CHAPTER 04 – PESTICIDES AND CHEMICAL CONTAMINANTS

SUBJECT:	**IMPLEMENTATION DATE**
TOTAL DIET STUDY **(FY 14/15/16/17)**	Upon Receipt
	COMPLETION DATE
	(LAB) 9/30/17

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODE : 37XYY99 USE APPROPRIATE PRODUCT CODES	04839 (pesticides, industrial chemicals, toxic elements, mycotoxins and radionuclides) 21839 (nutritional elements)

FIELD HARD COPY REPORTING REQUIREMENTS

A. <u>COLLECTING DISTRICTS</u>

Send the original of each collection report (CR) to the Kansas City Laboratory (HFR-SW360).

B. <u>DISTRICT FOLLOW-UP</u>

Send a brief summary of any follow-up to Total Diet Study (TDS) samples to the TDS monitor and KAN-LAB. Classify follow-up samples as "compliance samples". Charge all follow-up activities related to pesticides and industrial chemicals against the Pesticides and Industrial Chemicals in Domestic and Imported Foods Program, PAC 04004A, and follow-up related to toxic elements (i.e., arsenic, cadmium, lead, mercury, nickel) and radionuclides against the Toxic Elements in Food and Radionuclides in Food Program, PAC 04019A and 04019C, respectively, unless directed otherwise by the TDS Coordinator. Also contact the TDS Coordinator for PAC assignment for follow-up related to nutrient elements.

C. <u>LABORATORIES</u>

Kansas City Laboratory (KAN-LAB)
Winchester Engineering and Analytical Center (WEAC)

Prepare a Total Diet Market Basket Report (TDMBR) discussing analytical findings, and program issues for each market basket. Desired modifications to the TDS will be addressed in a separate memorandum and referenced in the report. Submit all reports and memoranda to the TDS monitor, with copies to the ORA Scientific Inquiries contact. The TDMBRs are due 30 days after the completion of all analyses of the market basket (including outliers, unusual findings, repeat analyses,

confirmations) and certification of data. All analytical results must be entered in the Field Accomplishments and Compliance Tracking System (FACTS) before submitting the TDMBR for the market basket. See FACTS reporting instructions in Part IV, Section G.

Arkansas Regional Laboratory (ARL)

Refer to the Pesticides and Industrial Chemicals in Domestic and Imported Foods Compliance Program (7304.004) for reporting requirements.

Should unusual or elevated dioxin concentrations be detected, ARL should contact CFSAN (Anthony Adeuya) for guidance on follow-up. Such follow-up should be reported under the Pesticides and Industrial Chemicals in Domestic and Imported Foods Compliance Program, PAC 04004D.

PART I - BACKGROUND

FDA's mandate to ensure the safety and wholesomeness of the food supply relies on its capacity to assess the potential risk of dietary exposure to unsafe concentrations of contaminants and for inadequate intake of nutrients. Estimating dietary exposure requires data on the frequency and concentrations of contaminants and nutrients in the U.S. food supply. The more comprehensive the monitoring and exposure estimates are, the more useful the information is for prioritizing food safety concerns, for identifying the contributions of specific foods to health risks, and for targeting food safety monitoring programs and activities. FDA's Total Diet Study (TDS), one of FDA's most comprehensive food safety monitoring programs, provides this information.

The TDS involves:

- purchasing a wide range of foods that represent foods most commonly consumed by the US population
- preparing the foods as for consumption (e.g., washing, peeling, cooking)
- analyzing them for toxic chemicals and certain nutrients
- using collected data to estimate total dietary exposure to assess whether or not specific chemicals pose a health risk, and to identify the foods that contribute most to exposure

The TDS differs from other food safety monitoring programs because:

- it focuses on chemicals in the total diet, not just targeted foods
- the foods are prepared as for consumption before analysis, resulting in more realistic estimates of the dietary exposure to contaminants and nutrients
- the TDS food list changes only periodically (about every 10 years), allowing for trend analysis of TDS results
- the analytical methods used in the TDS are generally more sensitive and able to detect lower concentrations of chemicals than would be measured in regulatory monitoring
- it is an ongoing program with continuous sample collections, thus providing a ready source of samples from which to draw for analysis of emerging contaminants

The TDS is a comprehensive monitoring program that provides a complementary approach to and helps to inform other monitoring programs.

Current TDS Methodology and Use of TDS Results

The TDS has been conducted continuously since the early 1960s. The current program involves collecting samples of about 280 different foods (including beverages) and analyzing each for toxic and nutrient elements, pesticide residues, industrial chemicals, and radionuclides. A table of TDS foods and the analytes for which each food is analyzed is provided in the TDS Food/Analyte Matrix (refer to Attachment A).

Four regional sample collections (one per region) (each referred to as a 'market basket') are carried out each year. For each market basket, samples of each TDS food are collected from each of three cities within the region. The three samples are combined to form a single analytical composite for each TDS food for that market basket.

The analytical results from the TDS are then combined with national food consumption data to estimate dietary exposures to these analytes for the total US population and for 14 age-gender subgroups, from infants to the elderly.

Because the TDS food list covers all major components of the diet, the exposure estimates provide a measure of total exposure to these substances as well as the contribution of each TDS food to the total exposure. The estimates of total exposure are compared with toxicological reference points such as Provisional Tolerable Weekly Intake (PTWI) or an Acceptable Daily Intake (ADI) to assess the potential risk to the population of overexposure to contaminants or to inadequate intake of nutrients. The exposure estimates also identify the foods and beverages that contribute most to the total exposure; this information can be used to target samples collected in other food safety monitoring and compliance programs and to help prioritize food safety initiatives.

