FDA's Total Diet Study: Monitoring U.S. Food Supply Safety

By Katie Egan
Series Editor: Catherine "Kitty" Bailey, M.Ed.

Studies often are conducted to monitor levels of chemical contaminants in foods and to estimate the dietary intake of these contaminants. One approach to this is a "total diet," or "market basket," study that involves the analysis of a group of foods that reflect the average food consumption patterns of a given population. Results of the analyses can then be used to estimate the average intake of contaminants from eating those foods.[1]

In the U.S., the Total Diet Study (TDS) has been conducted continuously by the U.S. Food and Drug Administration (FDA) since the early 1960s. It is an important component of the federal government's food safety and nutrition monitoring programs, with a focus on pesticide residues, industrial chemicals, elements and radionuclides. The TDS is unique among monitoring programs in that it determines levels of the analytes in foods as they would be consumed (table-ready), rather than levels on raw commodities or ingredients. This is particularly important for estimating the dietary intake of substances such as pesticide residues, which may be changed (reduced or increased) as a result of washing, peeling and cooking.

The primary purposes of the study are to monitor levels of these analytes in the U.S. food supply and to estimate their dietary intakes by selected age-gender groups in the U.S. population. This information also provides a tool for supporting regulatory actions and for tracking the impact of the regulations over time.[2] TDS results are used by other government agencies and by academic and nongovernmental organizations both in the U.S. and abroad.[3]

History of the TDS

In the late 1950s, many scientists were concerned about contamination of food by radioactive fallout from nuclear weapons testing. The isotope strontium-90 was a particular concern because of its long half-life and its potential to be deposited in bone.[4] Milk was thought to be the chief dietary source of strontium-90. Consequently, the U.S. Atomic Energy Commission and the U.S. Public Health Service, as well as similar agencies in the United Kingdom, Germany and Japan, began limited testing of milk for radionuclides. At about the same time, Consumer's Union, Inc. embarked on its own study of strontium-90 in milk and later, in collaboration with home economics departments in colleges and universities in 25 cities, tested a wider variety of foods.[5,6,7,8,9]

In 1961, FDA conducted its first TDS, which, as the name of the study implies, included foods and beverages that represented a typical American diet.[4] In those early studies, the foods were based on the diet of teenage boys 16-19 years of age, the group that consumes the greatest quantity of foods and therefore represents the highest potential for dietary exposure to contaminants. The first study was conducted in Washington, DC, where samples of 82 food items were purchased quarterly at four different supermarket chains. The following year, the study was expanded to include sample collections in four other cities (San Francisco, St. Louis, Minneapolis, and Atlanta). In each city, dietitians in local hospital or university kitchens prepared the foods; the FDA laboratory in Washington, DC, analyzed them.

Following the early studies, the program was expanded to include many more foods and analytes.[3,10] Until the early 1980s, foods were combined for analysis, at first as a single composite and later into either 11 or 12 food-group composites (e.g., meat and eggs, grains, and fruits). In 1982, the program underwent a major revision and FDA began to analyze 234 individual "core foods." These represented the foods and beverages most commonly consumed and those consumed in the greatest quantities by the U.S. population as reported in food consumption surveys conducted by the U.S. Department of Agriculture (USDA). This change in the TDS methodology provided FDA with information on the levels of nutrients and contaminants in specific foods rather than for food-group composites. This information could be linked to equally specific food consumption data, which enabled FDA to identify the foods that contributed most to the intake of contaminants and nutrients measured in the TDS.

The analytical focus of the TDS also has changed over the years. Initially, the foods were analyzed for two radionuclides (strontium-90 and cesium-137) and some pesticide residues (organophos-

phates and organochlorines). During the 1970s, FDA expanded the list of analytes to include additional pesticide residues, toxic elements and industrial chemicals. Beginning in 1973, FDA broadened the scope of the TDS even further to include nutrients, as well as contaminants; by 1983, foods were analyzed for 11 nutrient elements, and vitamin B6 and folate were added in the early 1990s.

