Food and Drug Administration
FY 2012 Congressional Budget Request
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FOODS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2010 Enacted [1]	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$783,449**	**$783,178**	**$781,449**	**$1,035,080**	**$253,631**
Center	$236,542	$236,354	$236,000	$302,750	$66,750
FTE	981	871	871	1,147	166
Field	$546,907	$546,824	$545,449	$732,330	$186,881
FTE	2,505	2,516	2,516	3,026	521
Program Level FTE	**3,486**	**3,387**	**3,387**	**4,173**	**687**
Budget Authority	**$783,449**	**$783,178**	**$781,449**	**$955,287**	**$173,838**
Center	$236,542	$236,354	$236,000	$300,869	$64,869
Field	$546,907	$546,824	$545,449	$654,418	$108,969
Pay Increase (non add)				*$1,795*	*$1,795*
Transforming Food Safety and Nutrition (non-add)				*$176,373*	*$176,373*
FDA Regulatory Science and Facilities (non-add)				*$2,377*	*$2,377*
Administrative and Contract Savings (non-add)				*-$6,707*	*-$6,707*
Budget Authority FTE	**3,486**	**3,387**	**3,387**	**3,824**	**338**
Center	981	871	871	1,137	156
Field	2,505	2,516	2,516	2,687	182
User Fees	**$0**	**$0**	**$0**	**$79,793**	**$79,793**
Voluntary Qualified Importer Program (VQIP) User Fee				**$61,232**	**$61,232**
Center				$232	$232
FTE				1	1
Field				$61,000	$61,000
FTE				265	265
Food Reinspection				**$6,825**	**$6,825**
Field				$6,825	$6,825
FTE				48	48
Export Certification				**$1,185**	**$1,185**
Center				$1,185	$1,185
FTE				7	7
Field				$0	$0
FTE				0	0
Recall User Fees				**$9,861**	**$9,861**
Center				$464	$464
FTE				2	2
Field				$9,397	$9,397
FTE				23	23
International Courier User Fee				**$690**	**$690**
Field				690	690
FTE				3	3
User Fee FTE	**0**	**0**	**0**	**349**	**349**

[1] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the +/- FY 2010 Enacted column.

The FDA Foods Program operates under the following legal authorities:

The Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
The 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 public health focus of the FDA Foods Program relies on a comprehensive, science-based, prevention-oriented approach to safeguard the American food supply. This approach focuses on the most important food safety issues in the life cycle of foods — from farm to table. FDA's goal is to identify and counteract potential threats to the food supply before they harm American consumers.

FDA regulates $417 billion worth of domestic food, $49 billion worth of imported foods, and $62 billion worth of cosmetics. This responsibility involves about 167,000 registered domestic food establishments, about 254,000 registered foreign facilities, and more than 3,500 cosmetic firms. FDA is responsible for all domestic and imported food, with the

*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.

exception of meat, poultry, and frozen, dried, and liquid eggs. FDA regulation takes place from the products' processing, or point of U.S. entry, to their point of sale.

Under the leadership of the Commissioner and the Deputy Commissioner for Foods, the FDA Foods Program — including the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA), with its field forces nationwide — protects and promotes the public health by keeping the American food supply safe, sanitary, wholesome, and properly labeled and by ensuring that cosmetic products are safe and properly labeled.

The FDA Foods Program executes its regulatory responsibilities through five sub-programs:

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

Prioritizing Prevention - Center Activities
Base Amount: $61,798,880 (All BA)

Public Health Focus

The public health focus of the Prioritizing Prevention sub-program is to protect the American food supply from unintentional and deliberate contamination and prevent food safety problems before they occur. Prevention is the cornerstone of an effective, food safety strategy. Ensuring that industry implements preventive control measures is essential to prevent intentional or unintentional contamination of the American food supply.

Public Health Outcome

Driven by science and modern information technology, CFSAN detects, identifies, and counters potential hazards before they harm American consumers. CFSAN also develops and implements uniform, science-based standards to strengthen and better integrate the American food safety system at the federal, state, and local levels, as well as to increase assurance that imported food is as safe as domestic.

CFSAN base funding in this sub-program provides the resources to support industry and protect consumers through scientific and analytical tools to better identify and understand food safety risks and the effectiveness of control measures used to protect the food supply on both a pre-market and post-market basis.

In the pre-market arena, CFSAN base programs protect the public health by assessing and evaluating the safety of infant formulas and assessing and evaluating substances that industry intentionally adds to food and substances that may become components of food because of contact with food packaging or during food processing. CFSAN gives special priority to reviewing new ingredients, treatments, and technologies that have the potential to reduce foodborne illness by decreasing levels of pathogens in food.

For example, FDA expanded the permitted use of irradiation as a treatment to reduce foodborne pathogens in iceberg lettuce and spinach. This irradiation provides producers with an additional tool to reduce levels of pathogens such as *E. coli* and *Salmonella* on these leafy greens. CFSAN also published guidance for manufacturers on microbiological considerations in preparing submissions for antimicrobial food additives. CFSAN issued several other authorizations for antimicrobial ingredients for fresh produce and for use in wash water during the processing of meat and poultry.

CFSAN base resources also support the evaluation of submissions for new and emerging technologies. Some of these include:

- food ingredients and packaging made using nanoengineered particles
- food ingredients produced from genetically engineered plants
- substances with the potential to cause allergic reactions in sensitive individuals.

CFSAN recently updated its guidance to petitioners for new food additives and food packaging components. For the first time, the updated guidance includes recommendations and considerations about changes in particle size. FDA also published a final rule requiring the labeling of the color additives carmine and cochineal extract to protect consumers who are allergic to these colors.

On a post-market basis, CFSAN base programs protect the public health by providing industry with information and requirements in the form of regulations and recommendations in the form of guidance on preventive controls. These controls help protect consumers from intentional and unintentional chemical and microbial contaminants in food products, from minimally processed foods, such as fresh produce, to processed foods, such as low-acid canned foods.

CFSAN also develops science-based safety standards that will reduce risk in a number of commodities. For example, CFSAN issued a new egg safety regulation, designed to prevent *Salmonella enteritidis* in shell eggs during production, transportation, and storage, that took effect in July 2009. The regulation requires preventive measures during the production of eggs in poultry houses and requires subsequent refrigeration during storage and transportation. These measures are expected to save thousands of lives from *Salmonella* over the next few years.

In April 2010, CFSAN launched a web site with information on the safe transportation of human food and animal feed. The site aggregates links to existing FDA regulations, guidances, and press releases providing a comprehensive information resource to commercial food transporters. Knowledge of and adherence to these regulations,

guidances, and press releases assists commercial food transporters in reducing the potential introduction of physical, chemical, biological, and other contaminants during the transportation of foods and feeds. CFSAN base resources also support activities to determine baseline levels of chemical contaminants in foods. Examples of such contaminants include furans, melamine, perchlorate, dioxins, lead, and pesticides. Base resources also allow CFSAN to protect public health by assessing potential problems, taking steps to remove products from the market that violate safety standards, and ensuring that manufacturers use appropriate control measures to reduce or eliminate contaminants in foods. For example, CFSAN base resources support annual data collection through the Total Diet Study (TDS) program to determine the levels of various contaminants and nutrients in foods. This is particularly important for estimating the dietary intake of substances such as pesticide residues, which may be reduced or increased as a result of washing, peeling and cooking.

During FY 2011, FDA will provide funding to the Center for Foodborne Illness Research and Prevention (CFIRP) to support food program activities, as noted in Section 728 of the FY 2010 Appropriations Act. The long-term health burden of acute foodborne disease is not well understood and there are few guidelines for long-term medical care. CFIRP will develop a framework for systematic follow-up of foodborne illness cases which will greatly enhance the ability to attribute long-term health problems resulting from acute foodborne illness.

Promoting Efficiency

Through the Prioritizing Prevention subprogram, CFSAN takes preventive action to protect consumers from food safety risks. In this subprogram, CFSAN also helps firms develop safe food packaging based on the latest science and avoid the risk and expense of recalling products that do not meet safety standards.

The CFSAN premarket review activities of this subprogram also alert industry to potential problems with new ingredients, labeling, or infant formula. Each year, CFSAN provides more than 100 consultations to assist industry. Through these consultations, CFSAN offers specific guidance to firms on how to best address safety questions relating to food ingredients and packaging. CFSAN also expedites the premarket review of FDA-regulated food ingredients and packaging, processing aids such as antimicrobials used to mitigate food contamination, and sources of irradiation that may have potential food safety benefits. These FDA activities help industry to:

- avoid potential safety problems and associated recalls
- more efficiently introduce new or changed infant formulas
- decrease the costs of innovation for food safety
- speed the entry of safe food products and technologies to market.

CFSAN also maintains essential scientific and technical expertise through this subprogram. This expertise allows CFSAN to provide international leadership for developing science-based Codex standards. Codex standards help ensure that food imports meet U.S. regulatory standards to protect American consumers, while also promoting fair trading practices that are important to the food industry.

Prioritizing Prevention - Field Activities
Base Amount: $107,199,000 (All BA)

Public Health Focus

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

- prevention, through outreach coordination and technical assistance to industry
- internal and external training, which increases expertise and encourages collaboration with external stakeholders
- ensuring that preventative controls are in place throughout the entire food supply chain, from the point of production, to delivery into the U.S. supply chain and ultimately, consumption by the public.

Public Health Outcome

In 2010, ORA participated in more than 50 outreach events at a variety of symposiums and conferences attended by regulated industry, other government agencies and foreign regulatory bodies. ORA continues its outreach efforts to ensure up-to-date communication of emerging issues and advancement of FDA policies and initiatives to internal and external stakeholders.

In FY 2010, FDA awarded a $1.0M cooperative agreement to the International Food Protection Training Institute (IFPTI). IFPTI supports the Integrated Food Safety System (IFSS) for regulatory and public health partners through its establishment of a catalog of existing food safety/food defense courses for the Partnership for Food Protection. In FY 2010, ORA offered five of these courses at the IFPTI facility.

In FY 2011, the Institute will continue to work with ORA personnel in obtaining its goal of establishing a comparable national training curricula for federal, state, local, territory and tribal food safety inspectors. This curriculum will serve as the foundation for ensuring consistency in training across all regulatory levels.

In FY 2010, ORA awarded funds to five associations under the Small Scientific Conference Grant and to 27 state and local regulatory agencies under the Food Protection Task Force Grant. These grants provided the resources the associations and regulatory agencies needed to convene meetings of key stakeholders to foster communication and collaboration on a range of topics including food safety and food security/protection, intervention and prevention through the review of food supply vulnerabilities.

