THE FOOD AND DRUG ADMINISTRATION'S TOTAL DIET STUDY: HISTORY, METHODOLOGY, AND RESULTS

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INTRODUCTION

Many countries conduct total diet studies to assess the safety and adequacy of national or regional food supplies. The methods and techniques used in total diet studies vary from nation to nation depending upon objectives, analytes of concern or interest, geographic area to be covered, population groups of interest, demographic variables, and available resources. Total diet studies are often a delicate balance between desired objectives and available resources. Because there are never enough resources to do these studies as completely and thoroughly as government agencies would like, important decisions (tradeoffs) must be made that, hopefully, do not jeopardize the health of the population. This paper describes the total diet studies as they are conducted in the United States.

OBJECTIVES

The primary objectives of the United States total diet studies are (1) to monitor the safety and nutritional quality of the food supply and of the diets of specific age-sex groups; (2) to identify potential public health problems with regard to pesticide residues, nutrients, radionuclides, industrial chemicals, and toxic elements in foods; and (3) to provide background information for policy decisions regarding food additives, pesticide use, nutrient fortification, and food labeling. In addition, results of the total diet studies are useful for identifying the dietary sources of pesticide residues, contaminants, and nutritional elements; guiding agency programs by identifying analytes of potential public health significance; alerting the agency about potential needs for action (e.g., increased surveillance, regulation, or communication with industry); and monitoring the effects and effectiveness of agency regulatory activities (1).

CHARACTERISTICS

The most important features of the United States total diet studies are continuous monitoring, national coverage, flexibility, and quality control.

Continuous Monitoring

There is ongoing collection and analyses of foods to maintain a current database on the composition of these foods and to identify trends and changes over time. The foods are collected and analyzed four times per year every year, and estimates of intakes are made every year and compared with previous results.

National Coverage

The collection of total diet study foods is rotated within four large geographic areas (east, south, central, and west) of the United States. This is made possible by the 21 FDA District Offices across the United States. Employees at these various facilities are requested to collect the specified foods at specific times and send them to a central laboratory.

Flexibility

The program is designed to allow for changes in food consumption patterns (foods analyzed and quantities eaten), the introduction of new analytes and deletion of those no longer of concern, changes in age-sex groups, and changes in geographical locations of food collections. Analyses of individual foods greatly enhance the flexibility of the program. (Prior to 1982, the foods were analyzed as food group composites.) Individual food analyses allow for the development of food composition databases for the analytes and greater flexibility in making dietary exposure estimates. Individual analyses also minimize the dilution effect in which an analyte in foods that are part of a composite may not be quantifiable because the foods containing it are only a small part of the composite.

Quality Control

The total diet study program is conducted with concern for quality control in terms of the foods purchased, analytical methods and procedures, and data analyses. The analytical work is centralized in three laboratories for consistency of sample treatment, analytical methods, and personnel and for efficiency in the use of laboratory equipment and staff.

HISTORY

The Food and Drug Administration (FDA) initiated its total diet studies in May 1961 in response to concern about levels of radioactive contamination in foods from atmospheric nu-

clear testing. For the first total diet study, foods were purchased quarterly between May 1961 and February 1962 from grocery stores in the metropolitan area of the District of Columbia. The diet contained 82 foods in quantities for a 14-day intake of a young male and was excessive in energy intake (4,200 kcal/day) to assess maximum exposure to dietary contaminants. The foods were prepared in an institutional kitchen in Baltimore, Maryland and analyzed as a single total diet food composite in the FDA Baltimore District Laboratory and the FDA Washington, DC Laboratory. The levels of strontium-90, cesium-137, organochlorine pesticide residues, organophosphorus pesticide residues, and selected nutrients were determined.

The total diet study has continued on a yearly basis since 1961 to monitor the levels of radionuclides, pesticide residues, toxic elements, industrial chemicals, and selected nutrients in the US food supply and in the diets of selected age-sex groups. The program continues to evolve to meet agency needs and to make improvements in methods and techniques.

METHODOLOGY

There have been many changes, refinements, and expansions in the total diet study program since 1961 regarding collection sites, foods collected, analytes, and analytical methodologies. Major dietary revisions in 1971, 1982, and 1991 were necessitated by the availability of newer national information on food consumption (Table 1). Changes in analytes or analytical methods have occurred with the major revisions and at other times during the program. The program as it currently exists will be described with mention of some changes from previous years.

