and products that present the greatest risk to public health and to allocate resources accordingly. FSIS will use the public health model of collecting, assessing, and responding to public health data.

FSIS is committed to introducing risk-based inspection at young chicken slaughter plants as quickly as possible with the goal of implementing risk-based inspection during the last quarter of FY 2008. For slaughter establishments, with the HACCP-Based Inspection Model Project (HIMP), we took the next step in using risk to focus the agency's inspection efforts. HIMP was designed to assess whether establishments could successfully perform sorting for food safety and other consumer protection defects, and whether FSIS, as is appropriate in a HACCP based system, could be effective in verifying the success of the establishment's efforts. The HIMP project has demonstrated that establishments can perform the sorting functions while at the same time provide enhanced control of *Salmonella* on raw carcasses. During 2005, while *Salmonella* was increasing across the whole industry from 13.5 to 16.3 percent positive, the HIMP establishments were reducing levels from 11.2 percent in 2004 down to 10.6 percent in 2005. The HIMP establishments have consistently had lower *Salmonella* levels than establishments with traditional inspection. For 2005, the HIMP establishments had a positive rate of 10.6 percent for "A" samples, 6.5 percent lower than the traditional level of 17.1 percent. Clearly, a noticeable difference. Based on what it has learned under the HIMP system, FSIS intends to propose an enhanced poultry inspection system in which off-line inspection program personnel verify that establishments are appropriately implementing their food safety controls throughout their processes, while appraising each carcass to ensure that no adulterated product enters commerce. This system will ensure that the agency's resources are used in the

most effective and efficient way possible to help us meet future food safety challenges, some of which are either evolving or unknown today. Once fully implemented, the system will produce eventual cost savings estimated at \$14 million annually, while assuring the public product wholesomeness and safety better than today's. Because of the costs of initial implementation and time necessary to issue a final regulation, this budget request includes no costs or savings for risk-based inspection poultry in FY 2008.

Food Agriculture and Defense Initiatives (+ \$21,707,000)

2. An increase of \$21,707,000 for food and agriculture defense, consisting of:

\$20,297,000 for Federal Food Safety Inspection;
 \$1,033,000 for State Food Safety Inspection; and
 \$377,000 for International Food Safety Inspection.

Food contamination, animal and plant diseases, and infestations can have catastrophic effects on human health and the economy. USDA, the Department of Health and Human Services, and the Department of Homeland Security are working together to create a comprehensive food and agriculture policy that will improve the government's ability to respond to the dangers of disease, pests and poisons, whether naturally or intentionally introduced. This budget proposes \$21.7 million to further improve FSIS' ability to detect and respond to intentional or accidental contamination in the food supply.

This initiative supports the agency's strategic goal: to enhance the safety and wholesomeness of meat, poultry, and egg products through effective inspection and policy implementation; and its objective of allocating resources to public health based on potential hazards – whether microbial, chemical, physical, intentional adulteration, or misbranding – resulting in safe, wholesome meat, poultry, and egg products.

a. An increase of \$14,528,000 for the Food Emergency Response Network (FERN), consisting of:

\$13,295,000 for Federal Food Safety Inspection;
 \$903,000 for State Food Safety Inspection; and
 \$330,000 for International Food Safety Inspection.

While FSIS' initial goal was to fund up to 100 laboratories for active participation in FERN, the agency now has restructured FERN. In this new approach, FSIS will select seven out of the 133 eligible labs and add to them the 18 currently funded labs for a total of 25 labs that will receive funding to participate in screening projects, method validation studies, and field trials of new methods for special threat agents in order to provide for full geographic representation for microbiological testing.

The goal of the FERN is to have a robust food testing laboratory network capable of (1) responding to an event involving the intentional or accidental contamination of the food supply, (2) maintaining U.S. agricultural and industrial economic stability by rapid identification if an event occurs, and (3) ensuring/restoring consumer confidence in the safety of the Nation's food supply by the Network's rapid response.

FSIS requests the funding to fully integrate up to 25 already existing and geographically dispersed FERN labs for microbiological testing capacity. The funding would primarily be to provide 25 State and local labs with the equipment and training necessary to be full partners in FERN, as well as to support a reagent stream for them through the use of surveillance and proficiency testing programs.

The 25 labs would provide National coverage, by region, with the expertise needed to meet the overall mission of FERN. All 25 labs would be capable of providing screening microbial tests and results for the 10 priority threat agents in all food matrices. Approximately 15 of these 25 labs nationwide would be funded as "Regional Reference Labs." In addition to the screening capacity, these labs would also serve as technical transfer labs, sharing knowledge and expertise particularly with the remaining unfunded FERN partner laboratories. If necessary, these funded labs would also conduct specific projects, as needed. Once funded, the public health infrastructure would be far better prepared to respond to a contaminated food supply, and would benefit the physical and financial health of the Nation.

This approach strives to reach the necessary levels of expertise and proficiency required to quickly and accurately respond to any potential threats to the Nation's food supply. After an event, the network would handle the recovery phase through surveillance assignments and other monitoring strategies that would be required to secure the public's confidence in the food supply and lessen the economic consequences of an event.

Within the established laboratory network, there must be open communication and a ready exchange of knowledge and expertise among our State and Federal partners. Sufficient funding to support the connectivity and integration of the various laboratory functions within FERN is necessary in order to ensure that an adequate number of already operating laboratories, strategically located across the Nation, are actually capable of conducting the many different analyses for the numerous threat agents of concern. One million of this initiative would be necessary to continue the development and maintenance of our secure communication databases and websites (eLEXNET and National Food and Agriculture Laboratory Committee) to continue FERN support. The benefits of this system will be an increased emergency response network through FERN's robust food-testing network system.

This initiative is also critically tied into and dependent upon two other major FSIS initiatives: the Public Health Data Communication Infrastructure System (PHDCIS) and the Public Health Information Consolidation Project (PHICP) which represent an overarching and robust effort to vastly improve and facilitate communications and data exchange between FSIS and its food safety partners.

The PHDCIS is designed to enhance the ability of all employees, industry, and laboratories to receive information to analyze, cooperate, and respond in real-time to emergencies and to take more preventive steps to reduce foodborne illness and food defense threats. PHDCIS also provides for a disaster recovery plan, broadband connectivity, and standardized microcomputers for both Federal and State inspectors.

The PHICP provides the means to implement an effective risk-based food safety system that can collect, assess, and respond to hazards and risks. PHICP also provides a single source for mission critical data reporting, uses predictive models to analyze real time data from FSIS and other Federal, State, and local agencies, provides Web-enabled transactional user interfaces, develops a standard Application Program Interface through web services for system integration, and delivers critical reports to agency program personnel and managers.

- b. An increase of \$2,525,000 for two data systems to support FERN, consisting of:
 - \$2,348,000 for Federal Food Safety Inspection;
 - \$130,000 for State Food Safety Inspection; and
 - \$47,000 for international Food Safety Inspection.

FSIS requests \$2,525,000 for two data systems to support FERN – the electronic laboratory exchange network (eLEXNET) and a repository of analytical methods. The eLEXNET is a nationwide, Web-based, electronic data reporting system that allows analytical laboratories to rapidly report and exchange standardized data. This system is currently operational in nearly 100 food-testing, public health, and veterinary diagnostic laboratories across the country. Combined data is then readily available to approved laboratories and key decision makers. The funding will be used to make eLEXNET available to additional FERN and other analytical, food-testing laboratories. This will require eLEXNET system management, travel, on-site computer programming, and training.

Access to current, properly validated methods used for screening, confirmation, and forensic analysis is critical to all laboratories. FSIS is working with the Food and Drug Administration (FDA) to develop a Web-based repository of analytical methods compatible with eLEXNET. Access to these methods will greatly enhance the ability of FERN and other laboratories to respond to emergencies, to use new methodologies and technologies, to enhance efficiency, and to trouble-shoot problems. The requested funding will be used to enhance the repository and to populate the repository with numerous methods that will be obtained from analytical laboratories.

- c. An increase of \$2,531,000 to enhance laboratory capabilities, consisting of:

\$2,531,000 for Federal Food Safety Inspection.

The requested funding will be used to purchase equipment that will provide the FSIS laboratories with the capability and capacity to perform the toxin and chemical testing that will be standardized across all FERN laboratories so that FSIS laboratories can properly lead the FERN effort against the threats to meat, poultry, and egg products. The FSIS laboratories will also purchase additional state of the art technologies that will be used to detect potential bioterrorism-associated pathogens. These include equipment compatible with the Select Agent Program and Laboratory Response Network of the Centers for Disease Control; Perkin-Elmer Victor Biowarfare systems, Luminex multiple analysis systems, and improved mass spectrometry systems.

- d. An increase of \$1,985,000 to conduct follow-up bio-security training, consisting of:
\$1,985,000 for Federal Food Safety Inspection.

The biosecurity awareness of the workforce must be refreshed on an ongoing basis to protect public health as threat agents become better known and countermeasures are worked out. Upon successful implementation of this initiative, the FSIS workforce will have the necessary skills and knowledge to respond expeditiously to threats against the food supply, resulting in greater security and safety of meat, poultry, and egg products.

- e. An increase of \$138,000 for additional food security activities, consisting of:
\$138,000 for Federal Food Safety Inspection.

FSIS also requests \$138,000 for additional food security activities, including surveillance and monitoring, enhanced inspection, physical security, technical assistance to States and support for the Office of Food Defense and Emergency Response.

3. A decrease of \$1,976,000 for Public Health Data Communication Infrastructure System (PHDCIS) [formerly Field Automation and Information Management Project or FAIM], consisting of:
\$1,976,000 removed from PHDCIS

Since first approved by Congress in 1995, the FAIM initiative provided standardized microcomputers, software, peripherals, and related support to both Federal and State inspectors. Each year, appropriated funding is used to continually provide replacement Personal Computers and field support. In FY 2008, FSIS will reduce PHDCIS spending by approximately \$2 million by providing fewer computers to both Federal and State inspection personnel. The industry standard for replacement of such equipment is 3 years. However, FSIS will move to a 5-year cycle in order to reduce annual spending.

**FSIS PRESIDENT'S BUDGET FISCAL YEAR 2008
PROPOSED LEGISLATION**

Program: Mandatory User Fees for Licensing and Performance

Proposal: Beginning in FY 2008, FSIS will collect two mandatory user fees for licensing and performance. The licensing fee totals \$92 million based on the size of the operation. This fee could include a performance component of some kind so that those that perform better have a lower fee and those that perform poorly have a higher fee. The performance fee, for a total of \$4 million, is a flat fee to be charged to those plants that have sample failures that result in retesting, have recalls, or are linked to an outbreak. Collections from these fees will be used to reduce appropriation needs for FY 2009.

Rationale: The meat, poultry, and egg products inspection services for all regularly scheduled and approved shifts are paid for with Federal funds. The proposed legislation would transfer a portion of the cost of current and proposed mandatory, Federal inspection services to the industries that directly benefit from them, and will reduce Federal costs. Requiring establishments to pay an annual licensing fee to cover a portion of FSIS' inspection costs creates a new concept and control mechanism for the agency and the industry. The goal for implementation of a user fee program would provide certain services to the regulated industry, and in return, cover a percentage of FSIS' cost of inspection-related services.

