“To take full advantage of our scientific capacity, however, we must move forward strategically. This means defining our mission needs carefully, prioritizing our research and other scientific efforts in accordance with those defined needs, and building bridges among scientists inside and outside FDA to generate synergies, make best use of resources and widely share the fruits of our collective scientific effort”

Leveraging Resources Strategically – FDA recognizes that to ensure the safety of foods and fulfill its public health mission, the agency must embrace new approaches. FDA is focusing on building a prevention-oriented, science- and risk-based food safety system.¹ Inherent in this new approach is the need to work closely with our strategic partners who assist FDA in fulfilling its public health mission and expand the science-base upon which future regulatory programs are developed.

CFSAN’s science and regulatory program is an integral component of the Agency’s foods program and leveraging is a key strategic tool that CFSAN uses to accomplish its mission. Leveraging consists of developing strategic partnerships² with other organizations, such as, an educational institution, another U.S. government agency, a foreign government counterpart, a corporation, and trade or consumer groups to achieve a common food safety goal. Additionally, our program and research offices encourage their scientists to develop collaborations focused on targeted projects with specific deliverables that assist the foods program in its risk-based decision making.

CFSAN’s Centers of Excellence (COEs) program is one of several approaches CFSAN uses to enhance our ability to reach a larger portion of the global food safety community. CFSAN currently supports four COEs: National Center for Food Safety and Technology (NCFST)³; Joint Institute for Food Safety and Applied Nutrition (JIFSAN); The FDA COE for Botanical Dietary Supplement Research at the National Center for Natural Products Research (NCNPR); and Western Center for Food Safety (WCFS).

This report highlights some of CFSAN’s collaborative efforts during calendar year 2012. Additional information on other selected research projects, risk analysis projects, and capacity building initiatives can be found in the Appendices.

---

¹ FDA Strategic Priorities 2011-2015 (http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm227527.htm; accessed 8 Feb 2013)
² Strategic partnerships are long-term joint programs where the partners agree on strategic goals that leverage their individual strengths; commit resources as appropriate; and share responsibilities.
³ NCFST is one of four research centers comprising the Institute for Food Safety and Health (IFSH). The NCFST focuses on the design and performance of a variety of collaborative and cooperative research projects across several research areas, including microbiology, chemical constituents, allergens, food processing, packaging, methods validation, and nutrition.
Collaborating with stakeholders to develop educational and instructional materials on produce safety – In FY 2010, FDA and USDA provided funds to Cornell University through a cooperative agreement from the Agricultural Marketing Service (AMS) to establish the Produce Safety Alliance (PSA). The Alliance is a broad-based partnership charged with developing a national education and training program for farmers and packers of fresh produce as well as regulatory personnel responsible for ensuring compliance with the proposed Produce Safety rule. The PSA is managed by Cornell University to ensure that personnel are available to coordinate and facilitate the efforts of the PSA. Both JIFSAN and WCFS are active participants in the Alliance (http://producesafetyalliance.cornell.edu/).

During CY 2012 progress continued towards the development of a curriculum for fresh fruit and vegetable food safety practices to assist growers and packers to be compliant with the requirements of the Produce Safety rule. The learning objectives for the curriculum were finalized laying the groundwork for content development. The learning objectives are reflective of the ten Working Group summary reports; the results from focus groups with 89 small fruit and vegetable growers across the country; and identified educational needs based on collaborator programs from around the country. The six modules developed will encompass worker health and hygiene, water (production and postharvest), soil amendments, wildlife, postharvest handling, and how to develop a farm food safety plan.

Developing Standardized Industry Oriented Training Materials – The Institute for Food Safety and Health (IFSH, see footnote 3) was provided funding through its cooperative agreement to establish a national Food Safety Preventive Controls Alliance (FSPCA; http://www.iit.edu/ifsh/alliance/index.shtml). The primary mission of the FSPCA is to develop a standardized core curriculum on food safety preventive controls to help firms producing human and animal foods for the U.S. market to comply with Food Safety Modernization Act (FSMA) regulations.

A Steering Committee has been established, comprising of food safety experts from industry associations, academic and extension service, and federal and state government agencies, to direct the activities of the FSPCA and design the structure of the training curriculum. Working groups (WGs) have been established to develop the curriculum content. The development of the curriculum design, course outline and working drafts of key chapters was facilitated through two face-to-face meetings and numerous teleconference meetings. An Editorial Subcommittee has

---

4 The Working Groups composed of 178 members that included farmers, food safety researchers, and food safety professionals.
5 The focus groups were held through the months of February to April to understand the challenges facing growers and the growers preferences related to implementing food safety practices on the farm. Additionally information on preferred learning style, educational media and what produces effective training sessions was obtained.
6 http://producesafetyalliance.cornell.edu/milestones.html (accessed 21 March 2013)
been established to review and synchronize contributions from each WG and further develop the materials for the training curriculum. The food safety preventive controls training curriculum will assist the U.S. food industry to be compliant with the preventive controls regulations and consistently produce safe foods for U.S. consumers. The curriculum will be the basis for training the cadre of trainers necessary to provide the training needed by industry.

