U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
February 2001

(This document also available in other languages.)

Center for Food Safety and Applied Nutrition

Overview

The Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the Food and Drug Administration (FDA). FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products. It is one of the oldest federal agencies whose primary function is consumer protection. The agency touches and directly influences the lives of everyone in the United States. FDA is recognized internationally as the leading food and drug regulatory agency in the world. Many foreign nations seek and receive FDA's help in improving and monitoring the safety of their products. FDA is part of the Executive Branch of the United States Government within the Department of Health and Human Services (DHHS) and the Public Health Service (PHS). *Additional information on FDA and HHS is available on the FDA web site, and HHS web site.*

MISSION

CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

SCOPE OF RESPONSIBILITY

Consumers spend twenty-five cents of every consumer dollar on products regulated by the FDA. Of this amount, approximately 75 percent is spent on foods.

The Center regulates $240 billion worth of domestic food, $15 billion worth of imported foods, and $15 billion worth of cosmetics sold across state lines. This regulation takes place from the products' point of U.S. entry or processing to their point of sale, with approximately 50,000 food establishments (includes more than 30,000 U.S. food manufacturers and processors and over 20,000 food warehouses) and 3,500 cosmetic firms. These figures do not include the roughly 600,000 restaurants and institutional food service establishments and the 235,000 supermarkets, grocery stores, and other food outlets regulated by state and local authorities that receive guidance, model codes, and other technical assistance from FDA. FDA enhances its programs by supporting state and local authorities with training and guidance to ensure uniform coverage of food establishments and retailers.

The economic importance of the American food industry is enormous. It contributes about 20 percent of the U.S. Gross National Product, employs about 14 million individuals, and provides an additional 4 million jobs in related industries.

In fiscal year 2000 (October 1, 1999 - September 30, 2000), FDA spent more than $280 million on food and cosmetic safety activities. The Center's primary responsibilities include:

- the safety of substances added to food, e.g., food additives (including ionizing radiation) and color additives
- the safety of foods and ingredients developed through biotechnology
- seafood Hazard Analysis and Critical Control Point (HACCP) regulations
- regulatory and research programs to address health risks associated with foodborne chemical, and biological contaminants
- regulations and activities dealing with the proper labeling of foods (e.g., ingredients, nutrition health claims) and cosmetics
- regulations and policy governing the safety of dietary supplements, infant formulas, and medical foods
- safe and properly labeled cosmetic ingredients and products
- food industry postmarket surveillance and compliance
- consumer education and industry outreach
- cooperative programs with state and local governments
- international food standard and safety harmonization efforts

Although the U.S. food supply is among the world's safest, the increase in variety of foods and the convenience items available has brought with it public health concerns. The complexity of the food industry, and the technologies used in food production and packaging, is increasing. Because a growing proportion of the American food supply is imported, CFSAN also works with international organizations (WHO, FAO, Codex) and occasionally directly with foreign governments to ensure their understanding of U.S. requirements and to harmonize international food standards.

Sources of food contamination are almost as numerous and varied as the contaminants themselves. These include everything from preharvest conditions to contamination introduced during processing, packaging, transportation, and preparation. Some of CFSAN's current areas of food safety concern are:

- biological pathogens (e.g., bacteria, viruses, parasites)
- naturally occurring toxins (e.g., mycotoxins, ciguatera toxin, paralytic shellfish poison)
- dietary supplements (e.g., ephedra)

- pesticide residues
- toxic metals (e.g., lead, mercury)
- decomposition and filth (e.g., insect fragments)
- food allergens (e.g., eggs, peanuts, wheat, milk)
- nutrient concerns (e.g., vitamin D overdose, pediatric iron toxicity)
- dietary components (e.g., fat, cholesterol)
- radionuclides
- TSE-type diseases (e.g., chronic wasting disease in elk)
- product tampering

STATUTORY AUTHORITY

FDA's regulatory authority for food and cosmetics comes from:

- The Federal Food and Drugs Act of 1906
- The Federal Import Milk Act (1927)
- The Federal Food, Drug, and Cosmetic Act of 1938, as amended
- The Public Health Service Act (1944)
- The Fair Packaging and Labeling Act (1966)
- The Infant Formula Act of 1980, as amended
- The Nutrition Labeling and Education Act of 1990
- The Dietary Supplement Health and Education Act of 1994
- Other Related Statutes

For additional information on these statutes, see:

- *The United States Food Safety System*
- *Laws Enforced by the FDA and Related Statutes*
- *Milestones in U.S. Food and Drug Law History*
- *The Long Struggle For The 1906 Law*
- *The Story Of The Laws Behind The Labels, Part I*
- *The Story Of The Laws Behind The Labels, Part II*

FDA's responsibility in the food area generally covers all domestic and imported food except meat, poultry, and frozen, dried and liquid eggs, which are under the authority of the U.S. Department of Agriculture (USDA's Food Safety and Inspection Service (FSIS), the labeling of alcoholic beverages (above 7% alcohol) and tobacco, which are regulated by the U.S. Department of the Treasury's Bureau of Alcohol, Tobacco, and Firearms (ATF), and the U.S. Environmental Protection Agency (EPA), which establishes tolerances for pesticide residues in foods and ensures the safety of drinking water.