The Agency also requests Congressional authorization to collect user fees for the costs of some identified services provided to industry beneficiaries. This fee will be assessed based on actual cost of the service provided to a particular establishment or based upon the average cost of a particular service. Under this performance-based approach, FSIS would charge establishments when poor performance triggers additional services to be performed by the Agency. Thus, this option provides an incentive for establishments to maintain and implement sound food safety systems.

Goal: USDA Strategic Goal 4: Enhance Protection and Safety of the Nation's Agriculture and Food Supply.

**Budget Impact
(\$ in millions)**

	FY 2008	FY 2009
Budget Authority	0	-\$96

FOOD SAFETY AND INSPECTION SERVICE
GEOGRAPHIC BREAKDOWN OF OBLIGATIONS AND STAFF YEARS
2006 Actual and Estimated 2007 and 2008

	FY 2006		FY 2007		FY 2008	
	Amount	Staff Yrs	Amount	Staff Yrs	Amount	Staff Yrs
Alabama	28,128,458	422	28,144,003	422	31,535,838	426
Alaska	516,756	6	517,041	6	579,354	6
Arizona	2,138,687	23	2,139,869	23	2,397,760	24
Arkansas	39,188,512	583	39,210,170	583	43,935,668	590
California	39,994,522	526	40,016,624	526	44,839,313	532
Colorado	13,740,240	171	13,747,834	171	15,404,684	173
Connecticut	1,231,123	16	1,231,803	16	1,380,257	16
Delaware	7,349,217	116	7,353,279	116	8,239,475	117
District of Columbia	177,274,155	783	177,372,123	783	198,748,500	792
Florida	9,127,026	120	9,132,070	120	10,232,641	121
Georgia	52,746,285	712	52,775,435	712	59,135,784	717
Hawaii	2,065,669	26	2,066,810	26	2,315,896	27
Idaho	3,305,863	47	3,307,690	47	3,706,323	47
Illinois	22,116,370	220	22,128,592	220	24,795,467	222
Indiana	9,113,275	114	9,118,312	114	10,217,225	115
Iowa	27,576,613	389	27,591,853	389	30,917,145	393
Kansas	20,164,624	278	20,175,768	278	22,607,294	281
Kentucky.....	10,149,739	162	10,155,348	162	11,379,242	164
Louisiana	8,155,851	97	8,160,359	97	9,143,822	98
Maine	891,792	11	892,284	11	999,820	11
Maryland	29,175,202	241	29,191,325	241	32,709,381	244
Massachusetts	1,690,596	24	1,691,530	24	1,895,389	24
Michigan	7,794,323	110	7,798,630	110	8,738,499	111
Minnesota	24,152,244	311	24,165,591	311	27,077,959	314
Mississippi	23,151,144	336	23,163,938	336	25,955,590	339
Missouri	22,825,810	315	22,838,425	315	25,590,847	318
Montana	1,979,015	18	1,980,108	18	2,218,745	18
Nebraska	24,990,581	368	25,004,392	368	28,017,850	372
Nevada	713,786	9	714,180	9	800,251	9
New Hampshire	493,027	7	493,300	7	552,751	7
New Jersey	5,909,468	78	5,912,734	78	6,625,320	79
New Mexico	1,250,177	10	1,250,868	10	1,401,619	10
New York	14,646,406	179	14,654,501	179	16,420,619	180
North Carolina	30,583,453	413	30,600,354	413	34,288,222	417
North Dakota	1,722,007	20	1,722,959	20	1,930,605	20
Ohio	11,583,008	97	11,589,409	97	12,986,132	98
Oklahoma	8,587,622	107	8,592,368	107	9,627,896	108
Oregon	3,655,782	46	3,657,802	46	4,098,630	47
Pennsylvania	28,115,477	378	28,131,015	378	31,521,285	382
Rhode Island	662,332	9	662,698	9	742,564	9
South Carolina	9,346,734	123	9,351,899	123	10,478,963	124
South Dakota	4,009,681	48	4,011,897	48	4,495,400	48
Tennessee	9,924,761	149	9,930,245	149	11,127,010	150
Texas	40,209,202	530	40,231,423	530	45,080,000	535
Utah	3,845,653	40	3,847,779	40	4,311,502	40
Vermont	898,332	5	898,829	5	1,007,153	5
Virginia	13,538,369	195	13,545,851	195	15,178,358	197
Washington	7,301,675	104	7,305,710	104	8,186,174	105
West Virginia	2,299,987	25	2,301,258	25	2,578,599	25
Wisconsin	15,793,251	171	15,801,978	171	17,706,388	172
Wyoming	293,670	-	293,833	-	329,245	-
American Samoa	19,775	0	19,786	0	22,171	0
Guam	67,377	1	67,414	1	75,539	1
Northern Mariana Islands.....	30,392	0	30,409	0	34,074	0
Puerto Rico	3,287,375	49	3,289,192	49	3,685,595	49
Virgin Islands	100,048	1	100,103	1	112,167	1
Subtotal, Available or Estimate.....	829,622,520	9,339	830,081,000	9,339	930,120,000	9,430
Unobligated Balance	+3,479					
Total, Available or Estimate.....	829,625,999	9,339	830,081,000	9,339	930,120,000	9,430

FOOD SAFETY AND INSPECTION SERVICE
CLASSIFICATION BY OBJECTS

2006 Actual and Estimated 2007 and 2008

Personnel Compensation:	<u>2006</u>	<u>2007</u>	<u>2008</u>
Washington, D. C.	\$67,662,149	\$69,360,038	\$71,441,000
Field	435,630,418	446,561,962	472,226,000
11 Total personnel compensation	503,292,567	515,922,000	543,667,000
12 Personnel benefits	168,708,772	172,427,000	190,069,000
13 Benefits for former personnel	1,137,939	1,931,000	1,931,000
Total pers. comp. & benefits	673,139,278	690,280,000	735,667,000
 Other Objects:			
21 Travel	32,353,775	32,354,000	42,000,000
22 Transportation of things	4,260,094	4,260,000	5,300,000
23.1 Rent payments to GSA	927,186	927,000	1,100,000
23.2 Rental payments to others	905,924	906,000	928,000
23.3 Communications, utilities and miscellaneous charges	9,634,991	9,635,000	14,157,000
24 Printing and reproduction	1,679,130	1,679,000	1,778,000
25.1 Advisory and assistance services	4,080,362	4,080,000	4,580,000
25.2 Other services	28,098,166	11,418,000	36,000,000
25.3 Other purchases of goods and services from Government accounts	16,205,462	16,205,000	16,700,000
25.4 Operation and maintenance of facilities	399,280	399,000	638,000
25.5 Research and development contracts	--	--	--
25.6 Medical care	47,458	47,000	72,000
25.7 Operation and maintenance of equipment	1,383,310	1,383,000	1,769,000
26 Supplies and materials	10,169,355	10,169,000	14,600,000
31 Equipment	2,841,268	2,841,000	8,500,000
41 Grants, subsidies and contributions	42,939,781	42,940,000	45,536,000
42 Insurance claims and indemnities	528,900	529,000	750,000
43 Interest and dividends	34,047	34,000	50,000
44 Refunds	-5,246	-5,000	-5,000
Total other objects	156,483,243	139,801,000	194,453,000
Total direct obligations	829,622,521	830,081,000	930,120,000
 <u>Position Data:</u>			
Average Salary, ES positions	\$156,777	\$160,383	\$164,232
Average Salary, GS positions	\$54,386	\$55,582	\$57,250
Average Grade, GS positions	9.0	9.0	9.0

Food Safety and Inspection Service (FSIS)

Status of Program

The Food Safety and Inspection Service (FSIS) is the public health agency in USDA responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. In carrying out this mandate, FSIS oversight responsibility covers 20 percent of the American food dollar.

FSIS' Present and Future Vision

The current food safety system, while strong, must adapt to the ever-changing realities of food safety and public health. During fiscal year (FY) 2006, FSIS continued to build upon its science- and risk-based activities to enhance public health protection. In recent years, the agency began work towards the realization of a comprehensive, risk-based approach that is formed by three mutually supporting components: (1) a public health data infrastructure, (2) an outreach effort to internal and external stakeholders, and (3) an enhanced and more robust risk-based inspection system (RBIS). FSIS has achieved significant milestones along the way with the implementation of Hazard Analysis and Critical Control Points (HACCP) as well as the implementation of risk-based pathogen controls. The overall goal of this effort is to further enhance and strengthen the agency's risk-based approach for pathogen control, and maintain the public's confidence in the safety of the Nation's food supply.

Public Health Data Infrastructure – To support more robust RBIS, the agency is building a public health data infrastructure to enable it to collect the data that is needed, analyze that data and respond to that data. The agency needs to get the right data to the right people at the right time to make the right decisions. Thus, FSIS needs to get data and information flowing seamlessly across the agency. Data must flow in real time and be continually analyzed so potential problems can be detected quickly, resources redirected as necessary, and resources used more efficiently to protect public health. The data must be reliable and securely assessable. In addition, these data systems must permit strategic decisions to be more traceable, measurable and easily audited. FSIS' risk-based approach must be driven by data to allow the agency to make proactive decisions affecting food safety and public health.

The data will come from pathogen testing, in-plant verification, noncompliance records, food safety assessments, traceable food borne illness outbreaks, inquiries to the agency's technical service center, and many other sources, and it will be in one central warehouse so that it can be accessed from many sites and for many purposes. Under a RBIS, the in-plant level data that will be provided by FSIS, will be based on a mathematical formula derived from data representing the inherent product risk and the establishment's risk control factor. FSIS will be using data to be proactive to protect public health beyond the in-plant inspection level.

Outreach to Internal, External, and International Stakeholders – The implementation of HACCP was the start of a more risk based system. FSIS needs to ensure that the regulated industry designs and implements an effective food safety system. All plants must have properly functioning HACCP systems. FSIS has a vital role in educating, as well as regulating, industry to meet this outcome. After conducting listening sessions in several locations, FSIS announced in May 2006 a groundbreaking initiative to provide assistance to owners and operators of small and very small plants to improve their food safety programs through a renewed, invigorated outreach initiative to small and very small plants. FSIS will regulate as necessary, but it will also assist them to bring up their level of performance.

In order to maintain progress toward a more robust RBIS, FSIS is using a transparent and inclusive process to seek input on a wide range of issues such as what factors should be considered in determining inspection intensity. In November 2005, the National Advisory Committee on Meat and Poultry Inspection (NACMPI) recommended, and FSIS adopted, a third-party to assist FSIS to reach out and gain input from stakeholders. FSIS wanted to ensure that all stakeholders participated in this process.