CFSAN maintains a website for the TDS where analytical results are posted and can be accessed by those interested in food safety and nutrition. http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm. Results from the TDS are widely used by other government agencies such as the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA), as well as by academia, the food industry and consumer groups. TDS results are also important for international food safety monitoring and standard setting activities. The World Health Organization (WHO), through its Global Environment Monitoring System (GEMS/Food) supports total diet studies as one of the most cost-effective means for assuring that people are not exposed to unsafe concentrations of toxic chemicals through food. The GEMS/Food program also maintains databases on contaminant concentrations in foods as well as exposure estimates, to which the U.S. and many other countries contribute results of their TDSs. These data are used for risk assessments conducted by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) and for development of international food safety standards by the Codex Alimentarius Commission (Codex).

Part II - PROGRAM MANAGEMENT

A. OBJECTIVES

- To determine concentrations of pesticide residues and industrial chemicals in food.
- To determine concentrations of the toxic and nutrient elements in foods.
- To determine concentrations of radionuclides in foods.
- To estimate daily dietary exposures to TDS analytes for the total U.S. population and fourteen age-gender groups, from infants to the elderly.
- To identify trends in the concentrations in foods and dietary exposures to all TDS analytes.
- To identify the contributions of individual TDS foods to the overall dietary exposure, which informs other monitoring programs that target specific foods/contaminants.
- To identify potential food safety hazards by comparing dietary exposures to TDS analytes with recommended intakes and toxicological reference points established by the FDA, FAO/WHO, the National Academy of Sciences, and other agencies and scientific bodies.
- To maintain a TDS website through which TDS results can be accessed by other government agencies, academia, consumer and industry groups, and individuals interested in food safety and nutrition.
- To contribute TDS results to the GEMS/Food database to be used for international risk assessments and standard setting.
- Following completion of a fiscal year's four market baskets, a review team consisting of the KAN-LAB TDS Coordinator and the CFSAN Pesticide Contacts will discuss and recommend adding or removing pesticide coverage across individual foods or food groupings in the TDS Program. The team will review pesticide data such as findings of the market baskets for the year and trends from previous years, recent findings from FDA's annual pesticide reports and USDA's Pesticide Data Program, and available pesticide usage data and any information from EPA regarding new and emerging pesticides of interest. Other TDS analytes will also be reviewed at that time and recommendations for changes in coverage will be made. All recommendations will consider the resources, costs, and practicality associated with the proposed changes, and justification will be provided for adding or eliminating coverage. Enactment of the recommendations will be decided by lead managers (or their designees) of CFSAN's Office of Analytics and Outreach (OAO), Office of Regulatory Science (ORS), Office of Compliance (OC), and the KAN Laboratory Director.

B. IMPLEMENTATION

CFSAN/Office of Compliance, Field Programs Branch will:

- select the Districts and cities where samples will be collected
- issue the Market Basket Collections Schedule annually, under a separate mailing, during the fourth quarter of each fiscal year preceding the year of collection

KAN Laboratory will:

- coordinate collection and analysis of TDS foods
- prepare shopping guides (one for each of four collection weeks) based on the analytical priorities established by CFSAN (refer to the Attachment A)
- notify the Director of Investigations Branch (DIB) of upcoming sample collections about 45 days prior to the first week of sample collection
- provide shopping guides to each collecting District 1-2 weeks prior to the first week of sample collection
- perform analyses for pesticide residues, industrial chemicals, and elements in foods (refer to the Attachment A)
- forward portions of TDS food composites to other laboratories with analytical responsibilities as specified below

Collecting Districts will:

- collect samples according to the shopping guides provided by KAN-LAB
- ship samples to the KAN-LAB

WEAC will:

- analyze selected TDS foods (refer to the Attachment A) from two market baskets each year (refer to TDS Market Basket Rotation Schedule, Part IV, p. 1.) for radionuclides

ARL will:

- analyze selected TDS foods (refer to the Attachment A) from one market basket each year (refer to TDS Market Basket Rotation Schedule, Part IV, p. 1) for dioxins under the auspices of the Pesticides and Industrial Chemicals in Domestic and Imported Foods Program

PART III - INSPECTIONAL

A. SAMPLE COLLECTION

For each market basket (MB), samples will be collected over a four-week period (which may be extended to additional weeks, as necessary, e.g. should a Federal holiday occur during the collection period) by the Districts designated by the TDS Market Basket Collection Schedule. Samples of each TDS food are collected in each of the 3 cities designated for that MB. Districts should make every effort to collect all food items listed on the shopping guides provided by KAN-LAB, visiting multiple major retailers if necessary. If they are unable to procure specific food items, District personnel should contact the TDS monitor (CFSAN) or the TDS coordinator (KAN-LAB). Any food item that was not collected should be noted by the collecting District on the shopping list or in an accompanying memorandum. KAN-LAB will maintain records of foods not purchased by the collecting District and will report this information in the KAN-LAB TDMBR. Samples are not typical domestic samples. **SAMPLES DO NOT NEED TO BE OFFICIALLY SEALED.** Please follow instruction provided by KAN-LAB with the shopping list.

Collecting Districts should follow these guidelines when purchasing the foods:

- Follow the guidance provided in the IOM Section 4.2.8.3.2 for the payment of samples.
- There is a separate shopping guide for each of the four collection weeks. Use the guides as they correspond to the shopping week (i.e., for week one, use shopping guide #1).
- Use one Collection Report (CR) per city per collection week. Use consecutive CRs for the four collection weeks, if possible. All samples are Investigational.
- List each store visited and the items collected from it under the “remarks” section of the CR.
- Purchase only a single brand of each food per city if possible. (Different brands may be purchased in each of the 3 cities.)
- Do not collect less than the total quantity per food as specified in the shopping guide.
- National brand items are preferred over store brand or generic brand name commodities
- For items that may be purchased fresh or frozen, fresh items are always preferable. The form purchased should be noted on the CR.
- Identify each item collected using the 3-digit number assigned to the product in the shopping guide. Do not deviate from the assigned item numbers. (Labels will be provided by KAN-LAB to facilitate item identification. Official seals are not required.)

