

Narrative by Activity:

Foods Program

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resource Table
Food Program

(dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 President's Budget	FY 2014 '+/ FY 2012
Program Level	\$875,001	\$866,920	\$880,357	\$1,106,604	\$231,603
Center	\$257,952	\$265,158	\$259,531	\$320,324	\$62,372
FTE	899	882	913	994	112
Field	\$617,049	\$601,762	\$620,826	\$786,280	\$169,231
FTE	2,816	2,664	2,771	3,116	452
Program Level FTE	3,715	3,546	3,684	4,110	395
Budget Authority	\$858,315	\$866,920	\$863,568	\$882,817	\$24,502
Center	\$257,488	\$265,158	\$259,064	\$266,408	\$8,920
Field	\$600,827	\$601,762	\$604,504	\$616,409	\$15,582
Budget Authority FTE	3,642	3,546	3,611	3,682	136
Center	897	882	911	905	23
Field	2,745	2,664	2,700	2,777	113
User Fees	\$16,686	-	\$16,789	\$223,787	\$207,101
Reinspection	\$6,825	-	\$6,867	\$7,134	\$309
Field	\$6,825	-	\$6,867	\$7,134	\$7,134
FTE	48	-	48	48	48
Voluntary Qualified Importer Program Fee	-	-	-	-	-
Recall User Fee	\$9,861	-	\$9,922	\$10,308	\$447
Center	464	-	467	485	21
FTE	2	-	2	2	2
Field	9,397	-	9,455	9,823	426
FTE	23	-	23	23	23
Food Establishment Reg. and Inspect. Fee	-	-	-	\$49,657	\$49,657
Center	-	-	-	22,820	22,820
FTE	-	-	-	28	28
Field	-	-	-	\$26,837	\$26,837
FTE	-	-	-	20	20
Food Importer User Fee	-	-	-	\$134,745	\$134,745
Center	-	-	-	13,810	13,810
FTE	-	-	-	10	10
Field	-	-	-	120,935	120,935
FTE	-	-	-	227	227
Cosmetics User Fee	-	-	-	\$16,660	\$16,660
Center	-	-	-	12,253	12,253
FTE	-	-	-	42	42
Field	-	-	-	4,407	4,407
FTE	-	-	-	18	18
Food Contact Notification User fee	-	-	-	\$4,548	\$4,548
Center	-	-	-	4,548	4,548
FTE	-	-	-	7	7
Field	-	-	-	-	-
FTE	-	-	-	-	-
International Courier User Fee	-	-	-	\$735	\$735
Field	-	-	-	735	735
FTE	-	-	-	3	3
User Fee FTE Total	73	-	73	428	428

The FDA Foods Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Federal Import Milk Act (21 U.S.C. 142-149)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Food Additives Amendment of 1958*
Color Additives Amendments of 1960
The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461)
Safe Drinking Water Act (21 U.S.C. 349)
Saccharin Study and Labeling Act*
Infant Formula Act of 1980*
Drug Enforcement, Education, and Control Act of 1986*
Nutrition Labeling and Education Act of 1990*
Dietary Supplement Health and Education Act of 1994*
Food Quality Protection Act of 1996*
Federal Tea Tasters Repeal Act (42 U.S.C. 41)
Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349)
Food and Drug Administration Modernization Act of 1997*
Antimicrobial Regulation Technical Corrections Act of 1998*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
Food Allergen Labeling and Consumer Protection Act of 2004*
Sanitary Food Transportation Act of 2005*
Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C.379aa-1)*
Food and Drug Administration Amendment Act of 2007*
Patient Protection and Affordable Care Act
FDA Food Safety Modernization Act (P.L. 111-353)

Allocation Method: Direct Federal/intramural; Contract

Program Description and Accomplishments

The Foods Program is a component of the FDA Foods and Veterinary Medicine (FVM) Program. The mission of the FVM Program is to protect and promote the health of humans and animals by ensuring the safety and proper labeling of the American food supply, animal feed and cosmetics, as well as the safety and effectiveness of animal drugs and devices. The FVM Program is comprised of the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the related field activities of the Office of Regulatory Affairs (ORA). The Office of Foods and Veterinary Medicine (OFVM) provides leadership and strategic direction to the FVM Program, including oversight of the wide range of responsibilities and activities of CFSAN and CVM.

*Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

The Foods Program consisting of CFSAN and ORA protects consumers by safeguarding the human food supply. Outbreaks of foodborne illness and contamination events have a substantial impact on public health – an estimated 48 million foodborne illnesses occur every year resulting in an estimated 128,000 hospitalizations and 3,000 deaths.¹⁸ The average cost per case of foodborne illness is estimated at \$1,626 and total more than \$78 billion per year.¹⁹

Congress recognized the unique challenges faced by FDA in the area of food safety in the 21st century, and gave the Agency a modern legislative mandate to meet these challenges by enacting the FDA Food Safety Modernization Act of 2011 (FSMA). FSMA directs FDA to build a food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm to table.

The FDA *Foods and Veterinary Medicine Program Strategic Plan*²⁰ (*FVM Strategic Plan*) provides a framework for the implementation of FSMA and places high priority on the prevention of foodborne illness of unknown origins, as well as illness that can be specifically attributed to known sources.

To achieve the goals of the FVM Strategic Plan, the Foods Program focuses on securing high rates of compliance with science-based food safety and labeling standards by implementing integrated, prevention-oriented, and risk-based programs to protect the safety and security of foods and cosmetics and to ensure that food labels contain useful and reliable information.

The Foods Program executes its regulatory responsibilities in the following subprogram areas:

- Prioritizing Prevention
- Strengthening Surveillance
- Strengthening Enforcement
- Improving Response and Recovery
- Nutrition & Labeling Strategies for Better Health
- Reinventing Cosmetics Safety.

¹⁸Centers for Disease Control and Prevention. 2011. Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

¹⁹Scharff, Robert L., "Economic Burden from Health Losses Due to Foodborne Illness in the United States," *Journal of Food Protection*, Volume 75, Number 1, January 2012, pp. 123-131(9).

²⁰ The FVM Strategic Plan can be found on the FDA web site at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf>

Prioritizing Prevention – Center Activities

Base Amount: \$7,781,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Prioritizing Prevention* activities support the *FVM Strategic Plan* goals of establishing science-based preventive control standards across the farm-to-table continuum, as well as promoting the safe production of dietary supplements. FDA uses the results of regulatory science, product surveillance, and risk analysis to inform standard-setting activities and focus efforts to address both known and unknown sources of foodborne illness. Compliance, enforcement and response activities, such as inspections, administrative and judicial remedies, and food-related incident response, help FDA address issues that occur in the farm-to-table continuum and provide insight into areas where additional or expanded standards, controls, outreach, and education would improve food safety results.

Public Health Outcome

As part of the Foods Program, CFSAN addresses food safety risks at multiple points of the food supply chain through a combination of regulations, guidance, technical assistance, education, training and outreach, model codes for food service establishments such as restaurants, and consumer advice. CFSAN sets standards for protecting the food supply from tampering or other deliberate actions, and evaluates the safety of food additives, color additives, dietary supplements, and infant formula. In addition, CFSAN partners with agricultural and industry suppliers, distributors and marketers to improve their knowledge of regulations, guidance, hazards, and mitigation strategies. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Issuance of Proposed Rules on Preventive Controls for Food Processing and Produce Safety: As part of FSMA implementation, FDA proposed two new food safety rules aimed at preventing and reducing foodborne illness in January 2013. The proposals were drafted following extensive outreach to industry, consumer communities, other government agencies, and the international community over the last two years. The first proposed rule would require makers of food to be sold in the U.S., whether produced at a foreign- or domestic-based facility, to have written plans that identify microbiological, chemical, physical, or radiological hazards that are reasonably likely to occur; specify the steps that will be put in place to prevent or minimize the hazards; identify monitoring procedures; record monitoring results; and specify what actions will be taken to correct problems that arise. The second rule proposes enforceable science and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms. These standards focus on agricultural water, soil amendments of biological origin, animal intrusion, worker health and hygiene, and equipment, tools, buildings, and sanitation. These two proposed rules are part of an integrated reform

effort that focuses on prevention and addresses the safety of foods produced domestically and imported.

Issuance of Interim Final Rule on Record Access Requirements for Food Firms: In February 2012, FDA issued an interim final rule amending its regulations on record-keeping by food firms to be consistent with FDA's access to records expanded by FSMA. The expanded records-access authority is expected to improve FDA's ability to respond to and contain safety problems with the human food supply. FDA also published an update to its guidance for industry, "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4)," to ensure the guidance is consistent with the new FSMA requirements.

Survey on the Occurrence of Foodborne Illness Risk Factors (2013-2022): In 2012, FDA continued to measure trends in the occurrence of foodborne illness risk factors--preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors to foodborne illness outbreaks at the retail level. FDA initiated this survey in 1998 and has created a new tool to better collect data for the Survey. The tool will be used over the next ten years and will provide FDA a solid foundation for developing a national retail food program model that can be used by Federal, state, local, and tribal agencies to improve identifying food safety risk and impact of industry food safety management systems.

Establishment of Alliance for FSMA Preventive Controls Training: In cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, FDA established the Food Safety Preventive Controls Alliance to develop training courses and materials on preventing contamination for both human and animal food during production. The materials to be developed by the alliance will help industry, particularly small- and medium-size companies, comply with the upcoming preventive controls requirements of the FDA Food Safety Modernization Act.

Preventing *Salmonella* – Egg Safety: *Salmonella* is the leading pathogen contributing to domestically acquired foodborne illness resulting in hospitalization and death. In its 2009 Egg Safety Rule, FDA established standards to protect consumers from *Salmonella* and save thousands of lives over the next few years. In FY 2012, FDA released a final Guidance for Industry on the production, storage, and transportation of shell eggs under the rule. The guidance document addresses questions regarding the requirements under the rule, including how to determine whether and when producers must comply with the requirements, *Salmonella* Enteritidis prevention measures, sampling and testing requirements, facility registration, and enforcement and compliance.

FSMA Food Facility Registration Guidance: FDA issued draft guidance on the Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories, as provided by section 102 of FSMA. The Act requires both domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal

consumption in the U.S. to register with the FDA. Requiring the submission of food product category information as part of a facility's registration will help FDA to better protect the public by enabling quicker, more accurate, and more focused responses to an actual or potential bioterrorist incident or other food related emergency.

Import Safety – Systems Recognition: FDA is currently working on pilot activities to explore the use of systems recognition, previously termed “comparability,” as one tool to help ensure the safety of imported foods and as a mechanism to establish a global coalition of regulatory partners. Systems recognition involves reviewing a foreign country’s food safety regulatory system to determine if it provides a similar set of protections to that of FDA. Systems recognition will allow the agency to identify where leveraging of resources is most appropriate, allowing FDA to focus its resources on the highest risk commodity-country combinations. Systems recognition will allow the agency to identify where leveraging of resources is most appropriate, allowing FDA to focus its resources on the highest risk commodity-country combinations.

Following completion of FDA’s first pilot with New Zealand, FDA and New Zealand’s Ministry of Primary Industries signed a systems recognition cooperative arrangement on December 10, 2012. The agreement recognizes each other’s food safety systems as comparable to each other, leading the way to a new level of regulatory cooperation to enhance food safety while facilitating trade between the two countries. This is the first time that FDA has recognized a foreign food safety system. A second pilot is currently underway with Canada under the U.S. Canada Regulatory Cooperation Council work plan, “Common Approach to Food Safety.”

Import Safety – Developing Sustainable International Food Safety Training: FDA has partnered with the University of Maryland’s Joint Institute for Food Safety and Nutrition (JIFSAN) to expand food safety training by developing strong sustainable partnerships with different regions of the world. The concept was piloted with the Bangladesh Shrimp and Fish Federation by establishing an Aquatic and Aquaculture Food Safety Training Center where a cadre of in-country trainers has conducted local programs for both the small aquaculture producers in rural areas and the larger companies. Based on the success of this endeavor, JIFSAN and FDA are using it as a model to establish other regional training centers for different food commodities.