Enhanced and a More Robust RBIS - FSIS envisions a system where it will capture and utilize the data it has to determine the level of inspection at processing plants and off-line slaughter assignments. Allocation of agency resources under risk-based inspection (RBI) at each inspected processing establishment will rely upon two measures of risk: (1) inherent risk, a measure of the risk posed to the public health by each type of processed meat or poultry product, and (2) risk control, a measure of the amount of actual risk control achieved by each establishment. Under an optimal system, the type and intensity of inspections at an establishment will be based on the establishment's performance, the items they produce, and the process they use. Plants with excellent food safety records, validated effectiveness in science-based policies, and in full compliance with FSIS' regulations, should benefit from that track record. The converse should also warrant increased action. FSIS' goal is to anticipate problems and correct them before regulatory enforcement action is ever needed. The agency will work to prevent problems before they occur. To accomplish that mission of developing a more robust RBIS, the agency selected the consulting firm Resolve, Inc. to assist in communications and opinion gathering, and utilize the NACMPI subcommittee on RBI in providing regular, ongoing feedback from stakeholders. Resolve Inc. solicited input from all of the agency's stakeholders, and managed two public meetings this fall at George Mason University.

PUBLIC HEALTH DATA INFRASTRUCTURE

Current Activities: Protecting public health in this day and time means being able to make necessary decisions based on real-time data in times of food safety and defense emergencies. FSIS must be able to access its own data, as well as data from all of its partner agencies, nationally and internationally, through Web-based business intelligence tools that analyze and display the data in terms of performance measures and projected outcomes. Using technology to assist the agency in identifying problems and predicting possible outcomes will enable the agency to act on the information with a more targeted and effective response. This system must be secure and have full back-up and failover sites that can come on line automatically should all or a part of the system be overloaded or fail. By using all of the data and tools available, these systems can be used to analyze and provide food safety and defense information quicker and more comprehensively than humans alone.

Beginning in FY 2006 and continuing into FY 2008 and beyond, FSIS will proceed with the design and implementation of a more robust RBIS that will be highly dependent upon the rapid delivery and automated analysis of public health data. In order for RBI to succeed, FSIS needs to streamline and integrate the public health data from all available sources into its daily decision making processes. This information will allow FSIS to efficiently and effectively manage its financial and human resources and protect the health and safety of the American consumer. The system will provide the means to implement an effective risk-based food safety system that can collect, analyze, and respond to hazards and risks.

The agency's current stove pipe data systems will need to be completely overhauled and consolidated to meet the needs of the new RBIS. Today, disparate FSIS applications and reporting tools manage, distribute, and syndicate a variety of electronic and print products. The current processes are error-prone and not efficient towards effectively delivering FSIS' goal of providing the right information to the right people at the right time. Data must be contained in easy-to-use, seamless information technology (IT) systems that can communicate with one another. The stovepipe approach where databases exist side-by-side but do not communicate with each other keeps FSIS from efficiently and effectively integrating data from all relevant sources so that risk-based decisions can be made.

Upon completion, FSIS' public health data infrastructure will connect all data points in real-time to efficiently collect, analyze, and respond to public health data. Data generated from all FSIS inspection actions and infrastructure support activities will be accurately integrated and instantly available, allowing managers and administrators to make informed decisions more efficiently and effectively. It is vital that inspection program personnel have rapid access to this data to perform their food safety mission properly

and effectively. As a result, the agency will be able to react more rapidly in a crisis to better protect public health.

In FY 2006, FSIS was able to take the first step and build a data warehouse where significant portions of data are all contained in one central location and data systems draw from this central warehouse. Additionally, in FY 2006, FSIS published a final FSIS Enterprise Architecture (EA) Blueprint Version 1.0 (including the baseline or "as-is" architecture). EA is the blueprint that is developed, implemented, maintained, and used to explain and guide how IT information management elements will work together to effectively accomplish the mission, goals, and objectives of the organization. EA is responsible for capturing the description of how the agency does its business, and what information, data, and technology are required to support the business. The EA Blueprint Version 1.0 was given a "Green" score by the Office of Management and Budget (OMB).

Also in FY 2006, the Technical Service Center (TSC) began collecting, categorizing, and analyzing customer queries for analysis in the first quarter of 2006. Patterns that emerge in this data are reviewed to improve customer service and as an early warning system that a new policy needs further clarification by issuing a series of questions and answers and plain language scenarios. So if the TSC identifies confusion about a policy via the questions, the TSC can add information to training that will help eliminate or resolve the potential uncertainties. Interactive Knowledge Exchanges (IKEs) are plain language scenarios that explain real life regulatory situations and appropriate actions in simple and easy to understand terms. In FY 2006, FSIS published seven IKEs to its Web site for agency and public review and ultimately for use by industry. When the agency publishes new issuances, such as FSIS Directives or Notices, it collects the most commonly asked questions and develops appropriate answers. FSIS then issues these Q&As as an FSIS Notice, which is also posted on FSIS' Web site, to ensure that any questions left unanswered in the original issuance are clearly explained. FSIS issued eight Q&A Notices in FY 2006.

Selected Examples of Recent Progress:

I. Better Use of Technology to Collect, Analyze, and Respond to Data

Food Safety Assessments (FSAs): Specially trained personnel conducted 1,500 focused FSAs through scientific assessment protocols. The FSAs determine the adequacy of the design of food safety systems in regulated establishments. Data obtained from FSAs enhance FSIS' outreach efforts to ensure that everyone is meeting the same requirements with well-designed food safety systems. The FSAs resulted in 87 suspensions of operations and 189 notices of intended enforcement actions.

Implemented New Processing Inspection Teams: In order to maximize workforce efficiencies, the agency implemented new, geographically based processing inspection teams. Existing inspection assignments merged, allowing team members extra time during their workdays to learn and implement increasingly complex food safety inspection requirements. Team inspection is designed to take a group of establishments and have a team of experts share oversight of public health assurance duties. Team inspection is not designed to reduce the workforce. Team inspection implements critical food safety and food defense objectives because it requires that experts work together to evaluate public health risks in multiple establishments and to determine as a team how best to address them. The agency implemented processing inspection teams in 24 locations, responsible for covering 361 establishments involving 88 consumer safety inspectors and managed by 22 frontline supervisors. The agency anticipates adding additional locations in calendar year 2007. FSIS has also implemented Public Health Veterinarian teams in approximately 25 locations.

More Rapid and Efficient Communication of Data to Protect Public Health: FSIS began replacing dial-up computer connections with high-speed satellite access to ensure that inspection program personnel located in base plants are linked to a fully integrated, real-time data communications infrastructure. Real time access to data is more vital if all agency personnel are going to collect, analyze, and respond on an on-

going basis. Inspection program personnel will be able to focus more of their time on inspection activities with broadband connectivity. This is necessary for our inspection program personnel and others to do their jobs properly and effectively and to react more rapidly in a crisis to better protect public health and save lives. During FY 2006, FSIS ordered very small aperture terminals (VSAT) for 713 field locations, installed all of the necessary servers and virtual private network hardware to support these locations, and completed the installation of VSAT at 60 locations. No VSAT training is necessary for inspectors. Approximately 2,300 broadband connections will be in place by summer 2007.

Using Data to Measure Performance in the Field: FSIS' AssuranceNet, a state-of-the-art, Web-based management control system, pulls inspection data from five databases using a data warehouse. In FY 2006, FSIS implemented the first phase of AssuranceNet to address its operations in the field and in the future it will be expanded to other program areas. It is a dashboard driven system that allows the agency to monitor how establishments, circuits, and districts are meeting over 50 performance measures in near real-time. The system alerts the agency when performance measures are exceeded.

Consumer Complaint Monitoring System (CCMS): CCMS is a national surveillance system that records, analyzes, and tracks consumer complaints, identifying possible food hazards and terrorist attacks on the food supply. In FY 2006, CCMS recorded 954 consumer complaints with approximately 150 resulting in further investigation. Currently, complaints come to the district or the USDA Meat and Poultry Hotline and are entered into CCMS by FSIS personnel. In addition to direct input from consumers, CCMS also receives complaints from the National School Lunch Program, the Food and Drug Administration (FDA), or through State and local departments of health and agriculture. This aids in getting more attribution data for the agency. The system allows complaints to be triaged and analyzed in a timely fashion, allowing for a rapid response.

FSIS is currently working with a contractor to enhance the analytic and reporting capabilities of CCMS. The upgrades include 24-hour-a-day coverage, complaint coverage, decision trees, and alerts systems. The CCMS upgrade will have an analytical modeling tool that improves the ability to detect the introduction of intentionally or unintentionally introduced foodborne threats. The system also will collect enough information to assist FSIS with traceback or traceforward investigations for identifying product disposition and/or the origin of hazards.

Review of State Meat and Poultry Inspection (MPI) Programs: The data collected at the State level is just as important as the Federal level. The comprehensive State review process consists of a two-phase review for determining whether State MPI programs meet mandated "at least equal to" requirements. The first phase is an annual review of the State self-assessment submission. The second phase is an on-site review to verify the accuracy and implementation of the State's self-assessment submissions. Currently, there are 28 cooperative State MPI programs. In FY 2006, FSIS conducted on-site reviews in 12 States and reviewed all 28 annual self-assessment submittals from 2005.

II. Continued Decline in Illnesses as Measured by Public Health Data

Foodborne Illness Declines: FY 2006 marked the 11th year of the FoodNet agreement between FSIS and the Centers for Disease and Control and Prevention (CDC). FoodNet conducted active surveillance for diseases transmitted commonly through food in ten U.S. States and metropolitan areas that represent 25 percent of the population in FY 2006. In April 2006, the CDC reported sustained reductions in foodborne illnesses from 1996-1998 through 2005: a 29 percent decline in illnesses stemming from *E. coli* O157:H7, a 32 percent decline from *Listeria monocytogenes*, a 30 percent decline from *Campylobacter*, a 49 percent decline from *Yersinia* and a 9 percent decline from *Salmonella*. We have discovered some *Salmonella* serotypes that affect public health have significantly increased. The report indicates that reductions in illness from dangerous foodborne pathogens are sustained. While these reported declines in foodborne illness are dramatic, the CDC reported rates of foodborne illness from *E. coli* O157:H7 and *Listeria*

actually increased slightly in 2005 compared to 2004, and some *Salmonella* serotypes also increased. We believe more can – and will– be done.

Furthermore, as the statistics in *Salmonella* show, control of this pathogen continues to be a challenge for USDA. Therefore, USDA announced a *Salmonella* initiative and the scheduling of FSAs to target broiler production in 2006 and 2007. This group of pathogens is associated with meat, poultry, and processed egg products, although foods not regulated by USDA can contain these pathogens and also contribute to human illness.

FoodNet data are used to evaluate progress toward meeting the Healthy People 2010 (HP 2010) national objectives for foodborne infections. The HP 2010 objectives and FoodNet findings in 2005 are as follows:

- *Listeria*: HP 2010 target is 0.25 infections per 100,000 population. The Healthy People 2010 goals for national health promotion and disease prevention called on Federal food safety agencies to reduce foodborne *Listeria* by 50 percent by the end of the year 2005 to 0.25 infections per 100,000 population. The 2005 incidence was 0.30 infections per 100,000 population.
- *Campylobacter*: HP 2010 target is 12.3 infections per 100,000 population. The 2005 incidence was 12.72 infections per 100,000;
- *Salmonella*: HP 2010 target is 6.8 infections per 100,000 population. The 2005 incidence was 14.55 infections per 100,000.
- *E. coli* O157: HP 2010 target is 1.0 infection per 100,000 population. The 2005 incidence was 1.06 infections per 100,000 population.