Organizational Structure

The total diet studies in the United States are conducted by the Center for Food Safety and Applied Nutrition (CFSAN), FDA in Washington, DC in conjunction with the FDA Kansas City District Office (KCDO) in Lenexa, Kansas. KCDO is the receiving site for the foods and is responsible for food preparation, test sample preparation, and analysis for pesticide residues and elements. The program requires the assistance of the FDA Office of Regional Operations (ORO) in Rockville, Maryland, which oversees the activities of the FDA District Offices across the United States. As noted above, the District Offices are responsible for collecting the total diet study foods and sending them to KCDO. Two other laboratories analyze the total diet study foods: the Winchester Engineering and Analytical Center (WEAC) in Winchester, Massachusetts, where foods are analyzed for radionuclides, and the Atlanta Center for Nutrient Analyses (ACNA) in Atlanta, Georgia, where the foods are analyzed for folic acid and vitamin B-6.

Selecting the Foods and Diets

There are currently 261 «core» foods in the total diet study program. The foods are selected by aggregating the much longer list of foods that are reported to be consumed by participants

TABLE 1
Basis for total diet study diets

Years Used	Diet Basis[a]	Diet Type
1961/62	1955 USDA HFCS	national diet for 16-19 year males
1962-70	1955 USDA HFCS	regional diets for 16-19 year males
1971-74	1965 USDA HFCS	regional diets for 15-20 year males
1975-82	1965 USDA HFCS	regional diets for 3 age-sex groups[b]
1982-91	1977-78 USDA NFCS & NHANES II	national diets for 8 age-sex groups[c]
1991-	1987-88 USDA NFCS	national diets for 14 age-sex groups[d]

[a] USDA - United States Department of Agriculture; HFCS - Household Food Consumption Survey; NFCS - Nationwide Food Consumption Survey; NHANES II - Second National Health and Nutrition Examination Survey, National Center for Health Statistics, Centers for Disease Control.
[b] 6-month infants, 2-year-old children, and 15-20 year-old males.
[c] 6-11 month infants; 2-year-old children; and females and males 14-16 years, 25-30 years, and 60-65 years.
[d] 6-11 month infants; children 2 years, 6 years, and 10 years; and females and males 14-16 years, 25-30 years, 40-45 years, 60-65 years, and 70+ years.

of national food consumption surveys. The current total diet study food list is based on the over 5,000 foods consumed by participants in the 1987-88 US Department of Agriculture (USDA) Nationwide Food Consumption Survey (NFCS). To develop the total diet study foods list, the foods in the USDA NFCS database are grouped by type, use, and composition. The food item within each group with the largest consumption was selected to represent the group and become a core food of the total diet study. For example, the consumption of apple pie in the total diet study represents the consumption of all fruit pies, strudels, and fruit/grain-based desserts.

The total diet study foods include traditional items (fruits, vegetables, grain products, meats, eggs, dairy products) as well as mixed dishes, fast foods, desserts, beverages, fats, and sweeteners. As noted above, each food in the total diet study represents a group of similar foods. The consumption of the group of foods (in grams per day) for a specific age-sex group is assigned to the total diet study food. In this way, the diets represent 100% of the weight and caloric content of typical diets.

Selecting the Age-Sex Groups

The original total diet study only included diets for young adult males (Table 1). Diets for infants and 2-year-old were added in 1975. The analyses of individual foods, which began in 1982, allow for increased flexibility in adding more age-sex groups. With the 1982 revision, there were 8 age-sex groups. Since the 1991 revision, there have been 14 age-sex groups.

Collecting and Shipping the Foods

Each year CFSAN issues instructions to specific FDA District Offices to collect the total diet study foods and to send them to KCDO. The total diet study foods are collected four times

per year, once from each of the four geographic areas of the United States (east, south, central, and west). Three cities are identified within each of the four geographic areas for food collection. The selected cities vary within a geographic area from year to year. Examples of collection sites are shown in Table 2. They are usually cities in standard metropolitan statistical areas with proximity to FDA District or Field Offices.

FDA investigators purchase the specified foods in the required quantities from local grocery stores and restaurants within the cities. Each collection is scheduled over a 4-week period. The shopping list does not specify brand names of products; that choice is left to the investigators. The investigators pack the foods for air freight shipment to KCDO. Perishable items are packed in dry ice.

Upon arrival at KCDO, the foods are checked to ensure that the correct items and correct quantities have been purchased. If any errors have been made or if foods have been damaged during shipment, the responsible District Office is contacted and asked to collect the specified items again. If the District Office is unable to obtain any of the specified food items, the Kansas City District laboratory obtains them locally. Foods in metal-based packaging are identified, and the specific type of metal-based packaging and the presence of lead-soldered seams are determined and recorded.