**Developing Sustainable Partnerships for Training the International Food Safety Community** –

With the successful development of the Aquatic and Aquacultural Food Safety Center (AAFSC) to promote cooperation in food safety training and research specifically focused on the aquaculture industry, FDA provided funding to pilot three additional virtual Food Safety Training Centers ([http://www.jifsan.umd.edu/training/centers/](http://www.jifsan.umd.edu/training/centers/)). The primary goal of these Centers will be to work with in-country partners to build capacity of both regulators and manufacturers in the use of international best practices in food safety management to better assure the safety of the food supply in a country or region. Each Center would focus on identified needs within the participating countries. These pilots serve as one model that FDA is investigating to expand the technical, scientific and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States as per FSMA Sec 305.

Based on input from the Posts and CFSAN Program Offices, three country/commodity pilots were identified: a Center in Mexico that will focus on Good Agricultural Practices and whose primary partner is SENASICA7; a Center in India that will focus on the Supply Chain Management for Spices and Botanical Ingredients and whose primary partners are CII-FACE8 and the India Spice Board; and a Center in Thailand that will focus on thermally processed foods and whose primary partner is The King Mongkut’s University of Technology Thonburi.

While negotiations with each of the in-country partners were initiated or continued in CY 2012, the Collaborative Centre for Supply Chain Management of Spices and Botanical Ingredients has progressed through Phase I; and a preliminary tri-partite agreement to collaborate has been signed by JIFSAN, CII-FACE, and the India Spice Board. A training program (Phase I) was conducted in Kochi, Kerala, India where 50 participants were introduced to GAPs, GMPs/GHPs and issues related to transportation. JIFSAN tapped subject matter experts at NCNPR as part of the teaching cadre. Of the 50 participants, nine were chosen to participate in the Phase II train-the-trainer workshop scheduled for spring of 2013.

---

7 SENASICA – Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria
8 CII-FACE – Coalition of India Industries – Food and Agriculture Centre for Excellence

“If we invest in local organizations in a responsible and focused way, we can save money and leave behind a legacy long after our dollars are spent”

Enabling Research to Validate Alternative Approaches to Produce Prevention-Based Controls – The Produce Safety Research Network hosted by WCFS, continued to develop a white paper on best practices for designing field trials to evaluate survival of foodborne pathogens in agriculture water and soil amendments used in produce production. These documents will serve as a framework for field trials spanning multiple agro-ecological areas. The first of these documents on agricultural water was published on-line with free access in December 2012. It is anticipated that the document on the use of raw manure as a soil amendment will be published on-line in early 2013. Results from the field trials that are developed based on the Network’s methodology will provide growers or associations data from scientifically-valid studies to support claims that an alternative approach, if appropriate, is at least as equally effective in reducing or eliminating pathogens as the standards in the draft Produce Safety Rule. The documents are available at the WCFS website http://wcfs.ucdavis.edu/saaw.php.

Providing Access and Outreach for FDA-iRISK, a Comparative Risk-Assessment Tool – FDA developed, in collaboration with RSI, and released for public use an innovative risk-assessment tool, FDA-iRISK. This tool can be used to model and estimate the effectiveness of new or proposed food-safety interventions and policies for reducing foodborne illness and to rank risk from various food-hazard combinations, for comparison. iRisk was launched on FoodRisk.org with an introductory webinar on October 4, 2012. Over 200 registrants from 26 countries, including representatives of domestic and foreign government food-safety agencies participated in the webinar. The webinar is hosted on the JIFSAN website.

FDA-iRISK predicts the number of cases of illness prevented by various interventions applied against specific contaminants, in specific foods, at any or all points, from farm to table. By expressing results as a standard public-health metric (DALYs), FDA-iRISK provides a common mechanism for comparing and ranking diverse kinds of risks among multiple food / contaminant combinations. Its automated features reduce the time and labor required for quantitative risk assessments in order to provide faster access to information for regulatory decisions, such as those involving policies or resource allocation. It gives industry and others – including countries that export food to the

---

“Science is the foundation—the critical underpinning—of everything FDA does to protect public health, and food safety is no exception. Congress recognized this basic fact when it enacted the FDA Food Safety Modernization Act (FSMA), which is all about harnessing science to understand and prevent food safety hazards.”

[From blog by U.S. FDA Deputy Commissioner for Foods, M. Taylor, J.D.; October 5, 2012]

---

U.S. – a free, globally accessible, online mechanism for assessing how to improve food safety. FDA-iRISK also fills an unmet need by serving as a global repository and data-sharing platform.