In FY 2012, JIFSAN, CFSAN, and FDA’s India Post established a partnership with the India Spice Board and the Coalition of India Industry-Food and Agriculture Center of Excellence to develop a program on Supply Chain Management for Spices and Botanical Ingredients. The first phase of the program, an in-country training program, was conducted in 2012; the second phase, a two-week internship program for small cadre of professionals who will become the in-country trainers is planned for early 2013. The initiative fosters and supports the implementation of modern food safety practices that protect the U.S. consumer from unsafe foods as required by FSMA and permits FDA to focus its future resources on other high priority food safety issues.

Prioritizing Prevention – Field Activities

Base Amount: \$111,373,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

ORA's top priorities for advancing public health and protecting consumers focus on:

- Prevention through outreach coordination and technical assistance to industry
- Internal and external training to increase expertise and encourage collaboration with external stakeholders
- Preventive controls throughout the food supply chain from production to delivery into the U.S. supply chain and ultimately to consumption by the public.

ORA achieves the overall FDA food safety strategy by focusing on preventing food safety problems rather than reacting to problems after they occur. These activities are part of the *FVM Strategic Plan* goals of establishing science-based preventive control standards and regulations across the farm-to-table continuum to protect the food and feed supply from contamination. This is accomplished by identifying the most significant foodborne contaminants and evaluating the effectiveness of existing controls for those contaminants.

Public Health Outcome

As part of the Foods Program, ORA participated in public outreach events that were attended by regulated industry, other government agencies, and foreign regulatory entities. Below are five examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Compendium of Microbiological Protocols and Chemical Tests (COMPACT): The FDA Compendium of Microbiological Protocols and Chemical Tests is a compilation of analytical detection methods for foods designed to support the mission of FDA. In FY 2012, COMPACT, which is housed within the Electronic Laboratory Exchange Network (eLEXNET), released a new method – “Detection of Toxic Elements” – and made it available to the chemistry community. The eLEXNET is a seamless, integrated, secure network that allows multiple agencies (federal, state, and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET added three new labs in FY 2012. As of October 2012, 174 laboratories are participating in eLEXNET by submitting food-testing data. eLEXNET successfully completed the initial phase of a data sharing pilot with Canada Food Inspection Agency and Health Canada. FDA and Canada are collaborating so both countries can share food generated laboratory data associated with chemistry, microbiological, and radiological disciplines within their respective laboratory network systems.

Manufactured Foods Regulatory Program Standards (MFRPS): ORA provided funding through a cooperative agreement to 26 state food regulatory programs to support implementation of the Manufactured Food Regulatory Program Standards. At the end of FY 2012, a total of 41 programs in 40 states were enrolled in MFRPS. To provide support to these programs, ORA's Office of Partnerships conducted 44 visits with states to assist in their implementation of the standards. In addition, ORA's audit team conducted 11 state assessments to determine the states' progress in implementing MFRPS. ORA funded 31 state regulatory program laboratories and a laboratory association, the Association of Public Health Laboratories, under two cooperative agreements to provide support, best practices and training for laboratories to achieve International Organization for Standardization (ISO) accreditation. By working with these public health partners, FDA is establishing a fully integrated food safety system to prevent foodborne illness through the adoption and uniform application of model programs, like the Manufactured Food Regulatory Program Standards and other appropriate program standards.

Voluntary Retail Program Standards: In FY 2012, ORA provided funding through a cooperative agreement to 38 state, local, county, and city regulatory agencies to support implementation of the Voluntary Retail Program Standards. This cooperative agreement funding provides the means for these programs to build their capacity, capability and infrastructure to increase implementation of the retail standards and better protect public health.

Egg Safety Rule: In FY 2010, FDA began regulating firms under 21 CFR Part 118, "Production, Storage, and Transportation of Shell Eggs. Since then, ORA has conducted more than 550 inspections and collected more than 150 shell egg samples including more than 2,000 environmental swabs. Twenty-two of the 150 samples and 51 individual environmental swabs were found positive for *Salmonella* Enteritidis (SE). ORA evaluates inspection and analytical findings and works with regulated industry to determine the appropriate corrective and regulatory actions such as issuance of warning letters, untitled letters, and voluntary recalls. ORA re-inspected firms with significant violations that warranted action by FDA to determine their compliance status. ORA also participated in industry outreach programs with the egg producing industry, providing education on compliance with the Egg Safety Rule.

In 2012, the Egg Safety Rule went into effect for smaller shell egg producers, those with between 3,000 and 49,999 laying hens. FDA has begun outreach efforts for this industry segment and began inspecting these smaller shell egg producers. Contracts were issued with eight state partners to conduct inspections of these facilities.

Integrated Food Safety System Cooperative Training Grants: Seven grantees involved in over 70 projects which covered all levels of regulatory responsibility, knowledge, skills, and abilities required for the technical specialist across multiple commodity areas. All of the grant projects contribute to the development and implementation of an

Integrated Food Safety System. The training and certification programs also support the Manufactured Food and Retail Food Regulatory Program Standards.

Performance Measures

The *Prioritizing Prevention* subprogram is supported by budget authority.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. <i>(Output)</i>	FY 2012: 92% Target: 80% (Target Exceeded)	80%	80%	Maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. <i>(Outcome)</i>	FY 2012 :547 enrolled Target: 502 enrolled (Target Exceeded)	502 enrolled	587 enrolled	+85
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: <i>Campylobacter</i> species. <i>(Outcome)</i>	CY 2010: 13.52 cases/100,000 CY 2010 Target: 12.4 cases/100,000 (Target Not Met)	11.9 cases/ 100,000	11.4 cases/ 100,000	- .5 cases/ 100,000
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing <i>Escherichia coli</i> O157:H7. <i>(Outcome)</i>	CY 2010: 0.95 cases/100,000 CY 2010 Target: 1.15 cases/100,000 (Target Exceeded)	1.09 cases/ 100,000	1.00 cases/ 100,000	- .09 cases/ 100,000
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: <i>Listeria monocytogenes</i> . <i>(Outcome)</i>	CY 2010: 0.27 cases/100,000 CY 2010 Target: 0.29 cases/100, (Target Exceeded)	.29 cases/ 100,000	0.27 cases/ 100,000	- .02 cases/ 100,000
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: <i>Salmonella</i> species. <i>(Outcome)</i>	CY 2010: 17.55 cases/100,000 CY 2010 Target: 14.9 cases/100,000 (Target Not Met)	14.5 cases/ 100,000	13.9 cases/ 100,000	- .06 cases/ 100,000
212409: Reducing foodborne illness in the population. By December 31, 2013, decrease the rate of Salmonella Enteritidis (SE) illness in the population from 2.6 cases per 100,000 (2007-2009 baseline) to 2.1 cases per 100,000. <i>(Outcome)</i>	CY 2011: 3.0 cases/100,000 Target: 2.3 cases/100,000 (Target Not Met)	2.2 cases/ 100,000	2.0 cases/ 100,000	.2 cases/ 100,000

Strengthening Surveillance – Center Activities

Base Amount: \$135,274,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Strengthening Surveillance* activities support the *FVM Strategic Plan* goals to strengthen scientific leadership, capacity, and partnership to inform public health decision making, and to improve effectiveness and efficiency across the farm-to-table continuum. These activities inform the use of resources across all sub-programs, allowing FDA to target standard-setting, compliance, and response activities to best address both known and emerging food safety concerns.

Public Health Outcome

As part of the Foods Program, CFSAN conducts surveillance of domestic and imported products and evaluates commodity and hazard-specific risks to inform resource use in addressing known and unknown sources of foodborne illness. CFSAN also invests in advanced sciences and technologies to more efficiently address issues threatening the food supply. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

New Modeling Tool Increases Risk Ranking Capacity and Rapid Risk Assessment of Emerging Issues: FDA developed and released for public use on October 4, 2012, an innovative risk-assessment tool, FDA-iRISK. FDA-iRISK automates the time- and labor-intensive process of developing mathematical models to simulate risk and intervention in food-production chains. FDA-iRISK predicts the number of cases of illness prevented by various interventions applied against specific contaminants, in specific foods, at any or all points, from farm to table. Its automated features reduce the time and labor required for risk assessments, to provide faster access to information for regulatory decisions, such as those involving policies or resource allocation, and to give industry and others, including countries that export food to the U.S., a free, globally accessible, online mechanism for assessing how to improve food safety. FDA-iRISK is one of six finalists in the 2013 HHS Innovates Awards, and received Honorable Mention at an awards event held in March 2013 at which the "Secretary's Picks" were announced.

Produce Safety Risk Analysis: FDA conducted an experimental field trial of crop contamination to validate FDA's On-Farm Produce Quantitative Predictive Risk Assessment Model (QPRAM). QPRAM is a risk model that simulates transfer of the bacterium from the environment to produce and enables prediction of foodborne illnesses resulting from crop contamination. In estimating risk, the model takes into account a wide variety of farming practices, such as application of irrigation water, and environmental factors, such as topography and location of wild and domestic animals. The field trial was conducted in collaboration with the UC Davis Western Center for Food Safety. The information from this risk model will support FDA efforts to prevent foodborne illness resulting from consumption of contaminated produce.

Development of New Rapid Method for Identifying *Salmonella enterica*: CFSAN has developed a polymerase chain reaction (PCR) method for serotyping (identifying) *Salmonella enterica*; this new method can determine the type of 30 of the most clinically relevant serotypes with the potential for additional serotypes as needed. CFSAN developed and published a manuscript entitled, “Evaluation of a PCR-Based Method for Identification of *Salmonella enterica* Serotypes from Environmental Isolates and Various Food Matrices.”

Development of Testing Protocol for Paralytic Shellfish Toxins: Federal waters off the New England Coast have been closed to shellfish harvesting since 1990 because of paralytic shellfish toxin (PST) outbreaks from algal blooms. FDA is responsible for advising the National Marine Fisheries Service (NMFS) about re-opening these regions to harvest, but FDA has not had the resources to investigate whether these areas are safe. FDA collaborated with NMFS, state shellfish authorities (Massachusetts, Rhode Island and Delaware), and industry to develop the On-Board Screening Dockside Testing Protocol, which requires pre-harvest screening of shellfish at sea using PST field kits. In 2011, this protocol was adopted into the National Shellfish Sanitation Program Model Ordinance as an approved marine biotoxin control strategy for use in federal waters. NMFS also provides an exempt permit for fishermen to harvest in affected areas as long as they follow the requirements of the protocol. The successful implementation and execution of the protocol enables industry to safely harvest an underutilized resource and provides FDA and NMFS with data to assess whether long-closed resources could be opened.

Listeria monocytogenes Market Basket Survey: In collaboration with other federal agencies, FDA completed Phase 1 of the *Listeria monocytogenes* Market Basket Survey, a comprehensive survey of ready-to-eat foods, to provide data on prevalence and levels of *Listeria monocytogenes* in food samples. *L. monocytogenes* imposes a particularly high mortality rate, and risk-assessment models have identified certain ready-to-eat foods that allow the growth of this pathogen, which can grow even during refrigerated storage, as higher-risk vehicles for transmission and subsequent listeriosis. The survey is providing vital data for risk models that compare listeriosis risk among ready-to-eat food categories. Phase II of the Market Basket Survey is underway to also examine characteristics of the foods, such as ingredients, formulations, and inhibitors.