Promoting Efficiency

ORA conducts outreach to ensure transparency, open communication and sharing of information and ideas with consumers, regulated industry and the import trade community. Prioritizing Prevention activities are proactive and generate efficiencies for industry, consumers and FDA because they help anticipate and prevent food safety problems. In addition to protecting public health, preventing such problems leads to efficiencies and savings for consumers and industry by avoiding the expenses associated with contaminated foods.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (*Output)*	FY 2009: 100% (Target Exceeded)	70%	90%	+20%
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. *(Outcome)*	FY 2010: 388 (Target Exceeded)	347 enrolled	423 Enrolled	+76
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)*	FY 2010: 5 labs (Target Met)	5 data exchange additions/conversions	5 data exchange additions/conversions	Maintain
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2008: 12.8 cases/100,000 (baseline)	12.3 cases/100,000	11.9 cases/100,000 (based on HP2020 Target)	NA*
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2008: 1.1 cases/100,000 (baseline)	1.0 cases/100,000	1.08 cases/100,000 (based on HP2020 Target)	NA*
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. (*Outcome)*	CY 2008: 0.29 cases/100,000 (baseline)	0.24 cases/100,000	0.28 cases/100,000 (based on HP2020 Target)	NA*
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2008: 16.2 cases/100,000 (baseline)	6.8 cases/100,000	14.4 cases/100,000 (based on HP2020 Target)	NA*

212409: Decrease the rate of *Salmonella Enteritidis* (SE) illness in the population (cases per 100,000). (*Outcome*)	FY 2009: 2.6 cases/100,000 (Historical Actual: average rate of SE illness from 2007 to 2009)	NA	2.2 cases/100,000	NA

* The FY 2010 targets for reducing the incidence of infection caused by *Campylobacter* species, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* species were set in the year 2000 as part of the **Healthy People 2010 Initiative**. The targets for FY 2010 were all calculated as 50% reductions from 1997 baseline incidence levels for these foodborne pathogens. The targets for 2010 have not yet been achieved for any of the pathogens included in this objective (though *Campylobacter* species, *E. coli* O157:H7 and *Listeria monocytogenes* are very close, with 48%, 47% and 38% reductions, respectively, as of the 2008 data). Further investigation is needed to identify sources for emerging *Salmonella* serotypes, since that rate of infection has increased in the past decade.
The FY 2011 targets start the next decade of targets as part of the **Healthy People 2020 Initiative**, and therefore the FY2012 targets are not comparable to the FY 2010 targets. In order to align the new targets for future reductions with more recent data, the baseline data for the FY 2011 targets are from FoodNet data collected from FY 2006 – FY 2008. Consequently, the FY 2011 targets show an increase over the Healthy People 2010 targets due to the new baseline. The Health and Human Services Office of Disease Prevention and Health Promotion (ODPHP) has recently given guidance to the Healthy People work groups on target setting for **Healthy People 2020**, recommending improvement targets of 10% over the 10-year period.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Center Activities

Base Amount: $114,801,090 (All BA)

Public Health Focus

The public health focus of the Strengthening Surveillance sub-program is to assess and communicate the specific risks associated with specific food products to American consumers and industry on a routine basis, as well as during foodborne illness outbreaks or cases of chemical contamination.

Public Health Outcome

CFSAN base activities for this sub-program center on the use of food safety surveillance information and scientific data and tools to prevent illness and injury from foods. Base activities also protect American consumers from harm by addressing foodborne outbreaks and cases of intentional or unintentional chemical contamination.

A significant focus of CFSAN base activities is using post-market surveillance information and scientific methods and tools to identify food products that pose a threat to public health. Funding for CFSAN base activities also supports improving the availability of chemistry and toxicology information for better safety and risk assessments and more rapid response to episodes of food contamination. For example, CFSAN base resources supported the prompt interim safety/risk assessment of melamine in response to finding this adulterant in Chinese dairy products.

CFSAN base resources also support the post-market monitoring of previously authorized substances added to food to assess the need to re-evaluate safety in light of new information. For example, CFSAN base resources are currently supporting a re-

evaluation of the safety of bisphenol A (BPA), phthalates, and related chemicals in light of recent research that suggests the possibility of adverse effects at levels lower than previously indicated.

CFSAN, along with other FDA components, is working to develop adverse events early warning systems that can integrate and mine data rapidly to detect real time signals of adverse events or consumer complaints associated with regulated products. The Reportable Food Registry is one such improved early warning system, where food processors can report the possibility of food contamination. These reports trigger rapid FDA and state response to determine and stop the cause before people become sick. FDA also worked with the National Institutes of Health to develop the Safety Reporting Portal (SRP), a unified system to submit adverse events, product problems, and/or safety reports associated with regulated products. The SRP assists industry in determining what specific data need to be submitted, improving the data quality of reports, and increasing the speed and accuracy of FDA response to potential public health problems. The SRP was launched on May 24, 2010.

Protecting food from intentional contamination is also a priority of CFSAN base activities. Understanding the risks and vulnerabilities for intentional contamination in the food production, processing, and distribution system helps further strengthen the food supply against targeting for intentional contamination. In FY 2010, CFSAN re-evaluated historical vulnerability and risk assessments on regulated foods to update them for technological advances, additional select agents, and new surveillance data. Through an interagency agreement with the Department of Energy, CFSAN supported the continued development of the CARVER + Shock vulnerability assessment tool which helps agricultural producers and food processors protect their products from deliberate contamination.

Another significant focus of CFSAN base activities is developing and validating new, rapid-detection technologies capable of identifying contamination that leads to foodborne illness. Current test results require anywhere from several days to weeks to deliver, which severely limits the ability to respond to outbreaks and emergencies and to complete timely surveillance activities. In FY 2009 and FY 2010, FDA developed new tests for *E. coli* 0157:H7, *Salmonella*, *Listeria monocytogenes*, *Shigella*, and marine toxins. CFSAN continues to evaluate other promising test methods and high-throughput technologies that will dramatically shorten the time it takes inspectors to identify pathogens in the food supply chain from more than a week to less than a day.

Promoting Efficiency

Through the Strengthening Surveillance Subprogram, CFSAN promotes efficient food safety research and development while minimizing the cost to industry to respond to food safety concerns. CFSAN uses its regulatory expertise to perform a unique coordinating role to develop and lead important collaborations with industry.

CFSAN research often provides essential non-proprietary data for discussions about particular test methods or product characteristics. In many cases, industry relies on CFSAN to provide uniform methods and establish standards to detect food contaminants and analysis of nutrients. These methods and standards promote food safety improvement and a robust and stable business environment.

CFSAN also provides essential science-based information that allows industry to efficiently and effectively respond to concerns about new chemical and microbial food safety threats -- including acrylamide, perchlorate, benzene, BPA, *Cronobacter sakasakii*, and *Salmonella* -- and food defense-related pathogens, such as *Clostridium botulinum* toxin. CFSAN works to quickly develop, validate, and verify methods to detect such contaminants and determine their levels in food. Likewise, CFSAN collaborates with industry to develop novel technologies to detect new and traditional foodborne contaminants. As a result, the Strengthening Surveillance Subprogram supports FDA's food safety and public health mission, while allowing industry to efficiently address emerging food safety concerns.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance – Field Activities
Base Amount: $273,955,000 (All BA)

Public Health Focus

To strengthen bio-security, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- laboratory analyses including sample analysis, product testing and methods development to enable ORA to develop solutions for specific regulatory problems.

These activities serve to minimize consumers' risk of exposure to adulterated food products by preventing the marketing of products, removing products from the market or ensuring that products do not reach the U.S. market. Early detection of contaminated or adulterated food products and their ingredients continues to be a priority within ORA.

ORA continues to advance regulatory science, increasing the breadth of its analytical capacity while improving laboratory efficiencies and outputs. One way ORA accomplishes these advances is through the continued development of laboratory methods. The international aquaculture industry, for example, has been concentrated in developing countries that lack regulation on drug use in food-producing animals.

Several antibiotics and other drugs are approved for use in aquaculture to improve productivity and increase yield. However, FDA continues to find a significant number of

unapproved drugs in seafood products, leading to concerns about product safety and drug withdrawal times. These conditions require FDA evaluation on a case-by-case basis.

Some of the unapproved antibiotics and drugs used in today's food products are carcinogens, some are toxic to the immune system, and some have other health impacts such as allergic reactions and adverse drug side effects. Since the products are not labeled as containing the drug, they cause unexpected health risks to the consumer. There is a growing concern that subclinical doses of antibiotics can contribute to the development of multidrug resistant pathogens.

To protect consumers from potentially harmful residues in the food that they eat, it is important that Agency oversight of food commodities include an analytical assessment for the presence of drug residues. ORA continues to develop analytical methods and expand field laboratory capabilities, both of which are imperative to meeting the ongoing issues and concerns related to food products.

Public Health Outcome

ORA continued to use the Chemistry and Microbiological Mobile Laboratories to support food defense initiatives and surveillance of import and domestic produce. The Mobile Laboratories are designed for high throughput screening of samples providing for expedited analytical timeframes and subsequent release of import shipments, which is crucial for perishable products such as produce. In 2010, supported by a total of 132 volunteers from the ORA field laboratories, the ORA Mobile Laboratories were deployed for a total of 35 weeks. A total of 8,015 samples of domestic and imported produce were analyzed. One deployment, focused on imported produce from Central and South America and Caribbean Islands, found a combined 7% violation rate for *Salmonella*, enterohemorrhagic *E. coli* (EHEC), and pesticides. The finding resulted in the addition of the firm and products to appropriate Import Alerts calling for the detention without physical examination of affected products.

In FY 2010, ORA re-invigorated the use of environmental sampling during domestic food facility inspections to assess the environmental conditions in which products are manufactured. These samples provide signals to FDA of areas of concern within a production environment and have led to numerous cases of industry electing to retain or destroy products that were manufactured in suspect conditions but have not yet been proven to be contaminated. Through surveillance efforts such as these, and joint FDA and industry action, ORA assures that potentially adulterated commodities do not enter into the U.S food supply. Additionally, ORA increased surveillance activities performed by the states on behalf of FDA by including in the Food Inspection Contract program several electives such as conducting environmental sampling during the inspection. In FY 2010, seven states chose to include this elective which called for the completion of up to 1,500 environmental sample collections within the year.

In FY 2010, ORA developed a new method to detect polycyclic aromatic hydrocarbons (PAHs) in oysters, shrimp, crabs and finfish. This method is currently being used to determine the concentration of PAHs in seafood from the Gulf of Mexico. Based on this test, FDA can confirm that the level of these chemicals in the Gulf seafood are below a level that would cause public health concern. This new method is being used for all samples collected and analyzed in support of determining whether the Gulf waters can be reopened to commercial fishing. The method was deployed to eighteen FDA and state laboratories participating in FDA's chemistry cooperative agreement with FERN.