B. STORAGE OF SAMPLES AFTER COLLECTION

Collecting Districts should, immediately after sample collection:

- keep frozen foods frozen
- freeze all meats, seafood items (except canned), butter, and margarine
- refrigerate perishables

C. SUBMISSION OF SAMPLES TO KAN-LAB

Collecting Districts should label, pack, and ship samples as follows:

- Attach the labels provided by KAN-LAB to each sample.
- Carefully follow the instructions provided by KAN-LAB for packing and shipping the samples. (Please call KAN-LAB with any questions about these procedures.) Ensure sample integrity by keeping frozen foods frozen and cold foods cold during shipment. Frozen foods should be shipped packed in gel packs, with the exception of ice cream, sherbet, popsicles, and milk shakes. These four items, from the week three shopping guide, should still be shipped with dry ice.
- Ship refrigerated and frozen items within one day of sampling (see Investigations Operations Manual (IOM) Section 4.5.5.5). If longer is needed to complete sample collection, contact the lab
- Ship samples:
  - o overnight via shipper with which the district contracts
  - o to arrive in KAN-LAB by Close-of-Business (COB) Wednesday of sampling week

  Ship samples to:
  US Food and Drug Administration
  Attn: Sample Preparation and Collection Coordinator - Total Diet Study
  11510 West 80th Street
  Lenexa, Kansas 66214

After samples are shipped, **Collecting Districts** should contact the TDS Sample Collection and Preparation Coordinator (see Section VI, Contacts). The following information should be provided:

- Collection week
- Number of shipping cartons or containers
- Name of carrier
- Tracking number
- Estimated date and time of arrival
- Other relevant remarks, e.g., "Sufficient dry ice to maintain frozen condition until 8:00 A.M.", etc.

PART IV – ANALYTICAL

Standard Operating Procedures (SOPs) referenced in the following sections contain all necessary analytical instructions, methods of analysis, safety and quality assurance requirements, reporting instructions, limits of quantitation (pesticides), limits of detection (elements), and lists of foods to be analyzed. Analyzing laboratories will keep SOPs updated and should notify CFSAN's Office of Analytics and Outreach (OAO), Office of Regulatory Science (ORS), and ORA/ORS of any revisions. Changes should also be reported to the TDS monitor.

A. SAMPLE RECEIPT

KAN-LAB will:

- log in food items as received
- retain food items in refrigerator or freezer, grouped by sample collection city

B. SAMPLE PREPARATION

KAN-LAB will:

- prepare and process samples of TDS foods as outlined in KAN-LAB.152 and related appendices and segregate portions of Item 380 (Bottled Water) from each individual city for elemental analysis
- maintain reserves of all intact samples of TDS foods as indicated in Attachment A for 30 days after the Market Basket Report has been sent to CFSAN
- maintain reserves of composite for all TDS foods for 30 days after the Market Basket Report has been sent to CFSAN

C. SENDING SAMPLES FROM KAN-LAB TO OTHER LABORATORIES

KAN-LAB sends portions of TDS composites from one market basket each year to ARL for dioxin analyses and from two market baskets each year to WEAC for radionuclide analyses. The specific market baskets from which samples are sent to these laboratories are rotated each year to provide greater geographic coverage. The table below provides the rotation schedule for the next 3 years.

TDS Market Basket Rotation Schedule for Radionuclide and Dioxin Analyses

FY	Market Basket 1	Market Basket 2	Market Basket 3	Market Basket 4
2014		WEAC	ARL	WEAC
2015	WEAC	ARL	WEAC	
2016	ARL	WEAC		WEAC
2017	WEAC		WEAC	ARL

1. Samples to be analyzed by WEAC:

KAN-LAB will send to WEAC a portion of at least 600 grams of each selected TDS food composite (refer to Attachment A) from two market baskets each year (refer to the TDS Market Basket Rotation Schedule above). Each portion of the composite should be double-bagged: the sample is to be placed in a self-sealing plastic bag, which is placed inside a similar self-sealing bag.

KAN-LAB will contact WEAC prior to shipping of samples to verify acceptable dates for shipping by KAN-LAB and receipt by WEAC of said samples. KAN-LAB should notify WEAC when samples have been shipped and provide all pertinent shipping information.

Ship food composites to:
Winchester Engineering and Analytical Center, HFR-NE460
Attn: Sample Custodian
109 Holton Street
Winchester, MA 01890

2. Samples to be analyzed by ARL:

KAN-LAB will send to ARL portions of selected TDS food composites (refer to the Attachment A) from one market basket per year (refer to the TDS Market Basket Rotation Schedule above). KAN-LAB should send at least 1,000 grams each of food composites that are to be freeze-dried before analysis and at least 400 grams each of other food composites. Each portion of the composite should be double-bagged: the sample is to be placed in a self-sealing plastic bag, which is placed inside a similar self-sealing bag.

KAN-LAB will contact ARL prior to shipping of samples to verify acceptable dates for shipping by KAN-LAB and receipt by ARL of said samples. KAN-LAB should notify ARL when samples have been shipped and provide all pertinent shipping information.

Ship food composites to:
FDA, Arkansas Regional Laboratory, HFR-SW500
Attn: Kirk Wilkes
3900 NCTR Road, Building 26
Jefferson, AR 72079

D. SAMPLE ANALYSES

All laboratories will:

- Follow methods as described in SOPs.
- Follow quality assurance and quality control procedures outlined in the SOPs or referenced methods.

KAN-LAB will:

- Analyze TDS foods from each market basket for selected pesticide residues, industrial chemicals, nutrient and toxic elements as specified in Attachment A.

