CHAPTER 04 – PESTICIDES AND CHEMICAL CONTAMINANTS

SUBJECT:	**TOXIC ELEMENTS IN FOOD AND FOODWARE, AND RADIONUCLIDES IN FOOD - IMPORT AND DOMESTIC**
IMPLEMENTATION DATE:	UPON RECEIPT
Product Codes:	All Food Codes (except Industry 53 (Cosmetics) and Industry 16 (Seafood))
Product/Assignment Codes:	REPORT INSPECTIONS UNDER THE FOLLOWING PACS: 04019A TOXIC ELEMENTS IN FOOD 04019B TOXIC ELEMENTS IN FOODWARE 04019C RADIONUCLIDES IN FOOD

FIELD REPORTING REQUIREMENTS:

1. Report all applicable Field Accomplishment and Compliance Tracking System (FACTS) operations (i.e., sample collections/analyses, field exams).

2. Report imports field exam using OASIS Work Type ‘FEX’ and ‘SAM’.

3. Report all analytical findings into the FACTS reporting system using the Problem Area Flag (PAF):

   Toxic Elements in Foods – ELE
   Toxic Elements in Foodware – CDW
   Radionuclides in Foods – NUC

TOXIC ELEMENTS IN FOOD AND FOODWARE AND RADIONUCLIDES IN FOOD

CFSAN, in conjunction with the Agency's field staff, is responsible for protecting public health by ensuring that the food supply is safe. To that end, levels of chemical contaminants in foods and the potential health hazard(s) of these contaminants are routinely monitored. Toxic elements and radionuclides are among the contaminants of concern; their presence in foods may be the result of past agricultural practices (e.g., use of pesticides containing toxic elements), industrial waste, the use of nuclear weapons, the generation of nuclear power, and the leaching of toxic elements from containers or utensils that come in contact with foods.

This program is designed to monitor for levels of toxic elements in products (specifically, foods and certain items that are designed for food use such as glazed ceramicware and silver-plated hollowware) that are most likely to contribute to the human exposure of toxic elements. This program is also designed to monitor radionuclides in food.

FDA considers information on a case-by-case-basis in determining whether a food or foodware that contains a toxic element or radionuclides is adulterated.

NOTE: The compliance program is organized into three distinct sections: Toxic Elements in Food, Toxic Elements in Foodware, and Radionuclides in Food. The section for each contaminant/product combination has specific instructions regarding sample collection, analysis, data reporting, and regulatory follow-up, unique to each section.

Center and Office contact information relevant to all three sections of the compliance program are listed in Part VI of Toxic Elements in Foods.

TOXIC ELEMENTS IN FOOD (04019A)

PART I – BACKGROUND

As part of its responsibilities for ensuring food safety, the Food and Drug Administration (FDA) monitors levels of certain toxic elements in foods and takes regulatory actions when warranted. In addition, FDA's Center for Food Safety and Applied Nutrition (CFSAN) uses this information to estimate dietary exposure to these contaminants and to identify the relative contributions of these foods to total exposure. CFSAN can also use this information when developing regulatory strategies and policies, including the establishment of action levels, to reduce concentrations of toxic elements (e.g., lead, cadmium, inorganic arsenic, and mercury) in both domestic and imported foods.

The Program monitors the foods of interest that can be major dietary sources of certain toxic elements with particular emphasis placed on foods consumed by children, who are the most sensitive and vulnerable. Program resources are directed at foods that may be significant sources of toxic elements in the diets of children. As an example, concerns about exposure to lead from certain candies has led FDA to provide guidance to industry on the recommended maximum level for lead in candy likely to be consumed frequently by small children (Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children FDA).

Closer to Zero is FDA's action plan to reduce exposure to arsenic, cadmium, lead and mercury from foods eaten by babies and young children. Additionally, FDA announces new actions aimed at further reducing toxic elements in food for babies, young children. Data on concentrations of these contaminants provide support for the development of action levels and industry best practices as well as monitoring exposure reduction over time.

In order to protect public health and minimize exposure to mercury from consumption of seafood, between 1990 and 2012, CFSAN collected and tested more than 4,600 samples of commercial seafood products for mercury. Less than 10% of the samples collected exceeded the 1 ppm action level for methylmercury. As part of Closer to Zero, additional seafood contract sampling is planned in FY24 for mercury and methylmercury to inform the joint FDA/EPA seafood advice.

PART II - IMPLEMENTATION

1. **Objective**

- To generate information on the concentration of toxic elements in selected foods.
- To take appropriate regulatory actions against violative products when warranted.
- To estimate dietary exposure to those elements, particularly for sensitive populations, or populations of concern.
- To identify the major dietary sources of these contaminants; this will aid CFSAN in directing its efforts to reduce these levels.

2. Program Management Instructions

In general, emphasis is placed on sampling and analysis of foods that are, or may be, significant dietary sources of toxic elements (e.g., lead, cadmium, inorganic arsenic, and mercury) in the diets of babies and young children and other special population groups.