Each laboratory can test approximately 20 samples every 24 hours using this method as compared to the existing method which is capable of testing 25 samples every 5 to 7 days.

In FY 2010, ORA purchased new equipment for field laboratories and developed new methods that allow a single test to detect specific drug residues in aquaculture and honey products, and confirm the levels of drug residues present. ORA's equipment purchase continued to expand its laboratory capacity by extending its capabilities to analyze seafood products for the presence of nitrofurans (known carcinogens) into three additional ORA field laboratories. The multi-residue analytical method ORA developed and implemented can analyze and confirm the presence of 18 different drug residues in shrimp products. The multi-residue method developed and implemented for honey allows for the detection of 17 different drug residues. Due to increased sampling stemming from joint actions with U.S Customs and Border Protection (CBP) and the ORA Office of Criminal Investigations (OCI), ORA field resources collected and analyzed 150% of the FDA target for FY 2010.

In FY 2010 ORA reevaluated and initiated changes to procedures involved in joint surveillance with facilities and products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and other organizations. The changes affect information sharing with the United States Department of Agriculture (USDA) and Occupational Safety and Health Administration (OSHA) regarding facilities such as the Wright County Egg Facility in Iowa. The Agencies are redesigning processes, including inspection, test results and oversight of proposed corrective actions by firms, to address contamination with *Salmonella* and other diseases and filth. The agencies are also evaluating information disclosure between CFSAN, the Environmental Protection Agency (EPA) and USDA on fresh produce safety at the farm and packing house. The information requested will assist CFSAN in concluding which production practice standards would best protect the public health if required by regulation, while creating minimal economic and environmental impact. ORA personnel are mediating information disclosure to OSHA regarding food facilities contained in the Food Facilities Database. These efforts will improve prevention and federal and state responses to outbreaks and contamination.

Due to an unusually wet and cool growing season on the east coast and in the Midwest in 2009, high levels of mycotoxin Deoxynivalenol (DON), also known as vomitoxin, were detected in wheat, corn and other grains harvested from that growing season. In FY

2010, ORA worked with the states to accomplish a comprehensive sampling and analytical effort in affected areas. The joint effort called for ORA and state sampling of milled wheat products such as milled wheat flour, wheat bran and wheat germ intended for use in the human food supply to determine the levels of DON present. Products that exceeded FDA advisory levels led to follow-up inspections with sampling of finished foods manufactured using the milled wheat products that exceeded FDA advisory levels. FDA took regulatory action as appropriate. Additionally, FDA developed multi-residue mycotoxin testing methods, which consolidated the previous process of an initial test to determine the presence of mycotoxins and a confirmation test for regulatory determination and action.

In 2010, ORA's Prior Notice Center (PNC) was able to expand its prior notice electronic targeting system capabilities, increase intelligence-related food shipment data mining, and create new targeting criteria to more effectively detect food shipments linked to high risk persons and firms. Additionally, the PNC performed more than 81,000 reviews of prior notice submissions, exceeding FDA's goal by over 1,000 reviews.

ORA is increasing efficiencies in reviewing import entries through the implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). This system gathers intelligence from various sources to allow for a more informed review of specific product entries. Data supporting product compliance will aid ORA in more quickly processing and releasing those entries while data more indicative of concerns or violations will result in the entries being flagged for additional scrutiny by ORA investigators. PREDICT allows ORA to target its resources in a more strategic manner. ORA's implementation of PREDICT allows for the expedited clearance of low risk products while allowing ORA to focus examination and sample collection resources on higher risk food products.

In FY 2010 ORA contracted with a third party to perform on site firm verifications of foreign food facilities that have registered with FDA as required by the Bioterrorism Act (BTA) of 2002. This contract allows for physical verification of a foreign firm at the location identified in the registration not only to confirm the existence of the facility but to verify the information supplied in the registration. On-site findings are then reported to FDA for appropriate follow up action, which includes for-cause inspection of the facility, addition of facilities to import alert where the manufacturing capabilities are not what was purported in the registration, and increased review of prior notice submissions to ensure accurate data is submitted.

In FY 2010, ORA evaluated handheld portable analytical tools for use in the early detection of contaminated food products. ORA qualified a variety of tools to date and started a multi-tiered implementation program. The implementation program allows ORA to phase in each class of tool for daily use by ORA field investigators at specific U.S. ports of entry. The analytical screening capacity and commodity range for each tool varies. Portable tools return analytical screening results within minutes of implementing the test, providing ORA field personnel with data to assist in making appropriate regulatory determinations. These tools provide for the release of safe

shipments into U.S. commerce and detention of shipments with violative screenings for further analysis by ORA field laboratories. The first tier of tools was deployed to several ORA field offices, and they are the first in a series of portable analytical tools that will be deployed to ORA field investigators to screen a variety of products for a multitude of safety concerns.

Promoting Efficiency

FDA field operations are establishing high throughput laboratories for analyzing food samples. These laboratories will allow ORA to analyze a greater volume of food samples in less time. Through this analysis, FDA can better protect consumers, make more timely regulatory decisions, and reduce the impact on regulated industry. These efforts not only provide greater assurance that foods are safe, they also maintain the efficient flow of trade.

In addition, high throughput laboratories protect the public by identifying product adulteration and environmental contamination. With this analysis, FDA and industry can efficiently address such problems and allow a firm to resume business operations as quickly as possible after correcting the food safety problem. The Field Operations of the Strengthening Surveillance Subprogram also allow ORA to identify, validate and implement new technologies to more readily detect adulterated food imports. These technologies prevent adulterated imported food from reaching U.S. consumers and allow FDA to more efficiently maintain the flow of commerce in foods that FDA regulates.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214306: The average number of days to serotype priority pathogens in food (Screening Only) (*Output)*	FY 2010: 10 working days (Historical Actual)	NA	4 working days	-6
214207: The number of assessments/questionnaires completed to initiate the process of establishing comparability of foreign country food safety systems to that of the US relative to public health outcomes. (*Output)*	NA	NA	9	+9
214201: Number of prior notice import security reviews. *(Output)*	FY 2010: 81,618 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2010: 170,392 (Target	140,000	160,000	+20,000

	Exceeded)			
214203: Number of Filer Evaluations. *(Output)*	FY 2010: 1,277 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2010: 8,658 (Target Exceeded)	7,000	7,000	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2010: 13 labs (Target Met)	13 labs	13 labs	Maintain

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Center Activities

Base Amount: $21,870,331 (All BA)

Public Health Focus

The public health focus of the Strengthening Enforcement sub-program is to prevent illnesses resulting from contaminated foods by targeting inspections and sampling and by focusing resources where they will have the greatest public health benefit.

Public Health Outcome

CFSAN base activities in this sub-program area concentrate on identifying, evaluating, and implementing risk-based programs to direct inspections, collect samples, and conduct sample analyses and field exams for the domestic and imported food supply. These efforts allow FDA to protect consumers and achieve the public health objective of preventing illnesses resulting from contaminated foods.

Recently, CFSAN conducted a qualitative risk assessment to identify, evaluate, and target ORA domestic field work priorities for sampling and inspecting products or processes of higher relative risk, using a three-step process to:

- estimate the likelihood of an adverse event occurring from the consumption or use of a product containing the hazards
- determine the relative severity of the health effect of that hazard
- combine data on the likelihood and severity to determine the risk category (high, medium, low).

Using this relative risk ranking approach, FDA adapted it to develop risk related priorities for imported products. This risk assessment allows CFSAN and ORA to link products and hazards of concern in a systematic and transparent manner for the first time.

CFSAN also initiated research into developing a risk-based tool to identify higher priority food firms based on the relative risk of the products that they manufacture, process, or distribute and the compliance history of those firms. In FY 2010, the risk-based model that relatively ranks domestic food manufacturers was enhanced to include the firm's compliance history and inherent factors, including foodborne outbreaks, recalls, and reports of adverse events. As a result, FDA now uses revised, risk-based strategies, such as increasing and targeting environmental sampling for *Salmonella* and/or *Listeria* during inspections of certain higher risk firms. This change has already resulted in numerous product recalls and at least two injunctions to date. The public health outcome of using this inspection and enforcement strategy when inspecting higher risk firms has and will continue to prevent illnesses resulting from contaminated foods.

In FY 2010, CFSAN base resources in this area supported improvements to the risk evaluation process and the development of quantitative or semi-quantitative tools to refine and improve the approach. CFSAN undertook additional work to refine risk evaluation methodology, obtain data to reduce uncertainty in the output of the risk models, and develop procedures to integrate the results into the joint Center/Field inspection work planning process. CFSAN used the results of these models to develop risk profiles or risk maps to assist in understanding the vulnerable steps or events where contaminants can be or are introduced into the food supply system.

For example, CFSAN developed a customizable fresh-produce risk ranking tool using data collected from the CDC and other scientific sources. The tool provides a systematic means of determining which produce/contaminant combinations are riskiest and ranks them in order of priority for interventions. The results of such tools allow FDA to implement appropriate mitigations or interventions to reduce health risks to American consumers.

Promoting Efficiency

By identifying food safety risks through inspections and by removing unsafe or substandard products from the market, FDA protects consumers and also supports industry efforts to produce safer foods. FDA enforcement actions may also allow firms to avoid the potential high costs that result from consumer illness or injury caused by contaminated foods.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities
Base Amount: $111,446,000 (All BA)

Public Health Focus

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 our 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 Inspections Contracts as important mechanisms for providing increased enforcement activities through an enhanced integrated food safety system.

Public Health Outcome

ORA investigators conduct physical inspections of regulated domestic and foreign food establishments.

In FY 2010, ORA increased the number of firms that were targeted for foreign inspection coverage by 144. Innovations included using risk factors to target firms to inspect, establishing dedicated foreign inspection cadres, and enhancing efficiencies associated with the foreign inspection program and process. The increased coverage provides a better understanding about the compliance status associated with firms that ship human food products to the U.S.

ORA started the Dedicated Foreign Food Cadre in July of 2009. The 13 cadre members bring over 160 years of experience conducting independent and complex inspections and developing compliance cases which very often resulted in regulatory actions. In FY 2010 the cadre contributed significantly by augmenting the existing foreign inspection program and exceeding the number of foreign food establishments inspected in the previous year by 144 inspections.

During FY 2010, ORA issued 668 Import Alert notices identifying modifications to human food products, food ingredients, and dietary supplements. These notices encompass various food and dietary supplement commodities and manufacturers. Some were a result of ORA import surveillance activities of regulated products at the time they were offered for import into the U.S. Others resulted from for-cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. Notable products covered under this process include shipments of tuna containing Salmonella Paratyphi implicated in illness outbreaks in 22 states and black pepper implicated in a multistate salmonelosis poisoning episode.