WEAC will:

- Analyze composites of selected TDS foods (refer to Attachment A) submitted by KAN-LAB from two market baskets each year (see TDS Market Basket Rotation Schedule, Section C) for radionuclides.

E. FOLLOW UP ON UNUSUAL ANALYTICAL FINDINGS

Any unusual analytical finding (as defined below) in the original composite sample should be confirmed by the analyzing laboratory as follows:

- Analyze in duplicate the reserve portion of the composite sample to confirm the original finding.
- If confirmed:
    - o analyze the intact samples from the 3 collection locations if available
    - o for fruit juices and other drinks (see Attachment B) with total As concentrations above 10 µg/kg, determine the total As level of the intact samples from the 3 collection locations and speciate any intact sample above 10 µg/kg for inorganic As.
    - o immediately notifies the CFSAN TDS Coordinator

Following are guidelines to determine when a finding is considered unusual:

For bottled water

- Any result that exceeds the standards established in *21 CFR Part 165, Section 165.110 Bottled water.*

For all other foods

Pesticide residues:

- Findings that may indicate a level in excess of an established tolerance.

- Findings for which there are no established tolerances AND that may indicate a level of regulatory significance (i.e., the level is at or above the LOQ of FDA's regulatory monitoring procedure for the suspect residue). Residue concentrations below regulatory method LOQs have no regulatory significance to FDA.

Elements:

- Findings for potentially toxic elements (arsenic, cadmium, chromium, mercury, lead) that are above the upper value of the "Reanalysis Range", which is based on the TDS historical values for potentially toxic elements.

- For nutrient elements, KAN-LAB Laboratory will identify all results that fall outside the range of TDS historical values; these will be reported in the TDMBR. Any of these findings that are significantly above or below the range of historical values will be reanalyzed to confirm the original finding, but analysis of intact samples is not required.

Radionuclides:

- WEAC will immediately notify the TDS Coordinator whenever unusual concentrations of radionuclides are found so that appropriate follow-up may be considered.

F. ANALYTICAL METHODS

Attachment A specifies the analyses to be performed for each TDS food. Analytical methods, and the laboratories responsible for the analyses, are specified below.

Multi-residue Method for Pesticides and Industrial Chemicals (KAN-LAB)
Analyze all items for pesticide residues and industrial chemicals using the AOAC International method 2007.01 as modified and described in KAN-LAB-PES.53 and related SOPs.

Acid Herbicides (KAN-lab)
Analyze selected foods for residues of acidic herbicides using the method described in SOP KAN-LAB-PES.77.

Element Methods

Multi-element ICP-MS Method for Food (KAN-LAB)
Analyze all foods (except bottled drinking water (item #380)) using Elemental Analysis Method 4.7 for the following elements: arsenic, cadmium, chromium, lead, manganese, mercury, molybdenum, uranium, vanadium, selenium,strontium and nickel.

Multi-element ICP-AES Method for Food (KAN-LAB)
Analyze all foods (except bottled drinking water (item #380)) using Elemental Analysis Method 4.4 for the following elements: potassium, zinc, copper, iron, phosphorus,magnesium, calcium, strontium and sodium.

Multi-element ICP-MS Method for Bottled Drinking Water (item #380) (KAN-LAB)
Analyze portions of each individual city sample of bottled drinking water (item #380) using Elemental Analysis Method 4.12 for the following elements: aluminum, antimony, arsenic, barium, beryllium, cadmium, Calcium, Magnesium, strontium, phosphorus, chromium, copper, iron, lead, manganese, mercury, nickel, selenium, silver, thallium, uranium and zinc.

Arsenic Speciation ICP-MS Method for Juice (KAN-LAB)
Analyze portions of each individual city sample of any fruit juice composite confirmed to have a total arsenic level above 10 µg/kg using Elemental Analysis Method 4.10 for the following arsenic species: total inorganic arsenic (sum of arsenite, arsenate), monomethylarsonic acid and dimethylarsinic acid. (http://www.fda.gov/EAM)

ICP-MS Method for Iodine (KAN-DO)
Analyze all TDS foods for iodine using the methods and procedures described in EAM 4.13

Radionuclide Methods

Gamma-ray Emitters (WEAC)
Analyze selected TDS foods from two market baskets each year (see the TDS Market Basket Rotation Schedule, Section C) for all detectable gamma-ray emitting radionuclides using the methods and procedures described in WEAC.RN.METHOD.3.0.

Strontium-90 (beta emitter) (WEAC)
Analyze selected TDS foods from two market baskets each year (see the TDS Market Basket Rotation Schedule, Section C) strontium-90 using the methods and procedures described in WEAC.RN.Method 2.0.

G. REPORTING ANALYTICAL RESULTS

All analytical results should be reported by the analyzing laboratory into the FACTS system as follows:

- **Pesticides and Industrial Chemicals (KAN-LAB):**
  Report results in FACTS under PAC 04839 using PAF KTD.

- **Toxic and Nutrient Elements (KAN-LAB):**
  Report results in FACTS under PAC 04839 for toxic elements and PAC 21839 for nutrient elements using PAF KTE.

- **Radionuclides (WEAC):**
  Report results (in units of Bq/kg decay corrected to analysis date) in FACTS under PAC 04839 using PAF NUC. Always report results for strontium-90, cesium-137 and potassium-40. Report all gamma-ray emitting radionuclides including, but not limited to, those listed in Part IV.D.

PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

When an unusual analytical finding has been confirmed according to the guidelines in Part IV, Section E, the TDS Coordinator will notify the CFSAN contact for Regulatory Guidance, who will coordinate scientific review with the appropriate program office.

Investigational samples are collected at retail; no regulatory/administrative follow-up will result directly from this Compliance Program.