The Total Diet Study Today

Today's TDS is a collaborative effort among FDA offices in the Washington, DC area and the FDA regional and district offices and laboratories.[10] FDA's Center for Food Safety and Applied Nutrition (CFSAN), recently relocated from Washington to College Park, MD, directs the content and focus of the program, develops analytical methods to be used in the TDS and evaluates and reports the data generated by it. The sample collections and analyses are the responsibility of the district offices and several of FDA's laboratories. But the principal focal point of TDS activities is the Kansas City District Laboratory in Lenexa, KS. A section of that facility was designed specifically to handle the special requirements of the TDS. Here, the sample collections are coordinated, the samples are logged and prepared, and the majority of analyses are conducted.

Total Diet Study Foods. The list of foods analyzed in the TDS is updated periodically to reflect current trends in food consumption. The list was last revised in 1990 and included 265 foods.[11] In 1991, additional infant and toddler foods were included in the food list specifically to provide more information on levels of pesticides and lead in the diets of young children. At this time, nearly 280 adult and infant foods are collected and analyzed in the TDS.

Sample Collections and Preparation. Sample collections, or market baskets, are generally carried out four times a year, once in each of four regions of the country (West, North Central, South and Northeast). FDA personnel throughout the country purchase each of the 280 foods from grocery stores and fast food restaurants in three cities within the region. Each year, different cities are selected for sample collections to provide more geographic representation. The foods are then shipped to FDA's Kansas City District Laboratory.

Each sample collection is preceded by a tremendous amount of planning and coordination by the staff at the Kansas City District Laboratory. Shopping lists are prepared for each person charged with collecting the samples. Labels are printed to identify each sample from each city. Once the samples arrive, the laboratory sends the foods to yet another location to be prepared table-ready. For the past 12 years, the women of the Belton United Methodist Church, located just outside of Kansas City, have taken on this task as a fund-raising project for the church. Their kitchen duties range from simply washing and peeling fruits to preparing entrees such as meatloaf and macaroni and cheese. These dedicated women follow recipes written specifically for the TDS, ensuring that ingredients from each of the three sampling locations are equally represented in the finished product. After the samples have been prepared, they are sent back to the laboratory where the foods are composited and analyzed.

Laboratory Analyses. For each of the four annual market baskets, FDA analyzes the 280 foods for more than 200 different components including elements (toxic and nutrient), pesticide residues, industrial chemicals, volatile organic compounds, radionuclides, and folate. The total number of laboratory analyses performed for each market basket is about 1,800. Most of the analyses (elements, pesticides and industrial chemicals) are performed at the Kansas City District Laboratory. Portions of the composites are sent to other FDA laboratories for determining concentrations of folate (the Atlanta Center for Nutrient Analysis in Georgia) and radionuclides (the Winchester Engineering and Analytical Center in Massachusetts). Other FDA contaminant monitoring programs, such as that for dioxins, also utilize portions of the TDS foods.

The list of analytes changes from time to time depending on current concerns, either from a contaminant or nutrient standpoint, and priorities within FDA. Work is ongoing in the laboratories at CFSAN's office in College Park, MD, and in Kansas City for developing new analytical methods to be used in the TDS, as well as to improve existing analytical techniques.

Analytical methods used in the TDS are able to detect residues at levels five to 20 times lower than most standard analytical techniques.[12,13] FDA conducts two types of food monitoring programs: regulatory monitoring and incidence/level monitoring. The goal of regulatory monitoring is to determine whether foods comply with food safety regulations. Incidence/level monitoring, including the TDS, is conducted primarily to increase FDA's knowledge about the normal levels of analytes–usually pesticide residues or other contaminants–found in foods. Levels of contaminants normally found in foods are well below the regulatory levels; for that reason, analytical methods used for the TDS are much more sensitive than those required for regulatory monitoring. Most TDS analyte concentrations are reported at less than 10 µg/kg (10 ppm), with some even as low as 0.1 µg/kg (100 ppb).