Listeriosis Risk by Subpopulation: In collaboration with CDC, the FDA completed an analysis to determine the relative risk of listeriosis according to age, pregnancy, and ethnicity, based on CDC’s FoodNet data. By quantifying the risk among these particularly high risk populations, the study is providing a better understanding of susceptibility for developing risk-assessment models and other disease-prevention efforts. Two papers co-authored by the two Agencies were published in *Clinical Infectious Diseases* in June 2012²¹.

²¹ Pouillot, R., Hoelzer, K., Jackson, K. A., Henao, O. L., & Silk, B. J. (2012). *Relative Risk of Listeriosis in Foodborne Diseases Active Surveillance Network (FoodNet) Sites According to Age, Pregnancy, and Ethnicity*. Retrieved from http://cid.oxfordjournals.org/content/54/suppl_5/S405.short

Egg Safety – Improved Detection Method: In response to a need for more rapid and sensitive screening protocols, FDA developed a highly sensitive microbiological detection method for *Salmonella* serovars Enteritidis and Heidelberg in eggs that reduces the time to obtain a confirmed isolate to five from nine days. This new method can be used to detect *Salmonella* contamination at levels as low as one cell of *Salmonella* in a 20 egg composited sample (e.g., a one liter pool). The method is currently being drafted for inclusion in FDA's Bacteriological Analytical Manual, which presents the agency's preferred laboratory procedures for microbiological analyses of foods and cosmetics. This method supports implementation of FDA's Egg Safety Rule testing requirements for shell eggs and egg-production environments. For more information about this project, please see CFSAN's FDA-TRACK page.²²

Strengthening Surveillance – Field Activities
Base Amount: \$286,015,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

To strengthen food defense and safety, surveillance and risk analysis, ORA conducts:

- Import prior notice and entry reviews
- Import field exams
- Import sample collections
- Domestic product reconciliation examinations
- Laboratory analyses including sample analysis, product testing, and methods development.

In the case of *Strengthening Surveillance*, ORA supports the overall FDA food safety strategy by:

- Establishing a structure to enhance risk-based decision making
- Developing metrics and goals for risk-based food safety priority setting
- Maintaining and strengthening mission-critical science capabilities.
- Improving centralized planning and performance measurement.
- Improving internal and external information sharing.

Silk, B. J., Date, K. A., Jackson, K. A., Pouillot, R., Holt, K. G., Graves, L. M., Ong, K. L., Hurd, S., Meyer, R., Marcus, R., Shiferaw, B., Norton, D. M., Medus, C., Zansky, S. M., Cronquist, A. B., Henao, O. L., Jones, T. F., Vugia, D. J., Farley, M. M., & Mahon, B. E. (2012). *Invasive Listeriosis in the Foodborne Diseases Active Surveillance Network (FoodNet), 2004–2009: Further Targeted Prevention Needed for Higher-Risk Groups*. Retrieved from http://cid.oxfordjournals.org/content/54/suppl_5/S396.short

²² "Rapid Testing and Identification of *Salmonella* in Foods,"

<http://www.accessdata.fda.gov/FDATrack/track-proj?program=cfsan&id=CFSAN-ORS-Rapid-Testing-and-Identification-of-Salmonella-in-Foods>.

Public Health Outcome

As part of the Foods Program, ORA conducts surveillance of the nation's food supply to monitor and evaluate the food safety system. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the FVM *Strategic Plan*.

Mobile Laboratories: In FY 2012, ORA continued to use Chemistry and Microbiological Mobile Laboratories to support FDA's food defense initiatives and surveillance of import and domestic produce. The Mobile Laboratories are deployed to sites around the country to increase rapid surveillance of food samples. During the summer, the Chemistry Mobile Laboratories deployed to Davie, Florida where more than 140 samples of fresh, imported produce were analyzed for illegal pesticide residues, nine of which were found to contain illegal levels of pesticides. The Microbiological Mobile Lab deployed on three separate occasions where 2,185 imported and domestic samples (21,850 sub samples) that included soil, water, and fresh produce with a history of association to foodborne-outbreak illnesses, were analyzed for enterohemorrhagic *E. coli* and *Salmonella*. Eleven samples were confirmed positive for *Salmonella* and one was confirmed positive for Shiga toxin 2 (*stx2*). ORA took regulatory action and refused entry of the goods into the U.S. The mobile laboratories were able to quickly report the results to a central command using the Incident Command System (ICS) structure. ICS contacted the appropriate collecting districts where dissemination of results occurred. In September 2012, while deployed in Salinas, California, the mobile laboratory responded to an outbreak of Salmonellosis linked to mangoes from Mexico. The Microbiological Mobile Laboratories participated in a collaborative project with the Lawrence Livermore National Laboratory (LLNL) Biological Operation exercise. The LLNL exercise demonstrated the effective collaboration of two agencies from collection to analysis. An automated high-throughput molecular platform was put in place for the 2012 deployments to advance the mobile lab's technological capabilities. This new platform effectively increased the mobile lab's analytical throughput by 50 percent. In addition, an effort to enhance the self-contained nature of the laboratories, the microbiological mobile laboratory initiated preparation of media in-house and confirmation of any 'cannot rule out' sample for microbial adulteration. These additional procedures allowed the mobile lab to operate predominately independent of a fixed-site lab.

Environmental Sampling: In 2012, ORA and state regulatory partners under contract with FDA continued to use environmental sampling during domestic, high-risk food facility inspections to assess the environmental conditions in which products are manufactured. These environmental samples are critical in identifying areas of concern within the production environment that lead to product contamination. As a result of FDA's efforts, industry took many actions to recall or destroy products that were manufactured under such conditions.

Political Convention Food Defense Surveillance Assignments: In May 2012, FDA issued a pilot food defense assignment in preparation for elections which involved inspections and collections based on food defense risk assessment models. ORA utilized the Food Emergency Response Network (FERN) cooperative agreement laboratories to analyze multiple matrices and analytes of food defense concern. In total there were 143 radiological samples tested, 119 microbiology samples, and 154 chemistry samples analyzed. Some samples required multiple analyte detection and all results were successfully reported in a timely manner. Feedback from the pilot assignment was used to strengthen and update the surveillance performed during the Democratic and Republican national conventions. During those assignments there were a total of 32 chemistry, 34 microbiology, and 41 radiochemistry samples analyzed. Overall the FERN labs analyzed more than 500 samples. This assignment strengthened the communication and response of laboratories nationwide to respond to a chemical, microbiological or radiochemical threat to our food supply, in a politically tense and highly populous event situation.

Handheld Portable Analytical Tool Pilot Program: ORA continues to pilot and implement handheld analytical tools. The tools allow ORA investigators to perform analytical screening of a variety of FDA regulated products to detect high level contaminants such as toxic elements or to detect the presence of Active Pharmaceutical Ingredients (APIs) in dietary supplements when the products are imported into the United States.

In FY 2012, ORA implemented two different handheld devices at locations throughout the nation. One of the tools allows ORA investigators to screen imported dietary supplements for the presence of APIs. After screening more than 200 products, ORA investigators found 44 of the products screened positive for the presence of APIs. Full analyses performed by ORA laboratories found all 44 products contained Sibutramine. Sibutramine substantially increases blood pressure and pulse rate and may present a significant risk for people with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. ORA subjected the product to detention without physical examination and worked with U.S. Customs and Border Protection to seize these shipments, keeping these dangerous products out of the U.S. market.

Increased Residue Testing in Domestic Products: A European Union (EU) audit of the U.S. residue testing program in foods produced in U.S. and exported to EU has revealed areas where increased surveillance is beneficial. In response to the recommendations of the EU audit, ORA has increased its sampling and testing of target domestic foods such as milk, honey, shell eggs, select aquaculture species, and select farmed game meat for drug residues and chemical contaminants. Historically ORA has focused on import products as they tend to exhibit a higher violation rate than domestic products. However, the increased surveillance in domestic products in response to the EU audit recommendation provides a unique opportunity to take a snapshot of the chemical contaminant profile exhibited by select domestic products. The increased surveillance was started in FY 2012 and the activities carry over into FY 2013. The increased surveillance targets collection of approximately 800 distinct samples and

testing of each of these samples for a number of families of compounds including pesticides, persistent organic pollutants, metals, and mycotoxins. The activity produces thousands of analytical data points and gives an expansive overview of the residue testing profile of the targeted domestic products.

Development of Nanotechnology Capability: A Nanotechnology Core Facility involving ORA's Arkansas Regional Laboratory (ARL) and FDA's National Center of Toxicology Research (NCTR) became fully operational. This facility provides the necessary analytical tools and advanced imaging equipment to adequately characterize nanoscale materials within multiple FDA regulated product classes. Additionally, scientists at ARL have developed a method to screen dietary supplements for total silver content using a portable analytical tool. As silver is the most widely used nanomaterial in consumer products, this method has allowed ORA to expand its laboratory capabilities and strengthen its ability to make science-based regulatory decisions.

Field and Label Examinations: During FY 2012, ORA performed field and label examinations on more than 190,000 entry lines of food related products, refused more than 14,000 entry lines of volatile food related products, and issued 56 Import Bulletins increasing FDA's field surveillance over suspected food products. Those activities are performed to identify readily visible violations such as verification that the product labeling meets applicable compliance requirements or determining the presence of macro filth. Physically verifying that refused entry lines are exported or destroyed is imperative to the protection of public health, ensuring that refused products are prevented from reaching U.S. consumers.

Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT): ORA completed full national rollout of the Mission Accomplishment and Regulatory Compliance Services (MARCS), Imports Entry Review (ER), and Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting to all 16 import Districts. MARCS Imports ER is FDA's new application to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups. PREDICT is FDA's electronic screening tool for import operations that replaces the legacy screening tool Operational and Administrative System for Import Support (OASIS). PREDICT screens all lines of imported products electronically submitted to FDA via U.S. Customs and Border Protection (CBP) interface. PREDICT is designed to calculate a customized risk score for every line in an entry based on a number of factors including inherent risk of the product, data anomaly rules, data quality rules, and the compliance history of the firms manufacturing or shipping of the product. PREDICT also has automated database lookups link to data stored in Center's databases, such as a firm's registration, product listing, and approval status.

Division of Food Defense Targeting (DFDT): ORA's DFDT was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002. DFDT carries out its role to protect U.S.

consumers from an intentional threat or actual terrorist attack on the U.S. food and feed supply. In FY 2012, ORA performed more than 81,000 prior notice reviews of food and feed. Every prior notice is electronically screened and targeted and all those identified as high risk receive an intensive security review.

Under the FSMA Smuggled Food/Feed Strategy, ORA collaborated with CBP and began targeting and conducting examinations of import shipments. The purpose of this collaboration was to identify and take enforcement action against those found to contain smuggled food/feed products. Smuggled food/feed presents a hazard to consumers and its entry erodes confidence in the safety of the food/feed supply. ORA and CBP conducted more than 1,000 examinations under this strategy and have taken action when appropriate, including the seizure of smuggled shrimp and peppers in FY 2012.

Performance Measures

The *Strengthening Surveillance* subprogram is supported by budget authority.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (Output)	FY2012: 6 working days Target: 6 working days (Target Met)	6 working days	4 working days	-2 working days
214207: The number of systems recognition assessments completed by participating countries to determine whether their level of food safety oversight is comparable to the level of food safety oversight of the FDA. (Outcome)	FY 2012: 6 assessments complete (Target Exceeded)	5	13	+8
214201: Number of prior notice import security reviews. (Output)	FY 2012: 81,888 Target: 80,000 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. (Output)	FY 2012: 171,783 Target: 160,000 (Target Exceeded)	160,000	160,000	Maintain
214203: Number of Filer Evaluations. (Output)	FY 2012: 1,338 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. (Output)	FY 2012: 10,229 Target: 7,000 (Target Exceeded)	7,000	7,000	Maintain

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214206: Maintain accreditation for ORA labs. (<i>Outcome</i>)	FY 2012: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain

Strengthening Enforcement – Center Activities

Base Amount: \$22,558,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program’s *Strengthening Enforcement* resources support the *FVM Strategic Plan* goal to achieve high rates of compliance with preventive controls and produce safety standards domestically and internationally. Inspections, field examples, and sample collection help FDA identify and address food safety risks throughout the production and handling stages of the global food supply chain, either in cooperation with industry or through compliance and administrative and judicial enforcement actions. These activities further provide information for FDA on areas where standards and outreach are working effectively to protect consumers and where additional efforts are required to strengthen the food safety system, including research and risk analysis on sources of foodborne contamination.

