Center for Food Safety and Applied Nutrition (CFSAN) Plan for Program Priorities, 2013-2014

Introduction

The Center for Food Safety and Applied Nutrition (CFSAN or Center) is a science-based, public health regulatory center in the Food and Drug Administration. The Center works to ensure that the nation's foods and cosmetics are safe and properly labeled. CFSAN's responsibilities are broad, dynamic, and complex, with a large proportion of the work devoted to addressing new and challenging issues:

- Globalization of the food supply chain
- Changing industry processes
- Consumer preferences for fresh and minimally processed foods

The following plan for program priorities outlines the Center's strategic goals and objectives for protecting the public from adulterated food and cosmetics and for providing useful nutritional information on food labels. The plan recognizes developments in the food and cosmetic sectors and incorporates new responsibilities, tools, and authorities established by the FDA Food Safety Modernization Act (FSMA).

The plan necessarily omits many other important CFSAN food safety, nutrition, and cosmetic programs and activities. These include review of infant formula notifications, pre- and post-market regulation of ingredients and packaging, monitoring for chemical contaminants, authorization of health and nutrient content claims, cosmetics labeling, and ongoing regulatory, enforcement, communications, education, international, and outreach activities. These programs and activities will continue to operate and receive appropriate leadership and management attention to function effectively and efficiently within the bounds of available resources. The Center has finalized a separate **Error! Hyperlink reference not valid.** (http://www.fda.gov/Food/FoodScienceResearch/ResearchStrategicPlan/default.htm). The CFSAN Science and Research Strategic Plan will ensure that the Center's science and research activities are aligned with the Foods and Veterinary Medicine Program's strategic goals and objectives.

Program Goals

The 2013– 2014 Plan for Program Priorities details specific objectives for achieving six key program goals. With the understanding that shifting national priorities and funding limitations may effect change, the Center is focusing its resources and staff to efficiently and effectively meet the challenges ahead.

1. Reduce foodborne illness rates and cosmetic injury rates each year.
2. Establish regulations, policies, guidances, and inspection and compliance strategies based on best science, prevention, and public health risk.
3. Increase compliance with newly created preventive control standards across the farm-to-table continuum.
4. Improve public health indicators through better nutrition and dietary choices.
5. Develop and swiftly deploy the fastest most effective methods for identifying, containing, and eliminating food and cosmetic hazards.
6. Achieve optimal use of staff and resources.

Program Goal 1: Reduce foodborne illness rates and cosmetic injury rates each year.

Objectives

1.1—Implement regulations, guidance, and surveillance to reduce risk of illness or injury

1.1.1: Publish final rule for manufacturing infant formula; a related proposed rule to add selenium to the list of required nutrients for infant formulas; and companion draft guidance on exempt and eligible infant formula.	2013
1.1.2: Publish final rule defining " gluten free" and on using the term on food labels, and a related proposed rule to clarify how FDA will determine compliance with the final gluten-free labeling rule for foods that cannot be tested for gluten using standard analytical methods (particularly fermented or hydrolyzed foods).	2013

1.1.3: Publish draft risk assessment and guidance on arsenic levels in apple juice.	2013
1.1.4: Determine whether guidance levels are needed for arsenic in other foods.	2014
1.1.5: Publish draft guidance to provide information to help growers, manufacturers, and food service operators understand and take steps to reduce potential human health risks posed by acrylamide levels in certain food products.	2013
1.1.6: Publish draft guidance for industry regarding the egg safety rule for layers with outdoor access.	2013
1.1.7: Publish final guidance on assessing the effects of significant manufacturing process changes, including emerging technologies (e.g., nanotechnology) on the safety of food ingredients (including color additives) and food contact substances.	2013
1.1.8: Publish final guidance on the safety of nanomaterials in cosmetic products.	2013
1.1.9: Develop draft guidance on lead in lipstick.	2014
1.1.10: Increase environmental sampling and targeted surveillance to identify violative products.	2013 & 2014
1.1.11: Draft proposed rule on recordkeeping requirements for high-risk foods to facilitate tracing.	2014
1.1.12: Publish guidance on current good manufacturing practice requirements for cosmetics.	2013

1.1.13: Publish draft guidance on conflict of interest for experts participating on GRAS panels.	2014

1.2—Improvesafety and labeling of dietary supplements and the supply chain.

1.2.1: Modernize postmarket surveillance system for regulating dietary supplements.	2013
1.2.2: Develop and implement risk-based compliance and regulatory strategies to address dietary supplement safety issues.	2013
1.2.3: Publish revised draft guidance on new dietary ingredients (NDIs) to increase premarket oversight of dietary supplements.	2013
1.2.4: Publish final guidance on new dietary ingredients (NDIs) to increase premarket oversight of dietary supplements.	2014
1.2.5: Publish final guidance to help dietary supplement and beverage manufacturers and distributors determine whether a liquid food product (such as energy drinks) may be labeled and marketed as a dietary supplement.	2013

Program Goal 2: Establish regulations, policies, guidances, and inspection and compliance strategies based on best science, prevention, and public health risk.