TDS analyses incorporate numerous controls and checks to ensure the quality of the results.[13,14] Laboratory equipment is checked regularly to ensure proper operation and control samples are analyzed to verify lack of contamination. Test materials, fortified with elements and other target compounds, are analyzed to demonstrate precision and accuracy of the analyses. Replicate analyses of TDS samples are conducted to confirm that original results are reproducible. After the analyses are completed, expert analysts review each finding for accuracy, compliance with regulatory limits, and consistency with historical concentra-

tions for each food/analyte combination. Samples with findings outside the historical ranges or those not in compliance with regulations are reanalyzed for confirmation of the initial laboratory result. If the finding is confirmed, the laboratory notifies CFSAN, which recommends an appropriate follow-up action.

TDS Results

On average, more than 14,000 analytical findings are detected each year in the TDS. Of those, about 5,000 (36%) are levels of toxic elements and chemical contaminants. Although this number may seem quite high—and may, in fact, have increased with time—this represents the increased sensitivity of analytical methods rather than an increase in the incidence of contamination. Most contaminants are present at very low levels; the values determined in the TDS generally fall within a narrow historical range. Radionuclides, when present, also are found at low concentrations, which is consistent with the near disappearance of contamination of this type since the early 1960s.[14] But from a risk assessment standpoint, the dietary intake of a contaminant is the important factor rather than simply the number of times the contaminant is detected in foods. Historically, the estimated intakes of contaminants based on FDA's TDS results have been well below acceptable limits established by the World Health Organization (WHO).[2,15]

For some contaminants, trends in decreasing concentrations and intakes can be demonstrated by the TDS. Most often this is a result of a remedial action taken many years before. Lead provides one of the best examples. During the 1970s, a number of regulatory actions were taken by various government agencies to reduce dietary and environmental exposures to lead.[16,17] For FDA-regulated products, industry voluntarily stopped using lead solder in cans in the late 1970s and it was finally banned by FDA in 1995 (21 *Code of Federal Regulations* (CFR) Part 189.240). Manufacturers of baby foods also took the initiative to change from cans to glass jars in the early 1970s. The U.S. Environmental Protection Agency (EPA) phased out leaded gas and lead pipes from the mid-1970s through the mid-1980s. Lead specifications for food additives were reviewed, with an emphasis on those consumed in the greatest quantities. The consequences of these actions can be seen in the TDS results. Average lead levels in baby foods decreased from 0.15 mg/kg in the early 1970s to 0.003 mg/kg by 1990.[17] From the early 1980s to early 1990s, the average lead concentration in canned foods decreased from 0.20 mg/kg to 0.01 mg/kg. The estimated average dietary intake of lead by teenage boys went from about 90 µg/day in the 1970s to about 4 µg/day in the 1990s—which is only about 2% of the Provisional Tolerable Daily Intake established by the WHO.[15,17]

In addition to reflecting the impact of regulations, TDS results also have identified potential problems that triggered subsequent investigation or regulatory action by FDA, or remedial action by industry. For example, levels of contaminants or nutrients are occasionally found to be outside the normal range, or residues of pesticides that are not registered for use in the U.S. are detected in TDS foods.

In one such incident in the late 1970s, unusually high levels of iodine were found in a number of TDS foods. Based on these findings, dietary intakes of iodine were estimated to be four to five times the Recommended Daily Allowance, with dairy products accounting for most of the intake.[18] At that time, iodine-containing cleaning supplies (iodophors) were widely used in the dairy industry and in some other food processing. The increase in levels of iodine in TDS foods was brought to the attention of industry and the use of iodophors was dramatically reduced.