“If we do not adequately ground our regulatory assessments and decisions on the best possible science, we will fail to adequately address potential threats to health, and will fail to deliver on the extraordinary promise that advances in science and technology can offer us today – and in the future – to improve all our lives.”

[From remarks by U.S. FDA Commissioner, Margaret A. Hamburg, M.D.; August 1, 2012 – 2012 FDA Foods Program Science and Research Conference, Silver Spring, MD]

**Conducting Mission Relevant Research through Partnerships** –

**Conducting Research to Inform Risk Assessments on Produce Safety** – Researchers from WCFS, USDA/ARS, and Virginia Tech are conducting field trials to obtain additional data for the Produce Risk Model, a quantitative risk assessment model under development by CFSAN, in collaboration with RTI. The field trials are being conducted in different growing regions (California, Maryland, and Virginia), on different crops (tomatoes, leafy greens) and using different pathogens (*E. coli* O157:H7, *Salmonella*).

The data are enabling CFSAN to develop transfer coefficients – rates of pathogen transfer from feces and soil, for example, to crops – to inform the model. The Produce Risk Model characterizes and predicts (1) risk of crop contamination resulting from specific farming and processing practices, (2) corresponding consumption risks, and (3) optimal intervention and sampling strategies for a given food/pathogen scenario. The model, which will become available for public use when completed, also retroactively predicts during an outbreak at what point in the production and supply chain the food in question had become contaminated, to assist traceback efforts. The latter was enabled, in part, by a virtual laboratory in which the model’s developers simulated pathways of individual items of virtual produce, to track their pathways through their food chains and likely points of contamination therein.

**Enhancing Science Capability for Pathogen Sub-typing** – FDA and JIFSAN scientists collaborated on source tracking, genomics, and antimicrobial resistance of microbial pathogens including *Salmonella* and Shiga toxin-producing *E. coli* (STEC) associated with human illness. Whole genome sequencing of food-borne bacteria is an important tool in the ability to traceback a foodborne outbreak. Draft genome sequences of eight *Salmonella enterica* serotype Newport strains from diverse hosts and locations have been made available in GenBank. These sequences are being analyzed by phylogenetics approaches in order to determine their evolutionary history. Whole genome sequencing analysis was also conducted among major non-

---

O157 STEC strains including, O26, O111, and O103.\textsuperscript{11} Phylogenetic trees revealed a close relationship between O26:H11 and O111:H11. The study indicated that STEC serotypes with the same H antigens might share common ancestors. The data will enable the development of enhanced diagnostic tools for identifying high risk STEC.

Genomic sequencing data complement the data used by regulatory officials obtained from pulsed-field gel electrophoresis (PFGE) data of cultured bacteria collected through Pulsenet. These data will become part of the database being developed through the 100K Genome project. These studies provide valuable scientific data to develop better tools for outbreak investigations and to conduct risk assessment on emerging foodborne pathogens.

**Understanding Survival of Salmonella in Low Moisture Foods** – In the last six years, there have been numerous outbreaks involving *Salmonella* associated with low-moisture foods including nuts, spices, pet food, cookie dough, cereals and snack foods. FSMA requires that facilities identify and evaluate foreseeable biological hazards such as *Salmonella* and identify and implement preventive controls to provide assurances that hazards identified will be significantly minimized or prevented. IFSH organized a cross-disciplinary international consortium of specialists from industry, academia, and government to develop scientific consensus among stakeholders on a framework for validation of preventive controls for low-moisture foods. Activities are aimed at establishing science-based risk prevention strategies for microbial inactivation in low-moisture foods.

Two IFSH research projects conducted on the safety of low-moisture food highlighted here are the survival of *Salmonella* in black pepper\textsuperscript{12} and sanitation guidelines for almond and nut butter processing\textsuperscript{13}. *Salmonella* survival in black pepper was dependent on the relative humidity and temperature of the environment. *Salmonella* inoculated into black pepper was able to grow if water activity was increased to 0.9793 +/- 0.0027. *Salmonella* rapidly died off in black pepper stored at high relative humidity (97%) and temperature (37°C), but was not completely eliminated. At lower relative humidity (< 33%) and temperature (25°C), however, *Salmonella* may survive for well over a year. Results from the project on sanitation for almond and nut butter processing, suggested that hot oil alone may not be efficient to eliminate *Salmonella* from a contaminated peanut butter processing line. A two-step process consisting of a hot oil cleaning step followed by a 60% isopropanol sanitization treatment was found to be


effective.

This research is building a “toolbox” for process validation by giving the industry the supporting data, knowledge, and tools needed to validate preventive controls for processing of low-moisture foods. The findings on the effect of water activity, humidity and temperature on survival of *Salmonella* on black pepper provide scientific data for a risk assessment of the product. The hot oil-isopropanol two-step process evaluated in this project is of direct benefit to the industry for more effective cleaning and sanitization of nut butter processing lines.