- **Planning instructions**

  To implement the program, Division personnel are directed to collect samples of selected foods and analyze them for specific elements as noted above. Each fiscal year, CFSAN Office of Compliance issues Sample Collection Operation Planning Efforts (SCOPE), which includes the name and the number of samples to be collected by each division.

  Except for a select few foods (e.g., bottled water, infant rice cereal, candy), FDA has not established regulatory levels, guidance levels, or action levels for toxic elements in most food products. Laboratory results that represent a potential health concern should be referred to CFSAN for evaluation. The Center will evaluate these results on a case-by-case basis and may recommend follow-up as appropriate. Even when allowable level in the standard of quality (21 CFR 165.110) in bottled water sample is exceeded, results must be referred to the Center for evaluation.

- **Interactions with Other Compliance Programs**

  This compliance program may have some interactions with the following CPMs. Use the appropriate PAC when reporting sample collections under this compliance program.
  - Domestic and Import Food Additives and Color Additives, 7309.006
  - Dietary Supplements – Foreign and Domestic Inspections, Sampling, and Imports, 7321.008
  - Preventive Controls and Sanitary Human Food Operations, 7303.040
    CP 7304.019 covers sampling, analysis, and enforcement instructions for toxic elements in food and foodware and radionuclides in food. The Preventive Controls and Sanitary Human Food Operations compliance program (CP 7303.040) covers, in part, inspections of manufacturers of foods that may require preventive controls for heavy metals and radiological hazards such as baby food puree, rice cereal, and candy, etc. Work conducted under CP 7303.040 will consider the risk of the food and previous toxic elements sample results. In particular, manufacturers of baby food with toxic elements analysis results which present health concerns should be considered a high priority for a full scope or focused PCHF inspection to assess preventive controls including supply-chain program and process controls. Conversely, an inspection performed under CP 7303.040 may yield observations that trigger the collection of samples for toxic elements analysis under CP 7304.019. These samples would be reported under the respective PAC from CP 7304.019 while inspections would be reported under the appropriate PAC from this compliance program (CP 7303.040)
  - Foreign Supplier Verification Program (FSVP) 7303.878

- **Resource Instructions**

  Resources for sample collections and analysis for Toxic Elements in Food are provided in the ORA Field Workplan.

- **Interactions with Other Federal Agencies, State and Local Counterparts, and Foreign Authorities**

  1. State and Local Counterparts:
     Divisions will collaborate with commissioned state agencies to make them aware of the requirements of the program (in advance of the beginning of the program) and deadlines for deliverables. Divisions will offer state agencies an opportunity to assist FDA with sample collections as necessary. State laboratories may share violative results with FDA. After reviewing the results, FDA may follow-up.

  2. The FDA Laboratory Flexible Funding Model (LFFM):
     LFFM is a comprehensive emergency response and surveillance cooperative agreement program (CAP) between FDA and FERN Partner laboratories. This program allows FDA to further support a National Integrated Food Safety Support (IFSS) by increasing national ability to detect, prevent, respond to, and recover from threats to the Country's food supply.

  3. Foreign Authorities:
     The FDA works with foreign governments and international standard-setting bodies to harmonize food safety laws, regulations and standards based on science. Further, Divisions may review the information found at International Cooperation on Food Safety.

PART III - INSPECTIONAL

1. **Operations**

2. **Inspections**

   Resources for inspection have not been planned under this compliance program.

3. **Sample Collections**

   General Information (domestic and import)

   Sample Collection Operation Planning Effort (SCOPE) (sharepoint.com) consistent with the current ORA Field Workplan ORA Field Work Plans (sharepoint.com) will be issued at the beginning of each fiscal year. The Collecting Division should contact the CFSAN Compliance Program Contact early in the fiscal year if there may be difficulties in completing the workplan-directed collections.

Bulk samples for toxic elements analysis should be collected in new plastic bags or other plastic containers and sealed in a manner to prevent contamination during handling and storage. Packaged foods in retail containers (e.g., in cans, glass, plastic bags, and other materials) are appropriate for collection if unopened and sealed.

Ensure that perishable samples are refrigerated or frozen, since spoilage adversely affects analysis.

Avoid contaminating the samples with analytes of interest. If perishable (fresh produce) samples are collected, the division may notify the analyzing laboratory in advance to prevent sample spoilage and contamination during transportation to the laboratory.

Collect pictures of the product and labeling and packaging information, such as the nutrition facts panel and serving size. For products not in retail packaging (exceptions: spices, juices, juice concentrates) collect/determine conditions of use.

Document the brand name, country of origin, manufacturer, batch or lot number, and any other pertinent identifying information. For juice samples, document whether the sample is a concentrate or ready-to-drink product. If the juice sample is a concentrate, document the Brix value.

Domestic Foods

Samples are surveillance. Collect domestic samples, as identified in the SCOPE. If divisions have reason to believe that there is a toxic element problem with specific foods, particularly foods which may be consumed by babies and young children, and the foods are not listed in the SCOPE, division may choose to collect these foods.

Import Foods

Collect import food samples, as identified in the SCOPE, at the port of entry or any location throughout the import admissibility process. The division may use their discretion to collect and follow-up on other foods, particularly foods which may be consumed by babies and young children.

