LEAGUE OF WOMEN VOTERS®

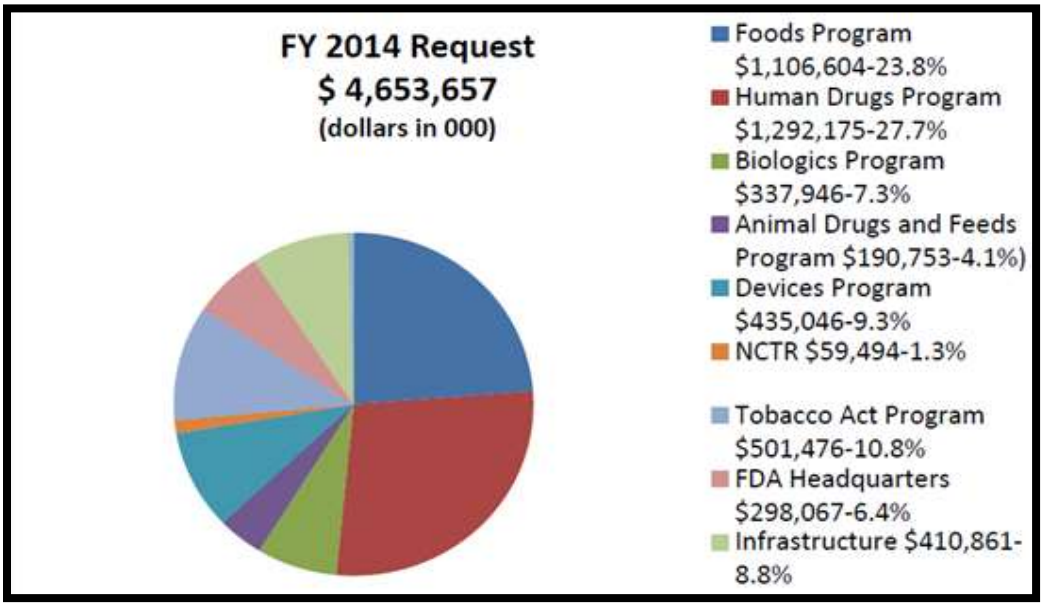
Food and Drug Administration (FDA)

The U.S. Food and Drug Administration in the Department of Health and Human Services protects public health by regulating domestically produced and imported human and animal drugs, biologics, medical devices, food and animal feed, cosmetics, and products that emit radiation. The FDA's Office of Foods and Veterinary Medicine (comprised of the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine) is charged with ensuring that the food supply is safe, sanitary, wholesome, and honestly labeled. FDA regulates more than $450 billion of domestic and imported foods.[1]

The FDA's authority extends over 80% of our foods, including dairy (milk, cheese, butter), plant products (vegetables, fruits, nuts, juices, spices, dietary supplements, seafood (finfish, shellfish, crustaceans, surimi-based), grain-based (bread, cereals, flour), and bottled water. The FDA also regulates animal feed.

FDA Food Safety Mission

The FDA food safety missions of particular interest include food additives[2], biotechnology[3], food labeling[4], and the production of educational materials.[5] The veterinary missions of interest include ensuring the safety of animal drugs[6], feeds[7] and regulation of genetically engineered animals.[8] The FDA accomplishes these missions by designing regulations and enforcing them through review of reports submitted by food suppliers, periodic inspections of food processing facilities, and investigations of reported food problems. These activities are supported by roughly 28% of the total FDA budget, as illustrated by the graph of the President's FDA budget request for 2014.[9]



Noteworthy Laws Affecting the FDA Food Safety Mission

The following list of key laws and regulations defining the FDA's mission illustrates the broad range of the Agency's responsibilities[10]:

- Approval of an FDA role in monitoring pesticide residues (1954)[11]
- Definitions and rules concerning food (1958) and color (1960) additives[12]
- Labeling and post-market monitoring of infant formula (1980)[13]
- Nutrition labeling and education (1990)[14]
- Food allergen labeling and consumer protection (2004)[15]
- Food Safety Modernization Act (2011), which calls for the FDA to prevent rather than simply respond to food contamination[16]

Because the FDA coordinates its activities with many other agencies responsible for food safety, they alone are not responsible for implementing the above noted laws.[17] The Food Safety Modernization Act is discussed in detail in the section on interaction of federal agencies. Food labeling, a major FDA food safety mission is described in a separate Agriculture Update paper.