**Obtaining Data to Inform a Risk Assessment on Spices** – In support of a draft risk profile that has been completed (see Appendix B), FDA undertook a comprehensive study of *Salmonella* contamination of spices imported into the United States.\(^\text{14}\) This study was part of a larger effort by FDA to conduct spice safety research in order to assess the public health risk of salmonellosis from consuming spices in the U.S. and to assist in the identification of mitigation options (see above). Shipments of imported spices offered for entry to the United States were sampled during the fiscal years 2007-2009. The data indicated that there was a wide diversity of *Salmonella* serotypes isolated from spices; a larger proportion of shipments of spices derived from fruit/seeds or leaves of plants were contaminated than those derived from the bark/flower of spices plants; and *Salmonella* prevalence was larger for ground/cracked spices than for shipments of their whole spice counterparts. Additionally, some shipments reported to have been subjected to pathogen reduction treatment prior to being offered for entry into the U.S. were found contaminated. Statistical differences in *Salmonella* shipment prevalence were also identified on the basis of the export country.

**Enabling Leveraged Research to Support Regulatory Actions** – Researchers at NCNPR determined that methylhexanamine (MHA), also known as dimethylamylamine (DMMA) is not naturally present in authenticated geranium (*Pelargonium graveolens*) leaves, stems, roots or oil at detectable levels (LOD – 10 ppb). The data show that MHA, if present at all, would be present at an amount less than 0.000001% in geranium oil.\(^\text{15}\) Thus, simple mathematics supports the fact that DMMA found in dietary supplements (at > 1 mg/g) sold in the U.S. must be synthetic. Although this study was supported by the U.S. Anti-Doping Agency, NCNPR coordinated the effort with CFSAN/DSS. The results of this study were used to support FDA’s position on the ten warning letters issued in 2012 ([http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm346576.htm#warning_le tters](http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm346576.htm#warning_letters)).

---


Building Laboratory Food Safety Capacity through Public-Private Partnerships – The International Food Safety Training Laboratory (IFSTL; www.ifstl.org) is a dedicated teaching facility located in College Park, Maryland next door to FDA’s Wiley building. It was developed through a public-private partnership between JIFSAN and Waters Corporation. The IFSTL delivers hands-on laboratory-based training to domestic and foreign scientists in the application of fit-for-purpose chemical and microbiological analytical techniques suitable for monitoring compliance with the broadest range of food safety standards. It provides an opportunity for FDA scientists to participate as part of the teaching cadre. The IFSTL is the first of a global network of training laboratories dedicated to training of analytical methods to detect food contamination. In 2012, Waters Corporation signed an agreement with the United Kingdom’s Food and Environment Research Agency (Fera) to establish the second laboratory in the network. It is anticipated that it will begin offering courses in early 2013. Waters Corporation is also negotiating with partners in China (CAIQ) and Australia to establish two additional training facilities.

Participating in APEC Partnership Training Institute Network (PTIN) – FDA and JIFSAN are actively participating in the activities of the Asian Pacific Economic Cooperation (APEC) Food Safety Cooperation Forum (FSCF) PTIN (http://fscf-ptin.apec.org/) to guide the development of training materials that can be used to strengthen food safety capacity within the APEC member countries. The PTIN provides a venue to engage the food industry, academics, and food safety regulatory bodies to communicate and exchange scientific and technical information related to international food safety standards and best practices. The focus of the PTIN activities in 2012 was to further the APEC laboratory capacity building initiative. The PTIN established a Scientific Technical Advisory Group (STAG) to coordinate and direct the development of future activities to support this initiative. The STAG developed a roadmap to assist member economies or their individual laboratories to identify and prioritize their capacity building efforts based in part on a similar tool developed by OIP and used in Mexico. The roadmap includes a series of self-assessment tools and a decision tree. It is anticipated that the roadmap will be piloted in two economies based on USDA/FAS priorities in FY 2013.

Leveraging Resources Regarding Lead Levels in Foods – CFSAN is a National Participating Institution in WHO’s Global Environmental Monitoring System – Food Monitoring and Assessment Programme (GEMS/Food Programme). As a participating institution, CFSAN reports US data on contaminant levels in foods and food-consumption data to the GEMS/Food database http://www.who.int/foodsafety/chem/gems/en/. CFSAN contributes to this effort through in-kind support to the GEMS/Food Programme. Starting in 2012, CFSAN scientists were detailed for short periods of time at WHO in Geneva to work with the Food Safety group on various food safety reports.

“The FSMA strategy recognizes that the food industry has the primary responsibility and capacity to produce safe food, but it calls for a new definition of public and private roles on food safety and a modern new framework for regulatory oversight, integration of government food safety efforts, and public-private collaboration.”