See Import Alerts for foods subject to detention without physical examination (DWPE) and Import Bulletins for special sampling consideration.

Domestic-Import Foods

Follow IOM 6.5.7 for instructions on Special Domestic Import Samples.

Domestic Import samples can be collected in two ways:

Domestic import samples can be collected in domestic channels from wholesalers or commercial markets after clearing U.S. Customs as long as the country of origin and the manufacturer can be determined.

OR

Under limited circumstances, Domestic import samples can be collected before the product reaches wholesalers or commercial markets. When an entry appropriate for sampling comes up for review, the sample is collected immediately after released "May Proceed" Notice of FDA Action has been issued.

The sample type in Field Accomplishments and Compliance Tracking System (FACTS) will be "DI", and the country of origin must be entered into the FACTS record as well. Collect records per IOM 4.1.4.8.

Food Products

Refer to SCOPE for food sample collections.

Collect samples of plant-based foods and animal-derived foods other than seafood products under Toxic Elements in Food program. Animal-derived foods including milk, honey, shell egg, gelatin, game meat, and other animal-derived food products, not regulated by USDA/FSIS, may also be collected.

Sample size

Samples should consist of twelve (12) randomly selected subsamples from a single lot. Each subsample should be 4 ounces or more. If the lot consists of individual "consumer size" containers, collect 12 randomly selected containers. If the lot consists of bulk size containers, collect 12 subsamples of at least 4 ounces each. Do Not co-mingle the subsamples collected from bulk containers. **For domestic samples only**, unless an exemption applies as specified in **IOM Chapter 4 (21 CFR 2.10(b))**, collect an additional 12 subsamples as a 702(b) sample portion, of equal portions from the same lot. If 12 additional subsamples of the same lot are not available, collect as many as possible as a 702(b) portion.

Normally, dietary supplement samples should not be collected under this compliance program unless otherwise directed by an assignment.

Sample Shipping

- Shipping instructions to maintain the integrity of frozen and refrigerated samples and the procedure to notify the receiving laboratory can be found in IOM, Sections 4.5.3.5, 4.5.3.6, and 4.5.5.5.
- Samples should be packaged with the appropriate refrigerant and shipped so that they are shipped to the laboratory no later than Thursday of each week. Unless prior arrangements are made, shipping on Fridays should be avoided as staff may not be present on the weekends to ensure proper sample receipt.
- Submit samples per the ORA Lab Servicing Table (LST) Dashboard, specifically for the elements (ELE) program.

4. **Reporting**

   Report resources utilized for sample collection using the following Program Assignment Codes (PACs) and Problem Area Flags (PAF):

PAC	PAF	PAF Description
04019A	ELE	Toxic Elements in Food

PART IV – ANALYTICAL

1. **Analyzing Laboratories**

   Per ORA Lab Servicing Table (LST Dashboard).

2. **Analyses to be Conducted**

   Food samples will be analyzed for lead, arsenic, cadmium, and mercury. Do not analyze individual subsamples. Composite an equal weight portion of the edible part of 12 subs. For domestic samples only, retain the remaining portion of each sub sample along with the remainder of the composite **as part of the 702(b) portion, in addition to any intact subsamples**. Water (ASTM Type I grade) may be used to aid homogenization but analytical results must be corrected for any added water.

3. **Methodology**

   Methods can be found on the Compendium website or EAM website.

   Foods Program Compendium of Analytical Laboratory Methods | FDA

   Elemental Analysis Manual (EAM) for Food and Related Products | FDA

   Analyze the analytical portion for arsenic, cadmium, lead, and mercury using FDA Elemental Analysis Manual (EAM) Method 4.7 Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion (EAM 4.7)

   For juices requiring arsenic speciation, use EAM Method 4.10 High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic Species in Fruit Juice (EAM 4.10).

   For rice and rice products requiring arsenic speciation, use EAM Method 4.11 Arsenic Speciation in Rice and Rice Products using High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination (EAM 4.11).

   For bottled water samples requiring toxic element analysis for arsenic, cadmium, lead, and mercury, use Environmental Protection Agency's Method 200.8 (EPA Method 200.8).

4. **Reporting**

- Report sample results including LOQ into the FACTS Data Reporting System under PAC 04019A using the Problem Area Flag (PAF): ELE.
- Results for additional quality control measurements (e.g., method blanks, fortified analytical portions, reference materials, etc.) are not required to be entered in the FACTS system but the laboratory must maintain this information for potential review by CFSAN to document analytical methods performance.
- Average concentrations are to be reported as unfortified analytical portion (UAP), as individual replicate analyses may be entered into FACTS as replicate analytical portion (RAP) values with the associated replicate number. Refer to Elemental Analysis Manual section 3.2 (https://www.fda.gov/media/89337/download) for entering LOD information and to section 4.10 (https://www.fda.gov/media/86499/download) for BRIX information.
- Electronic data packages for LC1, LC2 and LC3 samples are uploaded to CMS.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Toxic element findings in food are reviewed on a case-by-case basis by CFSAN. Samples of food with any findings that represent a potential health concern, that exceed an action level or guidance level, or represent atypically high values for that food type should be classified Lab Class 2 and referred to the respective Division Compliance Branch for review and referral to CFSAN's Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch.