The Center for Food Safety and Applied Nutrition is committed to science-based research and regulations.

Objectives:

2.1—Adopt new regulations that protect the food supply from contamination.

2.1.1: Expand and promote standards for uniform Food Code adoption, enrollment, implementation, and accountability.	ongoing
2.1.2: Publish proposed preventive control rule for safely transporting food.	2014*

2.1.3: Publish proposed rule for accreditation of third party auditors.	2013
2.1.4: Publish proposed rule for intentional contamination.	2013*
2.1.5: Develop for publication in 2015final rule for intentional contamination.	2014*
2.1.6: Develop for publication in 2015final preventive controls rule for food processing facilities.	2014*
2.1.7: Develop for publication in 2015final preventive controls rule for produce safety.	2014*
2.1.8: Develop for publication in 2015 final rule on accreditation of third party auditors.	2014*
2.1.9: Publish final rule prohibiting the use of certain cattle material to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics.	2014

**Dates may change depending on outcome of pending litigation.*

2.2—Continuously update the scientific basis for preventive control standards.

2.2.1: Establish metrics, including data acquired through outbreaks, for evaluating the effectiveness of preventive controls.	ongoing
2.2.2: Address approach to determine most significant foodborne contaminants for FSMA section 104(a).	2014
2.2.3: Address approach to determine high risk foods for FSMA section 204(d)(2).	2014
2.2.4: Publish final *Listeria monocytogenes* risk assessment for meats, cheese, and other ready-to-eat foods prepared in retail delis.	2013

2.2.5: Publish draft risk assessment(s) for arsenic in rice and rice products.	2014
2.2.6: Develop improved virulence-based assessment and surveillance of non-0157:H7 STEC in high priority food commodities.	2014
2.2.7: Complete projects related to the risk of microbiological hazards associated with *Salmonella* contamination of fresh cut tomatoes and peppers.	2014
2.2.8: Complete multi lab validations for an enhanced microbiological assay and complementary rapid qPCR assay for surveillance and detection of *Salmonella* Enteritidis directly from shell eggs.	2014

2.3—Develop and maintain leading-edge scientific computing capability.

2.3.1: Harmonize data collection and exchange of data for food products and ingredients in line with the FDA’ s Data Standards using the integrated Unique Ingredient Identifier/ Food Code.	ongoing
2.3.2: Develop a comprehensive database and related tools that will provide a new approach for creating a standardized, all-inclusive “ Catalog” of foods, agrochemicals used for growing foods, food additives, food ingredients, dietary supplements and cosmetics using the FDA’ s Substance Registration System	ongoing
2.3.3: Conduct outreach on electronic submissions through guidance and training to food industry using FDA’ s Electronic Submissions Gateway and FDA’ s Data Standards for Regulated Product Submissions for food ingredient applications.	ongoing

2.3.4: Expand cutting-edge information technology capability to enable CFSAN scientists to review and take agency actions efficiently to meet FDA’ s food safety review goals.	ongoing

2.4—Direct CFSAN research and review science capability and investment to priority areas.

CFSAN has employed a prioritization method that it continues to modify as needed.

2.4.1: Develop and apply analytical tools to available data to understand and forecast trends.	ongoing
2.4.2: Align food ingredient and cosmetics research programs with the FDA nanotechnology initiative.	2013
2.4.3: Continue to develop theChemical Evaluation and Risk Estimation System (CERES) and apply its knowledge base and *in silico* toxicology methodologies to the pre- and post-market safety evaluation of food and color additives, GRAS ingredients and food contact materials.	ongoing
2.4.4: Develop policy/regulatory options for “ energy drinks.”	2013

Program Goal 3: Increase compliance with newly created preventive control standards across the farm-to-table continuum.

An important provision under FSMA is the focus and specific directives on establishing new and strengthening existing preventive control measures throughout the food sector. CFSAN is addressing these as they relate to its responsibilities.

Objectives:

3.1—Facilitate effective implementation of preventive controls.

3.1.1: Issue draft updated good agricultural practices guidance.	2014

3.1.2: Issue draft guidance on acidified foods to help commercial food processors determine whether their food products are subject to FDA regulations regarding acidified foods, including regulations for specific current good manufacturing practice requirements, establishment registration, and process filing.	2013
3.1.3: Issue performance standards for specific hazards.	ongoing
3.1.4: Implement science-based strategies to educate consumers on the adoption of safe food handling practices as prevention measures.	ongoing

3.2—Ensure that safety standards are the same for imported food and cosmetics as they are for domestic food and cosmetics. Ensure that all foods meet preventive standards.

3.2.1 Refine process to determine appropriate foreign inspection targets based on risk and available resources.	2013
3.2.2: Effectively use capacity building and technical assistance programs in collaboration with other organizations.	2013
3.2.3: Refine process to file product processes subject to FDA regulations to utilize current technology to ensureadequacy and food safety for low acid canned food products.	2014
3.2.4: Complete systems recognition assessment with Canada under pilot program.	2014
3.2.5: Begin systems recognition assessment with Australia under pilot program.	2013

Program Goal 4: Improve public health indicators through better nutrition and dietary choices.