PART VI - CONTACTS, REFERENCES, ATTACHMENTS

A. CONTACTS

CFSAN

TDS Coordinator: Terry Councell, HFS-301, (240) 402-1108

ORA TDS Monitor/Compliance Program Inquiries: Jeffery Sumter, HFS-615, (240)402-3037

Scientific Inquiries:

Food list, sample collections: Judi Spungen, HFS-301, (240) 402-0242
Dioxin: Anthony Adeuya, HFS-317, (240)402-5759
Pesticides: Chris Sack, HFS-317, (240)402-2464

Analytical Methods Inquiries:

Elements: Bill Mindak, HFS-716, (240)402-2005
Pesticides: Jon Wong, HFS-706, (240)402-2127
Industrial chemicals:
General inquiries: Gregg Noonan, HFS-706, (240)402-2250
Specific inquiries:
Dioxin, PCBs: Doug Hayward, HFS-712, (240)402-1654
Radionuclides: Dave Anderson, HFS-716, (301)975-6272

Regulatory Guidance: Priya Rathnam, HFS-607, (240)402-2078

Scientific Inquiries (ORS/FFSS):
(a)Pesticide & Dioxin: Moh (Mohammed) R. Islam, ELEM RM3127, (240) 402-0552
(b)Elemental & Nutritional: James (Mike) Farrow, Atlanta, GA, (404) 253-2246

OFFO/DFFPOI/FFPOB: Rina Bhikha, ELEM RM2133, (301) 796-5483

OO/ORS/FFFS: Mohammed Islam, ELEM RM3127, (240-402-0552

LABORATORIES

KAN Laboratory (HFR-SW360):
TDS Coordinator: Kara Cooper (913)752-2730
Sample Preparation and Collections Coordinators: Ron Sisk, (913)752-2165
Jeannie Vonderbrink, (913)752-2193
Bridgette Mattern, (913)752-2188
Laboratory Director: Aref El-Demerdash (913)752-2126

Winchester Engineering And Analytical Center (HFR-NE460): Patrick Regan, (781)756-9707

Arkansas Regional Laboratory (HFR-SW500): Kirk Wilkes, (870)543-4012

B. ATTACHMENTS

Total Diet Study Food/Analyte Matrix and Juices for arsenic speciation

PART VII - CENTER RESPONSIBILITIES

A. OFFICE OF ANALYTICS AND OUTREACH (OAO)

In general, OAO

- Provides general direction on the technical aspects of the program
- Makes recommendations regarding expansion of the program (e.g., addition of analytes or foods)
- Reviews and compiles laboratory results
- Posts results on FDA’s website
- Publishes TDS analytical results in scientific journals

B. OAO/Environmental Exposure Branch

- Compiles the TDS food list
- Advises on substitutions of foods
- Determines food consumption amounts for selected population groups
- Estimates dietary exposure to TDS contaminants
- Publishes dietary exposure estimates in scientific journals

C. OFFICE OF REGULATORY SCIENCE (ORS)

- Develops analytical methodologies and associated quality control criteria

D. OFFICE OF COMPLIANCE (OC), Field Programs Branch

- Oversees the execution of the program
- Prepares drafts of the compliance program and other relevant guidance documents
- Facilitates clearance of above documents
- Monitors data through the FACTS
- Prepares ORA's Work plan for the Total Diet Study Program
- Acts as liaison between CFSAN and the field offices (including KAN-LAB and WEAC)
- Schedules the market baskets (collecting locations and dates)
- Prepares an annual program summary

TOTAL DIET STUDY FOOD/ANALYTE MATRIX

The table below lists all TDS foods and identifies the analyses that are performed for each. The table also indicates foods that are to be analyzed first (priority 1) and foods for which KAN-LAB maintains reserves of the intact samples pending certification of the market basket analyses.

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
001	Milk, whole, fluid	1		√	√	√	√	√	√
002	Milk, lowfat (2%), fluid	1		√	√	√	√	√	√
003	Milk, chocolate, lowfat, fluid	1		√			√	√	√
004	Milk, skim, fluid			√			√	√	√
007	Milk shake, chocolate, fast-food			√			√	√	√
010	Cheese, American, processed		√	√			√	√	√
012	Cheese, cheddar, natural (sharp/mild)		√	√			√	√	√
013	Beef, ground, regular, pan-cooked			√			√	√	√
014	Beef roast, chuck, oven-roasted			√			√	√	√
017	Ham, cured (not canned), baked			√			√	√	√
018	Pork chop, pan-cooked w/ oil			√			√	√	√
019	Pork sausage, pan-cooked			√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
020	Pork bacon, pan-cooked			√			√	√	√
021	Pork roast, loin, oven-roasted			√			√	√	√
022	Lamb chop, pan-cooked w/ oil			√			√	√	√
026	Turkey breast, oven-roasted			√		√	√	√	√
027	Liver (beef/calf), pan-cooked w/ oil			√		√	√	√	√
028	Frankfurter (beef/pork), boiled			√			√	√	√
029	Bologna (beef/pork)			√			√	√	√
030	Salami, luncheon-meat type (not hard)			√			√	√	√
034	Fish sticks or patty, frozen, oven-cooked			√		√	√	√	√
035	Eggs, scrambled w/ oil	1		√		√	√	√	√
037	Eggs, boiled	1		√		√	√	√	√
038	Pinto beans, dry, boiled		√	√			√	√	
039	Pork and beans, canned		√	√			√	√	√
042	Lima beans, immature, frozen, boiled		√	√	√		√	√	
046	Peas, green, fresh/frozen, boiled		√	√	√		√	√	
047	Peanut butter, smooth		√	√			√	√	√
048	Peanuts, dry roasted, salted		√	√	√		√	√	√
050	Rice, white, enriched, cooked	1	√	√	√	√	√	√	√
051	Oatmeal, plain, cooked	1	√	√	√	√	√	√	√
052	Cream of wheat (farina), enriched, cooked		√	√	√		√	√	