Foodborne Illnesses Investigation: During FY 2006, FSIS collaborated with 41 State and local health departments, the CDC, the National Park Service, FDA, and the Food and Nutrition Service to investigate reports of 63 foodborne disease clusters (including nine started in FY 2005) involving 1,406 ill people. Investigators found 25 outbreaks impacting 785 individuals to be presumptively attributed to FSIS regulated products.

III. Risk Based Verification Data

Microbiological Sampling:

The microbiological sampling has five major components in the FSIS program of sampling meat, poultry, and egg products and analyzing those samples for the presence of microbial pathogens.

- *E. coli* O157:H7 in Raw Ground Beef: In FY 2006, FSIS tested a total of 11,551 raw ground beef samples for *E. coli* O157:H7. Of these samples, 20 were from imported products, 11,417 were from Federally inspected establishments, and 114 were from retail stores. FSIS found 19 samples (0.16 percent) that confirmed positive for *E. coli* O157:H7 from Federally inspected establishments.

In FY 2006, the 19 positive samples led to four recalls affecting over 17,800 pounds of product. Products associated with the other 15 positive test results were voluntarily held by industry pending laboratory results and adulterated product did not enter commerce. FSIS had previously reported a statistically significant decrease in the percentage of positive samples from FY 2002 to FY 2003. Once such a statistically significant decrease has been reached, it becomes increasingly unlikely to continue to have further statistically significant decreases.

- *Salmonella* in raw meat and poultry products: The Pathogen Reduction/Hazard Analysis and Critical Control Point rule of July 25, 1996, established *Salmonella* performance standards in seven categories of meat and poultry products: broilers, market hogs, cows/bulls, steers/heifers,

ground beef, ground chicken, and ground turkey. As one part of its science-based food safety program, FSIS collects and analyzes samples for *Salmonella* to verify that HACCP systems are controlling *Salmonella*.

Each year an estimated 1.4 million people in the United States develop foodborne illness due to *Salmonella* organisms. Since the implementation of HACCP and efforts focused at pathogen reduction, the overall incidence of foodborne illness in the United States from *Salmonella* has decreased but it is still significantly above the Healthy People 2010 target. *Salmonella*, in fact, has become the most common bacterial cause of foodborne illness in the United States and the number of multi-drug resistant isolates has increased. Despite minor year-to-year fluctuations in individual categories, *Salmonella* rates in some classes of products have decreased to levels well below the pre-HACCP baseline levels. The following table shows the baseline levels and the levels for both FY 2005 and FY 2006 for *Salmonella* (both initial sampling and follow-up testing included):

Product	Pre-HACCP Baseline Prevalence (Percent Positive)	FY 2005 Results (Percent Positive) (**)	FY 2006 Results (Percent Positive)
Broilers	20.0	16.9	12.3
Market Hogs	8.7	3.4	4.4
Cows/Bulls	2.7	1.9	0.9
Steers/Heifers	1.0	0.8	0.3
Ground Beef	7.5	1.4	1.6
Ground Chicken	44.6	35.7	48.1
Ground Turkey	49.9	16.5	24.9
Turkeys	19.6 (*)	---	9.1

(*) Nationwide Sponge Microbiological Baseline Data Collection Program: Young Turkeys July 1997 – June 1998

(**) All samples

FSIS has been concerned with increases in *Salmonella* rates observed over the past three years (2003–2005) among three poultry product categories; broiler carcasses, ground chicken, and ground turkey. In response, FSIS increased resources allocated to comprehensive food safety assessments in establishments displaying negative performance trends and considered how best to integrate past performance into the *Salmonella* testing program.

FSIS was encouraged to see the percentage of positive samples for broiler carcasses drop in FY 2006 compared with FY 2005. Under the new risk-based sampling program, if a plant produces both whole carcasses and grinds poultry products, priority is given to the carcass sampling. Therefore, there have been too few ground poultry samples to draw any conclusions about the trend for those products.

In February 2006, FSIS announced an 11-step strategy for *Salmonella* reduction in products. To encourage industry to reduce *Salmonella* contamination of poultry products and to discuss possible means to accomplish such a reduction, FSIS held a public meeting in February, 2006, in Atlanta, Georgia, on “Advances in Post-Harvest Interventions to Reduce *Salmonella* in Poultry.” Meeting transcripts were posted on the FSIS Web site.

At the meeting, FSIS announced a comprehensive initiative to reduce the presence of *Salmonella* in raw products. The initiative will include targeting resources at establishments with higher levels of *Salmonella* and changes the reporting and utilization of FSIS *Salmonella* verification data test results. Where FSIS has performed targeted FSAs in establishments that have continually failed to control *Salmonella*, the results have shown a dramatic reduction in the level of

Salmonella. Therefore, it is apparent that these establishments can indeed control the incidence of *Salmonella* in the raw products they produce. Since February 2006, the agency's Enforcement, Investigations and Analysis Officers (EIAOs) have completed approximately 30 targeted food safety assessments as part of this initiative. FSIS will expand targeted food safety assessments in FY 2007. The 11 step strategy for *Salmonella* is:

- The results of individual sample tests will be sent to establishments as soon as those results have been made available. Then the establishments can take this information and adjust their process controls as needed.
 - Post the nationwide *Salmonella* data by class on a quarterly basis.
 - Begin collecting swab samples from turkey carcasses to assess the process control for this class that, according to baseline performance levels, is at 19.6 percent.
 - To better allocate agency resources, FSIS will characterize establishments by their performance within three categories: best pathogen control, intermediate pathogen control, and least pathogen control.
 - Scheduling frequencies will be modified. Therefore, establishments showing poor performance or process control may be scheduled more frequently with multiple sets in a year. Establishments showing good control may be scheduled as infrequently as once every two years.
 - Conduct food safety assessments in poor performing establishments.
 - Issue compliance guidelines regarding *Salmonella* during the slaughter of broilers.
 - More quickly determine serotypes for sample sets.
 - Pursue policies on subtyping or fingerprinting *Salmonella* utilizing or using pulsed-field gel electrophoresis in order to provide real-time communication among partners, as well as to facilitate early identification of common-source outbreaks.
 - Conduct ongoing baseline studies in all classes of raw products.
 - Watch intermediate and least pathogen control categories to see that they are adequately moving into the best pathogen control category.
- Testing Ready-To-Eat (RTE) Products: FSIS tests a wide variety of RTE products, such as hot dogs and deli meat, for *Salmonella* and *Listeria monocytogenes (Lm)* and a few RTE beef products for *E. coli* O157:H7. For FY 2006, *Salmonella* was detected in 15 (0.09 percent) of 16,513 product samples. In FY 2006, FSIS did not find any *E. coli* O157:H7 in 749 samples of RTE beef products.

FSIS conducts a sampling project (designated ALLRTE) where all types of RTE products are equally likely to be selected and tested for *Lm*. In FY 2006, FSIS analyzed 2,888 samples for *Lm* and found 17 positive samples (0.59 percent). In FY 2005, the percentage of positive samples in ALLRTE was 0.67 percent.

In FY 2006, FSIS continued intensified testing as a means of verifying preventive and corrective actions after an initial *Lm* positive and also conducted some special *Lm* studies in the post-Katrina environment. These efforts accounted for well over 3,000 additional laboratory analyses for *Lm*.

- Under our routine *Lm* Risk-Based (RLm) Sampling Program, FSIS tailors its verification activities to the interventions that plants choose to adopt and to the potential for *Listeria* growth in their products. Thus, FSIS conducts less sampling in those plants that have the best control programs for *Listeria* and more sampling, as well as in-depth FSAs in plants that adopt less vigorous programs.

In March 2006, FSIS issued Directive 10,240.5 that provides for the routine (not-for-cause) risk-based testing for the presence of *Lm* in establishments that produce RTE products. In addition to combined intensified testing for *Lm*, specially trained FSIS personnel will conduct a FSA in these establishments. The RLm program meets the USDA food safety objectives and strategic plan and will have 100

reviews completed by March 2007. In future years, FSIS intends to double the number of reviews to 200 per year.

- Testing Pasteurized Egg Products for *Salmonella*: FSIS began testing pasteurized egg products for the presence of *Salmonella* in 1995; before that, this was a function of the Agricultural Marketing Service (AMS). Products including pasteurized liquid whole eggs, liquid egg whites, liquid egg yolks, and dried egg whites are tested once per month in every plant in which they are produced. For FY 2006, FSIS tested 1,565 samples and found only two samples (0.13 percent) positive for *Salmonella*. In FY 2005, FSIS tested 1,557 samples and found three positive samples (0.19 percent). These levels have decreased dramatically since FSIS took over the program in 1995.

Microbiological Baseline Studies: Over the next several years, a series of recurring, nationwide baseline studies of raw beef, pork, chicken, and turkey products will take place. These baseline studies are designed to provide FSIS and the regulated industry with data concerning the prevalence and quantitative levels of selected foodborne pathogens and microorganisms that serve as indicators of process control. This data will enable the agency and industry to target interventions that effectively reduce the risk of foodborne pathogens associated with FSIS-regulated products. Additionally, these baseline studies will provide essential data for future risk assessments and permit the evaluation of trends.

- Raw Ground Beef Components Trim and Subprimals: The first of five baseline studies for components of raw ground beef examines the prevalence and the level of foodborne pathogens and indicator microorganisms in trim and subprimals for ground beef to be sold at retail. This baseline study began August 2005, and continued through December 2006.
- New Laboratory Contract and Future Baseline Studies: A contract was awarded to a third-party laboratory to perform the microbial analyses for future baseline studies: young chicken carcasses, ground chicken, and swine carcasses. Each product class will be examined for a number of foodborne pathogens and indicator organisms for the prevalence and the level of these microorganisms. In FY 2006, the infrastructure for the Young Chicken Baseline Study was established; carcass sampling began in November 2006.

Risk Assessments: During FY 2006, FSIS completed several mid- and long-term quantitative microbial risk assessments to guide agency regulations and efficient allocation of agency resources.