Public Health Outcome

As part of the Foods Program, CFSAN evaluates industry compliance with food standards and supports risk-based domestic and foreign safety inspections. CFSAN also leverages a variety of public health partners and regulatory mechanisms to verify the safety of food. Section 207 of FSMA provides FDA with the authority to detain food and prevent it from reaching the marketplace if there is reason to believe that the food is adulterated or misbranded. The food is held while FDA determines whether judicial enforcement action (e.g., seizure, injunction) is warranted. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

FSMA Enforcement Tools – Suspension of Facility Registration: Under FSMA, FDA received authorization to suspend a facility’s registration if there is a determination that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. If the registration of a facility is suspended, food cannot be imported into or exported from the facility and food cannot be introduced into commerce from the facility.

On November 26, 2012, FDA issued an order suspending the facility registration for Sunland, Inc., Portales, New Mexico. Sunland is a producer of raw and roasted peanuts and peanut butter products. FDA took this step after CDC identified peanut

butter manufactured by Sunland as the likely source of a twenty-state outbreak of *Salmonella* Bredeney and FDA found *Salmonella* in multiple environmental and product samples. In addition, an FDA inspection conducted from September to October 2012 found numerous significant deviations from current Good Manufacturing Practice requirements (cGMPs) that could result in cross-contamination between raw peanuts and peanut products.

In December 2012, a U.S. District of New Mexico judge signed a consent decree imposing requirements on Sunland to keep potentially harmful products from entering the marketplace. The consent decree requires that Sunland comply with cGMP regulations and retain an independent sanitation expert to develop a sanitation control program that the company must then implement. In addition, for the peanut butter plant, the company must conduct environmental monitoring and testing to ensure that disease-causing organisms are not present in the facility or in its finished foods and must have comprehensive inspections conducted by an independent sanitation expert. The consent decree permits Sunland to receive, hold, and distribute raw, unshelled peanuts from its storage buildings because the raw, unshelled peanuts are bound for processing facilities that include a “kill step” to eliminate *Salmonella* and other pathogenic bacteria.

Based on the requirements of the consent decree, FDA determined that adequate grounds no longer existed to continue the suspension actions and reinstated Sunland’s food facility registration. However, the company cannot process or distribute food from its peanut butter plant or peanut mill plant in Portales, New Mexico, until it has complied with the consent decree’s requirements to the agency’s satisfaction. Sunland must receive written authorization from the FDA prior to resuming operations at both its peanut butter and peanut mill plant. FDA continues work with Sunland to ensure that processing facilities include precautions to eliminate *Salmonella*.

Foreign Inspection Planning and Results: CFSAN developed a strategic plan to identify country/commodity combinations of interest based on identified risk factors and expert elicitation. The plan encompassed 26 commodity types in 54 countries and more than 3,700 potential foreign facilities. Processing of the plan included CFSAN communications with the embassy and foreign country competent authority in each identified country and FDA posts, when applicable. CFSAN then collected data and contacted each individual firm and transferred information on more than 1,700 firms to ORA to be targeted for inspection. ORA completed approximately 1,347 foreign inspections in 36 countries during FY 2012, exceeding the 1,200 goal set by FSMA.

CFSAN is evaluating the findings from these inspections and pursuing regulatory action when necessary against serious violations. Thus far, FDA added 21 firms to Import Alerts in order to subject the firms and their products to Detention without Physical Examination when offering their products for importation into the United States. FDA also issued Warning Letters to 21 firms and Untitled Letters to 15 firms.

Enhanced Models for Risk-based Selection of Domestic Inspection: Domestic facility risk categorization is part of a broader strategy to meet new inspection frequency

mandates under FSMA and ensure coverage of FDA's food facility inventory. In FY 2012, FDA developed a new framework for selecting domestic facilities for inspection based on factors of known safety risks, compliance history, and years since last inspection. As a result, FDA was able to categorize an estimated 80,000 domestic facilities as high-risk and non-high-risk. Additionally, FDA has developed a more structured method to prioritize sampling projects using a relative ranking tool as part of the decision-making process. Prioritizing surveillance, compliance and enforcement, and research projects for samples of finished product, ingredients, or environmental conditions helps to determine mechanisms for collection based on resource availability.

Dietary Supplement Enforcement Action: FDA recently took a variety of judicial enforcement actions to ensure industry compliance with dietary supplements safety standards. This included seizure action against products marketed with various therapeutic claims to treat serious diseases. The claims cause the products to be drugs, for which there is no FDA approval in place. FDA also worked with the Department of Justice to file injunctions against firms that did not comply with the dietary supplement current Good Manufacturing Practice (cGMP) requirements.

In addition to judicial enforcement actions, FDA issued 75 warning letters in 2012 related to failure to comply with the dietary supplement cGMP regulation. For example, in April 2012, FDA issued warning letters to ten manufacturers and distributors of dietary supplements containing dimethylamylamine (DMAA), for marketing products for which evidence of the safety of the product had not been submitted to FDA in accordance with the new dietary ingredient statutory notification requirement. As of April 2012, FDA had received 42 adverse event reports on products containing DMAA. Although the complaints did not establish that DMAA was the cause of the incidents, some of the reports included cardiac disorders, nervous system disorders, psychiatric disorders, and death. DMAA is known to narrow the blood vessels and arteries, which can elevate blood pressure and may lead to cardiovascular events ranging from shortness of breath and tightening in the chest to heart attack. Nine of the firms that received warning letters committed to ceasing formulating their products with the ingredient. Subsequent FDA inspections of three of the firms confirmed that they had discontinued use of DMAA in their products. FDA is following up with the remaining firms.

Strengthening Enforcement – Field Activities

Base Amount: \$167,081,000 (BA: \$ 150,859,000 / UF: \$16,222,000)

Public Health Focus and FDA Food Safety Strategy

One of ORA's main food safety duties is to perform risk-based inspections of food producers and provide strong, effective, and efficient enforcement of FDA laws and regulations. The safety of the nation's food supply continues to be a top priority for regulatory agencies. ORA views state-based contracts, grants, and cooperative programs such as the Food Inspection Contracts as important mechanisms for

providing increased enforcement activities through an enhanced integrated food safety system.

In the case of *Strengthening Enforcement*, ORA achieves the overall FDA food safety strategy by:

- Conducting risk-based domestic and foreign food safety inspections
- Implementing new enforcement tools
- Improving mechanisms for assuring that imported foods meet preventive controls standards
- Improving collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts.

Public Health Outcome

As part of the Foods Program, ORA conducts on-site inspections of regulated domestic and foreign food establishments and initiates enforcement actions to address violations of public health laws and regulations. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the FVM *Strategic Plan*.

Foreign Food Inspections: ORA performed 1,347 foreign food establishment inspections in 36 countries compared to 1,003 foreign food inspections conducted during the same period in FY 2011, a 34 percent increase. In FY 2012, an inspection of a foreign seafood processor revealed serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation. The inspection noted that the firm's HACCP plan for tuna failed to list adequate monitoring procedures and frequencies to control histamine formation and *Clostridium botulinum* growth and potential toxin formation. As a result of this inspection, ORA took regulatory action and issued a Warning Letter to the firm.

FDA uses risk factors to target firms to inspect, focuses the on-site inspections in the most critical areas, and continues to leverage the work of our dedicated foreign inspection cadre and FDA inspection staff located at FDA's foreign offices, and our district-based investigators to enhance overall coverage of the foreign establishment inventory. An inspection of a foreign chocolate manufacturer revealed that the firm had shipped 216 cases of chocolate bars to the U.S. from a lot that tested positive for *Salmonella risen*. As a result of this finding, the U.S. distributor was visited and the entire shipment was placed on hold therefore preventing the potentially contaminated chocolate bars from reaching the U.S. consumer.

Food Inspection Contracts: ORA awarded food inspection contracts to state agencies and territories. These contracts enhance an integrated food safety system by providing states and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections as well as inspections in high risk industries such as juice and

seafood under HACCP and low acid canned foods and acidified foods.

The 41 state programs currently enrolled in MFRPS conduct 96 percent of all GMP inspections performed under FDA contract. ORA created the Manufactured Food Regulatory Program Alliance through a cooperative agreement to provide additional resources, training, and support to programs that are implementing the standards. In FY 2012, FDA issued contracts with eight state programs to complete inspections under the Egg Safety Rule. In FY 2012, ORA saw 56 jurisdictions newly enroll in the voluntary retail program standards. Currently, 534 jurisdictions are enrolled.

Enforcement and Recall Activities: In FY 2012, there were nine injunctions and five seizures against food and dietary supplement processors and manufacturers. These enforcement actions protect consumer safety by assuring that processors and manufacturers comply with laws and violative food and dietary supplement products are not distributed into commerce.

FDA classified 317 Class I, 306 Class II, and 75 Class III recalls of food products. ORA monitors recalls of food products and ensures the effectiveness of the firm's recall to remove the defective product from commerce.

Office of Criminal Investigations (OCI): During FY 2012, ORA's OCI made 37 arrests and secured 32 convictions with fines, restitutions, and other monetary penalties in excess of \$9.8 million. Representative cases include:

Adulterated cheese- In April of 2012, four individuals from Mexico, Illinois, and Wisconsin were indicted on charges for conspiring to ship and distribute more than 110,000 pounds of Mexican cheese throughout the U.S. after FDA detained and ordered the cheese to be held for inspection. The cheese was later determined to be adulterated with *Salmonella*, *E. coli*, and other illness-causing bacteria. The four defendants scraped off mold and fungus from cheese returned by dissatisfied customers, re-sold it, and later lied to an FDA inspector to cover up the illegal redistribution/sales of the adulterated cheese. The four defendants owned or worked for companies responsible for importing and manufacturing the cheese.

Prickly pear- In California a group of import brokers were engaged in a scheme to defraud FDA. They helped customers import goods barred by FDA, including produce infected by *Salmonella* Agona, a life-threatening infectious bacteria. On one occasion, after a shipment of nopal cactus (also known as prickly pear) tested positive for *Salmonella*, coconspirators illegally changed the description of the nopal cactus' grower for subsequent shipments, for the purpose of evading future FDA inspections. Similarly, other offenders conspired to import Mexican snack foods that were mislabeled and adulterated with a prohibited dye.

OCI's investigation into adulterated and unsafe foods protects the public by ensuring compliance with FDA procedures designed to keep the public safe from food-borne

illnesses. The purchase of contaminated and adulterated products poses significant risks to the public health and has the potential to severely sicken consumers, and having effective criminal enforcement of the FD&C Act sends the message to the food industry that they must take their obligations seriously.

Performance Measures

The *Strengthening Enforcement* subprogram is supported by budget authority, Food Recall user fee, and Food Reinspection user fee.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214205: As required by the FSMA Legislation, cover 100% of the High Risk domestic inventory (approximately 22,000 firms) every three years. (Output)	FY 2012: 85%* (Historical Actual)	NA	33%	NA

*The assumed FY 2011 target would have been 33%, and the assumed FY 2012 target would have been 67%, although the goal was only officially established this year with the FY 2013 target. Because FDA is required to cover 100% of the firms every three years, the target for the first year of the new cycle, in this case FY 2014, returns to 33%.