TABLE 2
Examples of total diet study collection sites

Date	Region and Cities
June/July 1993	Western region
	Sacramento, CA
	Colorado Springs, CO
	Spokane, WA
October/November 1993	Southern region
	San Antonio, TX
	Raleigh, NC
	San Juan, PR
January/February 1994	Central region
	Rockford, IL
	Omaha, NE
	Fargo-Moorhead, ND
May 1994	Eastern region
	Albany-Schenectady-Troy, NY
	Nassau-Suffolk, NY
	Pittsburgh, PA

Preparing and Compositing the Foods

Foods that require preparation (i.e., washing, trimming, peeling) and/or cooking are sent to the kitchen of Belton Methodist Church in Belton, Missouri, which is under contract with KCDO. At the kitchen, the foods are prepared according to specified instructions and recipes. Tap water is used to clean and wash foods; distilled water is used in recipes and to cook foods. The prepared foods are placed in glass jars and returned to KCDO.

The table-ready foods from the three cities of each collection are combined in portions of equal weight and homogenized to produce a food composite for each food that represents the three cities of the specified region. Portions of each food composite are stored in plastic containers for elemental analysis and in glass jars for pesticide analysis. For one of the yearly collections, portions of each food are stored in wax-coated paper cartons for radionuclide analysis and in plastic bags for vitamin analysis.

Analytes

Aliquots of each food composite are analyzed for organic contaminants (pesticide residues and industrial chemicals), nutrient and toxic elements, and moisture at KCDO (Table 3). For one collection each year, food composites are sent from KCDO to WEAC for radionuclide analyses and to ACNA for folic acid and vitamin B-6 analyses. Pyrethroid pesticides were added to the program in 1989; organosulfur pesticides, ethylenethiourea, and substituted urea herbicides were added in 1990; and benomyl/thiabendazole was added in 1992. Folic acid, vitamin B-6, and moisture, were added to the program in 1991, while determinations for early-eluting industrial chemicals, higher- chlorinated dioxins (Cl_6-Cl_8), and iodine were discontinued. Analysis for iodine was discontinued because of quality control problems. It will resume after a suitable analytical method is developed and validated. Resource considerations have resulted in selective analyses of total diet study foods for mercury and some organic contaminants (Table 3).

Analytical Methods

The analytical methods used for elements, vitamins, moisture, pesticide residues, and radionuclides are summarized in Table 3.

Data Transfer

The concentrations of the analytes in the total diet study foods and quality control data, as determined by the three laboratories (KCDO, WEAC, and ACNA), are entered into the FDA computerized Laboratory Management System and transmitted to the FDA computer center in Rockville, Maryland. The data are then accessed, evaluated, and summarized by CFSAN personnel in Washington, DC. The analytical values (i.e., food composition data) are merged with data on food consumption, which are derived from national food consumption surveys, to provide estimates of daily intake.

TABLE 3
Total diet study analytes and analytical methods[a]

Analyte[b]	Analytical Method
Industrial Chemicals	
Polychlorinated biphenyls	Gas chromatography with electrolytic conductivity and/or electron capture detection
Early-eluting industrial chemicals (41)	
Higher-chlorinated dioxins	
Pesticide Residues	
Organohalogen pesticides	Gas chromatography with electrolytic conductivity and/or electron capture detection
Chlorophenoxy acids and pentachlorophenol (20)	
Pyrethroid pesticides (142)	
Organophosphorus pesticides	Gas chromatography with phosphorus mode flame photometric detection
N-methyl carbamates (95)	Liquid chromatography with post column derivatization and fluorescence detection
Substituted urea herbicides (49)	
Organosulfur pesticides (50)	Gas chromatography with sulfur mode flame photometric detection
Ethylenethiourea (40)	Liquid chromatography with electrochemical detection
Benomyl/thiabendazole (67)	Liquid chromatography with tandem ultraviolet and fluorescence detection
Elements	
Mercury (50)	Cold vapor atomic absorption spectrometry
Cadmium	Graphite furnace atomic absorption spectrometry
Lead	
Arsenic	Hydride generation atomic absorption spectrometry
Selenium	
Sodium	Inductively coupled plasma atomic emission spectrometry
Potassium	
Calcium	
Phosphorus	
Magnesium	
Iron	
Zinc	
Copper	
Manganese	

TABLE 3 (cont.)
Total diet study analytes and analytical methods[a]

Analyte[b]	Analytical Method
Iodine	Colorimetry
Vitamins	
Folic acid	Microbiologic assay
Vitamin B-6	
Moisture	Weight loss with microwave drying
Radionuclides	
Cesium-137	Gamma-ray spectrometry
Iodine-131	
Ruthenium-106	
Strontium-90	Beta particle counting

[a] This table is adapted from reference 2.
[b] The number in parentheses indicates the number of foods analyzed if it is different from 261.

PUBLICATIONS

The estimates of daily intake are made available to Congress, the scientific community, and the public through reports, the scientific literature, and trade and consumer publications. Some of the journals which carry these articles are the *Journal of the American Dietetic Association*, the *Journal of Food Composition and Analysis*, the *Journal of AOAC International*, and the *Journal of Radioanalytical and Nuclear Chemistry*.