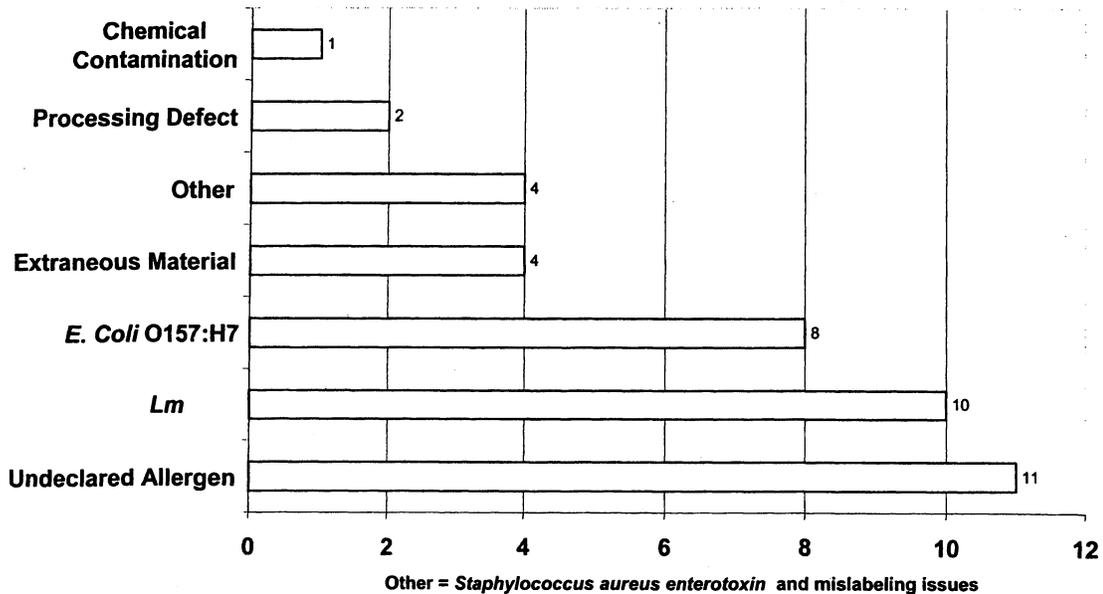
The following risk assessments were developed to guide FSIS in the development of regulations, and will be submitted to the Office of Risk Assessment and Cost-Benefit Analysis and OMB as part of the regulatory impact analysis when the corresponding regulations are completed:

- Completed an updated version of the 2001/2003 Harvard bovine spongiform encephalopathy risk assessment that incorporates more current scientific information, includes improvements in model function and reliability, and was revised based on independent peer review input. This quantitative risk assessment provides the scientific basis for FSIS' regulations for removal of specified risk materials from cattle during slaughter. This risk assessment was publicly presented in July 2006 for stakeholder input.
- Completed the development of a quantitative risk assessment for *Salmonella* in raw beef and poultry. This risk assessment provides the scientific basis for FSIS' *Salmonella* strategy through an evaluation of the reduction in foodborne illness associated with the prevalence and/or amount of *Salmonella* on poultry and beef that go into commerce, the impact associated with antimicrobial resistance and specific *Salmonella* serotypes of human health concern, and the influence of FSIS inspection and policies to reduce foodborne illness (e.g., role of verification testing).

IV. Data is Critical to Effective Recalls

In FY 2006, there were 40 recalls totaling 9,215,134 pounds: 16 beef, 11 poultry, four pork, and nine for combination products. As a basis for comparison, in FY 2005, there were 52 recalls totaling 3,409,382 pounds. Thirty-two of the recalls were considered Class I (where there is a *reasonable* probability that eating the food will cause health problems or death) and eight were Class II (where there is a *remote* probability of adverse health consequences from eating the food). Eighteen of the Class I recalls were directly related to microbiological contamination caused by the presence of *Lm* or *E. coli* O157:H7. For each recall, FSIS conducted effectiveness checks designed to ensure that the recalling firm has notified all recipients of the product to remove it from commerce. The following chart details the remaining recalls by source.

**FSIS Recalls FY 2006
By Problem Type (Total 40)**



- In 18 recalls, the producing establishment discovered the adulteration and identified the need to voluntarily recall the affected product. In ten cases, FSIS sampling discovered product adulteration. FSIS continues to monitor and provide enforcement of potentially contaminated product. EIAOs verify procedures so that returned product is controlled and appropriately disposed.
- FSIS' recall speed and efficiency has increased due, in part, to inspection program personnel collecting distribution information at an establishment before FSIS test results become final. If a recall is necessary, inspection program personnel are able to take immediate action.
- In FY 2005, three recalls were for *E. coli* O157:H7 where 1,147,850 pounds of product were recalled and 10,949 pounds were recovered. In FY 2006, eight recalls were related to *E. coli* O157:H7, where 275,594 pounds of product was recalled and 22,034 pounds were recovered. Therefore, even though there was an increase in the number of recalls due to *E. coli* O157:H7 in

FY 2006 compared to FY 2005, the overall exposure (in pounds) to public health decreased. More total pounds of product was also recovered in FY 2006 compared to FY 2005.

- The agency continues to encourage industry to hold product when a sample is taken. FSIS conducted a study of industry practices regarding holding of agency-tested product pending test results. Through mid-summer 2006, the latest period for which FSIS analyzed data, establishments held between approximately 80 and 100 percent of all meat and poultry products prior to receiving agency test results. Furthermore, with only one significant exception, establishments of all sizes have increasingly held more product prior to receiving agency test results every year since 2003, with large establishments holding almost all tested product every year since 2003.
- Beginning in 2002, FSIS entered into a series of Memoranda of Understanding to allow States to participate in the recall verification process. In March 2006, FSIS proposed a rule that would make public lists of retail outlets that have received products that have been recalled. While consignee identities and distribution lists have, in the past, been considered confidential business information, FSIS has concluded that it has the authority, and it is in the public's best interest, to release the names of retail consignees of recalled meat and poultry products and that doing so will enhance the effectiveness of the recall process.

V. Collecting and Responding to Data to Keep the Food Supply Safe and Secure

FSIS, in accordance with Homeland Security Presidential Directives- 3, 5, 7, and 9, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), is working to ensure it is prepared to prevent, respond, and recover from large-scale food emergencies and intentional contamination. In FY 2006, FSIS' activities better prepared the agency and its stakeholders to respond to and recover from food-related emergencies. Also, FSIS developed plans to maintain the agency's essential functions in the event that FSIS facilities or personnel are compromised. In addition, during FY 2006 (last quarter of Calendar Year 2005), FSIS prepared for and responded to Hurricanes Katrina and Rita during the 2005 hurricane season.

Food Emergency Response Network (FERN): FERN consists of Federal and State governmental laboratories responsible for protecting citizens and the American food supply from intentional acts of biological, chemical, and radiological terrorism. The goal of the FERN is to (1) have a robust food testing laboratory network with surge capacity capable of collecting data in order to respond to an event involving the intentional or accidental contamination of the food supply or even a hoax, (2) maintain U.S. agricultural and industrial economic stability by rapid identification if an event occurs, and (3) ensure/restore consumer confidence in the safety of the Nation's food supply by the rapid response the Network would allow.

While FSIS's initial goal was to have 100 laboratories participate in FERN, the agency developed plans in FY 2006 towards restructuring FERN. In this new approach, FSIS will select from the eligible labs and add to the 18 currently participating labs for a total of 25 labs that will provide for full geographic representation for microbiological testing.

The 25 labs would provide National coverage, by region, with the expertise needed to meet the overall mission of FERN. All 25 labs would be capable of providing screening microbial tests and results for the 10 priority threat agents in all food matrices. Approximately 15 of these 25 labs nationwide would be funded as "Regional Reference Labs". In addition to the screening capacity, these labs would also serve as technical transfer labs, sharing knowledge and expertise. If necessary, these labs would conduct specific projects, as needed. All 25 labs would be funded to participate in screening projects, method validation studies, and field trials of new methods for other threat agents. Once funded, the public health infrastructure would be far better prepared to respond to a contaminated food supply, and would benefit the physical and financial health of the Nation.

Food Defense Surveillance: Homeland Security Presidential Directive 3 established a threat advisory system to effectively communicate the level of risk of a terrorist attack to the American people. It prescribes that agencies develop appropriate “protective measures” in response to each of the five established threat levels. The measures include active surveillance through a series of food defense verification procedures performed daily in all FSIS-regulated facilities, including import inspection facilities and in-distribution facilities at certain frequencies based on the threat level to identify potential weaknesses in food defense systems of meat, poultry, and egg producers processing operations. In FY 2006, FSIS conducted approximately 1,200,000 food defense verification procedures in FSIS-regulated and State-inspected facilities. Results from the verification procedures are collected and analyzed and potential weaknesses and actions taken by the establishments to address them are documented in a Memorandum of Interview (MOI). MOIs are analyzed and the results influence outreach, guidance initiatives, and countermeasures development.

Food Defense Table Top Exercises: In order to better respond to an intentional attack or a large-scale food safety emergency involving meat, poultry, and egg products, FSIS conducts food defense table top exercises. These exercises offer FSIS the opportunity to test and validate standard operating procedures and directives for responding to non-routine incidents. These table top exercises also provide the framework for Federal, State and local government agencies, the food industry, and consumer groups to work together to detect, respond to, and recover from a non-routine incident involving the food supply. In FY 2006, FSIS conducted six table top exercises involving over 300 participants. Two of these exercises took place in Washington, D.C. and the remaining four occurred in California, Illinois, Minnesota, and North Carolina.

Non-Routine Incident Management System: The system will provide a common operating environment and facilitate coordinated communication and response activities across FSIS offices, and with FSIS field personnel, Federal, State, and local partners, and industry and consumers. The system will provide quicker information sharing as well as aid in notifying response personnel and capturing response activities.

Preparation of Continuity of Operations (COOP) Emergency Relocation Facilities: During FY 2006, FSIS ensured that emergency location facilities had the necessary documents and equipment to support FSIS’ essential functions for up to 30 days. The necessary telephone and data lines, videoconference technology, and equipment for handling classified information were installed at one COOP3 and two COOP4 sites (one primary and one alternate).

Ensuring the Security of Food Entering the United States:

- At the headquarters level, FSIS established a Hazard Evaluation Committee (HEC) to evaluate the potential public health implications of illegal foreign product discovered in commerce. Available 24 hours a day, the HEC provides guidance to FSIS field personnel on dispositions and further actions to be taken.
- FSIS and Customs and Border Protection’s (CBP) National Targeting Center (NTC) developed rule sets for targeting high-risk, FSIS-regulated shipments entering the country. The rule sets are based on FSIS’ vulnerability assessments, the eligibility of foreign countries and establishments, and individuals and companies with a past history of food-safety violations. FSIS conducted a two month pilot at the ports of Philadelphia, Pennsylvania, and Houston, Texas, to test the rule sets and the procedures developed for handling and testing potentially high-risk shipments. During the pilot, a total of 3,229 shipments were screened at the two ports using the rule sets. Of those, 52 shipments had rule sets scores high enough for concern (reinspection of imported product and possible product sampling), and three required further investigation to verify that the manufacturer or product did not pose a risk to the U.S. public.
- International Trade Data System (ITDS) consolidates existing systems and processes and will help USDA streamline its import and export regulatory processes and improve linkages with international partners, industry, and other government agencies. FSIS closely collaborated with AMS, Animal and Plant Health Inspection Service (APHIS), FDA, CBP, and about 20 other

Federal government agencies in support of the ITDS project. FSIS attended many meetings with agency officials to produce detailed business requirements for the nation's import inspection process. FSIS also met with the governments of Canada, Australia, and New Zealand in support of this project.

- FSIS investigators and Import Surveillance Liaison Officers partnered with members of the Department of Homeland Security – including U.S. Customs and Border Protection and the U.S. Coast Guard, FDA, USDA/APHIS Smuggling Interdiction and Trade Compliance, State Fish and Wildlife Services, and others for large scale investigations in 12 States. These operations focused on detecting and removing illegally imported products from commerce, and have helped to forge key relationships through which FSIS investigators can be alerted to further cases of illegally imported products.