Improving Response and Recovery – Center Activities

Base Amount: \$4,225,000 (BA: \$3,761,000 / UF: \$464,000)

Public Health Focus and FDA Food Safety Strategy

The Foods Program’s *Improving Response and Recovery* activities support the *FVM Strategic Plan* goal of improving detection of and response to foodborne outbreaks and contamination incidents. FDA detects and contains illness outbreaks and contamination incidents, and analyzes such events to improve the effectiveness of the food safety system. FDA also works closely with public health agencies and regulatory partners at Federal, State, local, tribal and territorial levels to improve data collection, analysis, sharing, and communication both within government and with industry and consumer stakeholders.

Public Health Outcome

As part of the Foods Program, CFSAN develops and adopts innovative technologies and processes, including enhanced implementation of the Reportable Food Registry, that enable improved response to foodborne outbreaks and contamination. CFSAN also conducts risk communications related to outbreaks and contamination incidents and uses data from incident investigations to inform prevention efforts. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Global Pathogen and Outbreak Detection Using Next-Generation Sequencing: CFSAN has partnered with food safety agencies and institutions from around the world to define and develop solutions to questions and challenges surrounding the deployment of next-generation DNA sequencing tools for public health and disease outbreak detection. In FY 2012, CFSAN hosted two international meetings with 24 different government agencies across 12 countries to establish a globally endorsed framework for using whole genome sequencing as the basis for global pathogen identification and disease detection. This effort will allow FDA to improve its foodborne illness outbreak response capability by creating stronger databases for outbreak source tracking and traceability of foodborne pathogens.

Public-Private Partnership to Spearhead Development of 100,000 Pathogen Genome Public Database: CFSAN recently partnered with the National Center for Biotechnology Information, the University of California Davis, BGI America, and Agilent Technologies, Inc. to launch a five-year effort to more quickly identify the source contamination in foodborne illness outbreaks and to keep additional contaminated product from entering the market. “The 100,000 Genome Project” will entail the genome sequencing of approximately 100,000 subtypes of common pathogens such as *Salmonella*, *Listeria*, and *Escherichia coli*. The information from this project will be made available in a free public database. This project will allow quicker identification of foodborne pathogens, and improved ability to pinpoint the sources of food contamination and to keep additional contaminated product from entering the market. Founders of the initiative, including several CFSAN microbiologists, were honored as recipients of the “Secretary’s Pick” for the 2012 Health and Human Services Innovates Award, presented by Secretary Sebelius at a special innovation awards event held in September 2012.

Second Annual Report for the Reportable Food Registry (RFR): The Reportable Food Registry (RFR) enables mandatory electronic reporting of adulterated and potentially harmful foods by industry, and speeds the identification and investigation of potential health hazards in food. In April 2012, FDA published the second “Reportable Food Registry (RFR) Annual Report.”²³ The report demonstrates the success of the program in improving the ability of the FDA to target its activities based on product risk and trace reportable foods throughout the farm-to-table continuum based on early warnings. The report also provides valuable insight on specific hazards affecting the food supply. The 225 primary reports for the second year involved products in 22 commodity categories. Salmonella accounted for 38.2 percent of hazards; undeclared allergens accounted for 33.3 percent; and *Listeria monocytogenes* accounted for 17.8 percent. In June 2012, FDA launched an updated RFR Rational Questionnaire to incorporate additional information that meets FSMA requirements to improve FDA’s ability to track patterns of adulteration in human food to target its inspection and response resources.

²³ “The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration.” Retrieved from <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/ucm200958.htm>

Seafood Response and Recovery Efforts: FDA has responded to numerous threats and outbreaks related to seafood. From 2008 to 2012 FDA responded to multiple diarrhetic shellfish poisoning (DSP) incidents caused by unprecedented blooms of a phytoplankton species in coastal waters of Texas and Washington State. The blooms produce toxins that cause DSP and have significant human health and economic impacts worldwide. CFSAN responded by providing subject matter expertise who provided technical expertise and training to state public health counterparts in Texas and Washington state.

FDA has also responded to outbreaks of ciguatera fish poisoning (CFP), which is caused by consumption of fish contaminated with polyether neurotoxins called ciguatoxins. CFP is one of the leading causes of finfish-related illness in the world, with severe acute and chronic effects. During 2012, CFSAN provided analytical assistance for CFP outbreak investigations to public health agencies in Texas, Florida, and Puerto Rico. In April 2012, CFSAN also offered a hands-on CFP training workshop for federal and state public health counterparts.

Improving Response and Recovery – Field Activities
Base Amount: \$49,327,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses.

ORA devotes resources to the prompt and efficient response to foodborne outbreaks and events. ORA also identifies and develops new investigational resources, tools, and training programs while establishing an infrastructure that support continued effective and efficient response. As FDA continues to move forward in meeting national food defense goals, it relies on states and local health agencies to assist in improving preparedness and response activities. Grant and cooperative agreement funds allow states and counties to increase efficiency in the areas of response, prevention, and intervention in addition to allowing for a larger pool of resources nationwide to strengthen food defense and mitigate safety issues.

In the case of *Improving Response and Recovery*, ORA achieves the overall FDA food safety strategy by exploring and adopting innovative technologies and processes to detect and investigate outbreaks and contamination incidents, and by using effective risk communications in response to such events. ORA responds to issues that occur across Farm-to-Table continuum based on analyses of outbreaks and lessons learned from earlier responses.

Public Health Outcome

ORA partners with public and private entities to leverage data sharing and personnel. Examples of these FDA outreach partnerships include state contracts, FERN laboratories, rapid response and state lab cooperative agreements, Partnership for Food

Protection, Food Protection Task Force grants, and 50 state meetings. In FY 2012 FDA funded the expansion of the Rapid Response Teams (RRTs) cooperative agreement with the inclusion of new states into the program.

In FY 2012 ORA provided funding to 36 state, local, tribal and territorial partners to support capacity building in the areas of recalls and inspections in support of Section 210 of FSMA. This work enables federal and state partners to improve their systems to quickly and effectively stop an outbreak and mitigate the concern. ORA supported the newly formed Coordinated Outbreak Response and Evaluation (CORE) organization, which was formed specifically to improve FDA's response to foodborne illness outbreaks. ORA, CFSAN, and CORE worked collaboratively on multiple outbreaks resulting in improved communications throughout FDA and with federal and state agencies. In FY 2012, a multi-agency Incident Management Group was formed comprised of FDA, the Centers for Disease Control and Prevention (CDC), and numerous state Health Agencies to investigate a nationwide *Salmonella* outbreak. The group was able to identify a specific foreign supplier of ground tuna suspected to be the source of the outbreak and remove the contaminated product from commerce. FDA worked with the foreign competent authority that subsequently closed the firm following a violative inspection.

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses. In FY 2012, ORA worked with the states to establish new and develop further existing Rapid Response Teams (RRTs), comprised of both ORA and state inspectors. An additional ten RRTs were funded by the end of FY 2012 which resulted in a total of 19 RRTs.

ORA scientists developed collaborations with the states of Massachusetts, New Hampshire, and Vermont to extend and enhance the much needed capability of surveillance testing for radionuclides in food samples. The Federal-State collaboration involved the collection and analyses of fish samples from these states for the presence of radionuclides. The study provided a baseline measurement for current and future comparisons and addressed the public's health concern of radionuclide contamination.

Japan Earthquake and Tsunami: As part of FDA's response to the March 2011 Japan earthquake and tsunami that caused explosions at Fukushima nuclear facilities, FDA issued Import Alert# 99-33 to identify products that were banned by the Japanese

government. FDA also continued its increased surveillance of Japanese food and drug products under Import Bulletin 99-B38, and provided a network of coverage to ensure no radiation-contaminated product reached U.S. consumers. Through the middle of July 2012, ORA field offices conducted more than 7,000 examinations and ORA field laboratories analyzed more than 200 samples, with no objectionable findings. At that point in time it was determined this increased level of surveillance was no longer warranted and coverage of products reverted back to routine surveillance levels.

Listeria monocytogenes Outbreak: In FY 2012, a U.S. foodborne outbreak of *Listeria monocytogenes* was associated with cantaloupes. The outbreak sickened many people causing hospitalizations and deaths. As part of FDA's response, ORA investigators, in collaboration with FDA's Coordinated Outbreak Response and Evaluation Network, CFSAN, CDC, and state and local health agency staff, conducted an investigation at the implicated farm and collected samples of cantaloupes as well as environmental samples at areas of interest. ORA field laboratory analysis confirmed the presence of *L. monocytogenes* in the cantaloupes, and FDA was able to work with the domestic farm to issue a recall. Throughout the event, FDA and CDC collaborated and updated the events on web postings, providing consumer guidance on proper cleaning and sanitizing of refrigerators, food contact surfaces, and utensils. These activities have improved FDA's response to outbreaks. Prevention of outbreaks substantially improves the safety of food consumed by the public.

Laboratory Information Management System (LIMS): ORA is in the process of developing the Laboratory Information Management System that seeks to improve the capability of the FDA labs to provide the necessary evidence, tracking, and effective sample management throughout the analytical process. The LIMS is a nation-wide automated system that corrects a major shortcoming in the methods that ORA Laboratories process and report on assigned samples. LIMS is capable of electronically capturing, storing, and reporting data pertaining to laboratory operations. LIMS provides the information technology enhancements to increase performance and the efficiency of the ORA laboratory operations.

Import Trade Auxiliary Communications System (ITACS): ORA made the Import Trade Auxiliary Communications System available to the public. ITACS is an internet portal that provides the import community the ability to check the status of individual entries, to submit entry documentation, and to provide the availability of information for targeted shipments. ITACS enhances the entry review process by providing the import community with the ability to provide information electronically and improve communication with ORA field offices.

Performance Measures

The *Improving Response and Recovery* subprogram is supported by budget authority and the Food and Feed Recall user fee.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). (Outcome)	FY 2012: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

Nutrition & Labeling Strategies for Better Health – Center Activities

Base Amount: \$17,093,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Nutrition & Labeling* activities support the *FVM Strategic Plan* goals of providing accurate and useful nutritional information and encouraging food product reformulation. Excess intake of calories, dietary fat, and sodium contribute significantly to rising rates of chronic disease, including hypertension, heart disease, stroke, diabetes, and obesity. CDC data indicate that more than 30 percent of the American adult population, approximately, 60 million people,²⁴ is obese and that 17 percent of children and adolescents aged 2 to 19 years are obese.²⁵ FDA investments enable consumers to choose a healthier diet and reduce the risk of chronic disease and obesity.

Public Health Outcome

As part of the Foods Program, CFSAN promotes healthful dietary practices through truthful and informative labeling on food items, menus, and vending machines. CFSAN works with industry and consumer groups to determine the best methods for conveying nutrition information and increasing awareness around these initiatives. In support of HHS and Administration priorities to improve childhood nutrition, CFSAN works to ensure that nutrition labels specifically targeted to parents and children are clear and informative. CFSAN also uses scientific leadership and influence and, when

²⁴"Overweight and Obesity – Adult Obesity Facts," Centers for Disease Control and Prevention. Retrieved from <http://www.cdc.gov/obesity/data/adult.html>

²⁵"Overweight and Obesity – Data and Statistics," Centers for Disease Control and Prevention. Retrieved from <http://www.cdc.gov/obesity/childhood/data.html>

appropriate, regulatory tools to foster the development of healthier food products. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Reduction of Trans Fat Blood Levels in Consumers due to Labeling Requirements:

FDA completed an updated intake estimate for *trans* fat, which showed that consumption of *trans* fat has decreased significantly from 2003 to 2010. The reduction coincides with FDA's requirement for manufacturers to declare *trans* fat levels on the Nutrition Facts panel along with saturated fat and dietary cholesterol, which became effective on January 1, 2006, and resulted in product reformulations to reduce or eliminate *trans* fat. Consistent with this FDA study, a recent study by the CDC demonstrated that the amount of *trans* fat (i.e., *trans* fatty acids) present in American consumers bloodstreams decreased by 58 percent from 2000 to 2008. Scientific evidence shows that consumption of saturated fat, *trans* fat, and dietary cholesterol raises low-density lipoprotein (LDL or "bad") cholesterol levels that increase the risk of coronary heart disease.