Divisions should submit referrals to CFSAN Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch via the Compliance Management System (CMS). A CMS Work Activity (District – Worksheet/Other Exam Review), for Domestic or Domestic Import samples, or Action (Detention Recommendation)/Sub Action: Lab Class 2 Heavy Metal Sample), for Import samples, should be created in response to sample results and the sample linked to the Work Activity or Action.

CFSAN Office of Compliance will consult with the Office of Food Safety (OFS) who will review analytical findings. OFS will further consult with the Office of Analytics and Outreach (OAO) to conduct an assessment of potential health hazards. OFS will then make a policy decision and recommend next steps for follow up.

CFSAN's Office of Compliance, Division of Field Programs & Guidance, in conjunction with OFS, may issue assignments and the Division of Enforcement may support regulatory action, if further follow up is warranted based on the sample results.

The analyzing labs and/or division compliance branches should promptly notify the CFSAN Compliance Program Contact via email if any results for bottled water exceed the allowable levels in the quality standard (21 CFR 165.110).

PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. **References**

- IOM Subchapter 4.5.3.5 – Frozen Samples. Referenced for instructions on shipping frozen samples.
- IOM Subchapter 4.5.3.6 – Refrigerated (Not Frozen) Samples. Referenced for instructions on shipping refrigerated samples.
- IOM Subchapter 4.5.5 – Sample Shipment. Referenced for sample shipment details.
- IOM Chapter 4 – Sample Schedule Chart 3 – Pesticide Samples. Referenced for minimum size of laboratory sample.
- IOM Subchapter 6.5.1 – Import Sample Collection (General)

2. **Program Contacts**

Compliance Program Contact:
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OFS Program Office Contact (Food):
Rhoma Johnson, CFSAN, Office of Food Safety
Division of Plant Products and Beverages, Spices and Seasoning Mixes Team
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OFAS Program Office Contact (Foodware):
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Regulatory Contact (Food and Foodware):
DE Chemical Contaminants Team
CFSAN, Office of Compliance
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CMS: CFSAN Food Adulteration Assessment Branch
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TOXIC ELEMENTS IN FOODWARE (04019B)

PART I - BACKGROUND

This section of the program focuses on foodware used for eating, storing, holding, and cooking foods, particularly liquids. Foodware includes but is not limited to items such as cookware, holloware, and/or ceramicware. The term ceramicware as used in this document refers to tableware for food use made by firing a nonmetallic mineral (such as clay) at a high temperature, and includes products such as: bone China, stoneware, earthenware, and porcelain. Foodware products may contain toxic elements (e.g., lead, cadmium, inorganic arsenic, and mercury) which can leach into food when the products are used for food purposes. Methods to detect leachable toxic elements in foodware depend on the toxic element and specific type of foodware.

Instructions regarding the types of products that should be inspected and considered for sampling is provided in Parts II and III of this section of the compliance program. The number of field tests, sample collections, and analyses to be conducted are indicated in the ORA Field Workplan.

PART II - IMPLEMENTATION

1. **Objective**

   - To examine and analyze domestic and imported foodware products to determine levels of leachable toxic elements.
   - To investigate the rate of compliance for domestic and imported foodware products.
   - To take appropriate regulatory actions against violative products when warranted.

2. **Program Management Instructions**

   Currently, emphasis for this section of the program is placed primarily on sampling and analysis of ceramicware, and secondarily on sampling and analysis of silver-plated hollowware. In the absence of a specific directive, other types of foodware should not be collected for routine surveillance without first consulting with the CFSAN Compliance Program Contact (see Part VI of Toxic Elements in Food). In the event a Division has reason to suspect a toxic element problem with foodware other than ceramicware or silver-plated hollowware, particularly foodware that may be used to prepare or serve food consumed by babies and small children, the Division is encouraged to contact the CFSAN Compliance Program Contact for sampling direction and support.

   FDA has established guidance levels for selected toxic element-foodware pairings (e.g., lead in ceramicware, cadmium in ceramicware, lead in silver-plated holloware – see Part V). For other toxic element-foodware pairings, FDA has not established regulatory levels, guidance levels, or action levels. For products which

are not subject to a relevant Compliance Policy Guide, laboratory results that represent a potential health concern should be referred to CFSAN for evaluation. The Center will evaluate these results on a case-by-case basis and may recommend follow-up as appropriate.

- **Resource Instructions**
  Resources for sample collections and analysis for Toxic Elements in Foodware are provided in the ORA Field Workplan.

- **Interactions with other Federal Agencies, State and Local Counterparts, and Foreign Authorities**

  1. State and Local Counterparts:
     Divisions will collaborate with commissioned state agencies to make them aware of the requirements of the program (in advance of the beginning of the program) and deadlines for deliverables. Divisions will offer state agencies an opportunity to assist FDA with sample collections as necessary. State laboratories may share violative results with FDA. After reviewing the results, FDA may follow-up.