Foreign Country Inspection System Equivalence Determinations: Each year, FSIS engages in three types of foreign inspection systems equivalence evaluations: initial equivalence determinations, individual sanitary measure determinations, and on-going verification and enforcement actions. These reviews are an important step to ensuring that foreign countries exporting meat, poultry, and processed egg products to the United States are producing product under equivalent requirements to what is required domestically in the United States and that U.S. public health is not compromised by the availability of foreign-produced products.

- Initial Equivalence Determinations: Initial equivalence determinations are conducted to determine whether a foreign food regulatory system is equivalent to that of the U.S. inspection system in the case of a country that is not presently eligible to export meat, poultry, or processed egg products to the United States.
 - In FY 2006, final equivalence determinations were made for Chile and China. Both countries were added to the list of countries eligible to export to the United States; Chile is eligible to export meat products and China is eligible to export processed poultry products that were raised and slaughtered in a country eligible to export raw product to the United States. The addition of these two countries brought to 37, the total number of countries eligible to export meat, poultry, and egg products to the United States.
- On-Going Equivalence Determinations and Enforcement Actions: FSIS determines whether foreign countries' inspection systems are maintaining equivalence and initiates additional actions when countries fail to meet U.S. requirements. FSIS uses port-of-entry data, audit results, as well as other information to determine whether a country is maintaining an equivalent inspection system or whether further measures are warranted to protect U.S. public health.
 - In lieu of an FSIS-instituted suspension, Brazil temporarily suspended its beef exports to the United States due to inspection system failures. The suspension was lifted on selected plants in two phases after FSIS auditors conducted follow-up visits and verified that the Brazilian government had addressed the deficiencies and implemented corrective actions.
 - An audit of Israel's poultry inspection system in December 2005, revealed inspection system failures, which called into question the wholesomeness of the product. In January 2006, Israel voluntarily suspended its exports as a result of poor audit results, but resumed exports in November 2006 after a satisfactory audit allowed the suspension to be lifted.

OUTREACH TO EXTERNAL, INTERNAL AND INTERNATIONAL STAKEHOLDERS

Current Activities:

While the agency has a regulatory role to ensure the safety of meat, poultry, and egg products, it also recognizes that consumers play a significant role in food safety. In addition to regulating industry to protect public health, FSIS also has a vital role in using education to protect the public health. As a result,

the agency has expanded its outreach to all internal and external stakeholders and has forged new relationships with public health partners across the globe.

Selected Examples of Recent Progress:

Small and Very Small Plant Outreach Program:

For USDA's more robust RBIS to be successful, all plants must have well-designed, food-safety and defense systems and fully understand HACCP. FSIS has taken a multi-pronged approach in order to ensure small and very small plants have the information they need to be successful.

- The agency held outreach and listening sessions for owners and operators of small and very small plants and State plants throughout the country reaching 725 people. In addition, approximately 200 people participated in two food defense Web cast only workshops geared towards small and very small plants. FSIS also held a strategy session hosted by the International HACCP Alliance to further identify the needs of small and very small plants.
- In May, 2006, for the first time ever, FSIS began conducting Regulatory Education Sessions to bring small and very small plant owners and operators together with inspection personnel to hear a common message about the regulations. The sessions were part of the FSIS Strategic Implementation Plan for Strengthening Small and Very Small Plant Outreach. During FY 2006, 16 sessions were conducted, serving a total of 653 participants from industry, FSIS, State, and other constituent groups. On average, the mix of participants was 40 percent from industry and 60 percent from inspection personnel. Summaries from evaluations of the sessions showed that 86 percent of participants said their expectations were met, and 94 percent said they would recommend the sessions to others. Due to the success of this initiative, FSIS plans to expand the number and type of sessions offered to assist small and very small plants to increase their understanding of the regulatory program.
- FSIS developed a "start-up" package for new meat, poultry, and egg products establishments. This package includes a number of resources to assist the owners and operators of small and very small plants when they are applying for a Grant of Federal inspection.
- Since July 2006, EIAOs have conducted over 250 outreach visits to small and very small establishments to improve communication between FSIS and small business owners. EIAOs explain the purpose and process the agency uses when conducting FSAs and offer resources to plant owners and operators to help them become prepared for an assessment.
- In June 2006, FSIS convened a meeting of representatives from eight small businesses to design food defense guidance materials that best serve small and very small FSIS-regulated facilities. Simplified versions of the FSIS *Self Assessment Checklist* and *Model Food Defense Plans* are currently being prepared in response to the feedback from the meeting for use specifically by small and very small plants.
- FSIS developed a coordinated, easily accessible, consistent, and customer-oriented outreach program that provides small and very small plants with "one stop" service for obtaining information, technical assistance, and answers to achieve compliance and promote food safety and food defense. In order to provide consistent answers, the agency provides a toll-free phone number and e-mail address to the owners and operators of small and very small plants. Furthermore, FSIS established a Web page with assistance specifically designed to meet the needs of small and very small plants.

- FSIS developed and distributed more than 11,000 HACCP and food safety resource materials and three separate mailings of guidance materials to more than 7,500 plant owners and operators and state HACCP coordinators and partners.

Consumer Outreach Program: The agency is committed to educating consumers to further reduce the proliferation of foodborne illness. FSIS has done this in the following ways:

- As a result of recommendations from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Subcommittee on Consumer Guidelines for the Safe Cooking of Poultry Products, FSIS announced a single safe minimum internal temperature of 165 °F to provide a margin of safety against pathogens such as avian influenza, *Salmonella* and *Campylobacter*.
- The agency distributed plain language flyers, "Listeriosis and Pregnancy: What is Your Risk? Safe Food Handling for a Healthy Pregnancy," in English and Spanish to more than 48,000 obstetricians and gynecologists nationwide.
- During Hurricane Katrina, the agency also coordinated the development of a consistent consumer message for sanitizing flooded canned goods with the FDA, the CDC, and the Environmental Protection Agency.
- During the first quarter of FY 2006, the Food Safety Mobile continued its redeployment to the hurricane-affected areas begun in September 2005, reaching an estimated 40,800 people and averaging daily crowds of 1,166 in the hardest-hit areas. The Food Safety Mobile was supplemented by a second vehicle in October 2005, which reached Hurricane Rita-affected areas in Texas and Louisiana, reaching an estimated 15,025 people with a daily average visit of 835 people. Through the one-on-one interaction with food safety experts who accompanied the Mobiles, in addition to the distribution of food safety education materials, refrigerator thermometers, household bleach, hand sanitizers, and refrigerator/freezer bags, there was an increase in the awareness of the importance of safe food handling, especially in situations such as flooding, power outages, and the disruption of normal daily living, in preventing and reducing the risk of foodborne illness.
- The FSIS Web site received nearly 35 million hits in FY 2006, compared with over 21 million hits in FY 2005. Among these were those who visited the virtual representative, "Ask Karen." Through "Ask Karen," the agency provided answers to more than 7,000 visitors posing more than 24,000 questions. "Ask Karen" is the only government-sponsored virtual representative in the world. Consumers may ask questions of the automated representative through an extensive database of frequently updated questions and answers, and receive responses about safely storing, preparing, and handling meat, poultry, and egg products.
- In September 2006, the agency co-launched the Be Food Safe campaign, an updated public education effort based on messages developed as part of the national Fight BAC campaign. At the Food Safety Education Conference in Denver, Colorado, the agency also unveiled a series of "At-Risk" brochures with similar content targeting specific groups, such as transplant recipients, cancer patients, diabetics, and those with HIV/AIDS.
- The USDA Meat and Poultry Hotline responded to more than 84,500 telephone and 1,848 email inquiries on the safe storage, preparation, and handling of meat, poultry, and egg products.

2006 Food Safety Education Conference: "Reaching At-Risk Audiences and Today's Other Food Safety Challenge, an innovative approach to increasing and sharing data available on food borne illness, was held September 27-29 in Denver, Colorado. More than 600 public health professionals and food safety

educators, public health officials, and medical professionals from 8 countries, 48 States, and 3 U.S. territories attended the three-day conference.

The purpose of the conference was to energize the medical and public health communities to discuss how to better reach at risk audiences, a large group which encompasses one in five Americans. Underreporting of food borne illness is a serious concern. Therefore, another key topic was how to increase the reporting of food borne illness and how to build the amount of attribution data available. The accurate and timely reporting of illness data will help FSIS evaluate programs, policies and approaches so that the agency can save lives.

Among the featured speakers were Agriculture Secretary Mike Johanns; Under Secretary for Food Safety Dr. Richard Raymond; Under Secretary for Food, Nutrition, and Consumer Service, Nancy Montanez Johner; Admiral John O. Agwunobi, M.D., Assistant Secretary for Health for the Department of Health and Human Services; and Georges Benjamin, M.D., Executive Director of the American Public Health Association.

Partnerships: FSIS developed and expanded active partnerships with international industry, academia, consumers, Federal, State, local public health partners to support the agency's outreach strategies.

- In partnership with APHIS and the Agricultural Research Service (ARS), FSIS developed an Interim Response Plan for Highly Pathogenic Avian Influenza (HPAI) in which FSIS:
 - Established a process to identify and coordinate agency volunteers to respond to HPAI emergencies.
 - Worked with leaders of ARS' Animal Health Programs to incorporate FSIS priorities into the ARS Avian Influenza Initiatives. The methods for testing poultry meat for Avian Influenza have been developed and validated by ARS scientists. Additionally, ARS determined avian influenza in poultry, meat, and egg products will be inactivated at temperatures that inactivate *Salmonella*.
 - Worked with industry on a voluntary hold and test plan.
 - Created a training program on HPAI delivered through AgLearn (a Web-based training application) to field personnel.
 - In September 2006, FSIS and APHIS hosted an avian influenza outbreak exercise. The exercise tested the response strategy and coordination between international, Federal, State and local public health agencies, the food industry, and consumer groups. The exercise provided a vital opportunity for stakeholders to work more closely together in preparing for the threat of a possible outbreak of HPAI in U.S. domestic flocks
 - Developed an Memorandum of Understanding with APHIS which defines mutually supportive roles and responsibilities in regard to HPAI.
- The NACMCF provides impartial, scientific advice to Federal food safety agencies for use in the development of an integrated national food safety systems approach from farm to final consumption to assure the safety of domestic, imported, and exported food. The Under Secretary for Food Safety is the current chair of NACMCF. The NACMCF is currently co-sponsored by FSIS, FDA, CDC, the National Marine Fisheries Service, and the Department of Defense Veterinary Service Activity. During FY 2006, FSIS oversaw March and September meetings of the NACMCF. FSIS provides the Web site on behalf of the committee.

Codex Alimentarius Commission The U.S. Codex Office, which reports to the USDA Under Secretary of Food Safety, coordinates all U.S. government and non-government participation in the activities of the Codex Alimentarius Commission. The U.S. Codex Office:

- Represented the United States at the meeting of the Codex Alimentarius Commission (July), which resulted in the adoption of 26 new or revised standards and related texts to food additives,

pesticide residues, veterinary drug residues, nutrition, labeling, methods of analysis and sampling, food import/export inspection and certification, as well as commodity standards (such as milk and milk standards).