Gluten-Free Labeling: In February 2013, FDA submitted to OMB for review a final rule that defines "gluten-free" for labeling food products, including dietary supplements, to better protect consumers who are gluten sensitive or who suffer from celiac disease.

Education and Outreach to Promote Healthy Diets: Partnering with the Joint Institute for Food Safety and Applied Nutrition, FDA co-sponsored a Dietetics and Nutrition Webinar in March 2012, for practitioners and educators in dietetics, as well as students, interns, and fellows who are preparing for professions in nutrition, food science and food technology. The information provided assists practitioners and educators in understanding FDA nutrition activities, such as food labeling, updating the Nutrition Facts panel, front of pack labeling, and dietary guidance statements. The webinar was designed to be interactive and the presentations were videotaped and made available for up to one year. This is an example of FDA's efforts to communicate valuable nutrition information to a wide audience in a resource efficient manner.

Revocation of Standard Identify for Artificially Sweetened Jelly, Preserves, and Jams: In December 2012, FDA published a proposal to revoke the standards of identity for artificially sweetened jelly, preserves, and jams. The action was taken primarily in response to a citizen petition submitted by the International Jelly and Preserve Association. FDA tentatively concluded that these standards are both obsolete and unnecessary in light of our regulations for foods named by use of a nutrient content claim and a standardized term. FDA also tentatively believes that this change will promote honesty and fair dealing in the interest of consumers.

Standard of Identity for Honey: In October 2012, FDA denied a Citizen Petition requesting the adoption of a standard identify for honey. The American Beekeepers Association and several American honey trade associations requested that FDA to adopt a standard of identity for honey. The petitioners maintained that a standard of

identity would inform consumers what “honey” means, combat economic adulteration, and promote honesty and fair dealing within the food trade. However, as FDA stated in the denial letter, the petitioners’ goals can be achieved using existing FDA authorities and therefore, a standard of identity for honey is not needed. FDA is also working on guidance about the composition and labeling of honey.

Performance Measures

The *Nutrition & Labeling* subprogram is supported by budget authority.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
212408: The percentage of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. (Outcome)	NA	NA	Set Baseline	NA

Reinventing Cosmetics Safety – Center Activities

Base Amount: \$7,781,000 (All BA)

Public Health Focus

FDA’s *Reinventing Cosmetics Safety* activities support the Agency’s goal of monitoring the safety of cosmetics marketed in the United States, whether manufactured domestically or imported. The cosmetic industry is changing rapidly as manufacturing becomes more global, as technologies become increasingly sophisticated, and as cosmetic ingredients become more complex. Products containing ingredients produced through nanotechnology and “cosmeceuticals,” the industry-named category of products that purports to straddle the line between cosmetics and drugs, both present particular scientific and public health challenges.

Public Health Outcome

As part of the Foods Program, CFSAN provides direction to industry through guidance and outreach, and conducts compliance and enforcement activities, product surveys, sample analyses, and laboratory investigations in order to prevent harm to consumers from unsafe cosmetics or ingredients. CFSAN also evaluates adverse event reports and consumer complaints, and maintains systems for voluntary cosmetic product registration. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Guidance and Outreach on the Safety of Nanomaterials in Cosmetic Products:

Nanotechnology is an area of emerging science that is increasingly being applied to the development and production of cosmetics. Nanoparticles used in cosmetic ingredients may result in products with different chemical or physical properties that may pose different safety issues.

In April 2012, FDA issued draft guidance on the safety assessment of nanomaterials when used in cosmetic products. The document advises industry that the legal requirements for cosmetics manufactured using nanomaterials are the same as those for any other cosmetics. The guidance also states that standard safety tests may need to be modified or new methods developed in order to conduct safety assessments for cosmetic products containing nanomaterials, and encourages manufacturers to consult with the agency before taking their products to market. Such consultation helps FDA experts address questions related to the safety or other attributes of nanotechnology products, or answer questions about their regulatory status.

Consumer Education and Outreach to Improve Cosmetics Adverse Event Reporting:

As cosmetics are not subject to FDA approval before they are made available on the market, consumers are one of the most important sources of information for FDA in identifying potential safety problems. In order to increase consumer awareness of the importance of reporting adverse events for cosmetic products, FDA recently developed a variety of data collection tools and consumer-friendly information resources. Key project accomplishments include development of a web-based survey that measured baseline consumer awareness levels, a Consumer Update entitled, "Bad Reaction to Cosmetics? Tell FDA," that was widely distributed through media outlets, a corresponding video, an *FDA Basics* webinar that included a live question and answer session, and the distribution of printed materials at four public health conferences.

International Cooperation on Cosmetics Regulation (ICCR) Meeting: In July 2012, FDA hosted the sixth meeting of the ICCR, a quadrilateral effort among the cosmetics regulatory bodies of the United States, Canada, the European Union and Japan. Topics included the characterization and safety assessment of nanomaterials, alternative (non-animal) test method validation, trace level contaminants (lead and 1,4-dioxane), standard operating procedures, endocrine disruptors, in-silico methods for cosmetic ingredient safety assessments, and future expansion of ICCR. In preparation for this meeting, FDA held a public meeting to allow for transparency of process and presentation of perspectives from consumer advocates and other stakeholders. The purpose of the multilateral framework of ICCR is to maintain the highest level of global consumer protection, while minimizing barriers to international trade.

Tattoo Ink Safety: CFSAN alerted tattoo artists, ink and pigment manufacturers, public health officials, health care professionals, and consumers that some tattoo inks, and pigments used to color them, can be contaminated with various pathogens. Contaminated products may place consumers at risk of infections, such as impetigo, cellulitis, herpes simplex, tetanus, staph, fungal infections, syphilis, leprosy and viral

warts. Serious infections related to *Mycobacterium chelonae* have been reported in at least five states since 2011, and are sometimes mistaken for allergic reactions, complicating treatment of the infection.

Currently there is no specific FDA regulatory requirement that tattoo inks be sterile, however, companies and individuals who manufacture or market cosmetics, including tattoo inks, have a legal responsibility to ensure the safety of their products. Manufacturers are not required to reveal their ingredients, which may include iron oxides (rust), metal salts, plastics. Homemade or traditional tattoo inks may also be made from pen ink, soot, dirt, blood, or other ingredients. FDA has advised consumers to request the use of sterile water to dilute inks when receiving a tattoo, so that bacteria are not introduced during the dilution process.

Reinventing Cosmetics Safety – Field Activities

Base Amount: \$3,253,000 (All BA)

Public Health Focus

ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the U.S..

Public Health Outcome

As part of the Foods Program, ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the U.S. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Cosmetic Accomplishments: ORA issued more than 55 notices identifying modifications to cosmetics-related Import Alerts encompassing violations related to microbiological contamination and non-permitted or undeclared color additives. An example is Import Alert # 53-15 published on November 7, 2012 “Detention Without Physical Examination of Eye Area Cosmetics Containing Kohl, Kajal, or Surma”, These actions were a result of ORA import surveillance collections and testing of regulated cosmetic products at the time they were offered for import into the United States. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

CDC notified FDA that *Mycobacterium Chelonae* was identified from skin biopsies samples that were taken from rashes on tattooed areas of people’s bodies. The outbreak was far reaching with 26 confirmed cases in five states. ORA investigators performed numerous inspections of tattoo establishments, gathering information, and collecting tattoo ink samples as well as environmental samples in the establishments.

Laboratories are analyzing the samples to help identify the source of the contamination and the investigation is ongoing.

Performance Measures

The *Reinventing Cosmetics Safety* subprogram is supported by budget authority and the Cosmetics user fee.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214208: Number of American consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (Outcome)	NA	Set baseline	+10% over baseline	NA

Information Technology Investments – Foods Program Activities (Base Amount displayed as a non-add item: \$117,362,345)

Public Health Focus and FDA Food Safety Strategy

FDA's information technology (IT) investments provide cross-cutting support across all *FVM Strategic Plan* goals. IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information in order to better monitor and evaluate the safety of the food supply from farm to table. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks.

Public Health Outcome and Accomplishments

FDA promotes improved public health through agile technology solutions designed to provide the right data at the right time to right people in support of risk-based decision making. This approach results in the prevention and mitigation of potentially harmful outbreaks of foodborne illnesses. Ongoing efforts to harmonize quality data lead to the timely adoption of science-based regulations that protect our food and feed supply, improve assurance that imported foods and feeds meet preventive controls standards, and improve collaboration with Federal, State, local, tribal, territorial and international stakeholders on inspection, compliance, and response efforts.

Center:

CFSAN invests in modern information technology and scientific computing tools and resources necessary to achieve regulatory, research, and administrative mission goals,

including implementation of the Food Safety Modernization Act. Below are examples of recent accomplishments enabled by CFSAN IT investments that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Launch of New Risk Assessment Website: In 2012, FDA launched a new risk assessment website²⁶ to provide public information on assessing risks and completed, current, and planned FDA projects, and to request public input. The website responds to the Institute of Medicine's call for greater visibility and transparency and informs the public that FDA not only responds to emergencies, but also acts to prevent such events.

New Electronic Option to Expedite Registration for Low-Acid Canned Food and Acidified Food (LACF/AF): In June 2012, FDA implemented electronic registration capability for foreign and domestic commercial LACF/AF facilities. Previously, paper forms were transcribed into the database and source documents manually filed in the event of litigation and to confirm information in the database. The new electronic option significantly expedites registration of facilities for manufacturers, processors, and packers of LACF/AF. Also, the new capability improves data quality of firm information to better inform FDA decision-making.

New E-application System for Certificates of Free Sale: FDA implemented an automated system for companies exporting food from the U.S. to file electronically for Certificates of Free Sale in June 2012. Such certificates are often requested by international customers or governments to verify that the products being exported meet certain standards. The FDA Unified Registration and Listing Systems (FURLS) Certificate Application Process (CAP)²⁷ allows exporters of conventional foods, including seafood, to apply online for a Certificate of Free Sale, reducing the amount of time required for the FDA to process requests and issue certificates.

Automated Research Tracking System: CFSAN led the expansion of the Center's Component Automated Research Tracking System (CARTS) across the entire FDA Foods and Veterinary Medicine Program to create a new, modern, automated tool that consolidates and standardizes management of all FVM scientific research portfolio projects. CARTS provides increased monitoring, including review and management of intramural and extramural projects, for foods, cosmetics, dietary supplements, safety, security, and nutrition research in CFSAN, CVM, and ORA. As an FDA enterprise system, CARTS also enhances the FDA's strategic planning capabilities and satisfies new FSMA requirements, including biennial research reports for Congress.

FSMA Biennial Registration of Food Facilities: FSMA amended section 415 of the F.D&C Act, which requires domestic and foreign facilities that manufacture, process,

²⁶“Risk Assessment /Safety Assessment,” Retrieved from <http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm>.

²⁷ “FDA Industry Systems,” Retrieved from <http://www.access.fda.gov>.

pack or hold food for human or animal consumption in the U.S. to register with FDA and renew their registrations with FDA every other year. FDA implemented biennial registration renewal for the 2012 cycle on October 22, 2012, by issuing guidance²⁸ and upgrading the Food Facility Registration Module (FFRM). The enhancements also included upgraded search functions and improved US Agent identification and verification processes. By enabling biennial registration, the FFRM upgrades and the data collected as a result will improve the agency's ability to respond to food-related emergencies more quickly and efficiently.