Objectives:

4.1—Implement science-based strategies that encourage consumers to choose healthy diets.

4.1.1: Educate consumers about the health benefits of the 2010 Dietary Guidelines for Americans.	ongoing
4.1.2: Conductconsumer outreach on use of the nutrition labeling.	ongoing
4.1.3: Publish proposed rules to update nutrition facts label and serving size information to improve consumer understanding and use of nutrition information on food labels.	2013
4.1.4: Publish guidance on medical foods.	2013
4.1.5: Publish draft guidance on substantiating structure function claims for infant formula.	2014
4.1.6: Develop for publication in 2015final rules to update nutrition facts label and serving size information to improve consumer understanding and use of nutrition information on food labels.	2014
4.1.7: Publish proposed rule on dietary guidance statements in food labeling to improve consumer understanding of the usefulness of a food or a category of foods in maintaining healthy dietary practices.	2014
4.1.8: Publish final rules for requiring nutrition information on menus and on vending machines.	2014

4.1.9: Support and encourage research to validate health benefits resulting from consumer dietary changes.	2013
4.1.10: Publish advice on fish consumption.	2013
4.1.11: Publish final guidance to help manufacturers who wish to voluntarily label their foods as being made with our without the use of bioengineered ingredients.	2013

4.2—Reduce sodium and industrially-produced *trans* fat in the food supply.

4.2.1: Advance plan for promoting broad, gradual reduction of added sodium in the food supply.	2013
4.2.2: Complete a plan for implementation in 2015 to promote broad, gradual reduction of added sodium in the food supply.	2014
4.2.3: Advance plan to further reduce the use of partially hydrogenated oils, the primary source of industrially-produced *trans* fat in the food supply.	2013
4.2.4: Complete plan to further reduce the use of partially hydrogenated oils, the primary source of industrially-produced *trans* fat in the food supply.	2014

4.3—Qualify biomarkers (biological indicators) that can be used in public health programs.

4.3.1: Support and encourage research on biomarker qualification.	ongoing
4.3.2: Develop studies that harness the human microbiome to advance nutrition based endpoints.	2014

Program Goal 5: Develop and swiftly deploy the fastest and most effective methods for identifying, containing, and eliminating food and cosmetic hazards.

Objectives:

5.1—Swiftly remove hazardous products from the market.

5.1.1: Enhance processes and information technology systems, including increasing speed, for collecting, monitoring, analyzing, and sharing data with regulatory and public-health agencies at federal, state, and international levels.	ongoing
5.1.2: Adopt common analytical methods throughout the FDA Foods and Veterinary Medicine Program.	ongoing
5.1.3: Transition or otherwise incorporate advanced molecular technologies to modernize and augment field capacity.	2014
5.1.4: Expand and promote the utilization of new enforcement tools such as mandatory recall, administrative detention, and suspension of registration to support prevention of market entry of hazardous products or to ensure their removal.	ongoing

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Program Goal 6: Achieve optimal use of staff and resources.

Objectives:

6.1: Strengthen leadership and management capability throughout the organization.

6.1.1: Continuously improve skills of supervisors and managers.	ongoing
6.1.2: Achieve greater accountability throughout the organization.	2013
6.1.3: Coach and expect strong leadership and sound decision making at all levels and across the organization.	2013

6.2—Strengthen external scientific and regulatory relationships to expand capability and impact.

6.2.1: Establish performance metrics to achieve maximum value from CFSAN’ s centers of excellence.	2013

6.3—Optimize roles, responsibilities, and functions.

6.3.1: Improve organizational flexibility and responsiveness by cross training staff in priority areas.	ongoing
6.3.2: Improve processes for travel, procurement, and timekeeping.	2013
6.3.3: Complete a review of the chemical safety program to determine overall program needs and how to meet the needs to better address today’ s chemical safety challenges.	2013
6.3.4: Complete a review of nutrition and related activities to identify, with respect to nutrition in America, what problems we have now, in the near future, and in the next 10– 15 years, and how CFSAN might best address them.	2014
6.3.5: Complete a review of the microbiology program to determine whether it is meeting program needs and whether there is duplication of efforts.	2014
6.3.6: Complete a review of the Office of Food Safety to identify a structure and set of functions that will enable it to achieve and maintain highly efficient operations, especially in light of the need to implement FSMA.	2013

6.3.7: Convene a work group to make recommendationsfor discussionby the Food Advisory Committee in 2013onhowto improve detecting signals of problems with the safety of chemicals in food (including dietary supplements) and cosmetics.	2013

Conclusion

The CFSAN Plan for Program Priorities, like the Food and Veterinary Medicine Program Strategic Plan, illustrates FDA’ s commitment to meeting today’ s food safety and nutrition challenges. This two-year plan for program priorities outlines strategic goals and objectives encompassing the breadth and complexity of the work we do. Although some objectives may be accomplished within the next two years, others are ongoing. We recognize that the availability of resources may influence our success; however, we are dedicated to achieving these goals and objectives as we continue to protect the public from adulterated and misbranded food and cosmetics and regulate nutritional information on food labels.