- In May 2006, hosted the meeting of the 16th session of the Codex Committee on Residues of Veterinary Drugs in Foods which completed work on draft standards for four compounds and also recommended a new set of risk analysis principles to be included in the Codex Procedural Manual.
- Facilitated the development of draft U.S. positions, representing consensus among government officials, trade associations, and consumer groups on issues under consideration in Codex committees through informal consultations and formal review by an inter-agency steering committee, and developed strategies to achieve U.S. objectives on key Codex issues through conference calls and meetings with counterparts in other countries prior to negotiating sessions.
- Organized and participated in U.S. delegations for nine other meetings of the Codex Committees.
- Promoted public involvement by organizing 11 public meetings to present U.S. draft positions for Codex negotiations and to solicit public comments, disseminated information on Codex to government and non-government stakeholders through extensive electronic distribution of documents and maintenance of a very active Web page, published a Federal Register notice on the sanitary and phytosanitary standard settings activities of the Codex Alimentarius Commission, and issued news releases to announce each public meeting.
- Organized a cross-cultural communications workshop in Washington, D.C. during March 2006, to improve the effectiveness of U.S. delegates and other U.S. officials in collaboration with African counterparts;
- In April 2006, organized a technical workshop in Maputo, Mozambique to initiate a working relationship between U.S. and African officials involved in the Codex Alimentarius Commission.
- Organized a technical workshop in Rio de Janeiro, Brazil during June 2006, on issues of common interest between the United States and Latin America/Caribbean officials, including a discussion of equivalence in the import/export of meat products.
- Organized in Washington, D.C. during September 2006, a week of technical consultations between a delegation of Codex officials from Africa, including Claude Mosha, Codex Chairman, and officials from U.S. government agencies and representatives from U.S. industry associations and consumer groups.

Training: Training and continuing education of the FSIS workforce is a cornerstone of public health protection. To accomplish this, FSIS is implementing an ongoing strategy to provide employees with a challenging program of initial training when they report to their first assignment, follow-up training that reinforces acquired skills, and advanced skills training to prepare the employee for performing complex public health protection duties.

- In May 2006, FSIS began conducting regulatory education sessions to bring small and very small plant owners and operators together with inspection personnel to hear a common message about the regulations. During FY 2006, 16 sessions were conducted, serving a total of 653 participants from industry, FSIS, State, and other constituent groups.
- FSIS partners with the Federal Law Enforcement Training Centers (FLETC) to train FSIS employees in regulatory enforcement and investigative techniques. In FY 2006, FSIS partnered with FLETC to train 71 participants – including EIAOs, Import Liaison Surveillance Officers, and Office of Program Evaluation, Enforcement, and Review investigators and enforcement analysts.
- In FY 2006, FSIS conducted a formal certified training course in Audit ISO 9000. Nearly 40 employees – including investigators, program review specialists, and compliance analysts – completed the training which provides methodology to conduct independent, impartial, unbiased

pre- and post-evaluations, audits, reviews, and assessments on the efficacy of FSIS programs and foreign and state audits and equal-to requirements.

- FSIS brought trainers closer to the workforce to make training more regionally based. This enabled the agency to deliver training faster and more efficiently to employees entering mission critical occupations, making it possible for them to become fully functional in performing their public health duties. The agency also has established training as a condition of employment, requiring entering employees to demonstrate mastery of concepts covered in training by passing a certification examination at the end of training.
- Food Safety Regulatory Essentials (FSRE) is HACCP-oriented training on the fundamentals of food safety verification and covers the types of products produced (raw, processed, or shelf stable), the pathogens of concern in those products, and the agency's public health strategies that apply to the employee's job duties. In FY 2006, FSIS delivered FSRE courses to 1,500 State and Federal Consumer Safety Inspectors, Public Health Veterinarians (PHVs), and field supervisors.
- FSIS provides training on EIAO methods to verify the design of establishments' food safety systems for scientific validity. The food safety assessments conducted using these methods have been critical in monitoring establishments' implementation of public health policies related to *E. coli* O157:H7 and *Lm*. The EIAO training also covers intensified verification sampling, a key component of the agency's risk-based testing. In FY 2006, 114 State and Federal employees completed EIAO training.
- PHVs undergo training that focuses on the veterinarian's regulatory role in verifying an establishment's food safety system, and prepares them to carry out FSIS' objective of having veterinarians spend 25 percent of their time on public health assessment and assurance. In FY 2006, 179 State and Federal PHVs completed this rigorous nine-week program.
- The course to train entering poultry and livestock slaughter inspectors covers the public health basics of slaughter inspection procedures. In FY 2006, 456 inspectors received this training.
- E-learning, which includes CD-ROM, video DVD, Web casting, and Web-based training, enables FSIS to provide training closer to the work site and train employees on recently issued policies. FSIS is also increasingly using AgLearn, USDA's learning management system, to deliver Web-based training. FSIS had 20 courses offered in an electronic format. Over 5,000 employees received an assignment to take one or more of these courses. Over 14,500 courses were completed electronically. Using this electronic method of training delivery saved the agency hundreds of thousands of travel dollars. Some examples of courses offered in an electronic format included courses on agency policies regarding export verification and food safety verification procedures. FSIS held its first three scientific seminars through e-learning in FY 2006.

ENHANCED AND MORE ROBUST RISK-BASED INSPECTION SYSTEM

Current Activities:

FSIS has a long history of protecting public health. In fact, 2006 marked the 100th year anniversary of the Federal Meat Inspection Act, which ushered in a new era of food safety on a national level.

While FSIS roles and responsibilities are guided by the statutes under which it operates – the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, the agency has adapted its programs and activities to today's needs. The challenge for the future is to better anticipate and more quickly respond to food safety and food defense challenges *before* they affect public health.

The agency's current system, while strong, must adapt to the ever-changing realities of food safety and public health. We need the advantages offered by an enhanced risk-based system. A risk-based system can be more fluid. It can more rapidly adapt to emerging hazards. It can also more easily identify problems that have occurred and anticipate problems to minimize risk. And a risk-based system allows us to more effectively align agency resources with the corresponding level of risk posed by specific hazards, products and processes.

This risk-based system must rely heavily on data to allow us to make correct proactive decisions affecting food safety and public health. FSIS has already made progress toward a risk-based approach to food safety, especially in our risk-based approach to pathogen control. The implementation of HACCP was the start of a more risk based system. The agency needs to ensure that the regulated industry designs and implements an effective food safety system. All plants must have properly functioning HACCP systems. FSIS has a vital role in educating, as well as regulating, industry to meet this outcome.

Selected Examples of Recent Progress:

An example of progress based on risk is FSIS' verification sampling program for *Lm*. Under this initiative, FSIS tailors its verification activities to the interventions that plants choose to adopt and to the potential for *Listeria* growth in their products. In other words, FSIS conducts less sampling in those plants that have the best control programs for *Listeria* and more sampling, as well as in-depth FSAs, in plants that adopt less vigorous programs. Based on our progress with *Listeria*, the agency is developing a risk-based verification system for *E. coli* O157:H7, and announced in February 2006 an 11-step risk-based strategy for *Salmonella*.

FSIS has been soliciting information on what types of public health data needed to make risk-based decisions. It is important to the agency that all stakeholders have the opportunity to participate in this process. The goal is to further enhance and strengthen that system so that we are fully prepared for today's food safety challenges and those that lie ahead. This more robust RBIS will allow us to use data to better identify those establishments and products that present the greatest risk to public health and to allocate resources accordingly. In other words, a processing plant that consistently demonstrates excellent control of pathogens and other food safety risks can be inspected less intensively. This would allow FSIS to direct its resources and attention to those processing plants having difficulty consistently meeting the critical food safety standards that ensure a safe and wholesome food supply for the American people.

The current FSIS risk-based approach will be driven by data to assess the public health risk posed by different types of products and the ability of the processing establishment to control risk in its plant. The agency is building a real-time, public health data infrastructure to enable agency personnel dispersed throughout the nation to collect necessary data, analyze those data, and to respond in a way that protects public health. In addition, the data system will permit strategic decisions to be more traceable, measurable, and easily audited.

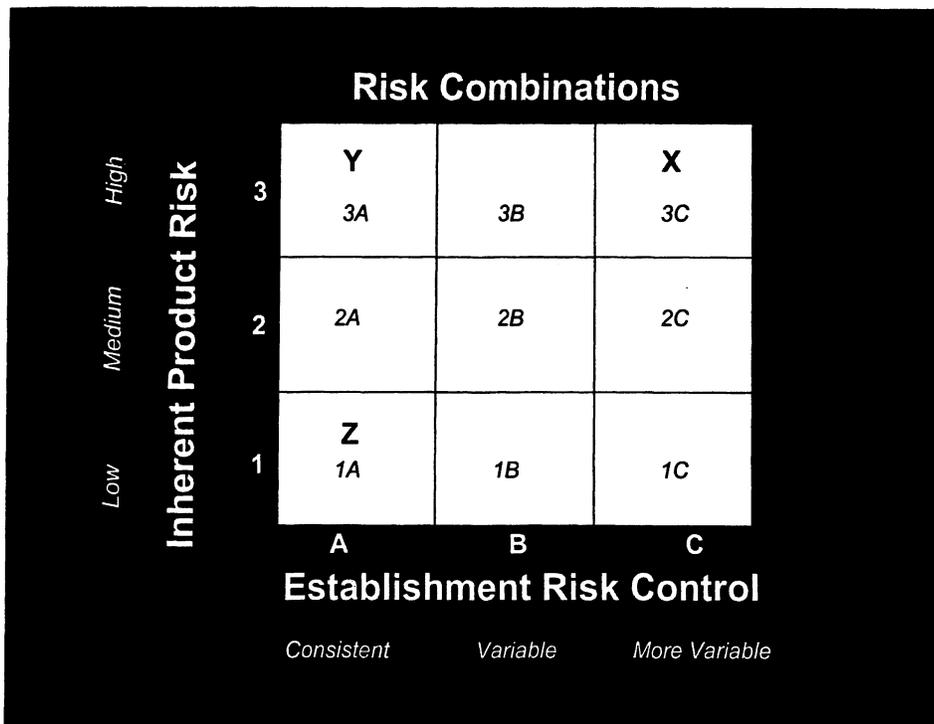
Data will be quickly integrated and analyzed to make effective risk-based decisions in areas such as inspection verification activities, policies, employee training, and outreach to industry. Data entering the system will come from pathogen testing, in-plant verification, non-compliance records, food safety assessments, traceable foodborne illness outbreaks, inquiries to FSIS' TSC, and many other sources. This data accumulation will allow data to flow seamlessly across the agency to make timely decisions based on risk to minimize potential problems.