In another incident, polychlorinated biphenyls (PCBs) were found in a ready-to-eat breakfast cereal in 1971.[3] FDA found that the chemical migrated into the food from the paperboard packaging that had been produced from PCB-contaminated recycled paper. The TDS finding ultimately led to regulations limiting the PCB content of paperboard intended for food contact use (21 *CFR* Parts 109.15 and 109.30). In 2000, a residue of oxyfluorfen, a herbicide used to control weeds, was detected in a sample of salmon.[13] Although it was not possible to confirm the source of the sample, the residue of oxyfluorfen was quite likely the result of a major spill of the pesticide that occurred earlier that year in Oregon's Columbia River—a major salmon-producing area in the U.S.

In the late 1990s, elevated levels of lead were found in a baby food (chicken and vegetables). The source was traced to carrots grown in fields previously used as apple orchards that had been treated with lead arsenate. In a similar situation, elevated levels of arsenic were found in a sample of peanut butter; the source was found to be peanuts grown in a field that had been treated with an arsenic-containing defoliant.

Other Uses of TDS Data. On a national level, results of the TDS are widely used by other government agencies, academic and research institutions, industry and consumer groups, and individuals with an interest in food safety and nutrition. Results of the study have always been available to the public, either through the Freedom of Information Act or publications in scientific journals. Now, CFSAN makes the TDS results available online (www.cfsan.fda.gov). As a result, the data are even more widely used and FDA gets frequent inquiries about the program.

In addition to its important role in monitoring the safety of foods domestically, the TDS data are becoming increasingly important in setting international limits for contaminants in food. Expansion of international trade in food has increased the need for international standards. This is accomplished primarily through the Codex Alimentarius Commission, the international food standard-

setting body established in the early 1960s by the United Nations Food and Agriculture Organization (FAO) and WHO.[19] The World Trade Organization (WTO) looks to Codex standards when settling trade disputes and requires that the standards be based on sound scientific principles.[20] Data on contaminant concentrations in foods–such as those generated by the TDS–are critical to establishing these international standards.

The Future of Total Diet Studies at Home and Abroad

Many developed countries besides the U.S. have experience in conducting their own studies, but few developing countries have the capabilities or infrastructure to support them. Planning and executing a TDS requires expertise in many different areas, from assessing food consumption patterns to managing the logistics of sample collection and preparation to analytical chemistry. Because of its long history and wide coverage of both foods and analytes, FDA's TDS is recognized worldwide as a model program.[3] FDA personnel have provided sample documentation and hands-on training to a number of countries.

As trade in food becomes more global and food safety becomes a higher priority, all countries also must be concerned about the safety of their own food supply and must be able to meet international standards. WHO, recognizing the need to assist developing countries in these endeavors, has cohosted two Total Diet Study workshops since 1999. The goal is to share expertise and establish an international network by bringing together countries with TDS expertise and countries wishing to develop their own studies. FDA is an avid supporter of this effort and was cohost of the first workshop, which was held in July 1999 at the Kansas City District Laboratory.

The TDS has served us well domestically for more than 40 years, providing assurance that our foods are safe and nutritious. The program has evolved to reflect changes in food consumption patterns, as well as concerns about contaminants. And now, with the increased importance of international trade and food safety standards, FDA and its TDS have even greater roles to play, both at home and abroad.

Katie Egan *is a nutritionist and consumer safety officer in the Office of Plant and Dairy Foods and Beverages (OPDFB), CFSAN, U.S. FDA. She and other colleagues in OPDFB provide technical guidance to the Total Diet Study and other monitoring programs at CFSAN. Egan reviews and compiles analytical data on contaminant levels in foods and provides estimates of dietary exposure as part of the safety assessments conducted by the office's Division of Risk Assessment.*

Series Editor ***Catherine "Kitty" Bailey, M.Ed.,*** *is Director of the Executive Operations Staff, Office of Operations, CFSAN, U.S. FDA. Please visit the website at www.cfsan.fda.gov for the latest regulatory and food safety news from the food divisions at FDA. Forward questions and topics you'd like to see covered in upcoming "Ask the Regulators" columns to julie@foodsafetymagazine.com.*

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