FDA maintains close communications with these and other federal agencies such as the U.S. Department of Commerce's National Marine Fisheries Service; the Centers for Disease Control and Prevention (CDC), the U.S. Department of Treasury's U.S. Customs Service; the Federal Trade Commission (FTC), the U.S. Department of Transportation (DoT), the Consumer Product Safety Commission (CPSC) and the U.S. Department of Justice (DoJ). In many instances, FDA has interagency agreements with them to delineate respective responsibilities. *For additional information on the food safety role of these federal agencies and the states, see*

- *Food Safety: A Team Approach*
- *www.FoodSafety.gov*
- *Federal/State Food Programs*

FDA regulates food products sold in interstate commerce, whereas products made and sold entirely within a state are regulated by that state. Center personnel work with state agriculture and health departments, to resolve food safety concerns and economic fraud cases, for example. *For additional information about state regulatory agencies , see*

- *Food Safety: A Team Approach - State and Local Governments*
- *www.FoodSafety.gov: The Government Agencies*

The Center is increasingly called on to work with international organizations, such as the Codex Alimentarius Commission--an international food standard-setting organization of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO)--and foreign governments, to help establish internationally recognized safety standards, rules and regulations for imported foods. In the past, most of the Center's standard-setting efforts dealt with U.S. products. But that is changing as a result of recent international treaties. Now, more and more food is traveling in international commerce. *For additional information about Codex see:*

- *Food and Cosmetics International Activities*
- *FDA Codex Activities*
- *U.S. Codex Office*

For additional information about FAO and WHO, see the FAO web site, and WHO Food Safety Programme.

While CFSAN's mission is to protect and promote public health, that responsibility is shared with others. Academia, health providers, other government agencies, regulated industry, and, of course, consumers all have a role to play. Although this has always been true, the demands and complexities of today's society make it more apparent now than ever before. Leveraging, collaboration, cooperation, or partnering is not new to the Center. The Center is actively involved in high-visibility endeavors such as the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) with the University of Maryland, and the National Center for Food Safety and Technology

(NCFST) with the Illinois Institute of Technology, a government/academia/industry collaboration that yields critical information that enhances our ongoing efforts to ensure the safety of food. *For additional information on JIFSAN and NCFST see the JIFSAN web site and NCFST web site.*

- *Information for consumers*
- *Information for Kids, Teens and Educators*
- *Information for Seniors*
- *More information on Women's Health*

In addition, formal agreements with the states for conducting inspections enhance the Center's ability to meet its public health mission.

FDA's Tools for Ensuring Food Safety

- inspection of establishments
- collection and analysis of samples
- monitoring of imports
- premarket review (e.g., food and color additives)
- notification programs (e.g., food contact substances, infant formula)
- regulations/agreements (e.g., memoranda of understanding)
- consumer studies, focus groups
- laboratory research
    - develop/improve methods for detecting pathogens and chemical contaminants in food
    - determine health effects of food contaminants
    - determine effects of processing on food composition
    - determine health effects of dietary factors
    - investigate factors that contribute to virulence of biological contaminants
- pilot plant for food processing and packaging and biotechnology studies
- cooperative activities/technical assistance
- collection and analysis of information
- stakeholder awareness through education and public meetings
- information and outreach on Center activities

Information about CFSAN's responsibilities and activities with respect to Cosmetics

THE ORGANIZATION

The Center has over 800 employees, who range from secretaries and other support staff to highly specialized professionals--such as chemists, microbiologists, toxicologists, food technologists, pathologists, molecular biologists, pharmacologists, nutritionists, epidemiologists, mathematicians, and sanitarians.

Other Center offices provide services to consumers, domestic and foreign industry and other outside groups regarding; field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical foods' issues. Most Center staff members work in the Center's headquarters in Washington, D.C. Beginning in the Fall of 2001, the majority of headquarters staff will move to a new facility in College Park, Maryland. The Center also operates research facilities in Laurel, Maryland and in Dauphin Island, Alabama. Other locations include JIFSAN in College Park, Maryland and NCFST near Chicago, Illinois.

For additional information about CFSAN's programs see the CFSAN web site.

For more information on the history of CFSAN's Organization, see History of CFSAN's Organization - 1993

November 2001: CFSAN Moves from Washington, DC to College Park, MD

December 1, 2003: Joseph A. Levitt Retires as Director of FDA's Center for Food Safety and Applied Nutrition; Dr. Robert E. Brackett to Succeed Him

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Overview & History

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