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
053	Corn/hominy grits, enriched, cooked		√	√	√		√	√	
054	Corn, fresh/frozen, boiled			√	√		√	√	
055	Corn, canned		√	√	√		√	√	√
058	Bread, white, enriched			√	√	√	√	√	√
060	Cornbread, homemade		√	√	√		√	√	√
061	Biscuits, refrigerated-type, baked			√			√	√	
062	Bread, whole wheat			√	√		√	√	√
063	Tortilla, flour		√	√			√	√	
064	Bread, rye			√	√		√	√	
065	Muffin, blueberry			√	√		√	√	√
066	Crackers, saltine		√	√			√	√	√
067	Corn/tortilla chips		√	√	√		√	√	√
069	Noodles, egg, enriched, boiled		√	√			√	√	
071	Corn flakes cereal		√	√	√		√	√	√
072	Fruit-flavored sweetened cereal		√	√	√	√	√	√	√
073	Shredded wheat cereal		√	√	√		√	√	√
074	Raisin bran cereal		√	√	√		√	√	√
075	Crisped rice cereal		√	√	√	√	√	√	
076	Granola w/ raisins		√	√			√	√	
077	Oat ring cereal	1	√	√	√		√	√	
078	Apple (red), raw (w/ peel)	1		√	√		√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
079	Orange (navel/Valencia), raw			√	√		√	√	
080	Banana, raw	1		√			√	√	√
081	Watermelon, raw/frozen			√			√	√	√
083	Peach, raw/frozen			√	√		√	√	√
084	Applesauce, bottled	1	√	√			√	√	
085	Pear, raw (w/ peel)			√	√		√	√	√
086	Strawberries, raw/frozen			√	√		√	√	√
087	Fruit cocktail, canned in light syrup		√	√			√	√	
088	Grapes (red/green), raw			√	√		√	√	√
089	Cantaloupe, raw/frozen			√			√	√	√
092	Grapefruit, raw			√	√		√	√	
093	Pineapple, canned in juice		√	√			√	√	√
095	Raisins		√	√		√	√	√	
097	Avocado, raw			√	√	√	√	√	
098	Orange juice, frozen conc, reconstituted	1	√	√		√	√	√	√
099	Apple juice, bottled	1	√	√		√	√	√	√
100	Grapefruit juice, bottled		√	√			√	√	
103	Prune juice, bottled		√	√		√	√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
105	Lemonade, frozen conc, reconstituted		√	√			√	√	√
107	Spinach, fresh/frozen,boiled			√	√	√	√	√	√
108	Collards, fresh/frozen, boiled			√	√	√	√	√	√
109	Lettuce, iceberg, raw			√	√		√	√	√
110	Cabbage, fresh, boiled			√	√		√	√	√
113	Broccoli, fresh/frozen, boiled			√	√		√	√	√
114	Celery, raw			√	√		√	√	
115	Asparagus, fresh/frozen, boiled			√	√		√	√	√
116	Cauliflower, fresh/frozen, boiled			√	√	√	√	√	√
117	Tomato, raw			√	√	√	√	√	
119	Tomato sauce, plain, bottled		√	√			√	√	√
121	Green beans, fresh/frozen, boiled			√	√		√	√	√
122	Green beans, canned		√	√			√	√	√
123	Cucumber, peeled, raw			√	√		√	√	√
124	Summer squash, fresh/frozen, boiled			√			√	√	√
125	Pepper, sweet, green, raw			√			√	√	√
126	Squash, winter (Hubbard or acorn), fresh/frozen, boiled			√			√	√	√
128	Onion, mature, raw			√	√		√	√	√
131	Beets, canned		√	√	√		√	√	√
136	Potato, boiled (w/out peel)	1		√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
137	Potato, baked (w/ peel)			√			√	√	√
138	Potato chips		√	√			√	√	√
142	Spaghetti w/ meat sauce, homemade	1	√	√			√	√	√
145	Chili con carne w/ beans, canned		√	√			√	√	√
146	Macaroni and cheese, prepared from box mix	1	√	√			√	√	√
147	Quarter-pound hamburger on bun, fast-food			√			√	√	√
148	Meatloaf, beef, homemade			√			√	√	√
152	Chicken potpie, frozen, heated		√	√			√	√	√
155	Soup, chicken noodle, canned, cond, prep w/ water	1	√	√			√	√	√
156	Soup, tomato, canned, cond, prep w/ water	1	√	√			√	√	
157	Soup, vegetable beef, canned, cond, prep w/ water	1	√	√			√	√	√
161	Dill cucumber pickles		√	√			√	√	√
162	Margarine, regular (not lowfat), salted		√	√			√	√	√
164	Butter, regular (not lowfat), salted		√	√			√	√	√
166	Mayonnaise, regular, bottled		√	√			√	√	√
167	Cream, half & half			√			√	√	√
168	Cream substitute, non-dairy, liquid		√	√			√	√	√
169	Sugar, white, granulated		√	√			√	√	√
170	Syrup, pancake		√	√			√	√	√
172	Honey		√	√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
173	Tomato catsup		√	√			√	√	
177	Ice cream, light, vanilla		√	√		√	√	√	√
178	Cake, chocolate w/ icing			√			√	√	√
183	Chocolate chip cookies		√	√			√	√	√
184	Sandwich cookies w/ crème filling		√	√			√	√	√
185	Pie, apple, fresh/frozen		√	√			√	√	√
186	Pie, pumpkin, fresh/frozen		√	√			√	√	√
187	Candy bar, milk chocolate, plain		√	√			√	√	√
190	Gelatin dessert, any flavor		√	√			√	√	√
191	Carbonated beverage, cola, regular		√	√			√	√	
193	Fruit drink, from powder	1	√	√			√	√	
194	Carbonated beverage, cola, low-calorie		√	√			√	√	
197	Tea, from tea bag		√	√			√	√	
198	Beer		√	√			√	√	
199	Wine, dry table, red/ white		√	√			√	√	
202	BF, Infant formula, milk-based, iron fortified, RTF	1	√	√	√	√	√	√	√
205	BF, beef and broth/gravy	1	√	√			√	√	√
207	BF, chicken and broth/gravy	1	√	√		√	√	√	√
211	BF, vegetables and beef	1	√	√		√	√	√	√
212	BF, vegetables and chicken	1	√	√			√	√	√
214	BF, chicken noodle dinner	1	√	√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
215	BF, macaroni, tomato and beef	1	√	√			√	√	√
216	BF, turkey and rice	1	√	√	√		√	√	√
218	BF, carrots	1	√	√			√	√	√
219	BF, green beans	1	√	√			√	√	√
220	BF, mixed vegetables	1	√	√		√	√	√	√
221	BF, sweet potatoes	1	√	√			√	√	√
223	BF, peas	1	√	√	√		√	√	√
225	BF, applesauce	1	√	√			√	√	√
226	BF, peaches	1	√	√	√		√	√	√
227	BF, pears	1	√	√	√	√	√	√	√
230	BF, juice, apple	1	√	√		√	√	√	√
235	Yogurt, lowfat, fruit-flavored	1		√			√	√	√
236	Cheese, Swiss, natural		√	√			√	√	√
237	Cream cheese		√	√			√	√	√
239	Luncheon meat, ham		√	√			√	√	√
240	Chicken breast, oven-roasted (skin removed)			√		√	√	√	√
241	Chicken nuggets, fast-food			√		√	√	√	√
244	Shrimp, boiled			√		√	√	√	√
248	Bread, multigrain			√	√		√	√	√
249	Bagel, plain, toasted			√			√	√	
250	English muffin, plain, toasted			√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
251	Graham, crackers	1	√	√			√	√	√
252	Crackers, butter-type		√	√			√	√	√
254	Peach, canned in light/medium syrup		√	√			√	√	