Funding History Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2010 through FY 2014 for the Foods Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010	\$783,178,000	\$783,178,000	\$0	3,387
FY 2011	\$836,244,000	\$836,244,000	\$0	3,605
FY 2012	\$866,920,000	\$866,920,000	\$0	3,546
FY 2013 Annualized CR*	\$880,357,000	\$863,568,000	\$16,789,000	3,684
FY 2014 Request	\$1,106,604,000	\$882,817,000	\$223,787,000	4,110

**Comparability Adjustments for the Food and Veterinary Medicine Program reorganization and reprogramming approved in FY 2012, that started in FY 2013: -42 FTE and -\$7.746M in the Foods Program; -8 FTE and -\$1.109M in the Animal Drugs and Feeds Program; +50 FTE and +\$8.855M in FDA Headquarters.*

Summary of Budget Request

The FY 2014 budget request for the Foods Program is \$1,106,604,000. This amount is an increase of \$231,603,000 above the FY 2012 Enacted level. The Center for Food Safety and Applied Nutrition amount in this request is \$320,324,000, which supports 994 FTE. The Field amount is \$786,280,000, which supports 3,116 FTE. The source of funding for this request is \$882,817,000 in budget authority and \$223,787,000 in user fees.

The FY 2014 budget request allows the Foods Program to continue to establish a prevention-focused domestic and import food safety system, foster improved diet and nutrition for American consumers, and improve the safety of dietary supplements and cosmetic products. These resources support FDA public health objectives of preventing

²⁸ "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)," Retrieved from <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm331959.htm>

illnesses caused by contaminated foods, protecting consumers from unsafe products, and supporting improved health and nutrition. The initiatives proposed under the requested budget will allow FDA to achieve HHS and Administration public health priorities, including requirements of the landmark FDA Food Safety Modernization Act of 2011.

Budget Request Details

Pay Increase (Total Program: \$3,764,000)

The request for \$3,764,000 in total budget authority for the Foods Program reflects a pay increase for civilian and Commissioned Corps staff. The Center's portion of the increase is \$1,127,000 and the Field's portion is \$2,637,000.

Prioritizing Prevention

Center Activities –

FY 2012 Enacted Base: \$71,021,000 (All BA)

FY 2014 Total Increase above Base: (+\$22,876,000 / 30 FTE)

FY 2014 Increase above Base for Proposed User Fees (Food Facility Registration and Inspection Fee, Food Import Fee, Food Contact Substances Notification Fee):
(+\$21,933,000 / 26 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Standard-setting for Food and Feed Safety (Proposed Food Facility Registration and Inspection Fee +\$8,802,000/ 11 FTE)

Foodborne illnesses linked to known causes are preventable if the parties involved in today's global food chain can be held accountable for implementing appropriate preventive measures at each step of the process where control of hazards is necessary. Standards and guidances are important prevention-focused tools that guide food industry efforts and provide the framework for accountability for meeting appropriate standards called for by FSMA. The more successful the food system is in implementing appropriate preventive measures in the production, processing, transportation, and preparation of foods, the safer the nation's food supply will be.

FDA will continue to develop science-based standards and guidance documents that support industry adoption of preventive controls for food processing and produce safety standards. FDA will also provide education and outreach to growers, industry, and consumers on new safety standards, as well as training and technical assistance to industry, and federal and state regulatory partners in support of implementation of new FSMA standards.

Transforming Food Safety: Import Safety (BA +\$943,000 / 4 FTE)

The United States markets are open to food imports from countries with divergent food safety standards and with varying levels of food safety oversight. Approximately 15-20 percent of all foods consumed in the U.S. originate from foreign sources. For example, 80 percent of the seafood and 25-35 percent of the produce eaten by American consumers is imported. To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including foreign supplier verification, systems recognition assessments, and improved foreign inspections.

With these resources, FDA will conduct assessments of regulatory food safety systems in countries that export foods to the U.S. to measure their performance against FDA program standards. FDA will use data generated by these assessments to prioritize food safety monitoring activities and thereby enhance the safety of the U.S. food supply.

Transforming Food Safety: Import Safety (Proposed Food Import Fee +\$8,583,000 / 8 FTE)

FDA will continue to conduct foreign food safety systems recognition assessments to determine which countries have comparable food safety systems or robust commodity-specific export programs. FDA will also develop and expand partnerships with other public health agencies to execute international outreach, training, capacity building, and technical support.

Proposed User Fee: Food Contact Substances Notification Fee (UF +\$4,458,000 / 7 FTE)

With resources funded by user fees, FDA will expand and develop the Food Contact Notification Program (FCN) to ensure stable, long-term viability of the current food contact substances authorization process. This stability and predictability is to the advantage of consumers, FDA, and the regulated industry because the FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. The user fees will also support continued development and updates of industry guidance, including guidance to address emerging regulatory challenges associated with the use of nanotechnology and endocrine active chemicals in food contact materials. In addition, user fee funds will enable FDA to continue its preeminence in the regulatory science applicable to food contact materials, benefiting both U.S. consumers and industry.

Prioritizing Prevention

Field Activities –

FY 2012 Enacted Base: \$111,373,000 (BA: \$111,373,000 / UF: \$0)

FY 2014 Total Increase above Base: (+\$20,228,000 / 26 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee +\$3,360,000 / 14 FTEs)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- Hire two FTE to develop and administer ORA food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard
- Hire three FTE to ensure programmatic objectives and implementation of the Integrated Food Safety System are coordinated and provide support for the governance structure
- Hire six FTE to serve as field state liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards
- Hire three FTE to develop and validate certification testing instruments.

Transforming Food Safety: Standard-setting for Food and Feed Safety (Proposed Food Facility Registration and Inspection Fee +\$14,000,000 / 0 FTE)

To implement and enforce preventive controls in food processing facilities, FDA will begin training more than 1,100 ORA inspections personnel, as well as 2,300 of FDA's state, tribal, and territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections in the new preventive controls framework. FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

Transforming Food Safety: Import Safety (Proposed Food Import Fee +\$2,868,000 / 12 FTE)

With this investment FDA will hire seven FTE to provide outreach and education on FSMA import provisions, including outreach to the import community and other federal agencies involved in the import process. FDA will also hire five FTE to implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process.

Strengthening Surveillance

Center Activities –

FY 2012 Enacted Base: \$135,274,000 (All BA)

FY 2014 Total Increase above Base: (+\$20,865,000 / 13 FTE)

FY 2014 Increase above Base for Proposed User Fees (Food Facility Registration and Inspection Fee, Food Import Fee): (+\$14,015,000 / 9 FTE)

FY 2014 Initiative Increases above Adjusted Actual Base:

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee +\$3,746,000 / 5 FTE)

With these resources, FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments in state, local, tribal and territorial regulatory and public health partners. These investments will provide more uniform coverage and safety oversight of the food and feed supply.

FDA will evaluate and implement new methods, training, fit-for-purpose method extension, and methods validation manuals, and deploy new instruments to expand laboratory capacity for the integrated national food safety system and support the FSMA mandate for laboratory accreditation.

Transforming Food Safety: Risk Analysis (BA +\$3,850,000 / 2 FTE)

Effective prevention strategies and new technologies are needed to reduce these risks to consumers. For example, contaminated produce contributes an estimated 1.29 million illnesses annually in the U.S. at a cost to society of approximately \$1.4 million.²⁹ Risk models provide government and industry with information to evaluate the value of current controls and better characterize the potential effectiveness of new controls to prevent illnesses.

FDA will continue to update FDA's risk ranking and prioritization tools such as iRISK, which is a web-based quantitative risk assessment tool designed to ensure broad accessibility and to facilitate sharing and integration of data between and among FDA and stakeholders. Data generated from these tools will be used to develop predictive risk assessment models, develop a food and feed product tracing system, prioritize resource allocation, measure implementation of produce regulation, and enhance decision making for food safety. In addition to developing and deploying these tools, FDA will support assessments of risk models to ensure the credibility, validity, and accuracy of the information used to inform the FDA decision-making processes.

Transforming Food Safety: Risk Analysis (Proposed Food Facility Registration and Inspection Fee +\$2,859,000 / 1 FTE; Proposed Food Import Fee +\$2,964,000 / 1 FTE)

²⁹ Batz, Michael et al. "Ranking the Risk: The 10 Pathogen-Food Combination with the Greatest Burden on Public Health." Retrieved from <http://www.rwjf.org/files/research/72267report.pdf>

FDA will continue to improve and implement data-driven risk ranking and prioritization tools to inform regulatory, compliance, and resource allocation decision-making critical to the successful implementation of FDA FSMA responsibilities. FDA will also adapt risk analysis tools for use by the public and industry to improve understanding and precision of risk evaluation of FDA-regulated commodities and associated hazards.

Transforming Food Safety: Science for Food Safety (BA +\$3,000,000 / 2 FTE)

FDA will invest in science based tools and methods to improve detection of contaminants and adulterants as well as improve rapid screening methods in fresh produce. Understanding factors governing colonization, persistence, and spread of pathogens such as *Salmonella* in fresh produce will result in development of more effective prevention and intervention strategies, as well as improve mitigation steps on the farm and in the farm-to-table continuum.

Additionally, FDA will focus on improved analytical methods, especially rapid screening methods, to support comprehensive post-market surveillance of the food supply. This work will focus on the development of improved extraction, detection, and data analysis procedures for the major classes of contaminants and adulterants in foods, such as pathogens, mycotoxins, heavy metals, and economic adulterants. This work will help FDA focus on achieving high rates of compliance by implementing new enforcement tools.

Transforming Food Safety: Science for Food Safety (Proposed Food Facility Registration and Inspection Fee +\$2,183,000 / 1 FTE; Proposed Food Import Fee +\$2,263,000 / 1 FTE)

This investment will allow FDA to establish food safety standards that are based on the latest scientific developments and that address hazards from farm-to-table. FDA will also apply research results to improve the speed and effectiveness of import screening.

FDA will develop innovative methods and tools to validate preventive controls and better detect pathogens and chemical contamination in foods, such as *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, Hepatitis A, viruses, and toxins. FDA will also develop and deploy new chemical detection technologies to better identify and address chemical hazards in the food supply both before and after illness occurs. Likewise, FDA will develop new methods and platforms for rapid fingerprinting of foodborne pathogens, along with methods for determining the geographic origin of contaminated food samples, to support rapid, high-throughput analysis in laboratories, in the field, and at the border.

Strengthening Surveillance

Field Activities –

FY 2012 Enacted Base: \$286,015,000 (BA: \$286,015,000 / UF: \$0)

FY 2014 Total Increase above Base: (+\$74,925,000/ 102 FTE)

FY 2014 Increase above Base for Prior Proposed User Fees (International Courier User Fee): (+\$735,000/ 3 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Import Safety (BA +\$5,245,000 / 2 FTE)

With this investment, FDA will continue to improve the overall effectiveness of FSMA implementation by providing cross-cutting support to achieve the *FVM Strategic Plan* goals. FSMA IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information to more effectively prevent public health events and ensure the safety of the food supply from farm to table. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources

ORA will:

- Continue integration of IT systems
- Expand risk targeting for imports in PREDICT by adding new data sources.

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee \$1,200,000 / 5 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. With these resources, ORA will:

- Hire four FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- Hire one FTE with user fees to serve as Scientific Coordinators. This resource will support the states as FDA moves to national standards for laboratories.

Transforming Food Safety: Import Safety (Proposed Food Import Fee \$67,745,000 / 92 FTE)

FDA will develop and implement a variety of approaches to ensure the safety of imported foods and feeds. This investment will allow FDA to improve responsiveness to inquiries concerning the import process or the status of imports by establishing a

national call center. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems. This investment also supports the design, testing, and implementation of a fee collection system to administer the import user fee program.