  2. Foreign Authorities:
     The FDA works with foreign governments and international standard-setting bodies to harmonize food safety laws, regulations and standards based on science. Further, Divisions may review the information found at International Cooperation on Food Safety.

PART III - INSPECTIONAL

1. **Operations**

Sample collection under this section of the program is prescribed for ceramicware and silver-plated hollowware, which are potential sources of lead and cadmium. Other types of foodware should not be collected for routine surveillance without first consulting with the CFSAN Compliance Program Contact (refer to Toxic Elements in Foods, Part VI). Specific sample collection schedules are not provided for foodware; refer to the workplan for the number of field exams and sample collections to be conducted.

Field examination of ceramicware is prescribed under this section of the program. Ceramicware is screened in the field for the presence of lead in glazes or decorations and based on the results of the screening tests, official samples are collected and sent to the laboratory for additional testing. Ceramicware is screened in the field for the possible presence of cadmium through visual examination. Field exams are not prescribed for other toxic element-foodware pairings.

Investigative activities may be appropriate as they relate to sample collection; however, targeted investigative activities are not routinely planned under this section of the program.

A. **Inspections**
Establishment inspections are not routinely planned under this section of the program.

B. **Investigations**
Investigative activities may be appropriate as they relate to sample collection; however, targeted investigative activities are not routinely planned under this section of the program.

Field Exams
Field examinations of ceramicware for lead and cadmium are described in this section. Based on the results of the screening tests, official samples are collected and sent to the laboratory for additional testing. In the absence of specific directives, field exams for other foodware items should not be conducted without prior CFSAN consultation.

Generally, do NOT conduct field exams on or collect the following types of products:

- Entire dinner sets
- Items specifically designed to contain dry food (i.e., salt and pepper shakers, sugar bowls)
- Items intended for decorative purposes only, which bear a permanent label stating, "NOT FOR FOOD USE - PLATE MAY POISON FOOD. FOR DECORATIVE PURPOSES ONLY," or items which may have a central hole preventing food usage
- Damaged pieces of ceramicware

Lead in Ceramicware
Rapid screening tests are conducted in the field on ceramicware items suspected of containing leachable lead. The results of the screening test determine whether official samples are collected for further analysis.

Although field exams may be performed on any ceramicware product, emphasis should be placed on the following types of ceramicware:

- Cups, mugs, and pitchers
- Highly decorated items
- Items intended for use by babies and young children
- Items routinely used to hold liquids, particularly acidic liquids (e.g., vinegar, juices)

The following characteristics are sometimes, but not always, indicative of ceramicware that releases excessive amounts of lead and should be considered when selecting ceramicware items for field exams:

- Dull appearance (low gloss)
- Rough or powdery feel
- Rough unprotected surface decals
- Traditional wares (e.g., Chinese classic enamel-on-porcelain wares, Mexican glazed folk terra cotta)

Ceramicware items are screened using a rapid screening test [Quick Color Test (QCT) or Rapid Abrasion Test (RAT)]. The screening tests are appropriate for testing silicate-based wares only (e.g., ceramicware); they are not appropriate for silver-plated hollowware or other foodware. Division servicing laboratories will provide the inspectional staff with supplies and instructions for the QCT and RAT when possible.

Commercially available QCT (e.g., LeadCheck Swab) and RAT are available. If using these kits, the investigator may need to purchase sandpaper (200 grit silicon carbide paper) separately to abrade the foodware when conducting the RAT.

Specific instructions for conducting screening tests and collecting samples are based on the type of ceramicware, as follows:

- Flatware (i.e., flat or shallow ceramicware – not to be confused with eating utensils)
- Small hollowware (excluding cups and mugs)
- Large hollowware (excluding pitchers)
- Cups, mugs, and pitchers

1. For flatware, small hollowware and large hollowware (excluding cups, mugs and pitchers) test all colors on food contact surfaces with the QCT.
    a) If results are positive or inconclusive, collect a sample for analysis (no further screening test is necessary).
    b) If results are negative, no further screening test for lead and no sample collection is necessary but perform a visual inspection for the potential presence of cadmium.

2. For cups, mugs and pitchers test all colors on food contact surfaces with the QCT.
    a) For cups, mugs and pitchers with positive QCT results, collect a sample for analysis (no further screening test is necessary).
    b) For glazed cups, mugs and pitchers that have negative or inconclusive QCT results perform the RAT on the bottom of the item.
        - If the RAT on the bottom is positive, collect a sample.
        - If the RAT on the bottom is negative or inconclusive, perform the RAT on the decorations on the food contact surface.
        - If the RAT on the decoration is positive or inconclusive, collect a sample.
        - If the RAT on the decoration is negative, no further testing or sample collection is necessary.
    c) For unglazed (e.g., porcelain) cups, mugs and pitchers that have negative or inconclusive QCT results perform the RAT on decorations on the food contact surface (not

on the bottom).

- If the RAT on the decorations is positive or inconclusive, collect a sample.
- If the RAT on the decorations is negative, no further testing or sample collection is necessary.