255	Pear, canned in light syrup		√	√			√	√	
256	Pineapple juice, frozen conc, reconstituted		√	√			√	√	√
257	Grape juice, frozen conc, reconstituted	1	√	√			√	√	√
258	French-fries, fast-food			√			√	√	√
259	Carrot, fresh, peeled, boiled			√			√	√	√
261	Tomato juice, bottled		√	√			√	√	√
263	Brussels sprouts, fresh/frozen, boiled			√			√	√	√
264	Mushrooms, raw			√		√	√	√	√
265	Eggplant, fresh, peeled, boiled			√			√	√	√
266	Turnip, fresh/frozen, boiled			√			√	√	√
267	Okra, fresh/frozen, boiled			√	√		√	√	
268	Mixed vegetables, frozen, boiled		√	√			√	√	√
269	Beef stroganoff w/ noodles, homemade			√			√	√	√
272	Tuna noodle casserole, homemade		√	√		√	√	√	√
275	Quarter-pound cheeseburger on bun, fast-food			√			√	√	√
276	Fish sandwich on bun, fast-food			√		√	√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
278	Egg, cheese, and ham on English muffin, fast-food			√			√	√	√
279	Taco/tostada w/ beef and cheese, from Mexican carry-out			√			√	√	√
281	Pizza, cheese and pepperoni, regular crust, from pizza carry-out			√			√	√	√
283	Soup, bean w/ bacon/pork, canned, cond, prep w/ water		√	√			√	√	√
285	Clam chowder, New England, canned, cond, prep w/ whl milk		√	√		√	√	√	√
286	Ice cream, regular (not lowfat), vanilla		√	√			√	√	√
288	Popsicle, fruit-flavored		√	√			√	√	
290	Doughnut, cake-type, any flavor, from donut store			√			√	√	√
291	Brownie		√	√			√	√	√
292	Sugar cookies		√	√			√	√	√
293	Candy, hard, any flavor		√	√			√	√	
294	Pretzels, hard, salted		√	√			√	√	
295	Syrup, chocolate		√	√			√	√	√
296	Jelly, any flavor		√	√			√	√	
298	Mustard, yellow, plain		√	√			√	√	√
299	Black olives		√	√			√	√	√
300	Sour cream			√			√	√	√
305	Coffee, from ground		√	√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
306	Carbonated beverage, fruit-flavored, regular		√	√			√	√	
307	Fruit drink (10% juice), canned or bottled	1	√	√			√	√	
309	BF, Infant formula, soy-based, RTF	1	√	√	√	√	√	√	√
313	BF, bananas	1	√	√		√	√	√	√
317	BF, teething biscuits	1	√	√			√	√	√
318	Salmon, steaks/fillets, baked			√		√	√	√	√
320	BF, squash	1	√	√			√	√	√
323	BF, cereal, oatmeal, dry, prep w/ water	1	√	√	√		√	√	√
324	BF, cereal, rice, dry, prep w/ water	1	√	√	√	√	√	√	√
328	BF, turkey and broth/gravy	1	√	√			√	√	√
331	Meal replacement, liquid RTD, any flavor		√	√			√	√	√
332	Cottage cheese, creamed, lowfat (2% milk fat)			√			√	√	√
333	Sour cream dip, any flavor			√			√	√	√
334	Beef steak, loin/sirloin, broiled			√			√	√	√
335	Luncheon meat (chicken/turkey)		√	√			√	√	√
336	Chicken breast, fried, fast-food (w/ skin)			√		√	√	√	√
337	Chicken thigh, oven-roasted (skin removed)			√		√	√	√	√
338	Chicken leg, fried, fast-food (w/ skin)			√		√	√	√	√
339	Catfish, pan-cooked w/ oil			√		√	√	√	√
340	Tuna, canned in water, drained		√	√		√	√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
341	Refried beans, canned		√	√			√	√	√
342	White beans, dry, boiled		√	√	√		√	√	√
343	Sunflower seeds (shelled), roasted, salted		√	√	√		√	√	√
344	Pancakes, frozen, heated		√	√			√	√	√
345	Breakfast tart/toaster pastry		√	√			√	√	√
346	Macaroni salad, from grocery/deli			√			√	√	√
347	Spaghetti, enriched, boiled	1	√	√			√	√	√
348	Apricots, canned in heavy/light syrup		√	√			√	√	√
350	Fruit juice blend (100% juice), canned/bottled	1	√	√			√	√	√
351	Cranberry juice cocktail, canned/bottled		√	√	√		√	√	√
352	Orange juice, bottled/carton	1	√	√			√	√	√
353	Potato salad, mayonnaise-type, from grocery/deli			√			√	√	√
354	Potatoes, mashed, prepared from fresh	1		√			√	√	√
355	Coleslaw, mayonnaise-type, from grocery/deli			√			√	√	√
356	Carrot, baby, raw			√			√	√	√
357	Lettuce, leaf, raw			√	√		√	√	√
358	Sweet potatoes, canned		√	√			√	√	√
359	Tomato salsa, bottled		√	√			√	√	√
361	Lasagna w/ meat, frozen, heated			√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
362	Beef w/ vegetables in sauce, from Chinese carry-out			√		√	√	√	√
363	Chicken w/ vegetables in sauce, from Chinese carry-out			√			√	√	√
364	Fried rice, meatless, from Chinese carry-out			√	√	√	√	√	√
365	Burrito w/ beef, beans and cheese, from Mexican carry-out			√			√	√	√
366	Chicken filet (broiled) sandwich on bun, fast-food			√			√	√	√
367	Soup, Oriental noodles (ramen noodles), prep w/ water	1	√	√			√	√	√
368	Pudding, ready-to-eat, flavor other than chocolate		√	√			√	√	√
369	Cake, white w/ icing			√			√	√	√
370	Granola bar, w/ raisins		√	√			√	√	√
371	Candy bar, chocolate, nougat, and nuts		√	√			√	√	√
372	Popcorn, microwave, butter-flavored		√	√	√		√	√	√
373	Sweet & sour sauce		√	√			√	√	√
374	Brown gravy, canned or bottled		√	√			√	√	√
375	Salad dressing, creamy/buttermilk type, regular		√	√			√	√	√
376	Salad dressing, creamy/buttermilk type, low-calorie		√	√			√	√	√
377	Salad dressing, Italian, regular		√	√			√	√	√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXIN (ARL)
378	Olive oil		√	√			√	√	√
379	Vegetable oil		√	√			√	√	√
380	Bottled drinking water (mineral/spring), not carbonated or flavored	1	√	√	√	a	a	√	
381	Coffee, decaffeinated, from ground		√	√			√	√	√
382	Tea, decaffeinated, from tea bag		√	√			√	√	√
385	Sorbet-fruit flavored		√	√			√	√	
386	Iced Cinnamon Roll			√			√	√	√
701	BF, cereal, mixed, dry, prep w/ water	1	√	√			√		√
711	BF, juice, pear	1	√	√			√		
712	BF, juice, grape	1	√	√			√		
713	BF, pears and pineapple	1	√	√			√		
714	BF, plums/prunes w/apples or pears	1	√	√			√		
717	BF, apricots w/ mixed fruit	1	√	√			√		
721	BF, fruit yogurt dessert	1	√	√			√		√
723	BF, arrowroot cookies	1	√	√			√		√
725	BF, cereal, oatmeal w/ fruit, prep w/ water	1	√	√			√		√
726	BF, chicken w/ rice	1	√	√	√		√		√
728	BF, vegetables and turkey	1	√	√			√		√