In FY 2010, ORA began staffing the Commercial Trade Analytical Center (CTAC), a facility designed to leverage numerous government agencies in information sharing and data analysis to identify safety risks in imported products. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA personnel are working closely with other government agencies on several ongoing cases including products in the human food program.

In FY 2010, FDA received new authorities under the Prevention of *Salmonella enteritidis* in Shell Eggs during Production, Storage, and Transportation Rule. In an effort to enforce the requirements of the rule, FDA is establishing and implementing a multi-tiered internal approach to:

- identify inspection requirements, resources, and tools

- develop and implement training of ORA field staff
- initiate inspections of facilities for evaluation of egg safety for prevention of *Salmonella enteritidis* (SE).

Initial inspections of a large producer in Iowa resulted in recalls of shell eggs. Eleven firms initiated recalls associated with the Salmonella enteritidis in shell egg event. There were 156 direct accounts and 3,982 sub-accounts (customers downstream, i.e, distributors, food service establishments, institutions, manufacturers and retail outlets) of Wright County Egg and Hillandale Farms of Iowa for which audit checks were performed.

Trade submission of accurate prior notice data for imported food shipments ensures ORA can complete meaningful bio-security risk assessments. In order to ensure compliance, ORA made more than 800 informed compliance calls to the trade in 2010 to obtain accurate prior notice data and inform/remind the trade community and regulated industry of the requirements. In conjunction with CBP, ORA executed compliance enforcement actions against more than 1,300 imported food/feed shipments where the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. These compliance actions required the trade community to submit accurate prior notice data for risk assessment before the imported food/feed shipments were allowed to enter the U.S.

FDA's global efforts in China and India contributed to surveillance inspections. Investigators working in China and India conducted for-cause and surveillance inspections. This facilitates follow up on critical issues (for-cause inspection) in a timely manner. Additionally, these international offices are providing more confidence building and joint activities with foreign regulatory agencies.

In FY2010, ORA awarded food inspection contracts to 41 State Agencies and one territory. These contracts enhance an integrated food safety system by providing states and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections. The contracts also include a subset of high risk industries such as juice and seafood Hazard Analysis Critical Control Point (HACCP), and low acid canned foods/acidified foods. Additionally, these contracts allow the states the option to include additional investigative mechanisms such as environmental sampling to assist in strengthening and protecting the food supply from unintentional and deliberate contamination and prevent food safety problems before they occur.

ORA also monitors recalls of food products that have been found to present safety concerns and assures the adequacy of the firm's recall to effectively remove the defective product from commerce. Through the classification process, the Center determines the level of public health risk the product presents. Appropriate public notification is also a component of the agency's recall program. In FY 2010, FDA classified and issued recall numbers for 2,235 Class I (most serious); 564 Class II; and 139 Class III recalls of food products compared to 492 Class I, 1816 Class II, and 473 Class III recalls in 2009.

In FY 2010, FDA's MARCS-Compliance Management System indicated 19 approved injunctions, 6 seizures of food products (including dietary supplements) and 82 emergency permit controls.

ORA's Office of Enforcement (OE) and Office of Criminal Investigations (OCI) also focus on enforcement. In March 2009, the Office of Enforcement assumed the responsibility for the Agency's Debarment Program, putting Agency-wide procedures in place to ensure that more rapid, transparent and consistent debarment actions are taken. These efforts also included hiring a full-time Regulatory Counsel to initiate and process debarment proceedings and creating and maintaining a page on FDA's website where all pending and completed debarment actions are listed and publicized, enhancing public health protection by assuring that businesses and individuals who deal in FDA regulated products do not procure the services of a debarred person. It is critical to ensure that the individuals who engaged in misconduct not be trusted with patient safety and the public's health. OE initiates a comprehensive review of cases referred quarterly by OCI and other cases referred by other sources throughout FDA for potential debaree candidates. In FY2010, as a result of these referrals and reviews, OE has debarred thirteen individuals with criminal convictions from participating in certain aspects of food and drug industry. Three of these thirteen individuals debarred include FDA's first food importer debarments.
http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm194263.htm

OE managed the collaboration of information disclosure between CFSAN and the Federal Trade Commission (FTC) regarding companies marketing caffeinated alcohol beverages, a food not generally recognized as safe and an unapproved new drug.

OCI's significant case activity in FY 2010 included 39 arrests and 26 convictions with fines and restitution in excess of $68.0 million. Two cases are highlighted below:

The July 2010 sentencing of a seafood wholesaler CEO culminated in an OCI investigation into the illegal importation of $15.5 million of misbranded and adulterated Vietnamese catfish, which led to a conviction of five companies and eight individuals associated with various Vietnamese catfish processors, U.S. importers, and seafood wholesalers. The investigation tackled the long-standing practice of mislabeling seafood to avoid Customs anti-dumping duties and an FDA import alert against antibiotic-tainted Vietnamese catfish. The defendants were ordered to pay $444,000 in fines, ordered to forfeit $12,197,930, and pay $64,173,839 in restitution. Additionally, the subjects of the investigation were sentenced to a total of 97 months of incarceration, six months home confinement and 162 months of probation.

The second case led to a 44 count indictment in August 2010, charging a U.S. honey importer, 11 business executives and four affiliated companies for conspiring to import $40 million of falsely labeled and adulterated Chinese-origin honey tainted with unapproved antibiotics and avoid Customs anti-dumping duties and an FDA import alert designed to intercept honey containing unapproved antibiotics. The indictment not only seeks the forfeiture of $78 million in unpaid anti-dumping duties, but addresses the

denial of a fair market for U.S. honey producers and the deliberate violation of laws designed to protect the U.S. food supply.

In FY 2010, FDA's Regulatory Procedures Manual (RPM) was revised to provide a process for issuing Warning or Untitled Letters based on evidence obtained by state personnel. The process allows FDA to issue Warning or Untitled Letters if the standards and criteria state personnel use provide reliable support for regulatory action consistent with the agency's guidance on regulatory actions and laboratory procedures. This is associated with an increase in the number of enforcement actions and a decrease in the time and resources required to prevent the continued distribution of adulterated products in U.S. commerce.

Promoting Efficiency

Examples of FDA efforts to promote efficiency through the Strengthening Efficiency Subprogram include the ORA Food Inspection Contract Program. The Food Inspection Contract Program – and similar contracts, grants and cooperative agreements that the Field executes through this subprogram – build an integrated food safety system designed to protect the nation's food supply and minimize consumers' exposure to adulterated and contaminated food products. FDA support for state inspections often supplements two-to-three state-funded food inspections, thereby increasing the reach of FDA and state food safety programs.

Through closer involvement with state food safety efforts, FDA gains valuable data on inspections funded with state resources. Through these grants and cooperative agreements, ORA increases the efficiency of an integrated food safety system by assuring state inspectors are better trained and more proficient, increasing the capabilities of states to respond to food incidents and outbreaks.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2011
214205: Number of high-risk food inspections. *(Output)*	FY 2010: 6,926 (Target Exceeded)	6,750	8,850	+2100

Improving Response and Recovery - Center Activities
Base Amount: $6,623,685 (All BA)

Public Health Focus

The public health focus of the Improving Response and Recovery sub-program is to protect American consumers from harm when foodborne illness outbreaks do occur. The public health focus involves responding more effectively with rapid and targeted product tracing and more accurately identifying the specific firms that are responsible for the food safety problem.

Public Health Outcome

CFSAN base program activities help create a structure for FDA, other public health agencies, and industry to exchange information and expertise in real time during an outbreak of foodborne illness. CFSAN uses this structure to achieve the primary public health objective of reducing the length of time between detecting and containing foodborne illness.

CFSAN base activities support the ability of FDA to respond faster, communicate more effectively to consumers and FDA food safety partners, and limit avoidable adverse economic consequences for affected industries. In FY 2010, these resources allowed the FDA, in partnership with the National Oceanic and Atmospheric Administration (NOAA) and the United States Coast Guard, to respond to issues of seafood safety stemming from the Deepwater Horizon oil spill. CFSAN assessed seafood safety through sampling and laboratory analyses and then used this information to make decisions to safely re-open harvesting areas. FDA also provided analytical and operational support to federal, state, and local agencies likewise involved in the response efforts.

As a result, FDA prevented consumers from being exposed to contaminated seafood caused by this environmental disaster. FDA was also able to help the Gulf fishing industry recover by providing assurance to consumers that seafood from re-opened fisheries was safe, helping to minimize the adverse impact of the spill on the American economy. FDA continues to monitor and evaluate on-going and long-term effects of the spill on seafood safety in FY 2011.

CFSAN base program activities also include: assessing issues and obstacles that hinder inter-agency data sharing and communication; identifying data systems useful for signal detection of potential adverse events; determining how to interconnect data systems in real time; and determining how to mine data for early signal detection. CFSAN is also working to develop unified, interoperable, information-sharing data systems between federal, state, and local agencies for effective signal detection and rapid response.

Promoting Efficiency

FDA response and recovery activities safeguard consumers, promote economic stability, and reduce costs to industry during incidents of foodborne illness or contamination. In addition to posing clear risks to consumers, foodborne illness outbreaks lead to reduced productivity and detrimental economic impact for individual food firms or for entire industry sectors through the loss of consumer confidence and protracted recalls. By quickly and effectively identifying contaminated products, FDA protects American consumers by removing products from the market place, while also helping industry to recover by accurately identifying firms that are responsible for the problem foods, as well as firms not associated with the safety problem.

Improving Response and Recovery - Field Activities
Base Amount: $49,360,000 (All BA)

Public Health Focus

With the integrated food supply chain, it is more important than ever for ORA to work with its regulatory partners, specifically its federal, state, local, tribal, and territorial partners, in order to protect the nation's food supply. To rapidly respond to outbreaks and facilitate recovery, ORA leverages its regulatory partnerships.

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 is continuing to work with the states to establish new and develop further existing Rapid Response Teams (RRTs), comprised of both ORA and state inspectors.

The Reportable Food Registry (RFR) is an electronic portal to which industry, public health officials and consumers can report when there is a reasonable probability that an article of human food will cause serious adverse health consequences or death to humans. RFRs provide regulated industry and consumers with an immediate reporting mechanism into FDA and also supply key information that is vital for effective FDA follow up activities.

To protect consumers from food borne pathogens and to rapidly and accurately trace and identify the sources of pathogens in the food supply, it is necessary to determine species and discriminate the pathogens isolated from food. This additional identification is needed to track pathogen to the source and origin of the food exposure whether from plant, farm, or human contamination sources.

ORA continues to devote resources to the prompt and efficient response to foodborne outbreaks and events associated with FDA regulated commodities. ORA continues to identify and develop new investigational resources, tools, and training programs while establishing an infrastructure that will support continued effective and efficient response.