Cadmium in Ceramicware

Although there is no validated screening test for testing the presence of cadmium in ceramicware, certain colors (red, orange, or yellow) used in the glaze or decorations are often indicative of items that release cadmium and may be considered for sampling. Investigators should rely on visual observation to select ceramicware samples for cadmium testing.

If the result of the screening test for lead in ceramicware is negative, visually inspect the ceramicware for the possibility that it may contain cadmium. If the presence of cadmium is suspected, samples are sent to the laboratory for analysis of cadmium.

Silver-plated Hollowware

There are currently no validated screening tests for silver-plated hollowware.

Other Foodwares

Field exams are not regularly performed for other types of foodware items in the absence of specific directives such as import bulletins. However, if the division has reason to suspect a toxic element problem with other foodware items, testing in the field in some manner may be appropriate. If concerns exist regarding other foodware items, contact CFSAN before conducting field exams.

2. **Sample Collections**

In the absence of a specific directive, sample collection is generally limited to ceramicware and silver-plated holloware. Other types of foodware should not be collected for routine surveillance without first consulting with the CFSAN Compliance Program Contact (see Part VI) of Toxic Elements in Food section.

If it is determined via the lead screening test that an official ceramicware sample is needed, individual pieces that have been screen tested on the food contact surface cannot be used for leach testing. Collect additional pieces of the ceramicware product for the official sample for leach testing.

Domestic samples

Unless directed otherwise, collect an official sample that consists of twelve (12) units total, six (6) units for analysis and six (6) units for 702(b) sample portion of identical size, shape, color, and design. Package the analytical portion and the 702(b) portion separately.

Import samples

Unless directed otherwise, collect an official sample that consists of six (6) units of identical size, shape, color, and design.

3. **Import Activities**

Import activities include field exams and sample collection, when appropriate.

4. **Reporting**

Report resources utilized for both domestic and import sample collection and all screening tests conducted by investigators using the following Program Assignment Codes (PACs) and Problem Area Flags (PAF):

PAC	PAF	PAF Description
04019B	CDW	Toxic Elements in Foodware

PART IV - ANALYTICAL

1. **Analyzing Laboratories**

Per ORA Lab Servicing Table (LST) Dashboard and specifically Toxic Elements in Foodware (CDW) program.

2. **Analyses to be Conducted**

When a set of ceramicware is collected for analysis, priority should be given to those pieces with the lowest actionable lead level (i.e., cups, mugs, and pitchers).

Disposition of Samples
For samples of ceramicware found to be in compliance, division may return the items after FDA analysis upon concurrence from the consignees.

For samples of "sterling" quality silver-plated hollowware or other expensive metalware that are still saleable after FDA analysis, division should attempt to return the items to the dealer for reimbursement if found to be in compliance. Samples that cannot be returned or that have been damaged should be sent via regular parcel post (do not certify or insure package) to:

Food and Drug Administration
Personal Property Management
(HFA-225) 5600 Fishers Lane
Rockville, MD 20852

For samples of silver-plated hollowware that are of less than “sterling” value, divisions should dispose of those samples locally.

3. **Methodology**

Analyze the analytical portion for cadmium and lead using FDA Elemental Analysis Manual

(EAM) Method 4.6 Inductively Coupled Plasma-Optical Emission Spectrometric Determination of Cadmium and Lead Extracted from Ceramic Foodware (https://fda.sharepoint.com/sites/insideFDA)

4. **Reporting**

Report results for subsamples and samples (including quality control analytical results) into FACTS using the Problem Area Flag (PAF): "CDW". Report the sample concentration limit (*e.g.,* SCL = X.XXX µg/ml) in the FACTS field "Limits."

Electronic data packages for LC1, LC2 and LC3 samples are uploaded to CMS.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

For regulatory guidance refer to the following Compliance Policy Guides (CPGs):

- CPG Section 545.400 – Pottery (Ceramics) Imported and Domestic – Cadmium Contamination.
- CPG Section 545.450 - Pottery (Ceramics) Imported and Domestic – Lead Contamination.
- CPG Section 545.500 - Silver-Plated Hollowware - Lead Contamination.

Imports

For products subject to a CPG, if the product tested exceeds the action levels stated in the CPGs, the divisions should detain the entry and forward a recommendation for Detention Without Physical Examination (DWPE) through addition to Import Alert 99-45 to the Division of Import Operations (DIO) via the Compliance Management System (CMS). The DWPE request must be accompanied by all analytical worksheets and other appropriate documentation (e.g., entry paperwork, collection report).

For products not subject to a CPG, CFSAN concurrence is needed to support detention and refusal. Divisions should submit a request for CFSAN review via CMS that includes all analytical worksheets and other appropriate documentation (e.g., entry paperwork, collection report). Cases should be submitted to CFSAN Dietary Supplement & Labeling Assessment Branch.

Domestic

For tested products subject to a CPG that exceeds the action levels stated in the CPG or for products not subject to a CPG that were tested and represent a potential health concern, CFSAN concurrence is needed to support action.