Allocation of agency resources under RBIS at each processing establishment will rely upon a combination of two measures of risk:

- *Inherent Risk of Product* – a measure of the inherent risk posed to public health by each type of processed meat or poultry product

- *Establishment Risk Control* –a measure of the amount of actual risk control achieved by each processing establishment

The two measures are coupled to develop a mathematical formula that will tell us the risk for each plant and product. Based on this data, we will determine the type and intensity of inspection activity at each plant, allowing us to foresee problems and focus resources and efforts on plants and processes that pose the greatest public health risk. RBI in processing is not about less than daily inspection, it is not about decreased spending on inspection activities, it is not a response to budget issues, and it is definitely not about FTE reductions. RBI is about better protecting the public’s health by putting finite resources where they are most needed and where they will make the most difference. The success of a more robust RBIS is predicated on the result of input from employees, consumer groups, industry, and all of the agency’s other food safety stakeholders working together.



Of the plants depicted in this chart, the least amount of time and resources would be expended on the plants in the lower left corner, more for the plants in the upper left corner and the most for the plant in the upper right corner. In the chart, note that the inherent product risk increases as the numbers increase on the Y (or vertical) axis, and the risk of the plant’s ability to control harmful bacteria increases as the numbers increase on the X (or horizontal) axis.

FOOD SAFETY AND INSPECTION SERVICE
Summary of Budget and Performance
Statement of Agency Goals and Objectives

The mission of the Food Safety and Inspection Service is to protect consumers by ensuring that the commercial supply of meat, poultry, and egg products moving in U.S. interstate commerce or exported to other countries is safe, secure, wholesome and correctly labeled and packaged.

USDA Key Outcome (2005-2010): Reduction in Foodborne Illness Associated with the Consumption of Meat, Poultry, and Egg Products.

Healthy People 2010 Goal: Reduce foodborne illness.

The FSIS has six strategic goals and nine strategic objectives that contribute to two of the Department's Strategic Goals and two of the Department's Strategic Objectives.

USDA Strategic Goal/Objective	Agency Strategic Goal	Agency Objectives	Programs that Contribute	Key Outcome
<p>USDA Strategic Goal 1: Enhance International Competitiveness of American Agriculture</p> <p>USDA Strategic Objective 1.3 – Improved Sanitary and Phytosanitary (SPS) System to Facilitate Agricultural Trade</p>	<p>Agency Goal 1: Establish policies and systems ensuring safe, secure meat, poultry, and egg products.</p>	<p>Coordinate all U.S. government and non-government participation in the sanitary and phytosanitary standards-setting activities of the Codex Alimentarius Commission.</p>	<p>Codex</p>	<p>An Improved Global Sanitary and Phytosanitary (SPS) System for Facilitating Agricultural Trade</p>

USDA Strategic Goal/Objective	Agency Strategic Goal	Agency Objectives	Programs that Contribute	Key Outcome
<p>USDA Strategic Goal 4: Enhance Protection and Safety of the Nation's Agriculture and Food Supply</p> <p>USDA Strategic Objective 4.1 – Reduce the Incidence of Foodborne Illnesses Related to Meat, Poultry, and Egg Products in the U.S.</p>	<p>Agency Goal 2: Protect public health by ensuring that meat, poultry, and egg products are safe, secure, and not adulterated or misbranded.</p> <p>Agency Goal 3: Conduct comprehensive risk and vulnerability assessments for foodborne hazards and intentional acts of terrorism.</p> <p>Agency Goal 4: Establish policies and systems ensuring safe, secure meat, poultry, and egg products.</p> <p>Agency Goal 5: Verify FSIS's effectiveness and efficiency in achieving its public health responsibilities.</p> <p>Agency Goal 6: Provide internal infrastructure to support food safety and food defense.</p>	<p>Objective 1.1: Inspect at slaughter, processing, in import plants and in commerce.</p> <p>Objective 1.2: Verify equivalence of State and exporting country systems.</p> <p>Objective 2.1 Identify key research needs; shape research agenda with public and private groups.</p> <p>Objective 2.2 Relate program outcomes with public health surveillance data.</p> <p>Objective 3.1 Prioritize policy development and outreach based on their impact on public health.</p> <p>Objective 4.1 Document strengths and identify methods for improvement.</p> <p>Objective 5.1 Develop training.</p> <p>Objective 5.2 Improve communications.</p> <p>Objective 5.3 Integrate financial and performance data.</p>	<p>Federal Food Safety and Inspection</p> <p>State Food Safety and Inspection</p> <p>International Food Safety and Inspection</p> <p>Field Automation and Information Management</p>	<p>Reduction in foodborne illness associated with the consumption of meat, poultry, and egg products.</p>

Selected Accomplishments Expected at the FY 2008 Proposed Resource Level:

FSIS will issue policies and procedures towards a more robust, enhanced risk-based approach to inspection. Through these efforts, USDA will move to reallocate its resources to focus more closely on food safety systems and prevent public health problems before they occur. This initiative advances a coordinated national and international food safety risk management system from farm-to-table and promotes the Department's strategic goal of enhancing the protection and safety of the Nation's Agriculture and Food Supply.

FSIS is developing a regulation that will require all egg products establishments to develop and implement a Sanitation Standard Operating Procedures (SSOP) and HACCP program. Additionally, FSIS will provide

outreach, training, and workshops for small and very small egg products establishments for the purpose of implementing this rule. Furthermore, all FSIS inspectors working in egg products establishments will receive training related to implementation of the rule.

FSIS is implementing its action plan to deliver a more comprehensive outreach program to promote risk-based food safety and food defense processes in small and very small plants. FSIS is committed to continuing its work with small and very small plant owners and operators to support their efforts to enhance the design of their food safety systems. Plant owners and operators must have the necessary tools for success, so education through outreach is an important focus for the agency. Ninety percent or more of the nearly 6,000 Federally inspected domestic facilities and a great majority of the 2,100 State inspected plants are small and very small plants. For USDA's more robust risk-based inspection system to be successful, all meat, poultry, and egg product plants must have well designed food safety and defense systems.

FOOD SAFETY AND INSPECTION SERVICE
Summary of Budget Performance
Key Performance Outcomes and Measures

Agency Mission: Protect consumers by ensuring that the commercial supply of meat, poultry, and egg products moving in U.S. interstate commerce or exported to other countries is safe, secure, wholesome, and correctly labeled and packaged.

Key Outcomes: Reduction in foodborne illness associated with the consumption of meat, poultry, and egg products. FSIS' key outcome restates USDA's Strategic Objective 4.1: reduce the incidence of foodborne illnesses related to meat, poultry, and egg products in the U.S.

Enhance International Competitiveness of American Agriculture through coordination of all U.S. government and non-government participation in the sanitary and phytosanitary standards-setting activities of the Codex Alimentarius Commission. This key outcome relates to USDA's Strategic Objective 1.3: improve sanitary and phytosanitary (SPS) system to facilitate agricultural trade.

Key Performance Measures: The continued mission of FSIS is to protect consumers by ensuring that the commercial supply of meat, poultry, and egg products moving in U.S. interstate commerce or exported to other countries is safe, secure, wholesome and correctly labeled and packaged.

FSIS agency goals embody USDA's Strategic Goal 4: *Enhance Protection and Safety of the Nation's Agriculture and Food Supply*, and specifically Objective 4.1 – *Reduce the Incidence of Foodborne Illnesses Related to Meat, Poultry, and Egg Products in the U.S.*

FSIS programs also contribute to USDA Strategic Goal 1: Enhance International Competitiveness of American Agriculture. FSIS contributes to USDA Objective 1.3 *Improved Sanitary and Phytosanitary (SPS) System to Facilitate Agricultural Trade*. In addition to FSIS' unique work with the Codex Alimentarius committees, FSIS houses the U.S. Codex Alimentarius office, whose principal purpose is the setting of international sanitary and phytosanitary standards.

FSIS' FY 2008 budget request is targeted at these core food safety strategies:

- Base program decisions and policy development on science;
- Apply the public health and technical skills of our workforce to foodborne hazards;
- Defend the food supply from intentional contamination;
- Manage the inspection program effectively and economically; and
- Continue effective public health outreach and education.

The FSIS FY 2008 budget request includes initiatives to maintain the 'gold standard' of this public health agency; to build up the infrastructure of its public health information system, including efforts to enhance the electronic exchange of export-import data; to prepare for future risk-based inspection; to defend the security of the food supply; to manage its human capital wisely; and to promote consumer protection standards at home and in the world arena.

Key Performance Targets

	2003 actual	2004 actual	2005 actual	2006 estimate	2007 target	2008 target
Pathogen Reduction						
Reduce overall public exposure to generic <i>Salmonella</i> from broiler carcasses using existing scientific standards *	n/a	n/a	n/a	45%	55%	65%
Decrease the overall percent positive rate for <i>Listeria monocytogenes</i> in ready-to-eat products through the use of Food Safety Assessments	0.90%	0.89%	0.70%	0.60%	0.65%	0.65%
Reduce the prevalence of <i>E. coli</i> O157:H7 on ground beef	0.37%	0.19%	0.17%	0.16%	0.20%	0.20%
Pathogen Reduction, Cost (\$000)	754,821,000	785,557,000	815,064,000	829,378,000	830,081,000	930,120,000

* FSIS currently compares how many establishments are in category 1 from one year to the next. Category 1 establishments demonstrate persistent capability of ensuring that the presence of *Salmonella* in sample sets is at or below half the current acceptable number of positives (i.e., for broilers, with the current standard at 20 percent, Category 1 establishments maintain the percent positives in the sample sets at 10 percent or lower.). As more establishments attain Category 1 status, FSIS believes that fewer people will be exposed to *Salmonella* from raw classes of product regulated by FSIS.

Full Cost by Strategic Objective

Program	2006 Amount (\$000)	2007 Amount (\$000)	2008 Amount (\$000)
Objective 1.3 – Improved Sanitary and Phytosanitary (SPS) System to Facilitate Agricultural Trade			
Codex			
Total direct cost	\$3,132	\$2,586	\$2,710
Indirect costs	468	386	405
Total Costs	3,600	2,972	3,115
FTE	11	7	7
Strategic Objective 4.1: reduce the incidence of foodborne illnesses related to meat, poultry and egg products in the U.S.			
Federal Food Safety and Inspection			
Total direct cost	645,805	646,204	730,043
Indirect costs	96,500	96,559	109,087
Total Costs	742,305	742,763	839,130
FTE	9,155	9,159	9,250
State Food Safety and Inspection			
Total direct cost	50,593	49,513	52,999
Indirect costs	7,560	7,399	7,919
Total Costs	58,153	56,912	60,918
FTE	29	29	29
International Food Safety and Inspection			
Total direct cost	13,109	16,839	18,143
Indirect costs	1,959	2,516	2,711
Total Costs	15,068	19,355	20,854
FTE	144	144	144
Public Health Data Infrastructure (formerly FAIM)			
Total direct cost	10,497	8,079	6,103
Indirect costs	-	-	-
Total Costs	10,497	8,079	6,103
FTE	-	-	-
Total for Strategic Objective 4.1:			
Total Costs	826,023	827,109	927,005
FTE	9,328	9,332	9,423
Total, All Strategic Objectives			
Total Costs (current law)	829,623	830,081	930,120
FTE	9,339	9,339	9,430