As FDA continues to move forward in meeting national food defense goals, it relies on states and counties 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.

Molecular techniques are available that provide additional identification and greater delineation of pathogens isolated from food products. These techniques provide evidence for rapid trace back to contamination sources. All microbiology laboratories have equipment to perform this testing and microbiologists are certified to perform this analysis. The results of these determinations inform inspections and provide evidence on source, level and extent of contamination by food borne pathogens. The data informs and directs inspections.

Public Health Outcome

Examples of these partnerships include State contracts, Food Emergency Response Network (FERN) laboratories, rapid response and state lab cooperative agreements, Bovine Spongiform Encephalopathy (BSE) contracts, and 50 State Meetings.

To date, ORA has developed nine RRTs through the use of cooperative agreements and will continue to develop the existing teams while working to enroll remaining states in the program. The established teams continue to work with federal and local partners (including 10 FDA districts) to explore, develop, implement, and share best practices. This work enables federal and state partners to improve their systems to more quickly and effectively stop an outbreak and mitigate the concern. When possible and appropriate, the partners can identify sources of contamination and contributing factors for the outbreak and reach conclusions and possible interventions for the prevention of future cases. The RRTs developed tools and guidance to share and facilitate improvement on key capabilities that are essential for effective responses to emergencies.

In FY 2010, ORA held a national Rapid Response Team (RRT) conference with all state and federal partners. The conference was devoted to sharing information, discussing adaptation of best practices and identifying next steps to achieve key objectives over the next year. FDA and its partners shared concepts and national initiatives affecting response, discussed metric development, increased engagement with the Council to Improve Foodborne Outbreak Response (CIFOR), and explored way to enhance programs involving the Center for Disease Control (CDC). Conference participants identified areas of strengths in each individual program for broader implementation across all RRTs. The teams worked through various operational challenges, and defined goals aligning FDA and other national priorities with those identified by state partners.

In FY 2010, ORA implemented procedures to distribute weekly situation reports to the

states as well as each Reportable Food Registry (RFR) with the respective affected state to ensure early involvement of state counterparts in emergencies and outbreaks. During recent potential public health crises involving food products such as peanuts, cookie dough and non-fat dry milk, FDA staff worked quickly to develop specialized web pages to assist the industry and consumers by providing them with up-to-date information about the outbreak, the status of FDA's investigation, FDA's and CDC's recommendations to avoid becoming ill, FDA's response efforts, and important links to additional information. The additional information included industry guidance documents, consumer updates, recall information, FDA contact information, informational videos, social media tools, and information about how to report complaints.

Also, during large-scale, high profile, Class 1 recall situations, FDA created, posted and maintained searchable databases in real-time to ensure that the public can quickly identify recalled products. The databases allow consumers to search recalled products in a single, easily accessible location, and with understandable terms including brand name, UPC code, or product description.

FDA/FERN continues to provide training and proficiency testing to its member laboratories. Ten proficiency tests were completed in FY 2010 in all three disciplines of microbiology, chemistry, and radiology.

Training courses are also provided in the three disciplines. FERN participated in a Department of Homeland Security directed Integrated Consortium of Laboratory Networks harmonized check sample analysis as a test of the Laboratory Network concept. Menu 2010, a nationwide exercise of the radiological laboratories, involved 35 laboratories participating in the methodology-driven exercise.

FDA is continuing to enhance its IT interconnectivity with its 44 contract states. These states, which include 23 that conduct Seafood Hazard Analysis Critical Control Point (**HACCP**) inspections, report inspectional information electronically into the electronic State Access to FACTS (eSAF) system for enhanced information sharing between FDA and these states. FDA has several projects underway to further increase information sharing through eSAF, with a current focus on recall audit checks and inspection audits, as aligned with efforts towards state compliance with the Manufactured Food Regulatory Program Standards. This promotes collaboration between FDA and the states that perform this work and will allow the sharing of data in an efficient and secure manner.

In response to the Deepwater Horizon Oil Spill, ORA's Chemistry Mobile Laboratory units were deployed to Tallahassee, Florida in the summer of 2010. While located at the Florida Department of Agriculture campus, ORA field chemists collaborated with the Gulf Coast Seafood Laboratory on the development and validation of an applicable screening method for testing Volatile Organic Compounds (VOCs) in seafood. ORA laboratories analyzed more than 300 composite re-opening samples, 100 surveillance

samples and 100 baseline samples from affected Gulf State waters for presence of oil contaminants. A composite sample is a mix of several individual animals. Tens of closed state harvesting areas were re-opened based on ORA's testing of collected samples. The ORA Chemistry Mobile Laboratories as well as ORA field laboratories will continue to provide public health assistance for local seafood merchants during the recovery phase of the Deep Water Horizon Oil spill that occurred in the late spring of 2010. Both the Chemistry Mobile Laboratory and several field laboratories were equipped or are being equipped to either screen for VOCs or Polycyclic Aromatic Hydrocarbons (PAH) in seafood harvested from areas in the Gulf that were directly impacted by the Oil Spill.

In FY 2010, ORA identified and established a High Throughput Environmental testing laboratory designed to serve as a single point resource in the analyses of up to 86,000 environmental samples per year. The dedicated laboratory will serve as the primary resource for several large scale environmental sampling assignments that will be completed in FY 2011.

As a result of foodborne outbreaks and emergencies, ORA re-invigorated the use of environmental sampling in facilities that are directly or indirectly associated with an outbreak or emergency. This inspection resource provides the Agency with a comprehensive evaluation of the environment in which a food commodity is manufactured and aids in identifying sources and routes of contamination within a facility. ORA is better able to make informed regulatory determinations and work with regulated industry to contain the contamination and identify all affected products for removal or retention from introduction into the U.S. supply chain.

Promoting Efficiency

Improving the coordinated, rapid response among Federal, State and local partners to food-related emergencies through FDA rapid response teams helps to minimize the public health consequences of a food safety incident. Better coordination also promotes more efficient food safety response by Federal, State, and local governments through improved coordination and stronger communication during a response.

The Reportable Food Registry (RFR) is an example of how FDA uses technology to prevent food safety threats from leading to consumer illness or death. The RFR provides a reliable mechanism to track patterns of adulteration in human food products. FDA investigates reports of RFR to assure that contaminated foods are contained and recalled before illness or injury occurs.

ORA's use of grants and contracts with the states continues to leverage working relationships with state counterparts at the local level to improve surveillance activities, to enhance an integrated food safety system and to respond to public health threats in a timely and efficient manner. These programs assist FDA efforts during trace-back investigations, provide greater inspection coverage for ORA, and enhance food safety and defense through increased communication and integration of key stakeholders.

During FY 2010, FDA field laboratories implemented FDA and National Oceanic and Atmospheric Administration test methods to allow FDA to rapidly and efficiently evaluate and clear seafood products from the Gulf Coast region that may have been affected by contamination from the Deep Water Horizon oil spill. Thanks to these test methods, all Gulf Coast waters were re-opened for business by the end of FY 2010.

During FY 2011, the ORA field laboratories and the mobile chemistry laboratory will continue to evaluate and clear seafood products affected by the oil spill. Having the mobile chemistry laboratories on site in the Gulf Coast increase allows FDA to more efficiently test and clear seafood products. FDA works closely with local seafood merchants, providing analytical results in a timely manner so that merchants can quickly evaluate the safety of their seafood in the shortest time.

Finally, to improve FDA's ability to support response and recovery, FDA Field operations continue to evaluate new technologies that provide faster, more efficient results.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2011
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2010: 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: $24,010,279 (All BA)

Public Health Focus

The public health focus of the Nutrition & Labeling Strategies for Better Health sub-program is to promote healthful dietary practices through truthful and informative labeling on packaged and other foods. Reducing the chronic disease burden of the U.S. population depends in large part on consumers having the knowledge to make wise food choices and the motivation to make those choices consistently throughout all stages of their lives.

Public Health Outcome

CFSAN base resources in this sub-program support achieving this objective through the regulation of food labels and by promoting education and research programs that support good nutrition. FDA also develops new tools that permit consumers to make

better food choices. These activities enable American consumers to make better use of current food labeling information to maintain health and reduce the risk of chronic disease and obesity.

Current nutrition initiatives include dietary guidance statements, updating the Nutrition Facts panel, sodium reduction, and regulatory activities that ensure food labels contain accurate information about the calorie and nutrient content of food that consumers can rely on. CFSAN also has new responsibilities resulting from the Nutrition Labeling of Standard Menu Items in Chain Restaurants under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H). Specifically, the law requires restaurants, similar retail food establishments and vending machine operators — all with 20 or more locations — to provide nutrition information for certain food items. As part of implementing this new requirement, on July 7,2010, FDA published a Federal Register notice soliciting data, and other information relevant to the implementation of the new requirement, such as information about chain retail food establishments and vending machine operators, determination of calorie content of foods offered by retail food establishments, and implementation and enforcement approaches. FDA issued a second Federal Register Notice on July 23, 2010 that explained how retail food establishments and vending machine operators not otherwise subject to the provisions of the new federal menu labeling requirements may voluntarily elect to become subject to them by registering with the FDA. FDA will publish proposed regulations by March 23, 2011 that specify the manner in which restaurants and similar retail food establishments and vending machine operators are to provide nutrition information.

CFSAN base resources were used in FY 2010 to support several regulatory activities to ensure that food labels were truthful and not misleading. CFSAN notified 17 food manufacturers that the labeling for 22 of their food products violated the Federal Food, Drug, and Cosmetic Act. The violations cited in the warning letters include unauthorized health claims, unauthorized nutrient content claims, and the unauthorized use of terms such as “healthy,” and others that have strict, regulatory definitions. In addition, CFSAN created and recorded a food labeling training webinar and video for FDA foreign post staff to use as a tool when aiding foreign food manufacturers on labeling their products for import into the U.S. CFSAN also completed the Spanish translation of the Food Labeling Guide, a comprehensive booklet that explains FDA’s food labeling requirements. Furthermore, CFSAN jointly sponsored with USDA a delegation to Ghana, Africa to conduct a week-long training on U.S. food labeling requirements to foreign manufacturers.

In FY 2010, CFSAN developed and validated a five-minute method for measuring *trans* fats based on Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) spectrometry. This rapid method can measure less than 1.5% of *trans* fat in total fat, representing a significant improvement in sensitivity and accuracy from previous methods. Given that partially hydrogenated vegetable oils are the major source of *trans* fat in the American diet, this new method allows FDA to ensure a large portion of Americans are accurately informed of *trans* fat content when making their dietary selections.