[From remarks by U.S. Deputy Commissioner for Foods, Michael R. Taylor; September 11, 2012 – 2012 FDA Science Writers Symposium, Silver Spring, MD]
projects, including a high-priority effort to enter, compile, and analyze data on lead levels in foods. These data will be used in a discussion paper that the Codex Committee on Contaminants in Foods (CCCF) is preparing for a March 2013 meeting. CFSAN will be the lead author.

Collaborating with our Canadian government colleagues to assess norovirus risk – FDA is collaborating with Health Canada, the Canadian Food Inspection Agency, Environment Canada, and Fisheries and Oceans Canada, to conduct a quantitative food safety risk assessment on norovirus in bivalve molluscan shellfish; specifically, oysters, clams, and mussels. The risk assessment is evaluating the impact of factors along the food-safety continuum on risk of norovirus from consumption of shellfish. Control measures currently recommended by the two countries are being studied, to determine their impact on public health. The potential of additional prevention/control measures also is being examined. The risk assessment will inform development of a Food Safety Objective and/or Performance Objective. The team has developed a conceptual model for the risk assessment, issued a Federal Register Notice to request data and information, and expects to have completed the data collection phase of the project by the spring of 2013.

Globalization creates real opportunities to collaborate and leverage our collective expertise and resources. Investments globally are critical to FDA’s success domestically.

[Mary Lou Valdez, FDA’s Associate Commissioner for International Programs in “Global Engagement Report”; http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm298576.htm; accessed 08 Feb 2013]
Appendix A – Research through Partnerships – Selected Highlights

“Fostering a culture of collaboration with other research and health agencies in the Federal government, State government agencies, academia, with private industry and with foreign regulatory bodies will expand scientific capability and permit the FVM Program to benefit from the great strides being made across the country and globally.”
[From FDA Foods and Veterinary Medicine Program Strategic Plan 2012-2016, April 2012, page 19.]

Produce Safety – Researchers at WCFS undertook a study to understand factors that impact the fate of E. coli O157:H7 and Salmonella in field\textsuperscript{16} and growth-chamber inoculated cilantro plants. Cilantro was chosen as a model leafy herb because it has similar growing conditions as lettuce. Growth chamber experiments\textsuperscript{17} were performed to evaluate the influence of inoculation method (wet and dry, influence of carrier) and humidity levels on the post-inoculation survival of E. coli O157:H7 and Salmonella on cilantro plants. High humidity and speed of desiccation rate consistently supported greater post-inoculation survival of E. coli O157:H7 in the chamber experiments. Inoculation of cilantro under simulated evening conditions (when humidity levels begin to increase) also supported greater survival. After 48 h, however, similar levels of E. coli O157:H7 were recovered from cilantro irrespective of the humidity at time of inoculation. Survival in wet or dry inoculum carriers was similar under both laboratory and field conditions; and survival of Salmonella was significantly better than for E. coli O157:H7. Increasing the interval from the time of contamination to the point of harvest significantly decreased the likelihood that E. coli O157:H7 would be in the harvested product. The data suggest that differences in the leafy green commodity may impact bacterial survival, which may require the development of different agricultural practices based on commodity.

Nanotechnology and Nanosafety in Food – Within the last decade, advances in nanotechnology have led to an explosion in novel materials available for use in a wide range of consumer products. There is concern that the physical and chemical properties that make nanoscale materials uniquely useful may also contribute to their toxicity. Researchers at CFSAN and the University of Maryland are studying the free radical related biological activity of nano-metal oxides because oxidative damage is the most common mechanism for toxicity induced by nanoscale materials. The research team has found dual enzyme-like activities of iron oxide nanoparticles to implicate their diminishing cytotoxicity\textsuperscript{18}, a pH dependent generation of hydroxyl radicals (self-oxidative dissolution) and


oxygen (cyclic redox reaction) induced by silver nanoparticles\textsuperscript{19}, which may contribute to their biological activities; and the activity of gold nanoparticles was found to be dependent on pH, similar to the silver nanoparticles, as well as exerting enzymatic activity similar to that of superoxide dismutase.\textsuperscript{20} Although the application of these nano-metal oxides as food additives or dietary supplements is rare and challenging, it is imperative that we establish a model system, simulating an intricate food matrix, in order to assess the safety of these nano-metal oxides.