Divisions should submit a complete regulatory action recommendation package, including sample analyses, for CFSAN review via a CMS Work Activity (District – Worksheet/Other Exam Review). The sample should be linked to the Work Activity and

CFSAN Dietary Supplement & Labeling Assessment Branch tasked with review. CFSAN will review the evidence on a case-by-case basis to determine Center support for the recommended action.

PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

References

FDA Elemental Analysis Manual (EAM) for Food and Related Products

Compliance Policy Guide Section 545.400 – Pottery (Ceramics) Imported and Domestic – Cadmium Contamination.
https://www.fda.gov/media/71762/download

Compliance Policy Guide Section 545.450 – Pottery (Ceramics) Imported and Domestic – Lead Contamination.
https://www.fda.gov/media/71764/download

Compliance Policy Guide Section 545.500 – Silver-plated Hollowware – Lead Contamination.
https://www.fda.gov/media/71764/download

Program Contacts

See Part VI of Toxic Elements in Food.

RADIONUCLIDES IN FOOD (04019C)

PART I – BACKGROUND

Routine analysis of foods for the presence and levels of radionuclides is an important component of FDA's food safety monitoring efforts. The greatest potential for accidental contamination results from peacetime uses of radioactive materials, such as for generating nuclear power, both domestically and internationally. Analysis of foods for selected radionuclides helps FDA guard against excessive dietary exposure to radionuclides and enables the Agency to gather data on the current levels and trends in radionuclide concentrations in foods.

Domestic samples are collected in areas near nuclear power plants; import samples are collected from countries most likely to have food products with radionuclide contamination. These monitoring efforts enable FDA to identify sources of radionuclide contamination and respond to nuclear accidents when appropriate.

For domestic food samples, specific locations in the vicinity of nuclear power plants (four sites for each fiscal year) are identified by CFSAN. The sampling sites and number of samples per site for each fiscal year is specified in the sample collection schedule (issued separately). General instructions for the types of foods to be sampled at each site are provided in Part III of this section of the program.

For import food samples, no specific sample collection schedule is provided. Guidance is provided to division personnel regarding the types of foods and countries of origin that are most likely to be affected by accidental contamination (refer to Part III, A.2).

PART II - IMPLEMENTATION

1. **Objective**

   - To monitor the incidence and concentration of radionuclides in foods produced in the vicinity of nuclear power plants in the U.S.
   - To monitor the incidence and concentration of radionuclides in foods imported from countries most likely to have food products with radionuclide contamination.

2. **Program Management Instructions**

   This section of the program targets foods from areas with greater potential for radionuclide contamination. Domestic samples are collected in areas near nuclear power plants; import samples are collected from countries most likely to have food products with radionuclide contamination. These monitoring efforts enable FDA to determine background levels of radionuclides in foods and to target sources of radionuclide contamination.

   - **Resource Instructions**
     Resources for sample collections and analysis for Radionuclide in Food are provided in the ORA Field Workplan.

PART III - INSPECTIONAL

1. **Operations**

   Refer to Sample Collection Operation Planning Effort (SCOPE) (sharepoint.com) for sample collection locations and collecting divisions.

2. **Inspections**

   Inspections are not planned under this compliance program.

3. **Sample Collections**

   Domestic Samples

   Each collecting division will be assigned to collect four samples of products harvested, produced, or caught as near as possible (within 10 miles) from the nuclear power plants. No separate 702 (b) portions are required.

   The following types of food products should be collected:
   - Fish (excluding smelt)
   - Milk
   - Raw vegetables
   - Food crops of local importance except for root crops

   Sample only food crops from commercial sources (i.e., do not sample "home gardens", etc). Fish samples may be obtained from fish and game commissions or park authorities, if not available from a commercial establishment.

   Indicate in detail on each FDA-464 the direction and distance from the nuclear power plant that the product was harvested, produced, or caught. Flag the collection report "RADIONUCLIDES IN FOODS-Domestic."

   Import Samples

   To the extent possible, each division should follow the workplan for number of samples to be collected and separate its sample collections evenly throughout the fiscal year.

   Collect products originating from countries potentially affected by accidental contamination. Examples of such countries, in rough order of priority, include Japan, Ukraine, Belarus, Russia, Latvia, Lithuania, Estonia, Sweden, Finland, Norway, Denmark, Poland, Slovakia, Czech Republic, Romania, Hungary, Yugoslavia, Bulgaria, Turkey, and Greece.

   Emphasis should be given to foods likely to be affected such as:
   - Concentrated fruit/vegetable processed products such as fruit juice concentrates (apple, blueberry, raspberry, etc.), vegetable juice concentrates (carrot, tomato, etc.), jams and preserves, etc.

- Grains/cereal type products such as pasta and macaroni
- Nuts and fruit/vegetable products such as dates, mushrooms, herbs, spices, tea
- Game meat such as reindeer, venison, and rabbit
- Powdered milk
- Fish and seafood

Sampling divisions will be notified by WEAC when shipments can be released. Negative sample results should be available within two working days following receipt of the samples by WEAC unless Sr-90 analysis is needed, in which case results will be available within 10 working days.

Sample Size

Sample size is 4 pounds **(edible portion)** for solids; 2 liters for liquids.