FOOD #	FOOD DESCRIPTION	PRIORITY	RESERVE INTACTS	Pesticides	Acid Herbicides	Mercury	Elements	RDNCLDES (WEAC)	DIOXING (ARL)
730	BF, apples with berries	1	√	√	√		√		√
731	BF, apples with fruit other than berries	1	√	√			√		√
732	BF, Macaroni & cheese w/ vegetables	1	√	√			√		√

[a]Elements listed in EAM 4.12 for each individual city sample.

Discontinued

182	Sweet Roll/Danish pastry
232	BF, custard/pudding
233	BF, fruit dessert/pudding
287	Sherbert, Fruit-flavored
326	BF, veal and broth/gravy
327	BF, lamb and broth/gravy
360	Stew, beef and vegetable, canned
700	BF, cereal, barley, dry, prep w/water
704	BF, juice, apple-cherry
719	BF, banana dessert
720	BF, peach cobbler/dessert
724	BF, zwieback toast
729	BF, macaroni and cheese

TOTAL DIET STUDY ARSENIC SPECIATION MATRIX

The table below lists all TDS foods that should be speciated for inorganic arsenic when total arsenic concentrations are above 10 µg/kg.

FOOD#	FOOD DESCRIPTION
098	Orange juice, frozen conc, reconstituted
099	Apple juice, bottled
100	Grapefruit juice, bottled
103	Prune juice, bottled
105	Lemonade, frozen conc, reconstituted
193	Fruit Drink, from powder
198	Beer
199	Wine, dry table, red/white
230	BF, juice, apple
256	Pineapple juice, frozen conc, reconstituted
257	Grape juice, frozen conc, reconstituted
261	Tomato juice, bottled
307	Fruit drink (10% juice), canned or bottled
350	Fruit juice blend (100% juice), canned or bottled
351	Cranberry juice cocktail, canned or bottled
352	Orange juice, bottled or carton
711	BF, juice, pear
712	BF, juice, grape