This investment will also increase port/border coverage by adding staff and expanding hours of operation, thus providing better screening for food safety while speeding up the overall entry admissibility process for safe products. Moreover, capital investments will be directed to acquire additional space at various border locations to support this effort. This will result in increased efficiency, better industry/FDA communication, reduced time to resolve problems, and improved movement of trade.

In addition, FDA will improve information technology to enhance risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will hire six FTE to implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data the agency receives.

FDA also plans to utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. Expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. This technology will also provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Likewise, FDA will research, test, validate, and purchase analytical tools for rapid screening of products at the border. The tools will allow for improved risk analytics by permitting targeting of products with the highest probability of being violative and the rapid release of all others into U.S. commerce.

Strengthening Enforcement

Center Activities –

FY 2012 Enacted Base: \$22,558,000 (All BA)

FY 2014 Total Increase above Base: (+\$5,230,000 / 10 FTE)

FY 2014 Increase above Base for Proposed User Fees (Food Facility Registration and Inspection Fee, Food Import Fee): (+\$5,230,000 / 10 FTE)

FY 2014 Initiative Increases above Adjusted Actual Base:

Transforming Food Safety: Foreign Inspections (Food Facility Registration and Inspection Fee +\$1,418,000 / 4 FTE)

To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including improved foreign inspections.

FDA will plan and evaluate foreign inspections, including review of inspection reports, testing and analysis of samples, development of decision support systems, and management of follow-up compliance actions. FDA will also continue to develop and expand the infrastructure and processes to enable timely enforcement action and follow-up compliance actions related to foreign inspections.

Transforming Food Safety: Domestic Inspections (Food Facility Registration and Inspection Fee +\$3,812,000 / 6 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential for holding the industry accountable for their responsibility to produce safe products.

FDA will improve enforcement tools and processes and modernize and expand compliance programs to reflect changes introduced by FSMA, including planning inspection work, analyzing trends of violative firms, and identifying firms who are non-compliant or who have not registered as a food establishment with the Agency.

Strengthening Enforcement

Field Activities –

FY 2012 Enacted Base: \$167,081,000 (BA: \$150,859,000 / UF: \$16,222,000)

FY 2014 Total Increase above Base: (+\$66,794,000 / 153 FTE)

FY 2014 Increase above Base for Current Law User Fees (Food Reinspection User Fee): (+\$309,000 / 0 FTE)

FY 2014 Increase above Base for Current Law User Fees (Food Recall): (+\$426,000 / 0 FTE)

FY 2014 Initiative Increases Base:

Transforming Food Safety: Import Safety (BA: +\$3,850,000 / 15 FTE)

This investment supports FSMA requirements by establishing an audit staff and developing comparability assessment models to oversee and conduct audits of domestic and international regulatory partners to measure performance against FDA program standards.

ORA will:

- Hire and train 15 FTE including auditors and program managers
- Implement internal procedures
- Collaborate and communicate with key stakeholders on internal integration and operational stand up of the staff
- Perform outreach with external stakeholders on final guidance documents and requirements.

Transforming Food Safety: Import Safety (Proposed Food Import Fee +\$50,322,000 / 123 FTE)

This investment will support the implementation of the Foreign Supplier Verification Program, which is a comprehensive prevention-focused import food program that relies more heavily on those in the food supply chain – food manufacturers, processors, packers, distributors, and importers – to provide assurances that the food imported to the U.S are safe and meet regulatory requirements.

In addition, this investment will allow FDA to implement registration verification of foreign firms by conducting a foreign supplier verification program. FDA will hire four FTE to provide program oversight.

Transforming Food Safety: Integrated Food Safety System (BA +\$3,850,000 / 15 FTE)

This investment supports implementation of the Integrated Food Safety System by expanding the staff that maintain and oversee assessments and audits of state food contracts. This includes assessments of states enrolled in Manufactured Food Regulatory Program Standards. It also includes collaboration with key FDA stakeholders to enhance training and development that FDA provides to the states.

FDA will modify existing surveillance infrastructure to provide a platform for ongoing high priority pathogen detection in the food supply, expand the number of states engaged in ongoing surveillance, and expand the number and types of commodities under surveillance based on burden of illnesses estimates and food consumption patterns in the United States. FDA will partner with the CDC, U.S. Department of Agriculture and FDA centers to develop rapid strain typing methods for rapid response to foodborne outbreaks.

ORA will:

- Perform 18-month assessments and begin conducting 36-month assessments of States enrolled in the MFRPS
- Collaborate with key FDA stakeholders to provide feedback on assessments to be used to enhance training and development provided to the states by FDA.

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee \$8,037,000 / 0 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will provide funding to federal, state, local, territorial and tribal regulatory and public health partners in the form of at least five states grants, contracts, cooperative agreements or inter-agency agreement between federal agencies. Ten of the state grants, contracts, cooperative agreements or inter-agency agreements between federal agencies will be funded with budget authority and ten will be funded with user fees. ORA also plans to improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations.

Improving Response and Recovery

Center Activities –

FY 2012 Enacted Base: \$4,225,000 (BA: \$3,761,000 / UF: \$464,000)

FY 2014 Total Increase above Base: (+\$21,000 / 2 FTE)

FY 2014 Increase above Base for Current Law User Fees (Food Recall): (+\$21,000 / 0 FTE)

Field Activities –

FY 2012 Enacted Base: \$49,327,000 (BA: \$49,327,000 / UF: \$0)

FY 2014 Total Increase above Base: (+\$240,000 / 1 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Planning and Response (Proposed Food Facility Registration and Inspection Fee \$240,000 / 1 FTE)

This investment will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts. This funding will also support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private industry. FDA will fund one FTE to develop and implement traceback procedures.

Nutrition & Labeling Strategies for Better Health

Center Activities –

FY 2012 Enacted Base: \$16,691,000 (All BA)

FY 2014 Total Increase above Base: (+\$477,000 / 0 FTE)

Reinventing Cosmetics Safety

Center Activities –

FY 2012 Enacted Base: \$7,781,000 (All BA)

FY 2014 Total Increase above Base: (+\$12,253,000 / 42 FTE)

FY 2014 Increase above Base for Proposed User Fees (Cosmetics User Fee)
(+\$12,253,000 / 42 FTE)

FY 2014 Initiative Increases above Base:

Proposed User Fee: Cosmetic Safety User Fee (UF +\$12,253,000 / 42 FTE)

FDA will use user fee funds to establish a Mandatory Cosmetic Registration Program (MCRP) that will require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and products with FDA. FDA will provide information gathered from the complete listing of marketed cosmetic products and their ingredients to industry to assist it in its safety evaluations and product modifications.

The user fees will also enable FDA to meaningfully participate in international harmonization efforts for cosmetic standards. As a result, FDA will be better positioned to fulfill its public health mission and will promote greater safety and understanding of cosmetic products being used regularly by consumers.

Reinventing Cosmetics Safety

Field Activities –

FY 2012 Enacted Base: \$3,253,000 (BA: \$3,253,000 / UF: \$0)

FY 2014 Total Increase above Base: (+\$4,407,000 / 18 FTE)

FY 2014 Increase above Base for Prior Proposed User Fees (Cosmetics User Fee):
(+\$4,407,000 / 18 FTE)

The user fee investment in the Cosmetics Program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used regularly by consumers. With this investment, FDA will refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities.

FOODS PROGRAM ACTIVITY DATA

PROGRAM WORKLOAD AND OUTPUTS	FY 2012 Actual	FY 2013 CR	FY 2014 Request
<i>FOOD AND COLOR ADDITIVE PETITIONS</i>			
Petitions Filed ¹	13	10	10
Petitions Reviewed ²	6	7	7
<i>PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES</i>			
Notifications Received	107	114	114
Notifications Reviewed ³	102	100	100
<i>INFANT FORMULA NOTIFICATIONS</i>			
Notifications Received ⁴	24	35	35
Notifications Reviewed ⁵	24	35	35
FDA Review Time	90 Days	90 Days	90 Days
<i>NEW DIETARY INGREDIENT NOTIFICATIONS ⁶</i>			
Submissions Received ⁷	45	50	50
Submissions Reviewed ⁸	45	50	50
FDA Review Time	75 Days	75 Days	75 Days

¹ This number is for the cohort of petitions filed in the FY.

² Number reviewed includes petitions approved, withdrawn, or placed in abeyance because of deficiencies during the FY.

³ Number reviewed includes notifications that became effective or were withdrawn.

⁴ A notification may include more than 1 infant formula.

⁵ Number of submissions reviewed includes some submissions that were received in the previous FY.

⁶ A single notification may address one or more new dietary ingredients. For example, FDA has received at least 15 notifications that pertain to 2 up to 16 new dietary ingredients in a single notification.

⁷ Number of submissions received in current FY includes some received late in the FY that are expected to be completed in the next FY when the due date occurs.

⁸ Number of submissions reviewed in the current FY includes some submissions that were received in the previous FY when the due date occurred in the current FY.

Combined Field Activities – ORA Program Activity Data			
Field Foods Program Activity Data (PAD)			
Field Foods Program Workload and Outputs	FY 2012	FY 2013	FY 2014
	Actual	Estimate	Request
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	10,086	10,326	10,326
Domestic Food Safety Program Inspections	7,523	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.
Imported and Domestic Cheese Program Inspections	266		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	382		
Domestic Fish & Fishery Products (HACCP) Inspections	1,422		
Import (Seafood Program Including HACCP) Inspections	252		
Juice HACCP Inspection Program (HACCP)	259		
Interstate Travel Sanitation (ITS) Inspections	1,053		
Domestic Field Exams/Tests	3,513		
Domestic Laboratory Samples Analyzed	10,621	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	1,347²	1,200	1,200¹
All Foreign Inspections	1,347	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	11,433	11,526	11,526
IMPORTS			
Import Field Exams/Tests	171,783	160,200	160,200
Import Laboratory Samples Analyzed	29,966	35,300	35,300
Import Physical Exam Subtotal	201,749	195,500	195,500
Import Line Decisions	10,805,094	11,482,234	12,201,809
Percent of Import Lines Physically Examined	1.87%	1.70%	1.60%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	81,888	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	9,306	10,523	10,523
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	430	273	273
State Contract Food Safety (Non HACCP) Inspections	8,161	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	1,062	1,104	1,104
State Contract Juice HACCP	69	103	103
State Contract LACF	76	68	68
State Partnership Inspections	430	273	273
State Contract Foods Funding	\$12,699,510	13,076,000	13,076,000
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	\$16,136,000	\$18,455,000	\$18,455,000
Total State & Annual FERN Funding	\$28,835,510	\$31,531,000	\$31,531,000
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	21,169	22,322	22,322

¹ For investigators hired with FY 2014 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2016. During the full performance year (FY 2016), the FY 2014 funding increase for inspections will allow OIP to conduct an additional 135 foreign food safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

² The FY 2012 actual unique count of foreign inspections includes 42 OIP inspections (10 for China and 32 for India).

Combined Field Activities – ORA			
Program Activity Data			
Field Cosmetics Program Activity Data (PAD)			
Field Cosmetics Program Workload and Outputs	FY 2012	FY 2013	FY 2014
	Actual	Estimate	Request
<i>FDA WORK</i>			
DOMESTIC INSPECTIONS			
<i>UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS</i>	100	100	100
Domestic Inspections	100	100	100
FOREIGN INSPECTIONS			
<i>UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS</i>	0	0	0
Foreign Inspections	0	0	0
IMPORTS			
Import Field Exams/Tests	1,600	1,600	1,600
Import Laboratory Samples Analyzed	0	630	630
Import Physical Exam Subtotal	1,600	2,230	2,230
Import Line Decisions	2,389,000	2,602,764	2,883,187
Percent of Import Lines Physically Examined	0.07%	0.09%	0.08%
<i>GRAND TOTAL COSMETICS ESTABLISHMENT</i>	100	100	100