RESULTS

Pesticides

Dietary intakes of pesticides in the total diet study have generally been less than 1% of the Acceptable Daily Intakes (ADIs) established by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations. One exception is that intakes of some persistent chlorinated pesticides (i.e., dieldrin) were closer to the ADIs in the 1960s and 1970s. Intakes of these persistent materials have declined steadily since the cessation of their agricultural uses over a decade ago. Dieldrin intakes are currently about one-twentieth of their level two decades ago. Although the intakes of persistent chlorinated pesticides have declined dramatically in the last 20 years, residues occur occasionally at low levels, primarily in foods of animal origin (1).

In the 1975 total diet study, a residue of the preservative and fungicide pentachlorophenol (PCP) was found in unflavored gelatin. PCP had been used to treat animal hides in slaughterhouses, and many of these hides were ultimately shipped to gelatin manufacturers. This use of PCP had been discontinued in the United States several years prior to the finding. Investigation revealed that the product in question was a mixture of domestic and Mexican gelatin. The Mexican gelatin was found to contain PCP and was ultimately diverted from food use (1).

Industrial Chemicals

In the 1971 total diet study, polychlorinated biphenyl (PCB) residues were found in a breakfast cereal. Followup investigation revealed that the chemical migrated from the paperboard package, which had been produced from PCB-contaminated recycled paper. This finding ultimately led to regulations limiting the PCB content of paperboard intended for food-contact use (1).

Nutrients

Estimated intakes currently indicate that the diets of some age-sex groups are low in copper, magnesium, calcium, zinc, and iron. Estimated intakes of sodium, potassium, phosphorus, selenium, and iodine meet or exceed dietary recommendations. The most notable result of the nutritional elements has been the high levels of iodine in US diets. Intake levels of iodine currently range from 150 to 370% of the Recommended Dietary Allowance (RDA), but have in the past exceeded the RDA for this element by tenfold. The major sources of this element have been dairy products, grain products, and foods containing the iodine-containing red food color FD&C No. 3.

RESOURCES

Currently, the total diet study requires 28 person-years of effort (the equivalent of 28 full-time employees per year). This time is divided among the staff at CFSAN, KCDO, WEAC, ACNA, FDA District Offices, and ORO. The cost of the program (including the salaries of the FDA employees) is about 3.9 million dollars per year. These costs include the purchase and transportation of the foods; laboratory chemicals; equipment maintenance; new equipment; inspector transportation expenses for collecting foods; periodic total diet study meetings in Kansas City; computer hardware, software, and maintenance; and the contract for food preparation.

PROGRAM ADVANTAGES

The total diet study provides for annual monitoring of a broad range of pesticide residues, contaminants, and nutrient elements in foods in their table-ready forms, and it allows for yearly estimates of intakes of pesticide residues, contaminants, and nutrient elements of selected age-sex

groups based on laboratory analyses. This type of information, which is available from no other source, is essential to monitor the safety and quality of the United States food supply and to identify potential public health problems. The total diet study played a major role in early identification of unusual findings (e.g., polychlorinated biphenyls, high levels of dieldrin, and excessive levels of iodine in the food supply), and it continues to provide a check on the effectiveness of current regulations and surveillance activities in protecting the public from harmful levels of pesticide residues, contaminants, or nutrient elements in foods. The demonstration of very low levels or the absence of residues or contaminants in foods and the demonstration of adequate nutrient element intake by the total diet study are important as they point out the continuing safety and dietary adequacy of the food supply. The total diet study also provides a baseline reference for determining the impact on the food supply of environmental contamination accidents (1).

Data from the total diet study have been widely used and accepted by other government agencies, industry, and professional groups. The total diet studies are part of the United States National Nutrition Monitoring System. The total diet study program is an efficient dietary model for pesticide residues, industrial chemicals, heavy metals, nutrient elements, and vitamins. Without this program, many expensive individual surveys would have to be instituted to respond to congressional, consumer, and other requests made to FDA. The total diet study model may not be suitable for other substances of dietary concern, such as food additives that have an unusual distribution or vary by brand name or other factors.

THE FUTURE

The periodic reports from the total diet studies assure legislators, scientists, and the public about the safety and nutritional adequacy of the United States food supply. The total diet study program will continue to evolve to meet the monitoring needs of FDA. Changes are expected in the near future to reflect advances in analytical methods for elements. Several additional elements, including aluminum, nickel, and molybdenum, are expected to become part of the routine analyses within the next few years. In addition, the food list and dicts will be updated to reflect more recent food consumption information from the Third National Health and Nutrition Examination Survey (NHANES III) conducted by the National Center for Health Statistics, Centers for Disease Control.

REFERENCES

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