Nature of FDA Guidelines

Unlike regulations, FDA's Guidance for Industry (GFI) publications provide instructions to FDA personnel and the regulated community on how to comply with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA. The GFI are the product of FDA's best current thinking; however, as the FDA notes in multiple locations on its website, the GFI are voluntary and not legally binding. They provide for regulatory flexibility by allowing alternative approaches if those approaches satisfy the requirements of the applicable statutes and regulations.[18] The GFI apply to a variety of production and processes including Generally Recognized as Safe (GRAS) determinations and the use of drugs in animal production.

Current Issues

Updating scientific procedures

FDA is under pressure to update their procedures and research protocols for making safety determinations on new additives, GRAS ("generally recognized as safe") substances, and genetically engineered foods and animal feed.

New additives require premarket testing and approval, but GRAS substances have no such requirement. To be considered GRAS, ingredients either must have an established history of safe use based on their widespread consumption prior to 1958, or, qualified experts widely agree, based on publicly available scientific data and information, that the ingredient is safe in its intended use.[19,20,21]

Concerns about GRAS substance determinations include studies questioning the safety of certain artificial colors, sweeteners, and preservatives as well as the voluntary nature of the program. Regarding genetically engineered foods, FDA evaluates a new GE food or animal feed for the

presence of or additional allergens or toxins based on its review of company-supplied studies but independent and/or long-term safety studies are not required.[22,23]

Federal and state appropriations to support the FDA food safety mission

Food safety was 42% of FDA budget in the 1970s and has been <25% since 2003. Comparing responsibilities and resources of the FDA with other food safety agencies calls attention to the FDA human resource and budgetary constraints. For example, FDA has approximately 2,000 inspectors to cover the more than 130,000 facilities for which it is responsible while USDA has 7,800 inspectors for just 6,800 facilities.[24] The disparity in human resources is due, in part, to the different rules : USDA is required to inspect virtually all meat carcasses while FDA food inspections are based on statistical sampling methods. The 2011 Food Safety Modernization Act, the most comprehensive food safety reform in 70 years, is expected to cost $1.4 billion over the next five years, yet roughly $50 million was appropriated by Congress for 2012. Growth in food imports, which now represent 15% of the U.S. food supply also presents a challenge, with FDA able to inspect only 2% of these imports annually.[25],[26] State departments of public health are partners in compliance, but face low and decreasing levels of both state and FDA funding to conduct inspections and product sampling.[27]

Recommended Reading

Bidwell, Jean and Regan, Beth. Saccharin, http://enhs.umn.edu/current/saccharin/index.html, accessed 10/18/13. Class assignment for PubH 5161 Regulatory Toxicology, Division of Environmental Health Sciences, School of Public Health, University of Minnesota, 2002.

> This story about the history of saccharin illustrates the complexity of FDA food safety determination process, the interaction of politics and science in the decision making process, and how FDA advice changes over time as new research becomes available.

International Food Information Council Foundation, "What's in Our Food: Understanding Common Food Ingredients," August 12, 2012, http://www.foodinsight.org/Resources/Detail.aspx?topic=What_s_in_Our_Food_Understanding_Common_Food_Ingredients, accessed 10/12/13.

> The FoodInsight.org website provides many useful fact sheets and discussions of food issues in addition to this specific document. Academics and industry leaders provide this website.

Wendee, Nicole, "Secret Ingredients: Who Knows What's in Your Food?" Environmental Health Perspectives, April 2013 11(4): a126-a133, http://www.ncbi.nih.gov/pmc/articles/pmc3620743/ -r20, accessed March 23, 2013.

> This article is an easy to read overview of the history of GRAS and its current status. It also contains references to government and non-governmental studies.

General Accountability Office, "FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)", GAO-10-246, Feb 3, 2010. http://www.gao.gov/products/GAO-10-246, accessed 10/11/13.