CFSAN further conducts several education and outreach efforts to promote healthful choices that reduce the risk of chronic disease and obesity. First, with the Cartoon Network, CFSAN maintains a Nutrition Label education program called SPOT THE BLOCK, with a focus on "tweens" — children ages 9-13 — aimed at building awareness of the nutrition label and label reading skills. Evaluation of the program shows that it is effective in getting children to respond to the messages, particularly to perceive the importance of knowing the serving sizes of the food that they eat. Second, CFSAN released a web-based program to inform consumers about using nutrition labels for "Healthy Weight Management." Third, CFSAN expanded an existing project with the National Science Teachers Association to include nutrition education for middle and high school teachers to help teach students to make healthful food choices using the Nutrition Facts Panel.

Promoting Efficiency

The Nutrition and Labeling Strategies sub-program allows American consumers to make informed decisions to improve their diet and health. According to data from the Centers for Disease Control and Prevention (CDC), chronic diseases cause seven out of 10 deaths each year.[1] Poor nutrition contributes to chronic diseases such as hypertension, heart disease and stroke. CDC data indicate that more than 30 percent of the American adult population, or 60 million people, are obese. Treating chronic disease accounts for approximately 75 percent of the $2.0 trillion that America spends on health care each year.[2] Twelve percent of the U.S. Gross Domestic Product goes to treat diseases that are largely preventable or manageable.[3] FDA's Nutrition and Labeling subprogram helps reduce the burden on the U.S. economy associated with obesity and chronic diseases by helping consumers maintain health and reduce the risk of chronic disease and obesity.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
212408: The number of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. (*Outcome)*	NA	NA	+5% over baseline	+5%

Reinventing Cosmetics Safety - Center Activities
Base Amount: $6,895,735 (All BA)

Public Health Focus

The public health focus of the Reinventing Cosmetics Safety sub-program is to protect the public health through FDA oversight of 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, technologies become increasingly sophisticated, and cosmetic ingredients become more complex. The category of products that straddles the line between cosmetics and drugs — "cosmeceuticals" — and products containing ingredients produced through nanotechnology present particular scientific and public health challenges.

Public Health Outcome

CFSAN base resources support product surveys and laboratory investigations and allow FDA to maintain systems for voluntary cosmetic product registrations. CFSAN cosmetics program activities include the evaluation of adverse event reports and consumer complaints. Information from these sources is essential for risk-based approaches to cosmetics post-market monitoring, inspection, and other enforcement activities.

Recent issues with lead in lipstick highlight the need for resources to support both safety assessment and postmarket monitoring of cosmetics. Lead is an unintended contaminant or impurity that can be present at very low levels in some color additives and in other common ingredients, such as water, that are used to produce cosmetics. CFSAN scientists developed and validated a highly sensitive method for the analysis of total lead content in lipstick. Using this method, CFSAN tested the lead levels of specific lipsticks. The results showed that the levels of lead found in these lipstick samples were extremely low and did not present a safety concern. FDA published these findings in November 2009 and investigated a wider range of lipsticks in FY 2010. If CFSAN determines that a safety concern for lead in lipstick exists, CFSAN base funding will support advising the industry and the public and to take appropriate action to protect the health and welfare of consumers.

CFSAN base activities also support several efforts focused on nanotechnology. Cosmetics represent one of the fastest growing areas for the application of this emerging technology. Nanoparticles used in cosmetic ingredients may result in products with different chemical or physical properties that may pose different safety issues. CFSAN base cosmetics program activities support collaborative laboratory investigations with the University of Maryland on various types of nanoparticles and the potential health hazards when used in cosmetics. CFSAN drafted guidance for industry and other stakeholders on the use of nanoscale materials in cosmetics to be published in FY 2011.

Promoting Efficiency

FDA administers the Voluntary Cosmetic Registration Program (VCRP), which benefits consumers and industry. Through VCRP, cosmetic manufacturers can register their manufacturing sites and submit ingredient listings for the products they market. This information allows FDA to stay abreast of the current cosmetics marketplace and guides FDA efforts to protect the health of consumers.

Information from VCRP is also critical to the activities of the Cosmetic Ingredient Review (CIR), an industry-sponsored organization that assesses the safety of cosmetic ingredients and makes the findings available to the public. FDA participates in the CIR, providing information about the types of products in which cosmetic ingredients are used and their frequency of use. The CIR uses this information to assess the safety of specific ingredients and in setting overall review priorities. This safety review program facilitates more efficient product development by providing industry with information on ingredients to avoid or limit to achieve new and safer products, which is a significant benefit to industry and consumers.

Reinventing Cosmetics Safety - Field Activities
Base Amount: $3,489,000 (All BA)

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 United States marketplace.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214208: Number of consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (*Outcome)*	NA	NA	+10% over baseline	+10%

Information Technology Investments – Foods Program Activities
(Base Amount displayed as a non-add item: $135,611,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. FDA also has a number of enterprise system projects that focus on improving the pre-

market review process for all regulated products, post-market surveillance, including adverse event detection, and future scientific computing capabilities of FDA. In addition, each center and office has program specific IT systems.

In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, the following are examples of IT development efforts to enhance IT as it relates to the ability FDA to advance the safety of imported and domestic food, thus enhancing public health and protecting American consumers. FDA is improving effective signal detection and rapid response by developing unified interoperable information-sharing data systems between federal, state, and local agencies. The Reportable Food Registry enables mandatory reporting of instances of adulterated and potentially harmful foods in commerce by industry and facilitates much earlier detection and removal of adulterated foods from commerce. FDA will continue improvements to processing the import data it receives through automated compliance targeting assessment algorithms using a screening tool known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). The rapid implementation of an enhanced scientific computing infrastructure will provide the backbone for the seamless integration of global and scientific data sources, improve trace back, limit the effects of adverse events, and better facilitate industry recovery. Taken together, IT projects such as these will enable FDA to adopt a more proactive response to food safety by capitalizing on pre- and post-market data, scientific research, and current events information to identify threats to the public health, ultimately reducing the incidence of food borne illness outbreaks.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	$457,104,000	$457,104,000	$0	2,569
FY 2008 Actual	$507,797,000	$507,797,000	$0	2,614
FY 2009 Actual	$712,769,000	$712,769,000	$0	2,995
FY 2010 Actual	$783,178,000	$783,178,000	$0	3,387
FY 2011 Continuing Resolution	$781,449,000	$781,449,000	$0	3,387

Summary of the Budget Request

The FY 2012 budget request for the Foods Program is $1,035,080,000. This amount is an increase of $253,631,000 above the FY 2010 Enacted. The Center for Food Safety and Applied Nutrition amount is $302,750,000, supporting 1,147 FTE. The Field amount is $732,330,000 supporting 3,026 FTE.

The base funding for the Foods Program is $781,449,000, which includes $236,000,000 for Foods Program Center activities and $545,449,000 for Foods Program Field activities.

Base funding allows the Foods Program to implement the Administration's vision of a new, integrated, and prevention-focused food safety system to better protect the American public. The initiatives proposed under the requested budget will allow FDA to achieve HHS and Presidential public health priorities, including the requirements of the landmark FDA Food Safety Modernization Act (FSMA). Funding the FY 2012 request will allow CFSAN to protect public health by:

- assessing potential problems
- ensuring that manufacturers use appropriate control measures to reduce or eliminate contaminants in foods
- taking steps to remove products from the market that violate safety standards.

These efforts all help FDA achieve its public health objective of preventing illnesses resulting from contaminated foods and protecting consumers by providing better information to make well-informed food choices to improve their health and help them reduce the risk of chronic disease. CFSAN program activities help to create a structure for FDA, other public health agencies, and industry to exchange information and expertise in real time during an outbreak of foodborne illness and other important emergencies pertaining to any CFSAN-regulated products.

The FDA Foods Program executes its regulatory responsibilities through five sub-programs: 1) Prioritizing Prevention; 2) Strengthening Surveillance and Enforcement; 3) Improving Response and Recovery; 4) Nutrition & Labeling Strategies for Better Health; and 5) Reinventing Cosmetics Safety.

Prioritizing Prevention

<u>Center Activities</u> (Base Amount: $61,798,880)

FY 2012 increase for Voluntary Qualified Importer Program: +$232,000; 1 FTE

FY 2012 increase for Food Export Certification User Fee: $1,185,000; 7 FTE

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls on Farms – FSMA Section 105 (+$5,717,000; 11 FTE)

The public health focus of this initiative is to reduce microbial contamination of fresh produce and increase public confidence in the produce supply through regulation of on-farm and postharvest handling of fresh fruits and vegetables. This investment will also support efforts by the FDA and federal, state, local, tribal, and territorial partners to improve food safety from farm to table. CFSAN will conduct the following activities with the resources in this sub-program:

- establish protective and practical performance standards for key risk factors and develop practical, risk-based preventive controls to enhance produce safety and protect the health of consumers
- provide extensive outreach, education, and technical assistance, especially for small growers, to foster compliance with food safety standards in coordination with regulatory partners, extension services, academia, and industry.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls for Food and Feed Processing – FSMA Sections 101, 103, 104, 110, 204, 405 (+$14,295,000; 37 FTE)

The public health focus of this initiative is to better prevent foodborne illness through implementation of preventive food safety controls in food processing facilities.

Investments in effective controls for hazards in food products will also enhance public confidence in food safety. CFSAN will conduct the following activities with the resources in this sub-program:

- develop and issue regulations, performance standards, and guidance necessary for a prevention-oriented food safety system designed to protect consumers
- develop uniform hazard analysis and risk-based controls guidance to facilitate proper implementation of preventive controls regulations and standards
- develop performance standards for food hazards and evaluate food safety plans for food facilities
- engage in extensive outreach, dialogue, and other efforts with the food industry to ensure FDA standards and guidance are protective and practical.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Safe Food Transport – FSMA Section 111 (+$2,197,000; 4 FTE)

The public health focus of this initiative is to address the risks to human or animal health associated with the transportation of food. Investments in preventive controls for the safe transport of food will enhance the safety of food through improved practices concerning sanitation, packaging, isolation, and other protective measures, including information sharing between shippers and carriers, recordkeeping practices, and

limitations on the use of vehicles. CFSAN will conduct the following activities with the resources in this sub-program:

- create and fund state and U.S. Department of Transportation inspection assignments to collect data on temperature control and other food safety concerns
- conduct comprehensive research on food transportation and evaluate safety and security issues specific to food transportation, such as sanitation, pest control, employees training, and safeguards against tampering
- define cleaning protocols for transportation vehicles, establish associated performance standards, and establish test methods to demonstrate compliance
- establish a training curriculum to address safety and security issues for food transportation workers
- draft a proposed rule and guidance on industry practices and transportation-related food safety risks
- encourage the use of cooperative compliance models though outreach to industry and the scientific community during the rulemaking process.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Retail Food Safety – FSMA Section 209 (+$2,640,000; 4 FTE)