**Allergens** – Food allergies affect an estimated 10-12 million people in the U.S. and the prevalence appears to be increasing. Reliable methods to detect and quantify food allergens are necessary in order to control allergens during manufacture, ensure compliance with food labeling, and ultimately improve consumer protection. Understanding how the allergenic proteins or markers of the allergenic proteins are affected by the food matrix and processing is of utmost importance in establishing accurate methods for quantifying them in foods. Scientists from IFSH, CFSAN/OFS, CFSAN/OARSA, NC State, and Eurofins collaborated in developing matrix-specific incurred reference materials (cookies\textsuperscript{21} and dark chocolate\textsuperscript{22}) for allergen testing to determine whether multiple allergens (peanut, milk and egg) in the same model food can be simultaneously detected, and the effect of processing on reference material stability and allergen detection. Concentrations of milk, peanut and egg in cookies and dark chocolate were measured using different ELISA kits. Results from baked cookies revealed that most kits were not accurate for quantifying any of the tested allergens after baking. Tempering dark chocolate decreased the detection of some of the protein markers for milk (casein and $\beta$-lactoglobulin), but had no significant effect on the detection of peanut, and egg. Further studies are on-going to evaluate peptide, protein and DNA markers for allergens in foods. The identification of stable allergen markers that can be detected in processed food matrices will enable development of reliable and accurate methods for detecting allergens both in food and in environmental samples obtained in food manufacturing facilities.

**Listeria monocytogenes in ready-to-eat-foods** - As part of collecting much-needed data for the update of the 2003 quantitative risk assessment on *Listeria monocytogenes* in ready to-eat foods (see Appendix B) FDA is collaborating with the USDA Agricultural Research Service (USDA/ARS). The data to be provided for the “Market Basket Survey” will involve prevalence, levels, and subtypes of *Listeria monocytogenes* in ready-to-eat (RTE) foods from retail stores. This project involves collaboration and leveraging resources among FDA, ARS, and FSIS. Sampling plan and study protocols have been developed by FDA/ARS/FSIS joint workgroups. The project was planned and developed with input from the L. monocytogenes RTE Risk Management/Advisor Team (in particular, regarding product selection and the issue of sample blinding) and ORS (testing method and isolates). Assisting in the sample collection are CFSAN’s ORISE fellow at the WCFS


(UC Davis) and students/staff at Drexel University and the University of Georgia. Phase I of the survey included 8,000 samples and has been completed. Preliminary analyses indicate that percent positives of *L. monocytogenes* in the RTE food categories in this study are appreciably lower than those in studies of similar scope and magnitude published a decade earlier. Phase II is underway. On completion of phase II, results from this study may be used to determine the extent of changes in the prevalence and levels of *L. monocytogenes* in higher-risk, higher-volume RTE foods over the past decade. A parallel study between FSIS and ARS will collect 6,500 RTE meat products from the same retail stores. Product labels from samples will be used to develop an ingredients database regarding formulation of different RTE food categories and types of inhibitors used. The findings from this baseline study, phases I and II, will provide data to assess changes (see Appendix B) in *L. monocytogenes* prevalence, levels, and molecular subtypes in RTE foods. This information is critical for sound policy decisions on further control of this pathogen, to reduce its public health burden.

**Botanical Ingredients**– The wide spread usage of Botanical Dietary Supplements in the U. S. market ($4.8 billion per year in 2008) dictates that a thorough scientific analysis of the plant materials that make up these products be evaluated for their composition as well as their inherent safety. The evaluation for botanicals for their potential safety issues is becoming an important research focus for the NCNPR program. NCNPR researchers are working closely with CFSAN to identify potential safety concerns for botanicals utilizing both in-vitro and in-vivo assays. Initial evaluation and bioassay guided fractionation of chamomile species (*Matricaria recutita L.* and *Anthemis nobilis*) for their potential sensitization in an LLNA screening assay has yielded significant results that will be followed up on in CY 2013. Additional in vivo screens were also established in-house for the evaluation of potential hepatotoxicity of botanicals as measured in a mouse model where the hepatotoxicity is manifested by elevation of aminotransferases and histopathological features of acute hepatocellular necrosis and/or biliary injury. A second mouse model was used to measure botanicals for their potential to induce positive reinforcement or cause aversive properties using a conditioned place preference paradigm procedure that is commonly used to evaluate drugs. In CY 2012 green tea (*Camellia sinensis*) was assessed for its potential hepatotoxicity activity and *Salvia divinorum* as well as *Mitragyna speciosa* were assessed for their inductive/aversive behavioral effects. Both models have provided a significant insight as to the safety profile for the tested botanicals, which are commonly used on the market and are relevant to public health.

**FDA and CDC Quantify Listeriosis Risk among Susceptible Populations** – In collaboration with the U.S. CDC, the FDA conducted an investigation to determine the relative risk of listeriosis according to age, pregnancy, and ethnicity, based on CDC’s FoodNet data. The study\(^{23}\) quantifies the increases in risk of listeriosis among older persons, pregnant women, and Hispanics in the U.S. By quantifying the risk among susceptible populations, the study has provided a better understanding of susceptibility to listeriosis, for risk assessments and disease-prevention efforts.