Sample Shipment

Pack and ship samples to prevent spoilage. Use air space with liquid. Avoid using formaldehyde but if necessary, contact WEAC first and ship according to DOT and IATA regulations.

Ship samples to:

Food and Drug Administration
Winchester Engineering and Analytical Center, HFR-NE400
ATTN: Sample custodian
109 Holton Street
Winchester, MA 01890

Contact Patrick M Regan, WEAC Analytical Branch Director, HFR-NE460, Phone: 781-756-9707 (Email: Patrick.Regan@fda.hhs.gov) as needed.
And
WEAC Scientific Contact
Patrick M Regan,
WEAC Analytical Branch Director,
HFR-NE460,

Phone: 781-756-9707
Email: Patrick.Regan@fda.hhs.gov

4. **Reporting**

Report the domestic sample collection into the FACTS Data Reporting System using the Problem Area Flag (PAF): NUC.

Report the import sample collections into “FDA’s Import Systems”.

PART IV - ANALYTICAL

1. **Analyzing Laboratories**

   The Winchester Engineering and Analytical Center (WEAC) is assigned to perform all analyses.

2. **Analyses to be Conducted**

   Analyze all **domestic samples** for tritium and gamma-ray emitters. Analyze two samples collected near each power plant for strontium-90. **For domestic samples only**, retain the remaining portion of each sub sample along with the remainder of the composite as the 702(b) portion.

   Analyze all **import samples** for cesium-134 and cesium-137. When cesium-137 is detected, analyze also for strontium-90.

3. **Methodology**

   - WEAC SOP for determination of Gamma-Emitting Radionuclides in Foods, WEAC-RN-METHOD.3.0.
   - WEAC SOP for the determination of γ-ray Emitting Radionuclides in Food Matrices Using Cerium Bromide γ-ray Spectrometry, WEAC-AB-TM.005.
   - WEAC SOP for the determination of Tritium in Foods, WEAC-RN-Method.8.0.
   - WEAC SOP for Analysis of Strontium-90 in Food by Liquid Scintillation Counting, SOP-000450.
   - EAC SOP for the determination of Strontium-90 in Foods by Internal Gas-Flow Proportional Counting, Method 2.0.

4. **Reporting**

   - Report results into the FACTS Data Reporting System under PAC 04019C using the Problem Area Flag PAF: NUC in units of Bq/kg decay corrected to collection date.
   - Electronic data packages for LC1, LC2 and LC3 samples are uploaded to CMS.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

If a sample is found to have a radionuclide concentration that exceeds regulatory limits, the laboratory conducts a confirmatory analysis. If the test results exceed action levels stated in CPG Section 555.880 - Guidance Levels for Radionuclides in Domestic and Imported Foods, a regulatory action recommendation is considered and forwarded to CFSAN Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch via the Compliance Management System (CMS) to CFSAN for review. A CMS Work Activity (District – Worksheet/Other Exam Review) should be created in response to sample results and the sample linked to the Work Activity.

PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. **References**

(See the attachments below)

- Determination of Gamma-ray Emitting Radionuclides in Foods. WEAC SOP WEAC-RN-Method.3.0.
- Determination of γ-ray Emitting Radionuclides in Food Matrices Using Cerium Bromide γ-ray Spectrometry. WEAC SOP WEAC-AB-TM.005.
- Determination of Strontium-90 in Foods by Internal Gas-Flow Proportional Counting, WEAC-R-N-Method 2.0.
- Analysis of Strontium-90 in Food by Liquid Scintillation Counting, SOP-000450.
- WEAC SOP for the Determination of Tritium in Foods, WEAC-RN-Method.8.0.

2. **Program Contacts: See Part VI of Toxic Element in Food.**

3. **Attachments**

- Determination of Gamma-ray Emitting Radionuclides in Foods. WEAC SOP WEAC-RN-Method.3.0.
- Determination of γ-ray Emitting Radionuclides in Food Matrices Using Cerium Bromide γ-ray Spectrometry. WEAC SOP WEAC-AB-TM.005.
- Determination of Strontium-90 in Foods by Internal Gas-Flow Proportional Counting, WEAC-R-N-Method 2.0.
- Analysis of Strontium-90 in Food by Liquid Scintillation Counting, SOP-000450.
- WEAC SOP for the Determination of Tritium in Foods, WEAC-RN-Method.8.0.

PART VII - CENTER RESPONSIBILITIES

The Office of Food Safety (OFS) and Office of Food Additive Safety (OFAS) will provide subject matter expertise in the maintenance and evaluation of the Compliance Program and provide guidance to the Office of Compliance with regard to program priorities, relevant evaluation questions, and recommended program changes. The Office of Compliance will lead the effort and work in conjunction with the Office of Food Safety to prepare routine compliance program evaluations. Evaluation will be conducted on a periodic basis and outline the program office's current objectives, general and specific program evaluation questions, list recommendations for process improvement, and highlight data patterns and trends for better targeting and resource allocation. The Office of Compliance will make these evaluations available internally to FDA. In addition, the Office of Compliance will prepare an annual summary report of this compliance program which will be available at Compliance Program Summaries.