The public health focus of this initiative is to reduce contamination of foods associated with food handling practices at the point of preparation and service through improved Food Code compliance at retail and foodservice outlets. Investments in retail food safety will enhance consumer confidence regarding food safety in the retail and foodservice sectors. CFSAN will conduct the following activities with the resources in this sub-program:

- promote more widespread state and local enrollment in, implementation of, and accountability for the FDA Retail Food Program Standards
- study and address obstacles that prevent adoption of the FDA Food Code
- collaborate with the retail industry to foster training and manager certification, and other industry-based initiatives to increase Food Code compliance
- revise the FDA Food Code and update the Retail HACCP Guides to keep them current with the understanding of effective risk mitigation strategies and concepts
- expand existing collaborations with institutional foodservice sectors, including school lunch programs, nursing homes, and hospitals, to promote enhanced understanding of the Food Code and foodborne illness prevention
- conduct research and provide advice on technologies and methods that prevent, mitigate or detect foodborne illness hazards in the retail environment
- develop guidance for the retail industry that describes best practices to control viral and bacterial pathogens and to reduce allergen hazards.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight – FSMA Sections 201, 211, 301-308 (+$7,737,000; 27 FTE)

The public health focus of this initiative is to increase assurance that the food imported into the U.S. is as safe as domestically produced food. This initiative will allow FDA to establish a comprehensive, prevention-focused imported food safety program by shifting from an import safety approach based on reacting to problems to one that prevents such problems from occurring at appropriate points along the global food supply chain. CFSAN will conduct the following activities with the resources in this sub-program:

- Conduct initial assessments to determine countries that have comparable food safety systems or robust commodity specific export programs, followed by periodic system audits of comparable countries
- Conduct initial assessments of recognized third party certification programs
- Establish programs to recognize and accredit third party certification programs for food imports, followed by periodic systems audits
- Develop and begin to implement an importer accountability verification program
- Establish partnerships with other public health agencies to execute international outreach, training, technical support, and capacity building, and conduct specific workshops for Good Agricultural Practices (GAPs) training.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Critical Capacity for Implementation of FSMA (+$1,015,000; 0 FTE)

This initiative directly supports CFSAN operations and its work with other FDA units to achieve the Administration's food safety priorities. The buildings that house CFSAN are at full capacity. Without additional space to support expanding food safety workload and corresponding staffing increase, CFSAN cannot successfully implement the FDA Food Safety Modernization Act. CFSAN will conduct the following activities with the resources in this sub-program:

- renovate and outfit existing, unfinished building space to increase facility capacity
- install security devices, such as biometric readers and enhanced security surveillance tools, to comply with Select Agent Security standards
- reconfigure existing laboratory facilities at the University Station building.

Field Activities (Base Amount: $107,199,000)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($3,725,000; 13 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 conduct the following activities with the resources in this subprogram:

- hire 3 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 1 FTE to serve in Headquarters for program oversight and as a program auditor and 1 FTE for program oversight thru ORA audits of regulatory and public health partners to measure performance against FDA program standards
- hire 2 FTE at Headquarters and 4 FTE as field state liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards (MFRPS)
- hire 2 FTE to develop and validate certification testing instruments.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls on Farms – FSMA Section 105 ($3,537,000; 6 FTE)

Investments to develop and disseminate knowledge and building capacity within and outside FDA to support the regulation of on-farm and post-harvest handling of fresh fruits and vegetables will reduce the risk of foodborne illness and enhance public confidence in the produce supply. ORA will conduct the following activities with the resources in this sub-program:

- hire 2 FTE to manage the program, provide assistance to State Regulators, and provide funding to State Regulators to attend the train-the-trainer courses and the Produce Safety Alliance training course.
- hire 4 FTE to serve as program and national Produce Safety experts
- develop a curriculum to train personnel assigned to produce safety compliance, inspection and enforcement activities. Provide training to FDA laboratory personnel regarding new training methods and detection protocols developed by the science program within FDA to use on produce directly from farms and on-farm/postharvest environmental.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls for Food Processing – FSMA Section 110 ($8,919,000; 2 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- develop preventive controls-based inspection training or revamp existing GMP training to address preventive controls

- administer training on preventive controls to both FDA and State investigators. These resources will fund approximately 3,380 personnel – ORA Inspection personnel and State, Tribal, and Territorial regulatory partners – to attend a one-week training course utilizing a combination of face- to-face and distance learning mediums.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Retail Food Code – FSMA Section 210 ($2,955,000; 2 FTE)

Investments will allow FDA to promote widespread state and local enrollment in, implementation of, and accountability for the FDA Retail Food Program Standards. ORA will conduct the following activities with the resources in this subprogram:

- establish contracts, cooperative agreements, or grants for state, local, territorial, and tribal agencies seeking to institute innovative compliance and enforcement strategies that promote improved and sustained managerial control of key operational risk factors
- Hire a contract monitor and state liaison.

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance

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Center Activities (Base Amount: $114,801,090)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls on Farms – FSMA Section 105 (+$1,342,000; 4 FTE)

Investments to support the regulation of on-farm and postharvest handling of fresh fruits and vegetables will reduce the risk of foodborne illness and enhance public confidence in the fresh produce supply. CFSAN will conduct the following activities with the resources in this sub-program:

- assess the value of specific preventive controls for safe produce growing and packing
- develop, evaluate, and validate rapid, specific, and sensitive microbiological test methods for various produce items and for environmental sampling on the farm and during postharvest handling
- estimate the risks associated with industry practices through field and laboratory microbiological studies.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls for Food and Feed Processing – FSMA Sections 101, 103, 104, 110, 204, 405 (+$2,119,000; 9 FTE)

Investments to support implementing preventing controls for food in processing facilities will result in better prevention of foodborne illness and increased public confidence through effective controls for hazards in food products and expanded inspection and compliance programs to facilitate the proper implementation of controls. CFSAN will conduct the following activities with the resources in this sub-program:

- validate the effectiveness of widely used process controls to provide industry and FDA with a better understanding of successful food safety processes
- develop and validate methods to evaluate performance standards for food hazards.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 202, 204, 205, 209, 210 (+$2,119,000; 9 FTE)

These investments support the implementation of an integrated, national food safety system that will provide greater and more efficient coverage of the food supply. The investments will reduce the incidence of foodborne illness by creating a sustainable public health infrastructure at all levels of government. CFSAN will conduct the following activities with the resources in this sub-program:

- assess the processes, data systems, and analytical capabilities needed to develop and manage a national work plan and share federal and state inventories to reconcile food establishment, inspection, and outbreak information
- develop and begin to implement standard laboratory practices, procedures, and national accreditation standards for food safety laboratories to ensure consistent and meaningful data for compliance, surveillance, and environmental samples.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight – FSMA Sections 201, 211, 301-308 (+$1,846,000; 2 FTE)

The public health focus of this initiative is to increase assurance that the food imported into the U.S. is as safe as domestically produced food. Investments in science will allow FDA to improve decision-making about the admissibility of imported food and to better target products from countries that pose the greatest risk. CFSAN will conduct the following activities with the resources in this sub-program:

- Develop and/or validate new methods, rapid test kits, data sources, and analytical packages to support faster and more accurate import screening and to better target sampling at the border.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Critical Capacity for Implementation of FSMA (+$13,755,000; 18 FTE)

To support FDA's farm-to-table prevention measures, FDA will invest in risk analysis, laboratory capacity, and scientific methods. In order to enhance the capability of the

FDA to identify adulterated products through improved risk analysis, CFSAN will conduct the following activities with the resources in this sub-program:

- Develop and test modern tools to identify, evaluate, and prioritize risks
- Establish systems that use these tools to support sound risk management decisions, mitigation strategies and effective risk communications practices
- Better prioritize sampling and inspection programs
- Enhance the Safety Reporting Portal and consumer complaint reporting system.

Likewise, in order to enhance current scientific capabilities, operations, and capacity, and develop and adopt novel rapid detection methods to better protect the American food supply, CFSAN will conduct the following activities with the resources in this sub-program:

- evaluate new detection technologies and develop new and improved methods for detecting contaminants and pathogens to improve response, recovery, and overall efficiency in food testing laboratories
- procure the necessary labor, equipment, and supplies to improve and expand the capabilities of laboratory facilities and to update scientific workstations and specialized laboratory computers.

FDA Regulatory Science and Facilities: Nanotechnology (+$750,000; 2 FTE)

For the FY 2011 nanotechnology initiative, CFSAN will conduct activities that support the following FDA-wide priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary research to address product characterization and safety. Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Field Activities (Base Amount: $273,955,000)

FY 2012 increase for Voluntary Qualified Importer Program: +$61,000,000; 265 FTE

FY 2012 Food Safety Training – FFSMA Section 209: +$8,000,000 / 0 FTE

FDA will spend $8.0 million on food safety training. FDA will develop and implement a national food safety training system to provide the knowledge and skills required for regulators and public health partners at all levels of government. FDA will also develop a related certification system to ensure the competency of the workforce. These resources support the authorities enacted by Congress in section 209 of the Food Safety Modernization Act. This investment will help ensure that FDA maintains a skilled national workforce to ensure that the food industry is meeting food safety standards.

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight for Food – FSMA Sections 201, 301, 302, 305, 306 and 307 ($12,444,000; 52 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- hire 3 FTE to establish equivalence standards and assess whether other nations' food safety systems are comparable to ours and establish standards for third-party certification for imported food
- hire 14 FTE to develop, implement and conduct VQIP inspections
- hire 1 FTE to liaison with Customs and Border Protection to develop, evaluate and share voluntary programs
- hire 22 FTE to implement the Import Accountability Verification Program
- hire 5 FTE in Headquarters Operations to handle Import Alerts, Import Bulletins, assignments, guidance documents, procedures, training, bond mitigation and compliance review
- hire 2 FTE to increase security review capacity at the Prior Notice Center
- hire 5 FTE to increase enforcement expectations, Import Alerts/Import Bulletins recommendations, refusals and mitigations.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($1,868,000; 8 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 conduct the following activities with the resources in this subprogram:

- hire 1 FTE to serve as a National Work Plan Manager and 1 FTE to serve as National Work Plan Analyst. These FTE will assist ORA with its movements towards an integrated national workplan.
- hire 3 FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- hire 2 FTE to serve as Scientific Coordinators and 1 FTE as an IT Specialist. These resources will support the states as FDA moves to national standards for laboratories.