Identifying Data Gaps Related to the Risk from Pathogens and Filth in Spices – FDA completed a draft risk profile describing current knowledge with respect to the public-health risk posed by consumption of pathogens and filth in spices, and the sources of such contamination. The draft, a result of collaborations and partnerships among FDA offices and with CDC, is under agency review. This profile includes in-depth analyses of foodborne outbreaks attributed to pathogen-contaminated spices; prevalence, characteristics, and levels of *Salmonella* and filth in spices throughout the farm-to-table continuum; and efficacy of regulatory, industry, and other mechanisms/mitigations. Also included is a list of critical data gaps that limit our understanding of the problem and possible solutions, and a discussion of potential risk-management options. Two reports on research undertaken to support the risk profile have been published (see pages 8-9).

Developing a Joint FDA/FSIS Risk Model of Cross-Contamination in the Retail Deli – A “virtual deli” model of *Listeria monocytogenes* in virtual delicatessens has been completed jointly by FDA and FSIS and is planned for release in 2013. Delis are complex settings in which cross-contamination may occur. Research shows that this potentially lethal bacterium is more likely to be present in deli meat if it is sliced and packaged on-site, in the deli, rather than by the manufacturer. The computer model mimics the sequences of events that may lead to cross-contamination in the deli, based on data derived, in part, from an FDA/University of Maryland observational study of real-world food-handling practices (http://foodrisk.org/pubs/naf/), and it will enable FDA to test the impact of risk-mitigation strategies. This collaborative effort is the basis for a more comprehensive observational study, using the notational observation tool, by CDC’s Environmental Health Specialists Network (EHS-Net) in collaboration with FSIS.

Updating 2003 Risk Assessment of *L. monocytogenes* in Select Categories of Ready-to-Eat Foods – FDA is collaborating with USDA/FSIS to update a quantitative assessment of the relative risk of serious illness or death from *Listeria monocytogenes* in selected categories of ready-to-eat (RTE) foods, first published in 2003. The purpose of the update is to take into account new scientific data and recent changes in industry practices aimed at reducing *L. monocytogenes* prevalence. Planning for the update was done with input from the *L. monocytogenes* RTE Risk Management/Advisor Team. The new assessment is aligned with new survey studies to fill key data gaps via contracts with a private laboratory and an Interagency Agreement with USDA/ARS (see Appendix A), and via growth studies by CFSAN Office of Applied Research and Safety Assessment (OARSA) and Office of Regulatory Science (ORS) researchers. Following planning and preparation steps already undertaken, FDA has established two IAGs with ARS, to provide funding for (1)
proximate analysis of pH (~2000 samples), $a_w$ (~1000 samples), and growth inhibitors (~500 samples) for *L. monocytogenes* in ready-to-eat (RTE) foods and (2) a study to determine growth of *L. monocytogenes* in a number of selected RTE products.

**Communicating and Collaborating with our Federal Partners** – The Interagency Risk Assessment Consortium (IRAC) is composed of 19 federal agencies or offices with risk assessment responsibilities and interest in food safety. CFSAN, the host agency, serves as executive secretary, co-chairs the Policy Council, has been serving on the Technical Committee and in the coming year will chair that committee. Through IRAC, the agencies work to improve risk assessment research and development of risk assessment tools; enhance communication on these issues; and promote greater use of quantitative risk assessment in regulatory decision-making. CFSAN and IRAC collaborators published a paper describing the findings from an IRAC-sponsored *Listeria monocytogenes* Dose-Response Workshop that was held in 2011. The workshop facilitated a dialogue among experts regarding the latest science on key factors and data to be considered in updating *L. monocytogenes* dose-response models. IRAC also joined with the Interagency Food Safety Analytics Collaboration (IFSAC) to conduct a series of webinars and a workshop on attribution and risk assessment, which addressed CDC methods of attribution (estimating risk from outbreak and illness data); and risk assessment methods and models (estimating risk from contamination, processing, consumption, and dose-response data), such as FDA's iRISK, the FSIS/CDC adaptation of the Danish model, and the FSIS "streamlined two-step" risk assessment. Details about the IRAC charter, annual reports, plans, other white papers, and outcomes of symposia and workshops can be found at [http://foodrisk.org/irac/](http://foodrisk.org/irac/).
Appendix C – Technical Capacity Building

“Food safety is fundamental to the health of individuals and the vigor and vitality of nations. Strong food safety systems are essential for averting threats of hunger, food-borne illness, and major economic losses. Strong food safety systems can facilitate trade and help promote economic development.”