National Sustainable Agricultural Coalition. "What is the Food Safety Modernization Act (FSMA)?" http://sustainableagriculture.net/fsma/overview-and-background/ undated, accessed

9/13/2013 and "Modified Requirements for Qualified Facilities (Preventive Controls Rule)," http://sustainableagriculture.net/fsma/learn-about-the-issues/modified-requirements-for-qualified-facilities/, accessed 10/13/13.

[1] FDA, Transforming Food Safety 2013 Budget Report, page 27, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM301409.pdf, accessed 11/14/13.

[2] See http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094211.htm, accessed 11/14/13.

[3] See http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm352067.htm, accessed 11/14/13.

[4] See http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm094536.htm, accessed 11/14/13.

[5] See http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm20026097.htm, accessed 11/14/13.

[6] See http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268128.htm, accessed 11/14/13.

[7] See http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm050223.htm, accessed 11/14/13.

[8] See http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm109066.htm, accessed 11/14/13.

[9] FDA FY 2014 Budget Request, http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm349712.pdf, accessed 11/14/13.

[10] See FDA, *Significant Dates in U.S. Food and Drug Law History*,(2012) for more detail. http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm, accessed 5/18/2013.

[11] See http://en.wikipedia.org/wiki/Pesticide_regulation_in_the_United_States#1950s, accessed 11/14/13.

[12] See http://www.foodadditives.org/cultures/FoodIngredientApproval_OnlineExtra.pdf, accessed 11/14/13.

[13] See http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm136118.htm, accessed 11/14/13.

[14] See http://web.archive.org/web/20071014014557/http:/www.fda.gov/ora/inspect_ref/igs/nleatxt.html#Standardized, accessed 11/14/13.

[15] See http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm, accessed 11/14/13.

[16] See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm, accessed 11/14/13, and also the Agricultural Update overview on "Interaction of Federal Agencies."

[17] See Agriculture Update on "Interaction of Federal Agencies."

[18] For examples see: http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/ucm112583.htm;

http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf, accessed 11/14/13.

[19] Frequently Asked Questions About GRAS, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm, accessed 10/23/13.

[20] What's in Our Food: Understanding Common Food Ingredients, International Food Information Council Foundation, http://www.foodinsight.org, accessed 10/23/13.

[21]For more comprehensive information on food additives responsibilities across governmental agencies, see Food Additives, http://www.nutrition.gov/whats-food/food-additives, accessed 10/23/13.

[22] Maricel V. Maffini, Heather M. Alger, Erik D. Olson, and Thomas G. Neltner. "Looking Back to Look Forward: A Review of FDA's Food Additives Safety Assessment and Recommendations for Modernizing its Program," *Comprehensive Reviews in Food Science and Food Safety*, Vol.12 (439-453)2013. http://onlinelibrary.wiley.com/doi/10.1111/1541-4337.12020/pdf, accessed 8/17/2013.

[23] Government Accountability Office. "FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)" GAO-10-246, Feb 3, 2010, http://www.gao.gov/products/GAO-10-246, accessed 10/9/2013.

[24] Robert E. Brackett, "Policy, Politics, and Progress in Protecting Our Food Supply." Presentation to the League of Women Voters of Illinois Annual Issues Briefing, January 28, 2012. Brackett is the former director of FDA's Center for Food Safety and Applied Nutrition and currently serves as the Director of the Institute for Food Safety and Health at the Illinois Institute of Technology.

[25] For a discussion of FDA's import program see FDA, "Ensuring the Safety of Imported Products" http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048631.htm, accessed 11/14/13; and "FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources" GAO-12-933, September 2012, http://www.gao.gov/products/GAO-12-933, accessed 10/23/13.

[26] Brad Racino, "Inspectors Struggle to Keep Up With Flood of Imports", News21, 2011, http://foodsafety.news21.com/2011/imports/border/index.html, accessed 10/9/2013.

[27] Department of Health and Human Services Office of Inspector General, "Vulnerabilities in FDA's Oversight of State Food Facility Inspections", December 2011 OEI-02-09-00430, http://oig.hhs.gov/oei/reports/oei-02-09-00430.asp, accessed 10/23/13.