Transforming Food Safety and Nutrition: Nutrition for Better Health – Menu and Vending Machine Labeling - ($6,289,000; 2 FTE)

FDA will partner with state, local, territorial, and tribal regulatory partners to establish inspection programs to evaluate compliance with the new menu labeling standards. ORA will conduct the following activities with the resources in this subprogram:

- establish Menu Labeling contracts. Contracts will be targeted to state agencies or subdivisions of a state, county or city government with the regulatory authority to administer rules or policies that govern the inspections of restaurants and similar retail food establishments chains subject to the Nutrition Labeling of Standard Menu Items in Chain Restaurants under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H).
- develop training for state inspectors to include web-based course and reference document
- hire 1 FTE to serve as Commissioning Agent and 1 FTE to serve as a Contract Monitor.

Transforming Food Safety and Nutrition: Laboratory Capacity and Capability (+$19,184,000; 80 FTE)

Using budget authority funding, ORA will build on existing capacity and capability through the hiring of an additional 80 laboratory analysts and technicians.

FDA Regulatory Science and Facilities: Nanotechnology ($277,000; 1 FTE)

ORA will conduct activities that support the following FDA-wide priorities:

- laboratory and product testing capacity
- scientific staff development and training
- collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Proposed User Fee: International Courier User Fee (+690,000; 3 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities, and the number continues to grow. These shipments are often destined for individual consumers or for illegal distribution. The user fee resources for this activity allow increased import surveillance of FDA-regulated products at express courier hubs.

Current FDA staffing does not match the expected growth in import volume. Federal Express and other couriers indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

With this new user fee, FDA will:

- conduct entry reviews
- sample collections and physical exams to determine product admissibility into the U.S.
- initiate compliance actions to prevent release of unsafe products into U.S. commerce
- establish import controls to prevent future unsafe products from entering U.S. commerce.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

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Center Activities (Base Amount: $21,870,331)

FY 2012 increase for Recall User Fee: +$464,000; 2 FTE

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight – FSMA Sections 201, 211, 301-308 (+$3,026,000; 12 FTE)

The public health focus of this initiative is to increase assurance that the food imported into the U.S. is as safe as domestically produced food. The FDA Import Oversight program will shift the burden of import compliance from the limited FDA inspection force to importers and others who participate in the foreign food supply chain. This investment will allow FDA to protect American consumers and address the threat to food safety posed by dramatic growth in the volume of imported food. CFSAN will conduct the following activities with the resources in this sub-program:

- better target FDA foreign food inspections to countries and facilities deemed to not have systems comparable to the U.S. system or not having robust export programs and that do not participate in third party certification programs
- assist ORA in improving risk informed timely admissibility decisions and enforcement;
- support ongoing subject matter expertise and support for entry admissibility and enforcement activities, including PREDICT, Import Bulletins/Alerts, and inspection and enforcement strategies.

Field Activities (Base Amount: $111,446,000)

FY 2012 increase for Food Reinspection User Fee: +$6,825,000; 48 FTE

FY 2012 increase for Recall User Fee: +$9,397,000; 23 FTE

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($32,328,000; 0 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 more uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- provide funding to federal, state, local, territorial and tribal regulatory and public health partners in the form of at least twenty states grants, cooperative agreements or inter-agency agreement between federal agencies.
- improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application and enforcement of food safety laws, and regulations.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight for Food – FSMA Sections 201, 301, 305, 306 and 307 ($12,435,000; 44 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- hire 2 FTE to perform periodic audits of Foreign Food Safety System Comparability Program
- hire 2 FTE to perform period audits of the Commodity Specific Export Certification Program
- hire 2 FTE to conduct audits of foreign regulatory bodies
- hire 15 FTE to perform performance assessments and audits of the Third-Party Certification Recognition/Accreditation Program
- hire 3 additional FTE to serve as foreign inspection trip planners
- hire 19 FTE to expand existing foreign inspection program
- hire 1 FTE to begin developing a foreign inspection Workplan.

Improving Response & Recovery

Center Activities (Base Amount: $6,623,685)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 202, 204, 205, 209, 210 (+$3,895,000; 10 FTE)

These investments support the implementation of an integrated national food safety system that will provide greater and more efficient coverage of the food supply. The investments will reduce the incidence of foodborne illness by creating a sustainable public health infrastructure at all levels of government. CFSAN will conduct the following activities with the resources in this sub-program:

- strengthen FDA preparedness, surveillance and outbreak detection, outbreak response and investigation, and post response activities under the FDA Foodborne Outbreak Team
- improve rapid response and recovery efforts by integrating and coordinating the capabilities of federal, state, and local partners to more efficiently use federal, state, and local response resources
- develop and implement traceback procedures
- align FDA operating procedures with the nationally recognized Council to Improve Foodborne Outbreak Response (CIFOR) recommendations (http://www.cifor.us/).

Field Activities (Base Amount: $49,360,000)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 301, 302, 305, 306 and 307 ($467,000; 2 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 conduct the following activities with the resources in this subprogram

- fund 1 FTE to develop and implement traceback procedures
- fund 1 FTE to ensure consistency with Council to Improve Foodborne Outbreak Response (CIFOR) guidelines.

Nutrition & Labeling Strategies for Better Health

Center Activities (Base Amount: $24,010,279)

FY 2012 Initiatives

Transforming Food Safety and Nutrition: Nutrition for Better Health (+$2,519,000; 5 FTE)

Menu and Vending Machine Labeling

The public health focus of this initiative is to promote improved diet and nutrition for American consumers and allow them to lower their risk of obesity and chronic disease, and improve their overall health. Nutrition labeling on restaurant menus and vending machine products is a vital tool for consumers to construct healthy diets. CFSAN will conduct the following activities with the resources in this sub-program:

- review regulatory issues associated with the final rule on restaurant menu labeling
- develop and implement extensive outreach and education efforts to promote the final rules on menu and vending machine labeling to both industry and consumers
- establish inspection programs to evaluate compliance with the new menu labeling standards, in partnership with state and local governments.

Advancing Regulatory Science: Nutrition for Public Health (+$1,350,000; 2 FTE)

The public health focus of this initiative is to enhance food-labeling programs to enable American consumers to make more informed and healthful food choices, maintain health, and reduce the risk of chronic diseases such as type 2 diabetes, cardiovascular disease, and obesity. Under this initiative, CFSAN will modernize food labels to enhance the usefulness of nutrition information to the consumer. Through the regulatory actions supported by this initiative, the Agency will develop nutritional criteria for labeling on the front of food packages that consumers can rely on to make informed choices for healthy eating. This initiative will allow FDA to increase use of nutrition labeling and standardize front of package labeling to enable food choices that help consumers lower their risk of chronic disease.

Field Activities (Base Amount: $0)

Reinventing Cosmetics Safety

Center Activities (Base Amount: $6,895,735)

Field Activities (Base Amount: $3,489,000)

BA Increase for Pay Costs: +$1,795,000 (Center: $573,000; Field: $1,222,000)

Contract and Administrative Savings: (Total Program: -$6,707,000; -30 FTE)

The Center for Food Safety and Applied Nutrition (CFSAN) will achieve contract savings by:

- reducing services provided by outside contractors.
- increasing competition by expanding the use of blanket purchase agreements and other agency-wide approaches to contracting.

The Field will achieve administrative savings by:

- reducing administrative support FTE, both in Headquarters and in the field offices
- consolidating tasks and eliminating redundancies, the Field anticipates productivity and efficiency gains throughout the organization.

CFSAN Program Activity Data

PROGRAM WORKLOAD AND OUTPUTS	FY 2009 Actual	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FOOD AND COLOR ADDITIVE PETITIONS				
Petitions Filed	6	8 [1]	10 [1]	10 [1]
Petitions Reviewed [1]	8	13 [1]	10 [1]	10 [1]
PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES				
Notifications Received	79	96 [4]	100 [4]	100 [4]
Notifications Reviewed [2]	87	73 [4]	100 [4]	100 [4]
INFANT FORMULA NOTIFICATIONS				
Notifications Received [5]	39	36	35	35
Notifications Reviewed [6]	29	39	35	35
FDA Review Time	90 Days	90 Days	90 Days	90 Days
NEW DIETARY INGREDIENT NOTIFICATIONS [7]				
Submissions Received [8]	54	45	55	60
Submissions Reviewed [9]	50	41	50	55
FDA Review Time	75 Days	75 Days	75 Days	75 Days

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

[2] Number reviewed includes notifications that became effective or were withdrawn.

[3] Due to a planned strategic re-deployment in FY 2007, this program was intended to be eliminated and result in the statutorily mandated safety review for food contact substances having to be submitted through the rulemaking process for food and color additives. Because the above redeployment did not take place under the FY 2007 CR or the FY 2008 CR, notifications have continued to be received. This number is greater because it includes those submissions received late in the previous fiscal year where the 120-day statutory timeframe begins in FY 2006 but ends in FY 2007.

[4] Our current estimates assume continued funding of the FCN program.

[5] A notification may include more than 1 infant formula.

[6] Number of submissions reviewed includes some submissions that were received in the previous FY.

[7] 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.

[8] Number of submissions received in current FY includes some received late in the FY that is expected to be completed in the next FY when the due date occurs.

[9] 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 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***8,745***	***10,099***	***12,099***
Domestic Food Safety Program Inspections	5,942	8,291	**To be determined**
Imported and Domestic Cheese Program Inspections	335	204	
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	479	545	
Domestic Fish & Fishery Products (HACCP) Inspections	2,082	1,361	
Import (Seafood Program Including HACCP) Inspections	339	375	
Juice HACCP Inspection Program (HACCP)	288	250	
Interstate Travel Sanitation (ITS) Inspections	998	1,057	
Domestic Field Exams/Tests	3,749	2,400	2,400
Domestic Laboratory Samples Analyzed	12,173	10,305	10,305
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***354***	***994***	***1,044***
All Foreign Inspections	354	994	*1,044* [1]
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***9,099***	***11,093***	***13,143***
IMPORTS			
Import Field Exams/Tests	170,392	140,200	140,200
Import Laboratory Samples Analyzed	30,374	26,549	26,549
Import Physical Exam Subtotal	**200,766**	**166,749**	166,749
Import Line Decisions	9,737,919	10,520,261	11,365,456
Percent of Import Lines Physically Examined	2.06%	1.59%	1.47%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	81,618	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,736***	***11,767***	***10,643***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***189***	***1,000***	***1000***
State Contract Food Safety (Non HACCP) Inspections	8,555	10,500	10,800
State Contract Domestic Seafood HACCP Inspections	1,098	1,200	1,250
State Contract Juice HACCP	76	100	125
State Contract LACF	84	60	75
State Partnership Inspections	189	1,000	500
State Contract and Grant Foods Funding	$16,372,900	$12,007,867	$12,968,497
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$16,705,000	$17,634	$17,730
Total State & Annual FERN Funding	**$33,077,900**	**$12,025,501**	**$12,986,227**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***19,024***	***23,860***	***24,786***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 264 foreign food inspections.