Developing a Standardized Training Curriculum to Assist Sprout Growers – The Sprout Safety Alliance (http://www.iit.edu/ifsh/sprout_safety/) , a public-private partnership was established in 2012. The Alliance is coordinated by IFSH and its goal is to develop a standardized training curriculum to assist sprout growers in minimizing food safety risks in sprout production. A Steering Committee has been established to develop the curriculum content and the training format. Over 50 participants from the U.S. and Canada have been involved in the Alliance Technical and Education & Outreach Working Groups (WGs). The Technical WG has developed detailed draft chapters and the Education & Outreach WG has scheduled initial training and feedback sessions for 2013 to reach out to the industry for input and feedback. The training curriculum will help U.S. sprout growers by enhancing the industry's understanding and implementation of best practices to promote sprout safety and to comply with the produce safety regulations promulgated under FSMA.

Building Laboratory Capacity through Hands-On Training – In 2012, IFSTL (www.ifstl.org) expanded its course offering and delivered seven courses covering such diverse topics as detection of mycotoxins; pesticides in fruits and vegetables; Cronobacter in infant formula; Salmonella in fresh produce; E. coli in fresh produce and meat; microscopic and chemical identification of botanical ingredients; and ISO 17025. The teaching cadre included IFSTL staff scientists; University of Maryland faculty and graduate students; and scientists from the FDA, USDA and EPA as appropriate. Participants worked in regulatory, third party and industry laboratories from Canada, Chile, China, El Salvador, Guatemala, Indonesia, Mexico, Pakistan, Peru, South Korea, Vietnam, and the United States. Eight of the participants were Cochran Fellows24. One course on pesticide analysis was sponsored in part by the USDA/FAS Emerging Markets program for participants from the APEC economies as a train-the-trainer program. Additionally, five on-line training modules were developed. These modules are intended to be introductory and to bring laboratory analysts up to a common baseline level prior to having hands-on laboratory training. It is anticipated that these will be posted in early 2013.

Enhancing Food Safety Risk Analysis Training – JIFSAN’s Food Safety Risk Analysis Professional Development Training Program (http://www.jifsan.umd.edu/prodev/) offers a summer integrated program (SIP), residency risk analysis fellowships, customized in-country training

24 The Cochran Fellowship Program provides participants from middle-income countries and emerging markets, and emerging democracies with high-quality training to improve their local agricultural systems and strengthen and enhance trade links with the United States. http://www.fas.usda.gov/ics/cochran/cochran.asp
programs, and on-line distance learning programs. In the June SIP participants represented Brazil, China, Hong Kong, Italy, Japan, Malawi and New Zealand.

The International Life Science Institute (ILSI)-Focal Point China, Coca-Cola and JIFSAN residency fellowship program in Food Safety Risk Analysis entered its second year. The program was designed to train young Chinese scientists for China’s Center for Food Safety Risk Assessment (CFSA) in the field of microbial risk assessment. After completing the three-week SIP, the second Residency Fellow developed a risk assessment model to assess the risk of *Campylobacter* infection from broiler chickens in China. The Fellow was mentored by JIFSAN SMEs who provided technical guidance to enhance the learning opportunity.

**Training FDA’s Inspectors on Dietary Supplement cGMPs** – In 2012 FDA (ORA-DHRD and CFSAN-DDSP) conducted two dietary supplement trainings for approximately 120 field personnel in Memphis, TN. Since 2009, these trainings have occurred in Memphis, TN to provide our inspectors with an opportunity to visit the NCNPR laboratory facilities where they receive hands-on training on the different analytical methodologies available to authenticate botanical ingredient. This experience enhances their ability to understand the records they review during dietary supplement cGMP inspections. Due to FSMA timelines and demands on added inspections, it is anticipated that 150 new inspectors will need to take the course in 2013 to be ready to conduct dietary supplement cGMP inspections.

**Delivering a Nutritionally-focused web-based Educational Event to the Public** – In March 2012, FDA and JIFSAN collaborated on the developing and delivering the Food and Nutrition Webinar. It was designed for dietetic interns, students and faculty in dietetics and nutrition, and practicing dietitians and nutritionists. The purpose was to communicate FDA’s nutrition and regulatory activities that are relevant to the practice of dietetics and nutrition to the public. The webinar was established to replace the FDA Food and Nutrition Workshops, which had an in-person attendance from the mid-Atlantic region and had been run for approximately 15 years.

The webinar was viewed by over 500 participants and its recordings, which are posted on JIFSAN’s website (http://www.jifsan.umd.edu/events/event_record.php?id=53) have been accessed over 3,000 times throughout 2012. In reaching a larger audience from across the nation and abroad, the webinar format was beneficial in providing up to date and accurate information on the topic of food and nutrition regulatory policies. Twelve Continuing Professional Education (CPE) credits were approved for the Webinar by the Commission on Dietetics Registration of the Academy of Nutrition and Dietetics.
“Achieving food safety is a shared responsibility and different types of stakeholders – including government, the food industry, consumers and their organizations, academic and scientific institutions, etc. – contribute to this capacity…”

[FAO – Strengthening national food control systems: A quick guide to assess capacity building needs, 2007]